

# *Introduction*

## **Adverse Event Reporting System (AERS) Report**

The Adverse Event Reporting System (AERS) is a computerized database maintained by the U.S. Food and Drug Administration (FDA) to support post-marketing safety surveillance of pharmaceutical and therapeutic biological products. It plays a critical role in identifying new adverse events and medication errors that may not have been detected during clinical trials.

This report presents comprehensive Graphical summaries, summary tables and patient-level listings derived from the AERS database to support ongoing pharmacovigilance activities. The analyses include adverse event frequencies, drug-event relationships, outcomes, and demographic trends. Data used in this report were sourced from AERS 2006Q1 updates, which are released by the FDA approximately 4 to 6 weeks after the end of each calendar quarter.

The AERS database includes the following core datasets:

- DEMO: Patient demographic and administrative information
- DRUG: Reported drug data (suspect, concomitant, interacting)
- REAC: Coded adverse event terms using MedDRA
- OUTC: Patient outcomes such as death, hospitalization, or disability
- RPSR: Sources of the report (healthcare professional, consumer, etc.)
- THER: Therapy dates (start/end) for reported drugs
- INDI: Indications for drug administration

***Patient-Level Listings***

The Patient-Level Listings section provides detailed, case-level adverse event data as reported to the AERS system. Each listing includes information on patient demographics, suspect and concomitant drugs, therapy dates, adverse event terms, outcomes, indications, and source of report.

These listings allow for case traceability and support in-depth clinical and regulatory review of individual adverse event reports.

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
100144838	10014483	8	Follow-up	.	20231123	20140317	20231205	Expedited	
1001678124	10016781	24	Follow-up	20120330	20231130	20140318	20231211	Expedited	
1002130539	10021305	39	Follow-up	20210415	20230523	20140319	20231130	Expedited	
100293662	10029366	2	Follow-up	.	20231108	20140322	20231115	Expedited	
100356167	10035616	7	Follow-up	20140321	20230928	20140325	20231002	Expedited	
1006401878	10064018	78	Follow-up	20121201	20231010	20140408	20231012	Expedited	
1007468610	10074686	10	Follow-up	20090714	20231204	20140414	20231215	Expedited	
100764782	10076478	2	Follow-up	.	20230925	20140414	20231002	Expedited	
1008408132	10084081	32	Follow-up	20140121	20231227	20140417	20231231	Expedited	
100941024	10094102	4	Follow-up	.	20231019	20140422	20231031	Expedited	DK-DKMA-ADR 22499697
1009418019	10094180	19	Follow-up	20130222	20231207	20140422	20231211	Expedited	
1014222251	10142222	51	Follow-up	20131201	20231220	20140430	20231227	Expedited	
101451672	10145167	2	Follow-up	20140201	20231121	20140501	20231128	Periodic	
1015212331	10152123	31	Follow-up	20131205	20231011	20140505	20231023	Expedited	
101621574	10162157	4	Follow-up	20140325	20180423	20140509	20231107	Expedited	
1016611037	10166110	37	Follow-up	20140430	20231011	20140512	20231023	Expedited	
101676303	10167630	3	Follow-up	.	20231113	20140512	20231128	Expedited	

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CA-009507513-1403CAN003893	MERCK	Jaworsky D, Thompson C, Yudin MH, Bitnun A, Brophy J, Samson L, et al.. Use of newer antiretroviral agents, darunavir and etravirine with or without raltegravir, in pregnancy, a report of two cases. Antiviral Therapy. 2010;15(4):585-8	8	Week
PHHY2012CA028320	NOVARTIS		56	Year
PHHY2014CA019281	NOVARTIS		.	
PHHY2014AU032943	NOVARTIS	Ducharlet K, Murphy K, Tan S, Dwyer KM, Goodman D, Aboltins C et al.. Recurrent Mycobacterium haemophilum in a renal transplant recipient. NEPHROLOGY. 2014;19(Suppl 1):14-7	32	Year
JP-B.I. Pharmaceuticals,Inc./Ridgefield-2014-BI-13006NB	BOEHRINGER INGELHEIM		84	Year
CA-ROCHE-1173339	ROCHE		71	Year
CA-ROCHE-1383185	ROCHE		52	Year
DK-UCBSA-117738	UCB		.	
PHHY2013CA116184	NOVARTIS		70	Year
DK-Accord-023209	ACCORD		.	
CA-ROCHE-1198539	ROCHE		28	Year
CA-ROCHE-1319269	ROCHE		52	Year
US-AMGEN-USASP2014031152	AMGEN		52	Year
CA-ROCHE-1393055	ROCHE		38	Year
US-SA-2014SA050696	SANOFI AVENTIS		40	Year
CA-ROCHE-1396927	ROCHE		34	Year
KH-BRISTOL-MYERS SQUIBB COMPANY-20721353	BRISTOL MYERS SQUIBB	Borand L, Madec Y, Laureillard D, Chou M, Marcy O, Pheng P, et al. Plasma concentrations, efficacy and safety of efavirenz in HIV-infected adults treated for tuberculosis in Cambodia (ANRS 1295-CIPRA KH001 CAMELIA trial). PLoS ONE. 2014 Mar 07;9(3):1-10. doi:10.1371/journal.pone.0090350.	.	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
		Y	.		20231205		HP	CA	CA	0	.	GROUP1
Adult	Female	Y	.		20231211		HP	CA	CA	56	.	GROUP3
	Male	Y	.		20231130		HP	CA	CA	.	.	MISSIN
	Male	Y	.		20231115		HP	AU	AU	32	.	GROUP2
Elderly	Female	Y	50	KG	20231002		Physician	JP	JP	84	50	GROUP4
	Female	Y	77	KG	20231012		HP	CA		71	77	GROUP3
	Male	Y	.		20231215		HP	CA	CA	52	.	GROUP3
	Female	Y	.		20231002		Physician	DK	DK	.	.	MISSIN
	Male	Y	.		20231231		Consumer	CA	CA	70	.	GROUP3
	Female	Y	.		20231031		Physician	DK	DK	.	.	MISSIN
Adult	Female	Y	54.4	KG	20231211		Consumer	CA		28	54.4	GROUP2
	Male	Y	89.5	KG	20231227		Consumer	CA		52	89.5	GROUP3
	Female	Y	.		20231127		Consumer	US	US	52	.	GROUP3
	Female	Y	101	KG	20231023		Consumer	CA	CA	38	101	GROUP2
Adult	Female	Y	.		20231107		Physician	US	US	40	.	GROUP2
	Female	Y	.		20231023		Consumer	CA	CA	34	.	GROUP2
		Y	.		20231128		HP	KH	KH	.	.	MISSIN

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101676313	10167631	3	Follow-up	.	20231113	20140512	20231121	Expedited	
101678657	10167865	7	Follow-up	20140503	20231019	20140512	20231022	Expedited	
1017130214	10171302	14	Follow-up	.	20231212	20140514	20231219	Expedited	
1017572232	10175722	32	Follow-up	20121201	20231108	20140516	20231115	Expedited	
101780773	10178077	3	Follow-up	20140401	20231128	20140518	20231201	Expedited	
101916392	10191639	2	Follow-up	20110101	20231023	20140523	20231103	Expedited	
1020642923	10206429	23	Follow-up	20111201	20231129	20140530	20231211	Expedited	
102371704	10237170	4	Follow-up	20130101	20231023	20140613	20231101	Expedited	
1027487983	10274879	83	Follow-up	20151125	20231013	20140702	20231016	Expedited	
1028518546	10285185	46	Follow-up	20140703	20231205	20140708	20231211	Expedited	
1030948614	10309486	14	Follow-up	.	20231212	20140717	20231220	Expedited	
103443973	10344397	3	Follow-up	20140701	20231122	20140728	20231128	Expedited	
1035913611	10359136	11	Follow-up	20190901	20231208	20140804	20231219	Expedited	
103687216	10368721	6	Follow-up	20140506	20231031	20140807	20231105	Expedited	
103749689	10374968	9	Follow-up	20140714	20180424	20140811	20231107	Expedited	
103892335	10389233	5	Follow-up	20080401	20231205	20140818	20231213	Expedited	
103928076	10392807	6	Follow-up	20070101	20231106	20140819	20231111	Periodic	

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KH-BRISTOL-MYERS SQUIBB COMPANY-20721361	BRISTOL MYERS SQUIBB	Borand L, Madec Y, Laureillard D, Chou M, Marcy O, Pheng P, et al. Plasma concentrations, efficacy and safety of efavirenz in HIV-infected adults treated for tuberculosis in Cambodia (ANRS 1295-CIPRA KH001 CAMELIA trial). PLoS ONE. 2014 Mar 07;9(3):1-10. doi:10.1371/journal.pone.0090350.	.		
US-GlaxoSmithKline-A1072709A	GLAXOSMITHKLINE		.		
US-PFIZER INC-2014131046	PFIZER		63	Year	
CA-ROCHE-1176621	ROCHE		65	Year	
CA-ROCHE-1403298	ROCHE		59	Year	
LK-ABBVIE-14P-145-1240272-00	ABBVIE	Perera MAL, Yogaratnam J. De novo delayed onset hypothermia secondary to therapeutic doses of risperidone in bipolar affective disorder. Ther Adv Psychopharmacol. 2014 Apr; 4(2):70-74.	75	Year	
CA-ROCHE-1408363	ROCHE		46	Year	
TN-ABBVIE-14P-160-1247792-00	ABBVIE	Charfi O, Zaiem A, Sahnoun R, et al. Multiple drug hypersensitivity in an epileptic woman. Fundam Clin Pharmacol.. 2014, 28, 58-59.	50	Year	
CA-ROCHE-1404692	ROCHE		46	Year	
CA-ROCHE-1267909	ROCHE		49	Year	
CA-ROCHE-1435384	ROCHE		72	Year	
NL-AMGEN-NLDSP2014055453	AMGEN		81	Year	Elderly
CA-ROCHE-1444820	ROCHE		70	Year	
PHHO2014IT006782	NOVARTIS		68	Year	
ES-SA-2014SA095168	SANOFI AVENTIS		68	Year	Elderly
PHHY2014CZ097031	NOVARTIS	Sperl J, Frankova S, Kieslichova E, Oliverius M, Janousek L, Honsova E et al.. Urgent liver transplantation for chemotherapy-induced HBV reactivation: a suitable option in patients recently treated for malignant lymphoma. TRANSPLANTATION PROCEEDINGS. 2013;45(7):2834-7	42	Year	
US-JNJFOC-20140814952	JOHNSON AND JOHNSON		.		Child

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<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Y	.		20231121		HP	KH	KH	.	.	MISSIN
	Y	.		20231022		Physician	US	US	.	.	MISSIN
Female	Y	.		20231219		Consumer	US	US	63	.	GROUP3
Female	Y	57	KG	20231115		HP	CA		65	57	GROUP3
Female	Y	.		20231202		Physician	CA		59	.	GROUP3
Female	Y	.		20231103		Physician	LK	LK	75	.	GROUP3
Female	Y	.		20231211		Consumer	CA	CA	46	.	GROUP2
Female	Y	.		20231101		HP	TN	TN	50	.	GROUP2
Male	Y	100	KG	20231016		HP	CA		46	100	GROUP2
Female	Y	79	KG	20231211		Consumer	CA		49	79	GROUP2
Male	Y	.		20231220		Physician	CA	CA	72	.	GROUP3
Female	Y	56	KG	20231128		Pharmacist	NL	NL	81	56	GROUP4
Female	Y	.		20231219		Physician	CA	CA	70	.	GROUP3
Male	Y	77	KG	20231106		Physician	IT	IT	68	77	GROUP3
Female	Y	89	KG	20231107		Physician	ES	ES	68	89	GROUP3
Male	Y	.		20231213		HP	CZ	CZ	42	.	GROUP2
Male	Y	.		20231111		Lawyer	US	US	.	.	MISSIN



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103928375	10392837	5	Follow-up	20080101	20231129	20140819	20231206	Periodic	
103985405	10398540	5	Follow-up	20170101	20231108	20140821	20231114	Expedited	
104003092	10400309	2	Follow-up	20110814	20231124	20140821	20231201	Expedited	
1040513313	10405133	13	Follow-up	20110815	20231211	20140825	20231221	Expedited	
1041491125	10414911	25	Follow-up	20140217	20230301	20140828	20231206	Expedited	
104232052	10423205	2	Follow-up	.	20231220	20140902	20231227	Periodic	
104232195	10423219	5	Follow-up	20000101	20231009	20140902	20231015	Expedited	
104232203	10423220	3	Follow-up	.	20231101	20140902	20231107	Periodic	
104266473	10426647	3	Follow-up	20080101	20231011	20140903	20231019	Periodic	
104490482	10449048	2	Follow-up	.	20231213	20140912	20231221	Expedited	
104580772	10458077	2	Follow-up	.	20231213	20140917	20231221	Expedited	
104580883	10458088	3	Follow-up	.	20231213	20140917	20231221	Expedited	

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US-JNJFOC-20140814953	JOHNSON AND JOHNSON		.		Child	Male
PHHY2014CA054596	NOVARTIS		50	Year		Female
GB-SA-2014SA109535	SANOFI AVENTIS		76	Year	Elderly	Male
CA-ROCHE-1454049	ROCHE		56	Year		Female
PHHY2012CA025137	NOVARTIS		.		Adult	Female
US-JNJFOC-20140827195	JOHNSON AND JOHNSON		.			Male
US-JNJFOC-20140827145	JOHNSON AND JOHNSON		.		Child	Male
US-JNJFOC-20140827162	JOHNSON AND JOHNSON		.			Male
US-JNJFOC-20140827151	JOHNSON AND JOHNSON		.		Child	Male
FR-AUROBINDO-AUR-APL-2014-09752	AUROBINDO	Priez-Barallon C, Carlier J, Boyer B, Benslimma M, Faiiton L, Mazoyer C, et al.. Quantification of Pregabalin Using Hydrophilic Interaction HPLC-High-Resolution MS in Postmortem Human Samples: Eighteen Case Reports. Journal of Analytical Toxicology. 2014;38:143-148	51	Year		Male
FR-AUROBINDO-AUR-APL-2014-09568	AUROBINDO	C. Priez-Barallon, Carlier j , Baptiste B, Benslimma M, Faiiton L, Mazoyer c et al.. Quantification of Pregabalin Using Hydrophilic Interaction HPLC-High-Resolution MS oin Postmortem Human samples. Journal of Analytical Toxicology. 2014;38:143-148	34	Year		Male
FR-AUROBINDO-AUR-APL-2014-09569	AUROBINDO	Cedrtc Priez-Barallon, Jeremy Cariicf, Baptiste Boycr, Mouoir Benslimma, Laurent Fanton, Cedrie Mazoyer, Yvan Gaillard. Quantification of pregabalin using hydrophilic interaction HPLC-high-resolution MS in postmortem human samples: eighteen case reports. Journal of Analytical Toxicology. 2014;38:143-148	42	Year		Female

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Y	.		20231206		Lawyer	US	US	.	.	MISSIN
Y	.		20231114		Physician	CA	CA	50	.	GROUP2
Y	.		20231201		HP	GB	GB	76	.	GROUP4
Y	.		20231221		Consumer	CA	CA	56	.	GROUP3
Y	.		20231206		HP	CA	CA	.	.	MISSIN
Y	.		20231227		Lawyer	US	US	.	.	MISSIN
Y	.		20231016		HP	US	US	.	.	MISSIN
Y	.		20231108		Lawyer	US	US	.	.	MISSIN
Y	.		20231019		Lawyer	US	US	.	.	MISSIN
Y	.		20231221		HP	FR	FR	51	.	GROUP3
Y	.		20231221		HP	FR	FR	34	.	GROUP2
Y	.		20231221		HP	FR	FR	42	.	GROUP2

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104635823	10463582	3	Follow-up	20020830	20231011	20140919	20231018	Periodic	
104665748	10466574	8	Follow-up	20040101	20231113	20140922	20231120	Expedited	
104825157	10482515	7	Follow-up	20000101	20231027	20140929	20231031	Expedited	
105144244	10514424	4	Follow-up	20141002	20231101	20141013	20231107	Expedited	
1051596718	10515967	18	Follow-up	20131024	20231208	20141014	20231215	Expedited	
1052690058	10526900	58	Follow-up	20140701	20231003	20141020	20231005	Expedited	
1054038738	10540387	38	Follow-up	20140723	20231106	20141024	20231114	Expedited	
105481232	10548123	2	Follow-up	.	20231204	20141028	20231219	Expedited	
105524185	10552418	5	Follow-up	.	20231217	20141029	20231228	Periodic	
105741013	10574101	3	Follow-up	.	20231016	20141110	20231019	Expedited	
1058928657	10589286	57	Follow-up	20141101	20231101	20141118	20231113	Expedited	
105947013	10594701	3	Follow-up	.	20231101	20141120	20231113	Expedited	
1060157312	10601573	12	Follow-up	20151008	20231003	20141124	20231016	Expedited	
106091663	10609166	3	Follow-up	.	20231122	20141126	20231204	Expedited	

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US-JNJFOC-20140911281	JOHNSON AND JOHNSON		4	Year	Child	Male
US-JNJFOC-20140913723	JOHNSON AND JOHNSON		13	Year	Adolescent	Male
US-PFIZER INC-2014265641	MYLAN		67	Year		Female
CA-JNJFOC-20141001651	JOHNSON AND JOHNSON		37	Year	Adult	Female
PHHY2013CA024321	NOVARTIS		70	Year		Male
CA-ROCHE-1341517	ROCHE		75	Year		Male
PHHY2011CA65816	NOVARTIS		56	Year		Male
DK-SUN PHARMACEUTICAL INDUSTRIES LTD-2014SUN02397	RANBAXY	-. -. -;-	.			Female
US-JNJFOC-20141016940	JOHNSON AND JOHNSON		.			Male
PHHY2012FR136303	NOVARTIS	Morio F, Robert T, Leterrier M, Cassagnau E, Pape PL, Danner-Boucher I, et al.. Phaeohyphomycosis due to Alternaria infectoria: A single-center experience with utility of PCR for diagnosis and species identification. MEDICAL MYCOLOGY. 2012;50:594-600	56	Year		Male
CA-ROCHE-1491350	ROCHE		61	Year		Female
US-AUROBINDO PHARMA LTD, UK-AUR-APL-2014-05801	AUROBINDO	Adam R.Bosak, Aaron B Skolnik. PMID: 24805103 (PubMed). JMEDITOXICOL. 2014	23	Year		Female
CA-INCYTE CORPORATION-2013IN001206	INCYTE		.			
IT-AUROBINDO-AUR-APL-2014-09196	AUROBINDO	Romigi A, Placidi F, Izzi F, Albanese M, Marchi A, Marciani MG, et al. Lacosamide as treatment of focal symptomatic epilepsy in a patient with Liver alcoholic cirrhosis. Epilepsia. 2014;55(suppl.):4-246	64	Year		Male

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<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Y	.		20231018		Lawyer	US	US	4	.	GROUP1
Y	.		20231120		HP	US	US	13	.	GROUP1
Y	.		20231031		Consumer	US	US	67	.	GROUP3
Y	62	KG	20231107		HP	CA	CA	37	62	GROUP2
Y	110.2	KG	20231215		HP	CA	CA	70	110.2	GROUP3
Y	73	KG	20231005		Consumer	CA		75	73	GROUP3
Y	.		20231114		HP	CA	CA	56	.	GROUP3
Y	.		20231219		Physician	DK	DK	.	.	MISSIN
Y	.		20231228		Lawyer	US	US	.	.	MISSIN
Y	.		20231019		HP	FR	FR	56	.	GROUP3
Y	.		20231113		Consumer	CA	CA	61	.	GROUP3
Y	.		20231113		HP	US	US	23	.	GROUP1
Y	.		20231016		Consumer	CA	CA	.	.	MISSIN
Y	.		20231204		Physician	IT	IT	64	.	GROUP3

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
106336646	10633664	6	Follow-up	20060310	20231115	20141205	20231123	Expedited	
106352232	10635223	2	Follow-up	.	20231127	20141205	20231130	Expedited	
106520463	10652046	3	Follow-up	20140301	20231127	20141215	20231206	Periodic	
1069198853	10691988	53	Follow-up	20130404	20231207	20150106	20231218	Expedited	
1070483325	10704833	25	Follow-up	.	20231120	20141127	20231205	Expedited	
107314353	10731435	3	Follow-up	.	20231122	20150123	20231202	Expedited	
107316442	10731644	2	Follow-up	.	20231129	20150123	20231214	Expedited	
1074008517	10740085	17	Follow-up	20131126	20231201	20150127	20231206	Expedited	
107408544	10740854	4	Follow-up	.	20231218	20150127	20231228	Periodic	
1074197911	10741979	11	Follow-up	.	20231201	20150127	20231207	Expedited	
107584123	10758412	3	Follow-up	.	20231108	20150203	20231113	Periodic	
1075880717	10758807	17	Follow-up	20150101	20231003	20150203	20231013	Expedited	
1078729218	10787292	18	Follow-up	20150116	20231130	20150211	20231207	Expedited	
1080136616	10801366	16	Follow-up	20150101	20231031	20150217	20231104	Expedited	
108390175	10839017	5	Follow-up	20090101	20231118	20150220	20231129	Expedited	
108824172	10882417	2	Follow-up	.	20231023	20150303	20231103	Expedited	
1088288812	10882888	12	Follow-up	.	20231017	20150303	20231020	Periodic	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending report</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>
US-JNJFOC-20141119040	JOHNSON AND JOHNSON		14	Year	Adolescent	Male
IT-UCBSA-2014020602	UCB	Romigi A, Placidi F, Liguori C, Izzi F, Marchi A, Tarquini E, et al. Lacosamide as add-on treatment of focal symptomatic epilepsy in a patient with alcoholic liver cirrhosis. Epilepsy + Behaviour case reports. 2014;2:161-3	64	Year		Male
US-PFIZER INC-2014341931	PFIZER		60	Year		Female
CA-ROCHE-1516574	ROCHE		74	Year		Male
CA-APOTEX-2014AP005774	APOTEX		64	Year		Female
US-AUROBINDO-AUR-APL-2015-00309	AUROBINDO	Walton J, Byrum M, Shumaker A, Coury DL.. Prolonged bradycardia and hypotension following guanfacine extended release overdose. Journal of Child and Adolescent Psychopharmacology. 2014;8(24):463-465	8	Year		Male
AU-RANBAXY-2015R3-91920	RANBAXY		.			Male
CA-ROCHE-1314168	ROCHE		68	Year		Female
US-PFIZER INC-2015031417	PFIZER		66	Year		Female
US-PFIZER INC-2015030234	PFIZER		62	Year		Female
US-JNJFOC-20150112301	JOHNSON AND JOHNSON		.			Male
US-PFIZER INC-2015038990	PFIZER		72	Year		Female
CA-ROCHE-1535957	ROCHE		51	Year		Female
CA-ROCHE-1536217	ROCHE		.			Female
GB-AUROBINDO-AUR-APL-2015-01375	AUROBINDO		58	Year		Male
DE-TEVA-544221GER	TEVA		.			Male
US-PFIZER INC-2015074600	PFIZER		77	Year		Male



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Y	.		20231123		HP	US	US	14	.	GROUP1
Y	.		20231130		Physician	IT	IT	64	.	GROUP3
Y	59	KG	20231206		Consumer	US	US	60	59	GROUP3
Y	.		20231218		Consumer	CA	CA	74	.	GROUP3
Y	68	KG	20231205		HP	CA	CA	64	68	GROUP3
Y	.		20231202		Physician	US	US	8	.	GROUP1
Y	.		20231214		Consumer	AU	AU	.	.	MISSIN
Y	136.1	KG	20231206		Consumer	CA		68	136.1	GROUP3
Y	.		20231228		Consumer	US	US	66	.	GROUP3
Y	83.91	KG	20231207		HP	US	US	62	83.91	GROUP3
Y	.		20231114		Lawyer	US	US	.	.	MISSIN
Y	59	KG	20231013		Consumer	US	US	72	59	GROUP3
Y	.		20231208		Physician	CA	CA	51	.	GROUP3
Y	71.2	KG	20231104		HP	CA		.	71.2	MISSIN
Y	100	KG	20231129		Physician	GB	GB	58	100	GROUP3
Y	.		20231103		HP	DE	DE	.	.	MISSIN
Y	78.84	KG	20231020		Consumer	US	US	77	78.84	GROUP4

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
109031962	10903196	2	Follow-up	.	20230930	20150311	20231008	Expedited	
109108923	10910892	3	Follow-up	.	20231025	20150312	20231101	Expedited	
109174139	10917413	9	Follow-up	.	20231016	20150316	20231021	Expedited	PHHY2015ES028667
1092018038	10920180	38	Follow-up	20150101	20231103	20150317	20231108	Expedited	
109448672	10944867	2	Follow-up	20131101	20231113	20150323	20231122	Periodic	
109651512	10965151	2	Follow-up	.	20231009	20150330	20231016	Expedited	
109680288	10968028	8	Follow-up	20150101	20231025	20150330	20231031	Expedited	
1097587654	10975876	54	Follow-up	20140101	20231107	20150401	20231112	Expedited	
1098206364	10982063	64	Follow-up	20130101	20231213	20150403	20231215	Expedited	
109893399	10989339	9	Follow-up	20190114	20231127	20150406	20231204	Expedited	
1099047564	10990475	64	Follow-up	20150312	20231107	20150406	20231108	Expedited	
109916134	10991613	4	Follow-up	20130101	20231217	20150406	20231221	Periodic	
109922307	10992230	7	Follow-up	.	20231102	20150406	20231105	Expedited	
109948122	10994812	2	Follow-up	20140101	20231025	20150407	20231030	Expedited	
109971003	10997100	3	Follow-up	20131201	20231210	20150408	20231221	Expedited	
1102019552	11020195	52	Follow-up	20120807	20231116	20150413	20231123	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending report</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>
US-AUROBINDO-AUR-APL-2015-01933	AUROBINDO	C. Okoli, D. Degrand, C. DuBeau.. Chicken or Egg? Unscrambling agitation and antipsychotics. Journal of the American Geriatrics Society. 2014;62(A15):S24-S25	91	Year		Female
US-JAZZ-2014-US-016722	JAZZ		.			Male
PHHY2015ES028667	NOVARTIS		47	Year		Female
PHHY2015CA028279	NOVARTIS		2	Year		Female
US-JNJFOC-20150305685	JOHNSON AND JOHNSON		14	Year	Adolescent	Male
US-ROCHE-1555489	ROCHE	Omuro A, Correa D, Moskowitz C, Matasar M, DeAngelis L, Kaley T, Gavrilovic I, Nolan C, Pentsova E, Grommes C, Abrey L and Sauter C. Rituximab, methotrexate (MTX), procarbazine, and vincristine (R-MPV) followed by consolidation high-dose chemotherapy (HDC) and autologous stem-cell transplant (ASCT) for newly diagnosed primary CNS lymphoma (PCNSL).. American Society of Clinical Oncology 2012;:-.	.			
US-JAZZ-2015-US-004364	JAZZ		.			Female
PHHY2014CA142506	NOVARTIS		.		Elderly	Female
CA-ROCHE-1350337	ROCHE		.			Female
US-PFIZER INC-2015113764	PFIZER		57	Year		Female
CA-ROCHE-1551832	ROCHE		57	Year		Male
US-PFIZER INC-2015117274	PFIZER		64	Year		Female
PHHY2015FR036316	NOVARTIS	Khanafer N, Neuraz A, Benet T, Cour M, Persat F, Labussiere H et al.. Acute graft-versus-host disease, invasive aspergillosis and Clostridium difficile colitis after peripheral blood stem cell transplantation: A complex network of causalities and a challenge for prevention. ANAEROBE. 2015;33:98-100	58	Year		Male
BR-BIOMARINAP-BR-2015-105960	BIOMARIN		.			
US-AEGERION-AEGR000303	AEGERION		58	Year		Female
CA-ROCHE-1137189	ROCHE		46	Year		Female

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Y	.		20231008		HP	US	US	91	.	GROUP4
Y	175	KG	20231101		Consumer	US	US	.	175	MISSIN
Y	.		20231021		HP	ES	ES	47	.	GROUP2
Y	.		20231108		HP	CA	CA	2	.	GROUP1
Y	.		20231122		Lawyer	US	US	14	.	GROUP1
Y	.		20231016		HP	US		.	.	MISSIN
Y	.		20231031		Physician	US	US	.	.	MISSIN
Y	.		20231112		HP	CA	CA	.	.	MISSIN
Y	47	KG	20231215		Consumer	CA		.	47	MISSIN
Y	113.4	KG	20231204		Consumer	US	US	57	113.4	GROUP3
Y	83.5	KG	20231108		HP	CA		57	83.5	GROUP3
Y	69.388	KG	20231221		Consumer	US	US	64	69.388	GROUP3
Y	.		20231105		HP	FR	FR	58	.	GROUP3
Y	.		20231030		Consumer	BR	BR	.	.	MISSIN
Y	96.599	KG	20231221		HP	US	US	58	96.599	GROUP3
Y	97	KG	20231123		HP	CA		46	97	GROUP2

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>	<i>Manufacturer's unique report identifier.</i>
1102109863	11021098	63	Follow-up	20141110	20231204	20150413	20231215	Expedited		CA-ROCHE-1563162
110215902	11021590	2	Follow-up	.	20231019	20150413	20231030	Expedited		FR-BAYER-2015-127997
1102411313	11024113	13	Follow-up	20140101	20231017	20150413	20231024	Expedited		PHHY2014CA064714
110462235	11046223	5	Follow-up	.	20231026	20150418	20231109	Expedited		FR-AUROBINDO-AUR-APL-2015-03294
110471852	11047185	2	Follow-up	20150101	20231109	20150420	20231118	Periodic		US-AMGEN-USASL2015037321
110577006	11057700	6	Follow-up	20141017	20231011	20150423	20231016	Expedited		US-ROCHE-1566328
110734563	11073456	3	Follow-up	20150413	20231124	20150428	20231128	Expedited		US-SHIRE-US201503423
110755913	11075591	3	Follow-up	20150101	20160119	20150429	20231025	Expedited		JP-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-026565
1107567522	11075675	22	Follow-up	20110317	20231212	20150429	20231219	Expedited		PHHY2011CA22905
110781863	11078186	3	Follow-up	19990516	20231009	20150430	20231016	Periodic		US-JNJFOC-20150414691
1109083723	11090837	23	Follow-up	.	20201209	20150505	20231202	Expedited		CA-BAYER-2015-099605
110972475	11097247	5	Follow-up	.	20231204	20150507	20231214	Expedited		US-PFIZER INC-2015148952
110995353	11099535	3	Follow-up	.	20230821	20150508	20231104	Expedited		DE-AUROBINDO-AUR-APL-2015-04015
111012256	11101225	6	Follow-up	20150101	20231116	20150508	20231121	Expedited		US-SHIRE-US201503872

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

Coded name of manufacturer sending repor		Literature Reference information.	Numeric value of patient's age at event.	Unit abbreviation for patient's age	Patient Age Group code	Code for patient's sex	Whether (Y/N) this report was submitted	Numeric value of patient's weight.	Unit abbreviation for patient's weight.
ROCHE			59	Year		Male	Y	95	KG
BAYER		Khanafer N; Neuraz A; Benet T; Vanhems P; Cour M; Argaud L; Persat F; Labussiere H; Michallet M. Acute graft-versus-host disease, invasive aspergillosis and Clostridium difficile colitis after peripheral blood stem cell transplantation: A complex network of causalities and a challenge for prevention. Anaerobe. 2015;33 (-):98-100	58	Year	Adult	Male	Y	.	
NOVARTIS			68	Year		Male	Y	.	
AUROBINDO		Nagham Khanafer, Antoine Neuraz, Thomas Benet , Martin Cour, Florence Persat, Helene Labussiere, Laurent Argaud, Mauricette Michallet, Philippe Vanhems. Acute graft-versus-host disease, invasive aspergillosis and Clostridium difficile colitis after peripheral blood stem cell transplantation: A complex network of causalities and a challenge for prevention.. Anaerobe. 2015;33:98-100	58	Year		Male	Y	.	
AMGEN			54	Year	Adult	Female	Y	.	
ROCHE			41	Year		Female	Y	78.542	KG
TAKEDA			33	Year		Female	Y	.	
BRISTOL MYERS SQUIBB			54	Year	Adult	Female	Y	.	
NOVARTIS			48	Year		Male	Y	.	
JOHNSON AND JOHNSON			14	Year	Adolescent	Male	Y	.	
BAYER			64	Year	Adult	Female	Y	69	KG
PFIZER		Valeshabad, A.. Posterior segment toxicity after gemcitabine and docetaxel chemotherapy. Optometry and Vision Science. 2015;92(5):e110-3	78	Year		Female	Y	.	
AUROBINDO		Evelyn Pawlik, Hellmut Mahler, Benno Hartung, Gerd Plasser, Thomas Daldrop. Drug-related death: Adulterants from cocaine preparations in lung tissue and blood. Forensic Science International. 2015;249:294-303	28	Year		Male	Y	.	
TAKEDA			.			Female	Y	77	KG

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
20231215		Consumer	CA	CA	59	95	GROUP3
20231030		HP	FR	FR	58	.	GROUP3
20231024		HP	CA	CA	68	.	GROUP3
20231109		HP	FR	FR	58	.	GROUP3
20231117		Consumer	US	US	54	.	GROUP3
20231016		HP	US		41	78.542	GROUP2
20231128		HP	US	US	33	.	GROUP2
20231025		Physician	JP	JP	54	.	GROUP3
20231219		HP	CA	CA	48	.	GROUP2
20231016		HP	US	US	14	.	GROUP1
20231202		Consumer	CA	CA	64	69	GROUP3
20231214		Physician	US	US	78	.	GROUP4
20231104		HP	DE	DE	28	.	GROUP2
20231121		Physician	US	US	.	77	MISSIN

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
111043705	11104370	5	Follow-up	20100101	20231220	20150511	20231227	Periodic	
111044465	11104446	5	Follow-up	20140101	20230925	20150511	20231002	Expedited	
111092522	11109252	2	Follow-up	20140101	20230927	20150513	20231003	Periodic	
111186103	11118610	3	Follow-up	19980101	20231013	20150518	20231017	Periodic	
111191394	11119139	4	Follow-up	20060801	20231206	20150518	20231213	Periodic	
1112193211	11121932	11	Follow-up	20130423	20231215	20150519	20231222	Expedited	
111403192	11140319	2	Follow-up	20081101	20231025	20150525	20231102	Periodic	
111408893	11140889	3	Follow-up	.	20231110	20150525	20231117	Periodic	
111425004	11142500	4	Follow-up	20130101	20231207	20150527	20231215	Expedited	
111430143	11143014	3	Follow-up	.	20150511	20150526	20231116	Expedited	
111500224	11150022	4	Follow-up	20150101	20231121	20150529	20231128	Expedited	
111513767	11151376	7	Follow-up	20141101	20231221	20150601	20231228	Expedited	
111665733	11166573	3	Follow-up	20040101	20231108	20150605	20231114	Periodic	



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>
US-JNJFOC-20150506056	JOHNSON AND JOHNSON		.		Adolescent	Male
US-JNJFOC-20150506063	JOHNSON AND JOHNSON		.		Adolescent	Male
US-JNJFOC-20150506080	JOHNSON AND JOHNSON		.		Adult	Male
US-JNJFOC-20150511265	JOHNSON AND JOHNSON		1	Decade	Child	Male
US-JNJFOC-20150511271	JOHNSON AND JOHNSON		8	Year	Child	Male
US-AEGERION PHARMACEUTICALS-AEGR000731	AEGERION		50	Year		Female
US-JNJFOC-20140704236	JOHNSON AND JOHNSON		18	Year	Adult	Male
US-JNJFOC-20141004783	JOHNSON AND JOHNSON		.			Male
US-JAZZ-JPI-P-034500	JAZZ		.			Female
US-AUROBINDO-AUR-APL-2015-04261	AUROBINDO	Gong Z, et al. Flare of CRPS symptoms after lidocaine infusion.. Journal of Pain. 2015;16(41):S75	27	Year		Female
US-JAZZ-2015-US-007755	JAZZ		.			Female
FR-SHIRE-FR201504520	TAKEDA		40	Year		Female
US-JNJFOC-20150601079	JOHNSON AND JOHNSON		.		Child	Male

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Y	.		20231227		Lawyer	US	US	.	.	MISSIN
Y	.		20231002		Lawyer	US	US	.	.	MISSIN
Y	.		20231004		Lawyer	US	US	.	.	MISSIN
Y	.		20231017		Lawyer	US	US	10	.	GROUP1
Y	.		20231213		HP	US	US	8	.	GROUP1
Y	80.726	KG	20231222		Physician	US	US	50	80.726	GROUP2
Y	.		20231102		Lawyer	US	US	18	.	GROUP1
Y	.		20231117		HP	US	US	.	.	MISSIN
Y	75	KG	20231215		HP	US	US	.	75	MISSIN
Y	.		20231116		HP	US	US	27	.	GROUP2
Y	.		20231128		HP	US	US	.	.	MISSIN
Y	.		20231228		HP	FR	FR	40	.	GROUP2
Y	.		20231114		Lawyer	US	US	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
1117182022	11171820	22	Follow-up	20140201	20231030	20150608	20231114	Expedited	
111731695	11173169	5	Follow-up	20150101	20231013	20150608	20231017	Expedited	
111755239	11175523	9	Follow-up	20150421	20231218	20150609	20231229	Expedited	
111772814	11177281	4	Follow-up	.	20231113	20150610	20231122	Expedited	
111787964	11178796	4	Follow-up	.	20150716	20150610	20231001	Expedited	
1118598419	11185984	19	Follow-up	20150101	20230901	20150612	20231128	Expedited	
111984347	11198434	7	Follow-up	20131220	20231122	20150618	20231204	Expedited	
1119850317	11198503	17	Follow-up	.	20231205	20150618	20231208	Expedited	
112024568	11202456	8	Follow-up	20150316	20231018	20150619	20231030	Expedited	
1121274917	11212749	17	Follow-up	20150605	20231115	20150623	20231129	Expedited	
1121749411	11217494	11	Follow-up	20140717	20231221	20150625	20231228	Expedited	
112237713	11223771	3	Follow-up	20120601	20231215	20150629	20231222	Periodic	
112281423	11228142	3	Follow-up	.	20231101	20150630	20231110	Expedited	
112305158	11230515	8	Follow-up	20140612	20231220	20150701	20231226	Expedited	
112362434	11236243	4	Follow-up	20150101	20231017	20150702	20231023	Expedited	
112534824	11253482	4	Follow-up	20150624	20231012	20150709	20231020	Expedited	
1126655518	11266555	18	Follow-up	20150501	20231006	20150713	20231013	Expedited	
112687622	11268762	2	Follow-up	20130612	20231121	20150714	20231130	Expedited	
112845682	11284568	2	Follow-up	.	20150203	20150720	20231001	Periodic	
112845693	11284569	3	Follow-up	20141212	20150109	20150720	20231001	Periodic	
112877752	11287775	2	Follow-up	20130612	20231121	20150721	20231201	Expedited	GB-MHRA-EYC 00125277

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
CO-INCYTE CORPORATION-2015IN002457	INCYTE		.		
US-JAZZ-2015-US-008155	JAZZ		.		
CZ-ABBVIE-15P-217-1399419-00	ABBVIE		17	Year	
US-PFIZER INC-2015192642	PFIZER	Eshki, M.. Twelve-year analysis of severe cases of drug reaction with eosinophilia and systemic symptoms: a cause of unpredictable multiorgan failure. Arch Dermatol. 2009;145 (1):67-72	30	Year	
ES-TAKEDA-2015MPI003803	TAKEDA		.		
PHHY2015CA066638	NOVARTIS		57	Year	
CA-ROCHE-1595645	ROCHE		25	Year	
CA-AMGEN-CANSP2015012893	AMGEN		67	Year	Elderly
CA-ROCHE-1596879	ROCHE		56	Year	
CA-AEGERION PHARMACEUTICALS-AEGR001107	AEGERION		55	Year	
CA-ROCHE-1599129	ROCHE		59	Year	
US-AMGEN-USASP2015062152	AMGEN		52	Year	Adult
US-AUROBINDO-AUR-APL-2015-05521	AUROBINDO	Akhtar J, et al.. Atypical neuroimaging findings in a patient presenting with overdose: A case report. Clinical Toxicology. 2015;53:306abstr154	67	Year	
CA-ROCHE-1601882	ROCHE		58	Year	
US-JAZZ-2015-US-009771	JAZZ		.		
JP-PFIZER INC-2015221062	PFIZER		74	Year	
PHHY2015CA069517	NOVARTIS		69	Year	
GB-MACLEODS PHARMACEUTICALS US LTD-MAC2015001858	MACLEODS		.		
US-TAKEDA-2015TUS001380	TAKEDA		.		
US-TAKEDA-2015TUS000289	TAKEDA		37	Year	
GB-SA-2015SA102482	SANOFI AVENTIS		71	Year	Elderly

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Y	.		20231114		HP	CO	CO	.	.	MISSIN
Male	Y	79	KG	20231017		Consumer	US	US	.	79	MISSIN
Female	Y	69	KG	20231229		Physician	CZ	CZ	17	69	GROUP1
Female	Y	.		20231122		Physician	FR	FR	30	.	GROUP2
	Y	.		20231001		Physician	ES	ES	.	.	MISSIN
Female	Y	.		20231127		HP	CA	CA	57	.	GROUP3
Male	Y	.		20231204		Consumer	CA	CA	25	.	GROUP1
Female	Y	73	KG	20231207		Physician	CA	CA	67	73	GROUP3
Female	Y	.		20231030		Consumer	CA	CA	56	.	GROUP3
Male	Y	63.492	KG	20231129		Pharmacist	CA	CA	55	63.492	GROUP3
Female	Y	126.4	KG	20231228		Physician	CA	CA	59	126.4	GROUP3
Female	Y	.		20231222		Consumer	US	US	52	.	GROUP3
Female	Y	.		20231110		HP	US	US	67	.	GROUP3
Female	Y	.		20231226		Physician	CA	CA	58	.	GROUP3
Female	Y	.		20231023		Consumer	US	US	.	.	MISSIN
Female	Y	40	KG	20231020		Physician	JP	JP	74	40	GROUP3
Male	Y	.		20231013		HP	CA	CA	69	.	GROUP3
	Y	.		20231130		Consumer	GB	GB	.	.	MISSIN
	Y	.		20231001		Consumer	US	US	.	.	MISSIN
Female	Y	73.16	KG	20231001		Consumer	US	US	37	73.16	GROUP2
Female	Y	59.42	KG	20231201		Consumer	GB	GB	71	59.42	GROUP3

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
112904962	11290496	2	Follow-up	20130612	20231121	20150722	20231202	Expedited	GB-MHRA-EYC 00125277
1129109810	11291098	10	Follow-up	20150112	20231123	20150722	20231130	Expedited	
113024092	11302409	2	Follow-up	20130612	20231113	20150723	20231120	Expedited	
113066405	11306640	5	Follow-up	.	20230131	20150723	20231009	Expedited	
1131105412	11311054	12	Follow-up	20160512	20231221	20150727	20231227	Expedited	
113145098	11314509	8	Follow-up	.	20231207	20150727	20231220	Periodic	
113146645	11314664	5	Follow-up	.	20231025	20150727	20231030	Expedited	
113155356	11315535	6	Follow-up	20150617	20231210	20150728	20231221	Expedited	
113222892	11322289	2	Follow-up	20150101	20231212	20150730	20231218	Periodic	
113257456	11325745	6	Follow-up	20140822	20231102	20150731	20231107	Expedited	
1134491610	11344916	10	Follow-up	20150723	20231130	20150806	20231203	Expedited	
113600164	11360016	4	Follow-up	20141023	20231110	20150810	20231121	Expedited	
113625366	11362536	6	Follow-up	.	20231218	20150810	20231229	Expedited	
113625446	11362544	6	Follow-up	.	20231124	20150810	20231226	Expedited	
113659802	11365980	2	Follow-up	20150722	20150803	20150811	20231001	Periodic	
113662138	11366213	8	Follow-up	20150510	20231127	20150811	20231129	Expedited	
113685715	11368571	5	Follow-up	.	20231026	20150812	20231102	Expedited	
113755943	11375594	3	Follow-up	20080101	20231002	20150813	20231005	Periodic	
1138286731	11382867	31	Follow-up	.	20231017	20150814	20231024	Expedited	
113868659	11386865	9	Follow-up	20140201	20231031	20150817	20231114	Periodic	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
GB-Accord-032254	ACCORD		71	Year	Elderly
PHHY2015CO021693	NOVARTIS		55	Year	
GB-AUROBINDO-AUR-APL-2015-06499	AUROBINDO		71	Year	
FR-ABBVIE-15P-056-1432036-00	ABBVIE		.		
CA-ROCHE-1612806	ROCHE		64	Year	
US-PFIZER INC-2015237832	PFIZER		55	Year	
BR-BIOMARINAP-BR-2015-106908	BIOMARIN		.		
US-AEGERION PHARMACEUTICALS-AEGR001891	AEGERION		71	Year	
US-AMGEN-USASP2015075635	AMGEN		38	Year	Adult
CA-ROCHE-1429439	ROCHE		36	Year	
US-ABBVIE-15P-163-1437185-00	ABBVIE		19	Year	
NL-AEGERION-AEGR001916	AEGERION		.		
PHHY2015CA096506	NOVARTIS	Farrell B, Merkley VF, Thompson W. Managing polypharmacy in a 77-year-old woman with multiple prescribers. CMAJ. 2013;185(14):1240-5	77	Year	
PHHY2015CA094468	NOVARTIS	Farrell B, Merkley VF, Thompson W. Managing polypharmacy in a 77-year-old woman with multiple prescribers. CMAJ. 2013;185(14):1240-5	77	Year	
US-TAKEDA-2015MPI005254	TAKEDA		88	Year	
BE-ABBVIE-15P-013-1440942-00	ABBVIE		34	Year	
PHHY2015CA096504	NOVARTIS	Farrell B, Merkley VF, Thompson W. Managing polypharmacy in a 77-year-old woman with multiple prescribers. CMAJ. 2013;185(14):1240-5	77	Year	
GR-Eisai Medical Research-EC-2015-009480	EISAI		54	Year	Adult
CA-PFIZER INC-2015267393	PFIZER		60	Year	
US-PFIZER INC-2015267334	PFIZER		60	Year	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Female	Y	59.42	KG	20231202		Consumer	GB	GB	71	59.42	GROUP3
Male	Y	101	KG	20231130		Consumer	CO	CO	55	101	GROUP3
Female	Y	59.42	KG	20231121		Consumer	GB	GB	71	59.42	GROUP3
Male	Y	.		20231006		HP	FR	FR	.	.	MISSIN
Male	Y	.		20231227		Consumer	CA	CA	64	.	GROUP3
Female	Y	91	KG	20231220		Consumer	US	US	55	91	GROUP3
	Y	.		20231030		Consumer	BR	BR	.	.	MISSIN
Male	Y	78.912	KG	20231221		HP	US	US	71	78.912	GROUP3
Female	Y	.		20231217		Consumer	US	US	38	.	GROUP2
Female	Y	.		20231107		HP	CA		36	.	GROUP2
Female	Y	.		20231203		Physician	US	US	19	.	GROUP1
	Y	.		20231121		Physician	NL	NL	.	.	MISSIN
Female	Y	.		20231229		HP	CA	DE	77	.	GROUP4
Female	Y	.		20231226		HP	CA	CA	77	.	GROUP4
Male	Y	.		20231001		Physician	US	US	88	.	GROUP4
Female	Y	.		20231129		Physician	BE	BE	34	.	GROUP2
Female	Y	.		20231102		HP	CA	CA	77	.	GROUP4
Female	Y	.		20231005		Physician	GR		54	.	GROUP3
Female	Y	.		20231024		Consumer	CA	CA	60	.	GROUP3
Female	Y	67	KG	20231114		Consumer	US	US	60	67	GROUP3



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
113895298	11389529	8	Follow-up	.	20231009	20150817	20231011	Expedited	
1140884841	11408848	41	Follow-up	20150624	20231220	20150823	20231227	Expedited	
114216053	11421605	3	Follow-up	.	20231017	20150826	20231101	Expedited	
1142723210	11427232	10	Follow-up	20061010	20231031	20150827	20231109	Expedited	
114378733	11437873	3	Follow-up	.	20231016	20150831	20231018	Expedited	
1144435333	11444353	33	Follow-up	20141001	20231122	20150902	20231204	Expedited	
1144476723	11444767	23	Follow-up	20150818	20231205	20150902	20231208	Expedited	
114473694	11447369	4	Follow-up	.	20231109	20150902	20231115	Expedited	
1145016915	11450169	15	Follow-up	20170201	20231206	20150903	20231213	Expedited	
1145717522	11457175	22	Follow-up	.	20231017	20150904	20231020	Expedited	
114731322	11473132	2	Follow-up	20100116	20231127	20150908	20231212	Expedited	
114734765	11473476	5	Follow-up	20150311	20230713	20150908	20231219	Periodic	
114749292	11474929	2	Follow-up	.	20161115	20150908	20231130	Periodic	
1147514547	11475145	47	Follow-up	20130603	20231108	20150908	20231110	Expedited	
114756606	11475660	6	Follow-up	.	20231016	20150909	20231028	Periodic	
114798209	11479820	9	Follow-up	20140101	20231108	20150909	20231116	Expedited	
1148683512	11486835	12	Follow-up	.	20231129	20150910	20231212	Periodic	
1149087937	11490879	37	Follow-up	20140101	20231205	20150910	20231208	Expedited	
114958534	11495853	4	Follow-up	.	20230929	20150911	20231004	Expedited	
115140276	11514027	6	Follow-up	20130101	20231019	20150916	20231027	Periodic	
1151574948	11515749	48	Follow-up	20050101	20231205	20150916	20231215	Expedited	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
GR-BAXTER-2015BAX043802	BAXTER		.	
CA-ROCHE-1599373	ROCHE		55	Year
IN-MACLEODS PHARMA UK LTD-MAC2015001943	MACLEODS	Chowdhry V, Padhi M, Mohanty BB, Mohapatra S.. Fluoroquinolones: An under-recognized cause for delirium.. Journal of Anaesthesiology Clinical Pharmacology. 2015;31(3):410-411	.	
US-SA-2014SA109088	SANOFI AVENTIS		56	Year
US-BAXALTA-2015BLT001410	TAKEDA		.	
CA-ROCHE-1628295	ROCHE		64	Year
CA-AMGEN-CANSP2015088930	AMGEN		40	Year
IT-B.I. Pharmaceuticals,Inc./Ridgefield-2015-BI-46714GD	BOEHRINGER INGELHEIM	Lorena M, Autolitano A, Natale G, Uberti F, Vitali F, Schiantarelli C. Telmisartan/hydrochlorothiazide-induced hepatotoxicity. Arch Med Sci. 2015 Aug;11:4: 893-894.	72	Year
CA-ROCHE-1629749	ROCHE		41	Year
CA-AMGEN-CANSP2015088317	AMGEN		60	Year
FR-JAZZ-JPI-P-010717	JAZZ		.	
US-JAZZ-2015-US-003883	JAZZ		42	Year
CA-JAZZ-2014-CA-017416	JAZZ		.	
CA-ROCHE-1188683	ROCHE		29	Year
PHEH2015US014980	NOVARTIS		.	
US-JAZZ-2015-US-010685	JAZZ		.	
US-PFIZER INC-2015294983	PFIZER		52	Year
CA-AMGEN-CANSP2015093585	AMGEN		3	Year
CA-PFIZER INC-2015298314	MYLAN		.	
US-AMGEN-USASP2015094722	AMGEN		57	Year
CA-PFIZER INC-2015293060	PFIZER		1	Year

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Female	Y	.		20231011		Consumer	US	GR	.	.	MISSIN
	Female	Y	48	KG	20231227		HP	CA		55	48	GROUP3
	Female	Y	.		20231101		Physician	IN	IN	.	.	MISSIN
Adult	Female	Y	83.9	KG	20231109		Physician	US	US	56	83.9	GROUP3
	Female	Y	.		20231018		Consumer	US	US	.	.	MISSIN
	Male	Y	76.5	KG	20231204		Consumer	CA	CA	64	76.5	GROUP3
Adult	Female	Y	73	KG	20231208		Physician	CA	CA	40	73	GROUP2
Elderly	Female	Y	.		20231115		Physician	IT	IT	72	.	GROUP3
	Female	Y	.		20231213		HP	CA		41	.	GROUP2
Adult	Female	Y	.		20231020		HP	CA	CA	60	.	GROUP3
		Y	.		20231212		Physician	FR	FR	.	.	MISSIN
	Female	Y	.		20231219		Consumer	US	US	42	.	GROUP2
	Male	Y	.		20231130		Consumer	CA	CA	.	.	MISSIN
	Female	Y	68	KG	20231110		HP	CA		29	68	GROUP2
	Male	Y	86.168	KG	20231028		Consumer	US	US	.	86.168	MISSIN
	Male	Y	122	KG	20231116		Physician	US	US	.	122	MISSIN
	Female	Y	.		20231212		HP	US	US	52	.	GROUP3
Child	Female	Y	64	KG	20231208		HP	CA	CA	3	64	GROUP1
	Female	Y	.		20231004		Consumer	CA	CA	.	.	MISSIN
Adult	Female	Y	.		20231027		Consumer	US	US	57	.	GROUP3
	Female	Y	64	KG	20231215		Physician	CA	CA	1	64	GROUP1

### ADVERSE EVENT REPORTING SYSTEM (AERS) Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
115173833	11517383	3	Follow-up	20150101	20231106	20150917	20231113	Expedited	
1151945678	11519456	78	Follow-up	20150901	20231218	20150918	20231225	Expedited	
115203716	11520371	6	Follow-up	20150115	20231010	20150918	20231017	Expedited	
1156227656	11562276	56	Follow-up	20150817	20231012	20150928	20231020	Expedited	
115668012	11566801	2	Follow-up	.	20231104	20150929	20231109	Expedited	
115732526	11573252	6	Follow-up	20150101	20231117	20150929	20231121	Expedited	
1157787013	11577870	13	Follow-up	20150918	20231116	20150930	20231116	Expedited	
115800019	11580001	9	Follow-up	20130101	20230814	20150930	20231019	Periodic	
1158070941	11580709	41	Follow-up	.	20231017	20150930	20231023	Expedited	
115863238	11586323	8	Follow-up	20140101	20231117	20151001	20231130	Expedited	
115900453	11590045	3	Follow-up	20150923	20231127	20151002	20231129	Expedited	
115907586	11590758	6	Follow-up	20190101	20230725	20151002	20231019	Periodic	
115921113	11592111	3	Follow-up	.	20231201	20151005	20231212	Periodic	
115925813	11592581	3	Follow-up	.	20231214	20151005	20231225	Expedited	
1161812071	11618120	71	Follow-up	20150416	20231218	20151010	20231225	Expedited	
116289952	11628995	2	Follow-up	.	20231214	20151014	20231222	Expedited	
116313907	11631390	7	Follow-up	20180829	20231213	20151014	20231220	Expedited	
1163175032	11631750	32	Follow-up	20140501	20231206	20151015	20231211	Expedited	
116502727	11650272	7	Follow-up	20150601	20231108	20151021	20231115	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
US-VERTEX PHARMACEUTICALS-2015-003432	VERTEX	McKinzie CJ, Goralski JL, Noah TL, Retsch-Bogart GZ, Prieur MB. Worsening anxiety and depression after initiation of lumacaftor/ivacaftor combination therapy in adolescent females with cystic fibrosis. J Cyst Fibros. 2017	.	
CA-AMGEN-CANSP2015095516	AMGEN		43	Year
JP-ROCHE-1635363	ROCHE		5	Year
AU-SA-2015SA133432	SANOFI AVENTIS		36	Year
IT-SUN PHARMACEUTICAL INDUSTRIES LTD-13SUNGE09P	RANBAXY	D'epiro S, Salvi M, Mattozzi C, Giancristoforo S, Campoli M, Zanniello R et al. Gemcitabineinduced extensive skin necrosis. Case Rep Med. 2012;2012:3 pages	82	Year
US-INCYTE CORPORATION-2015IN003888	INCYTE		.	
US-PFIZER INC-2015319862	PFIZER		17	Year
US-JAZZ-2015-US-014728	JAZZ		.	
CA-ABBVIE-15K-028-1471671-00	ABBVIE		.	
US-AEGERION-AEGR000766	AEGERION		.	
US-SHIRE-US201512036	TAKEDA		32	Year
US-JAZZ-2015-US-014987	JAZZ		.	
US-PFIZER INC-2015327961	PFIZER		68	Year
US-AUROBINDO-AUR-APL-2011-05923	AUROBINDO	Cole Jon B. Failure of High Dose Insulin and Intravenous Fat Emulsion in 2 patients with Poison-Induced Cardiogenic Shock. 2011 North American Congress of Clinical Toxicology. 2011;49(6):537 - 538	50	Year
PHHY2012CA016363	NOVARTIS		62	Year
IR-BAUSCH-BL-2015-023543	BAUSCH AND LOMB	Tajdini M. Spontaneous myopericarditis in a patient under dexamethasone: A double-edged sword. Journal of the Saudi Heart Association. 2015;27 (4):292-294.	47	Year
CA-ROCHE-1645569	ROCHE		50	Year
CA-ROCHE-1389860	ROCHE		50	Year
US-ARIAD PHARMACEUTICALS, INC-2014US003442	TAKEDA		57	Year

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Female	Y	49	KG	20231113		HP	US	US	.	49	MISSIN
Adult	Female	Y	97	KG	20231225		Physician	CA	CA	43	97	GROUP2
	Female	Y	41.7	KG	20231017		Physician	JP		5	41.7	GROUP1
Adult	Female	Y	81.5	KG	20231020		HP	AU	AU	36	81.5	GROUP2
	Female	Y	.		20231109		Physician	IT	IT	82	.	GROUP4
		Y	.		20231121		Consumer	US	US	.	.	MISSIN
	Male	Y	78	KG	20231116		Consumer	US	US	17	78	GROUP1
	Male	Y	86.168	KG	20231019		Consumer	US	US	.	86.168	MISSIN
	Female	Y	96	KG	20231023		HP	CA	CA	.	96	MISSIN
	Female	Y	67.12	KG	20231130		HP	US	US	.	67.12	MISSIN
	Female	Y	69	KG	20231129		Physician	US	US	32	69	GROUP2
	Male	Y	.		20231019		Consumer	US	US	.	.	MISSIN
	Female	Y	.		20231212		HP	US	US	68	.	GROUP3
	Female	Y	.		20231226		HP	US	US	50	.	GROUP2
	Female	Y	.		20231225		HP	CA	CA	62	.	GROUP3
	Male	Y	.		20231222		Physician	IR	IR	47	.	GROUP2
	Female	Y	.		20231220		Physician	CA	CA	50	.	GROUP2
	Female	Y	85	KG	20231211		Consumer	CA		50	85	GROUP2
	Female	Y	.		20231115		Consumer	US	US	57	.	GROUP3

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
116530282	11653028	2	Follow-up	20150701	20151008	20151022	20231001	Expedited	
116533853	11653385	3	Follow-up	.	20231204	20151022	20231207	Expedited	
116545458	11654545	8	Follow-up	20150924	20231018	20151023	20231023	Expedited	
1166352379	11663523	79	Follow-up	20151001	20231114	20151027	20231115	Expedited	
116787914	11678791	4	Follow-up	.	20230721	20151028	20231019	Periodic	
1168672145	11686721	45	Follow-up	20050101	20231212	20151030	20231222	Expedited	
1168789257	11687892	57	Follow-up	20150101	20231023	20151030	20231029	Expedited	
1169217617	11692176	17	Follow-up	20120416	20231030	20151103	20231107	Expedited	
116951916	11695191	6	Follow-up	20150101	20231103	20151103	20231110	Expedited	
1169665434	11696654	34	Follow-up	20160928	20230731	20151104	20231011	Expedited	
117037909	11703790	9	Follow-up	20110101	20231018	20151106	20231026	Expedited	
117194573	11719457	3	Follow-up	.	20231005	20151110	20231011	Expedited	
1174511318	11745113	18	Follow-up	20150203	20170213	20151117	20231202	Expedited	
117720064	11772006	4	Follow-up	20150601	20181002	20151124	20231129	Expedited	
117754363	11775436	3	Follow-up	20070101	20231108	20151125	20231113	Periodic	
117754734	11775473	4	Follow-up	20090101	20231120	20151125	20231124	Periodic	
117759165	11775916	5	Follow-up	20030101	20231122	20151125	20231130	Periodic	
117760955	11776095	5	Follow-up	20070101	20231113	20151125	20231120	Periodic	
117761465	11776146	5	Follow-up	20060101	20231206	20151125	20231212	Periodic	
117761484	11776148	4	Follow-up	20030101	20231108	20151125	20231116	Periodic	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
FR-TAKEDA-2015TJP016888	TAKEDA		71	Year
US-BAXALTA-2015BLT002285	TAKEDA		.	
US-SHIRE-US201512825	TAKEDA		17	Year
CA-ROCHE-1649929	ROCHE		41	Year
US-JAZZ-2015-US-017138	JAZZ		.	
US-PFIZER INC-2015369554	PFIZER		53	Year
PHHY2015CA139740	NOVARTIS		44	Year
CA-ROCHE-1652064	ROCHE		37	Year
CA-TAKEDA-2015TUS015121	TAKEDA		.	
BR-GLAXOSMITHKLINE-BR2015GSK033029	GLAXOSMITHKLINE		.	
CA-009507513-1510CAN014496	MERCK		65	Year
CA-BAXTER-2015BAX059687	BAXTER		66	Year
US-BAYER-2014-075047	BAYER		71	Year
PHHY2015CA152735	NOVARTIS		58	Year
US-JNJFOC-20151107124	JOHNSON AND JOHNSON		.	
US-JNJFOC-20151105780	JOHNSON AND JOHNSON		.	
US-JNJFOC-20151102264	JOHNSON AND JOHNSON		.	
US-JNJFOC-20151105670	JOHNSON AND JOHNSON		14	Year
US-JNJFOC-20151105758	JOHNSON AND JOHNSON		.	
US-JNJFOC-20151104402	JOHNSON AND JOHNSON		.	



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Female	Y	.		20231001		HP	FR	FR	71	.	GROUP3
	Female	Y	.		20231207		Consumer	US	US	.	.	MISSIN
	Female	Y	.		20231023		Physician	US	US	17	.	GROUP1
	Female	Y	95	KG	20231115		HP	CA		41	95	GROUP2
	Male	Y	.		20231019		HP	US	US	.	.	MISSIN
	Female	Y	50	KG	20231222		Consumer	US	US	53	50	GROUP3
	Female	Y	.		20231029		Consumer	CA	CA	44	.	GROUP2
	Male	Y	.		20231107		Consumer	CA	CA	37	.	GROUP2
	Female	Y	.		20231110		Consumer	CA	CA	.	.	MISSIN
		Y	.		20231011		Physician	BR	BR	.	.	MISSIN
	Female	Y	.		20231026		HP	CA	CA	65	.	GROUP3
	Female	Y	.		20231011		HP	CA	CA	66	.	GROUP3
Elderly	Female	Y	78.005	KG	20231202		Consumer	US	US	71	78.005	GROUP3
	Female	Y	.		20231129		Physician	CA	CA	58	.	GROUP3
	Male	Y	.		20231114		HP	US	US	.	.	MISSIN
Adolescent	Male	Y	.		20231125		Lawyer	US	US	.	.	MISSIN
Adolescent	Male	Y	.		20231201		Lawyer	US	US	.	.	MISSIN
Adolescent	Male	Y	.		20231120		Lawyer	US	US	14	.	GROUP1
Child	Male	Y	.		20231212		HP	US	US	.	.	MISSIN
Child	Male	Y	.		20231116		Lawyer	US	US	.	.	MISSIN

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
1178230313	11782303	13	Follow-up	.	20231124	20151127	20231128	Expedited	
117835832	11783583	2	Follow-up	.	20151118	20151127	20231001	Periodic	
1178453618	11784536	18	Follow-up	20120201	20231212	20151130	20231219	Expedited	
117876845	11787684	5	Follow-up	20100101	20231213	20151130	20231221	Expedited	
1178812814	11788128	14	Follow-up	20141201	20231205	20151201	20231212	Expedited	
1179178614	11791786	14	Follow-up	20220101	20231011	20151201	20231020	Expedited	
118087772	11808777	2	Follow-up	.	20150323	20151207	20231127	Expedited	
118134552	11813455	2	Follow-up	20151024	20231019	20151209	20231023	Expedited	
118168512	11816851	2	Follow-up	20060101	20231122	20151210	20231130	Expedited	
118171395	11817139	5	Follow-up	20050101	20231113	20151210	20231120	Periodic	
118171404	11817140	4	Follow-up	20050101	20231025	20151210	20231030	Periodic	
118171962	11817196	2	Follow-up	20030101	20231122	20151210	20231129	Periodic	
118172344	11817234	4	Follow-up	20140101	20231009	20151210	20231012	Periodic	
118172912	11817291	2	Follow-up	20110101	20231011	20151210	20231017	Periodic	
118173123	11817312	3	Follow-up	20050601	20231127	20151210	20231205	Periodic	
118191622	11819162	2	Follow-up	20131016	20231213	20151210	20231224	Periodic	
118193895	11819389	5	Follow-up	20050101	20231113	20151210	20231122	Periodic	
118197754	11819775	4	Follow-up	20090101	20231108	20151210	20231116	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
CA-ROCHE-1667732	ROCHE		64	Year
US-TAKEDA-2015TUS017019	TAKEDA		.	
CA-ROCHE-1668217	ROCHE		22	Year
US-JAZZ-2015-US-020310	JAZZ		.	
CA-ROCHE-1513163	ROCHE		61	Year
US-PFIZER INC-2015398901	PFIZER		56	Year
US-ROCHE-1555252	ROCHE		5	Decade
US-SHIRE-US201515591	TAKEDA		36	Year
US-JNJFOC-20151110142	JOHNSON AND JOHNSON		.	
US-JNJFOC-20151112186	JOHNSON AND JOHNSON		.	
US-JNJFOC-20150702928	JOHNSON AND JOHNSON		.	
US-JNJFOC-20151110133	JOHNSON AND JOHNSON		.	
US-JNJFOC-20151125769	JOHNSON AND JOHNSON		20	Year
US-JNJFOC-20151110744	JOHNSON AND JOHNSON		.	
US-JNJFOC-20151115172	JOHNSON AND JOHNSON		13	Year
US-JNJFOC-20151104766	JOHNSON AND JOHNSON		12	Year
US-JNJFOC-20151110717	JOHNSON AND JOHNSON		.	
US-JNJFOC-20151110712	JOHNSON AND JOHNSON		.	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Female	Y	69	KG	20231128		HP	CA		64	69	GROUP3
		Y	.		20231001		Physician	US	US	.	.	MISSIN
	Female	Y	.		20231219		Physician	CA	CA	22	.	GROUP1
	Female	Y	.		20231221		HP	US	US	.	.	MISSIN
	Male	Y	83.9	KG	20231212		Consumer	CA		61	83.9	GROUP3
	Female	Y	.		20231020		Consumer	US	US	56	.	GROUP3
	Female	Y	.		20231127		Consumer	US		50	.	GROUP2
	Female	Y	.		20231023		Consumer	US	US	36	.	GROUP2
Child	Male	Y	.		20231130		HP	US	US	.	.	MISSIN
Adolescent	Male	Y	.		20231120		Lawyer	US	US	.	.	MISSIN
Adolescent	Male	Y	.		20231030		Lawyer	US	US	.	.	MISSIN
Child	Male	Y	.		20231129		Lawyer	US	US	.	.	MISSIN
Adult	Male	Y	77.18	KG	20231012		Lawyer	US	US	20	77.18	GROUP1
Adolescent	Male	Y	69	KG	20231017		Lawyer	US	US	.	69	MISSIN
Adolescent		Y	.		20231206		Lawyer	US	US	13	.	GROUP1
Adolescent	Male	Y	.		20231224		HP	US	US	12	.	GROUP1
Adolescent	Male	Y	.		20231122		Lawyer	US	US	.	.	MISSIN
	Male	Y	.		20231116		HP	US	US	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

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118278119	11827811	9	Follow-up	20150101	20231003	20151211	20231013	Expedited	
118406256	11840625	6	Follow-up	20150201	20231003	20151216	20231013	Expedited	
118406345	11840634	5	Follow-up	20151101	20231003	20151216	20231013	Expedited	
118490297	11849029	7	Follow-up	.	20231208	20151218	20231220	Expedited	
1185945712	11859457	12	Follow-up	20150301	20190719	20151221	20231026	Expedited	
118666423	11866642	3	Follow-up	20151208	20231005	20151224	20231011	Expedited	
118688722	11868872	2	Follow-up	.	20231108	20151225	20231117	Expedited	
118688732	11868873	2	Follow-up	.	20231108	20151225	20231116	Periodic	
118689052	11868905	2	Follow-up	.	20231108	20151225	20231120	Expedited	
118689122	11868912	2	Follow-up	.	20231108	20151225	20231117	Periodic	
118689132	11868913	2	Follow-up	.	20231108	20151225	20231120	Periodic	
118689152	11868915	2	Follow-up	.	20231108	20151225	20231117	Periodic	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
AT-BIOGEN-2015BI118342	BIOGEN		58	Year
AT-BIOGEN-2015BI030172	BIOGEN		48	Year
AT-BIOGEN-2015BI158079	BIOGEN		45	Year
FR-AUROBINDO-AUR-APL-2015-11339	AUROBINDO	Evrard J, Farnier E, Carcel C, Lachenal F, Vial T, Pont E. Proton Pump Inhibitor and High-dose Methotrexate: Two Cases Reports.. Therapie. 2015;70(6):527-535	80	Year
US-BIOGEN-2015BI061888	BIOGEN		56	Year
US-SHIRE-US201516348	TAKEDA		41	Year
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091330	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091321	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091327	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Khushalani NI, Ye F, Guminski A, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091325	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091326	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091329	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Male	Y	.		20231013		Physician	AT	AT	58	.	GROUP3
	Male	Y	84	KG	20231013		Physician	AT	AT	48	84	GROUP2
	Female	Y	.		20231013		Physician	AT	AT	45	.	GROUP2
	Male	Y	.		20231220		HP	FR	FR	80	.	GROUP4
	Male	Y	.		20231026		Consumer	US	US	56	.	GROUP3
	Male	Y	.		20231011		Consumer	US	US	41	.	GROUP2
		Y	.		20231117		Physician	US	US	.	.	MISSIN
		Y	.		20231116		Physician	US	US	.	.	MISSIN
		Y	.		20231121		Physician	US	US	.	.	MISSIN
		Y	.		20231117		Physician	US	US	.	.	MISSIN
		Y	.		20231120		Physician	US	US	.	.	MISSIN
		Y	.		20231117		Physician	US	US	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
118689222	11868922	2	Follow-up	.	20231108	20151225	20231116	Periodic	
118689722	11868972	2	Follow-up	.	20231108	20151225	20231117	Expedited	
118689842	11868984	2	Follow-up	.	20231108	20151225	20231117	Expedited	
118689852	11868985	2	Follow-up	.	20231108	20151225	20231117	Expedited	
118689862	11868986	2	Follow-up	.	20231108	20151225	20231117	Expedited	
118689872	11868987	2	Follow-up	.	20231108	20151225	20231116	Expedited	
118689952	11868995	2	Follow-up	.	20231108	20151225	20231117	Expedited	
118712772	11871277	2	Follow-up	.	20231125	20151228	20231205	Expedited	



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091332	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	8	Decade
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091584	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091323	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091328	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091324	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091319	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-091331	BRISTOL MYERS SQUIBB	Johnson DB, Sullivan RJ, Ott PA, Carlino MS, Khushalani NI, Ye F, et al. Ipilimumab therapy in patients with advanced melanoma and preexisting autoimmune disorders. JAMA Oncology. 2016 Feb;2(2):234-40.doi:10.1001/jamaoncol.2015.4368.	.	
IN-MYLANLABS-2015M1047035	MYLAN	Arun Kumar K, Kar R, Jacob SE, Basu D, Dubashi B. Therapy-related acute leukemia-a series of three cases. Indian-J-Hematol-Blood-Transf 2015;31 (Suppl. 1):S74 abstr. PR 12.	9	Year

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Elderly	Male	Y	.		20231116		Physician	US	US	80	.	GROUP4
		Y	.		20231117		Physician	US	US	.	.	MISSIN
		Y	.		20231117		Physician	US	US	.	.	MISSIN
		Y	.		20231117		Physician	US	US	.	.	MISSIN
		Y	.		20231117		Physician	US	US	.	.	MISSIN
		Y	.		20231116		Physician	US	US	.	.	MISSIN
		Y	.		20231117		Physician	US	US	.	.	MISSIN
	Male	Y	.		20231205		HP	IN	IN	9	.	GROUP1

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
118713032	11871303	2	Follow-up	20140201	20231125	20151228	20231204	Expedited	
118745404	11874540	4	Follow-up	20150201	20231124	20151229	20231206	Expedited	
118806382	11880638	2	Follow-up	.	20231212	20151230	20231218	Expedited	
1189796319	11897963	19	Follow-up	20141029	20231102	20160108	20231114	Expedited	
119104223	11910422	3	Follow-up	20151228	20160203	20160112	20231102	Expedited	
119219533	11921953	3	Follow-up	.	20231219	20160115	20231229	Expedited	
119270783	11927078	3	Follow-up	20100514	20231114	20160119	20231120	Expedited	
1192728610	11927286	10	Follow-up	20170811	20231213	20160119	20231220	Expedited	
119314973	11931497	3	Follow-up	20150101	20231113	20160120	20231122	Periodic	
119326774	11932677	4	Follow-up	20160101	20231003	20160120	20231012	Expedited	
1193375735	11933757	35	Follow-up	20140806	20231005	20160121	20231009	Expedited	
119338255	11933825	5	Follow-up	.	20231219	20160121	20231220	Expedited	
1193535523	11935355	23	Follow-up	20150401	20231102	20160121	20231109	Expedited	
1193793115	11937931	15	Follow-up	20160217	20231127	20160122	20231204	Expedited	
119478563	11947856	3	Follow-up	20160109	20231010	20160125	20231012	Expedited	
1196876534	11968765	34	Follow-up	20141208	20231102	20160128	20231109	Expedited	
119875983	11987598	3	Follow-up	20160118	20231214	20160202	20231226	Expedited	
119911782	11991178	2	Follow-up	20080101	20231113	20160203	20231122	Periodic	
120093639	12009363	9	Follow-up	20151101	20231018	20160205	20231026	Expedited	
1204027949	12040279	49	Follow-up	20201127	20231030	20160208	20231106	Expedited	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
IN-MYLANLABS-2015M1047095	MYLAN	Arun Kumar K, Kar R, Jacob SE, Basu D, Dubashi B. Therapy-related acute leukemia-a series of three cases. Indian-J-Hematol-Blood-Transf 2015;31 (Suppl. 1):S74 abstr. PR 12.	62	Year	
FR-AUROBINDO-AUR-APL-2015-10456	AUROBINDO	Farnier E, Charhon N, Papillon L, Tod M. Interaction between Amoxicillin Clavulanic Acid and Fluindione: Two Case Reports. Therapie. 2015	89	Year	
US-BAXALTA-2015BLT003536	TAKEDA		.		
CA-ROCHE-1691303	ROCHE		66	Year	
CN-AMGEN-CHNCT2016002129	AMGEN		50	Year	Adult
IR-BAUSCH-BL-2016-001383	BAUSCH AND LOMB	Poorzand H, Esfehani R, Hosseinzadeh P, Vojdanparast M. Acute myocardial infarction in a young male wrestler: A case report.. ARYA Atherosclerosis. 2015;11(6):366-369.	23	Year	
US-BIOGEN-2010BI026507	BIOGEN		39	Year	
US-PFIZER INC-2016017133	PFIZER		82	Year	
US-INCYTE CORPORATION-2015IN005886	INCYTE		.		
US-VERTEX PHARMACEUTICALS-2016-000027	VERTEX		26	Year	
CA-ROCHE-1434589	ROCHE		73	Year	
US-SHIRE-US201600378	TAKEDA		.		
US-PFIZER INC-2016017803	PFIZER		74	Year	
CA-ROCHE-1698822	ROCHE		42	Year	
US-TAKEDA-2016TUS000751	TAKEDA		82	Year	
CA-ROCHE-1219752	ROCHE		40	Year	
CA-ROCHE-1703661	ROCHE		41	Year	
US-JNJFOC-20160106388	JOHNSON AND JOHNSON		33	Year	Adult
CA-ROCHE-1660533	ROCHE		81	Year	
BR-GLAXOSMITHKLINE-BR2015GSK160212	GLAXOSMITHKLINE		.		

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Female	Y	.		20231204		HP	IN	IN	62	.	GROUP3
Male	Y	69	KG	20231207		HP	FR	FR	89	69	GROUP4
Female	Y	49.887	KG	20231218		Physician	US	US	.	49.887	MISSIN
Male	Y	.		20231114		HP	CA	CA	66	.	GROUP3
Female	Y	.		20231101		Physician	CN	CN	50	.	GROUP2
Male	Y	.		20231229		HP	IR	IR	23	.	GROUP1
Female	Y	87.168	KG	20231120		Consumer	US	US	39	87.168	GROUP2
Female	Y	85	KG	20231220		Consumer	US	US	82	85	GROUP4
	Y	.		20231122		Consumer	US	US	.	.	MISSIN
Male	Y	.		20231012		Consumer	US	US	26	.	GROUP2
Female	Y	87	KG	20231009		HP	CA		73	87	GROUP3
Male	Y	.		20231220		Consumer	US	US	.	.	MISSIN
Male	Y	124	KG	20231109		Consumer	US	US	74	124	GROUP3
Male	Y	.		20231204		HP	CA	CA	42	.	GROUP2
Male	Y	73.923	KG	20231012		HP	US	US	82	73.923	GROUP4
Male	Y	67	KG	20231109		Physician	CA		40	67	GROUP2
Female	Y	.		20231226		Physician	CA	CA	41	.	GROUP2
Male	Y	.		20231122		HP	US	US	33	.	GROUP2
Female	Y	88	KG	20231026		Physician	CA		81	88	GROUP4
	Y	.		20231106		Physician	BR	BR	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
120604794	12060479	4	Follow-up	.	20231018	20160210	20231024	Periodic	
120664487	12066448	7	Follow-up	20110101	20231115	20160210	20231124	Periodic	
120668283	12066828	3	Follow-up	20020101	20231006	20160210	20231016	Periodic	
120740156	12074015	6	Follow-up	20151219	20160301	20160212	20231120	Expedited	
120751903	12075190	3	Follow-up	20150101	20231030	20160212	20231107	Expedited	
120779963	12077996	3	Follow-up	20121002	20160325	20160215	20231001	Expedited	
1207853043	12078530	43	Follow-up	20150101	20230926	20160216	20231006	Expedited	
120813973	12081397	3	Follow-up	20160203	20170227	20160216	20231001	Expedited	
1208222832	12082228	32	Follow-up	20160101	20231031	20160217	20231107	Expedited	
1209904323	12099043	23	Follow-up	20140731	20230922	20160222	20231002	Expedited	
121031125	12103112	5	Follow-up	20150201	20231003	20160222	20231013	Expedited	
1210599713	12105997	13	Follow-up	.	20231030	20160223	20231107	Expedited	
121083429	12108342	9	Follow-up	20160124	20231130	20160224	20231212	Expedited	
121090126	12109012	6	Follow-up	20170331	20231031	20160224	20231110	Expedited	
1211671714	12116717	14	Follow-up	20160201	20231204	20160225	20231208	Expedited	
121178303	12117830	3	Follow-up	.	20231213	20160226	20231222	Expedited	
121210477	12121047	7	Follow-up	.	20231205	20160226	20231218	Periodic	
1212230540	12122305	40	Follow-up	20151219	20231215	20160226	20231221	Expedited	
121225423	12122542	3	Follow-up	.	20160218	20160226	20231001	Expedited	
1213390067	12133900	67	Follow-up	20141010	20231010	20160301	20231012	Expedited	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviatio n for patient's age</i>	<i>Patient Age Group code</i>
US-PFIZER INC-2016076192	PFIZER		64	Year	
US-JNJFOC-20160110442	JOHNSON AND JOHNSON		.		Adolescent
US-JNJFOC-20160124515	JOHNSON AND JOHNSON		.		Child
PHHY2016IT015729	NOVARTIS		72	Year	
US-JAZZ-2016-US-002250	JAZZ		.		
DE-TAKEDA-2016TEU001015	TAKEDA		71	Year	
CA-ROCHE-1711280	ROCHE		46	Year	
JP-TAKEDA-2016TJP002336	TAKEDA		57	Year	
CA-ROCHE-1711853	ROCHE		71	Year	
CA-ROCHE-1714373	ROCHE		44	Year	
AT-BIOGEN-2015BI021264	BIOGEN		50	Year	
US-ARIAD-2014US004171	TAKEDA		.		
DE-ROCHE-1714639	ROCHE		5	Year	
CA-ROCHE-1715516	ROCHE		43	Year	
SE-SA-2016SA037008	SANOFI AVENTIS		39	Year	Adult
GB-AUROBINDO-AUR-APL-2016-02066	AUROBINDO	C. Marini Bettolo , M. Guglieri, H. van Ruiten, V. Straub, K. Bushby, H. Lochmuller. Cautionary tale in Duchenne muscular dystrophy-Opioids in neuromuscular disorders. Neuromuscular Disorders. 2015;25 (Suppl. 2):S200	30	Year	
US-PFIZER INC-2016060858	PFIZER		39	Year	
PHHY2015CA172640	NOVARTIS		61	Year	
GB-TAKEDA-2016TUS003380	TAKEDA		.		Adult
CA-ROCHE-1474767	ROCHE		49	Year	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Female	Y	.		20231024		Physician	US	US	64	.	GROUP3
Male	Y	.		20231124		HP	US	US	.	.	MISSIN
Male	Y	.		20231016		Lawyer	US	US	.	.	MISSIN
Male	Y	86	KG	20231120		Physician	IT	IT	72	86	GROUP3
Female	Y	.		20231107		Consumer	US	US	.	.	MISSIN
Female	Y	74	KG	20231001		Physician	DE	DE	71	74	GROUP3
Female	Y	.		20231006		Physician	CA	CA	46	.	GROUP2
Male	Y	72.2	KG	20231001		Physician	JP	JP	57	72.2	GROUP3
Male	Y	.		20231107		Consumer	CA	CA	71	.	GROUP3
Female	Y	26.786	KG	20231002		Physician	CA	CA	44	26.786	GROUP2
Male	Y	108	KG	20231013		Physician	AT	AT	50	108	GROUP2
Female	Y	.		20231107		Consumer	US	US	.	.	MISSIN
Male	Y	21	KG	20231212		Physician	DE	DE	5	21	GROUP1
Female	Y	66	KG	20231110		Physician	CA	CA	43	66	GROUP2
Female	Y	.		20231208		Physician	SE	SE	39	.	GROUP2
Male	Y	.		20231222		Physician	GB	GB	30	.	GROUP2
Female	Y	.		20231218		Consumer	US	US	39	.	GROUP2
Female	Y	.		20231221		Consumer	CA	CA	61	.	GROUP3
Female	Y	.		20231001		Physician	GB	GB	.	.	MISSIN
Male	Y	70	KG	20231012		HP	CA		49	70	GROUP2



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
121344112	12134411	2	Follow-up	.	20231019	20160301	20231122	Expedited	
121344172	12134417	2	Follow-up	.	20231019	20160301	20231122	Expedited	
121344383	12134438	3	Follow-up	.	20231130	20160301	20231208	Expedited	
121345362	12134536	2	Follow-up	.	20231019	20160301	20231122	Expedited	
121345672	12134567	2	Follow-up	.	20231019	20160301	20231122	Expedited	
121349972	12134997	2	Follow-up	.	20231019	20160301	20231122	Expedited	
121350152	12135015	2	Follow-up	.	20231130	20160301	20231208	Expedited	
121350502	12135050	2	Follow-up	.	20231019	20160301	20231121	Expedited	
121351362	12135136	2	Follow-up	.	20231130	20160301	20231208	Expedited	
121351453	12135145	3	Follow-up	.	20231130	20160301	20231208	Expedited	
121351482	12135148	2	Follow-up	.	20231019	20160301	20231122	Expedited	
121351512	12135151	2	Follow-up	.	20231019	20160301	20231122	Expedited	
121355224	12135522	4	Follow-up	.	20231006	20160302	20231012	Periodic	
1213893320	12138933	20	Follow-up	.	20231128	20160302	20231205	Expedited	
121389514	12138951	4	Follow-up	20130101	20231005	20160302	20231009	Expedited	
1213946925	12139469	25	Follow-up	20121119	20231202	20160303	20231208	Expedited	
121400216	12140021	6	Follow-up	.	20231011	20160303	20231013	Expedited	
121614898	12161489	8	Follow-up	20150616	20231009	20160309	20231012	Expedited	
121684513	12168451	3	Follow-up	20100701	20231003	20160310	20231013	Expedited	
121851406	12185140	6	Follow-up	20160201	20231114	20160316	20231120	Periodic	
1218588315	12185883	15	Follow-up	20160307	20231003	20160317	20231012	Expedited	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
US-JAZZ-2016-US-003816	JAZZ		44	Year	
US-JAZZ-2016-US-003770	JAZZ		19	Year	
US-JAZZ-2016-US-003774	JAZZ		19	Year	
US-JAZZ-2016-US-003767	JAZZ		44	Year	
US-JAZZ-2016-US-003759	JAZZ		41	Year	
US-JAZZ-2016-US-003811	JAZZ		49	Year	
US-JAZZ-2016-US-003785	JAZZ		54	Year	
US-JAZZ-2016-US-003760	JAZZ		44	Year	
US-JAZZ-2016-US-003800	JAZZ		39	Year	
US-JAZZ-2016-US-003780	JAZZ		32	Year	
US-JAZZ-2016-US-003798	JAZZ		24	Year	
US-JAZZ-2016-US-003802	JAZZ		19	Year	
US-JNJFOC-20160205989	JOHNSON AND JOHNSON		.		Adolescent
US-PFIZER INC-2016132391	PFIZER		68	Year	
US-JAZZ-2016-US-003580	JAZZ		33	Year	
CA-ROCHE-1162790	ROCHE		43	Year	
NO-MYLANLABS-2016M1007622	MYLAN	Giverhaug T.Nordmo E. Nord-Norge R... Polypharmacy and drug interactions as risk factors for metformin-associated lactic acidosis.. Utposten. 2010;1:42-43	63	Year	
DE-ROCHE-1719994	ROCHE		75	Year	
AT-BIOGEN-2010BI041689	BIOGEN		37	Year	
US-PFIZER INC-2016155329	PFIZER		76	Year	
JP-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-019298	BRISTOL MYERS SQUIBB		63	Year	Adult

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Male	Y	.		20231122		Consumer	US	US	44	.	GROUP2
Female	Y	64.55	KG	20231122		HP	US	US	19	64.55	GROUP1
Female	Y	.		20231208		Consumer	US	US	19	.	GROUP1
Male	Y	.		20231123		Consumer	US	US	44	.	GROUP2
Female	Y	.		20231122		Consumer	US	US	41	.	GROUP2
Male	Y	101	KG	20231122		Consumer	US	US	49	101	GROUP2
Female	Y	.		20231208		Consumer	US	US	54	.	GROUP3
Female	Y	.		20231121		Consumer	US	US	44	.	GROUP2
Female	Y	.		20231208		Consumer	US	US	39	.	GROUP2
Female	Y	.		20231208		Consumer	US	US	32	.	GROUP2
Female	Y	.		20231122		Consumer	US	US	24	.	GROUP1
Female	Y	.		20231122		Consumer	US	US	19	.	GROUP1
Male	Y	.		20231012		Lawyer	US	US	.	.	MISSIN
Female	Y	48	KG	20231205		Consumer	US	US	68	48	GROUP3
Female	Y	.		20231009		HP	US	US	33	.	GROUP2
Female	Y	64	KG	20231209		HP	CA		43	64	GROUP2
Female	Y	.		20231013		Pharmacist	NO	NO	63	.	GROUP3
Female	Y	62	KG	20231012		Physician	DE	DE	75	62	GROUP3
Female	Y	.		20231013		Physician	AT	AT	37	.	GROUP2
Female	Y	49.887	KG	20231120		Consumer	US	US	76	49.887	GROUP4
Female	Y	44	KG	20231012		HP	JP	JP	63	44	GROUP3

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
1219006311	12190063	11	Follow-up	20151123	20231003	20160318	20231006	Expedited	
1219366031	12193660	31	Follow-up	20160101	20231127	20160321	20231211	Expedited	
121944728	12194472	8	Follow-up	20160311	20180108	20160321	20231121	Expedited	
121983432	12198343	2	Follow-up	.	20231213	20160322	20231224	Periodic	
121985282	12198528	2	Follow-up	.	20231108	20160322	20231114	Periodic	
122095957	12209595	7	Follow-up	20150401	20231129	20160325	20231201	Expedited	
1220965353	12209653	53	Follow-up	20130101	20231208	20160325	20231212	Expedited	
122104123	12210412	3	Follow-up	.	20231207	20160325	20231220	Expedited	
122120732	12212073	2	Follow-up	.	20231221	20160325	20231228	Periodic	
122199782	12219978	2	Follow-up	.	20231128	20160330	20231208	Periodic	
122200518	12220051	8	Follow-up	20160323	20231206	20160330	20231218	Expedited	
1223166310	12231663	10	Follow-up	20150512	20231106	20160401	20231110	Expedited	
1224068929	12240689	29	Follow-up	20120801	20231124	20160406	20231129	Expedited	
122443472	12244347	2	Follow-up	.	20231019	20160407	20231028	Periodic	
1224849317	12248493	17	Follow-up	20160308	20231116	20160408	20231128	Expedited	
122512633	12251263	3	Follow-up	20080101	20231213	20160410	20231220	Periodic	
122535006	12253500	6	Follow-up	20070101	20231031	20160411	20231106	Periodic	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending report</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
CA-ROCHE-1570622	ROCHE		76	Year	
CA-ROCHE-1728458	ROCHE		43	Year	
PHHO2016TH004060	NOVARTIS		45	Year	
US-JNJFOC-20160308004	JOHNSON AND JOHNSON		.		
US-JNJFOC-20160308495	JOHNSON AND JOHNSON		.		
CA-ROCHE-1565100	ROCHE		40	Year	
CA-ROCHE-1213265	ROCHE		.		
US-AUROBINDO-AUR-APL-2016-03784	AUROBINDO	Siegel AJ, Forte SS, Bhatti NA, Gelda SE. Drug-Related Hyponatremic Encephalopathy: Rapid Clinical Response Averts Life-Threatening Acute Cerebral Edema. Am J Case Rep. 2016	63	Year	
US-PFIZER INC-2016109613	PFIZER		.		Adult
US-BIOGEN-2016BI00204485	BIOGEN		.		
CA-ROCHE-1733307	ROCHE		70	Year	
US-PFIZER INC-2016188673	PFIZER		66	Year	
CA-ROCHE-1188566	ROCHE		53	Year	
US-AMGEN-USASL2016041252	AMGEN		56	Year	Adult
CA-ROCHE-1739434	ROCHE		75	Year	
US-JNJFOC-20160318403	JOHNSON AND JOHNSON		.		
US-BIOGEN-2016BI00218257	BIOGEN		.		

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Female	Y	72	KG	20231006		HP	CA		76	72	GROUP4
Female	Y	.		20231211		Consumer	CA	CA	43	.	GROUP2
Male	Y	77	KG	20231121		Physician	TH	TH	45	77	GROUP2
Male	Y	.		20231224		Lawyer	US	US	.	.	MISSIN
Male	Y	.		20231114		Lawyer	US	US	.	.	MISSIN
Male	Y	.		20231201		HP	CA		40	.	GROUP2
Female	Y	62	KG	20231212		HP	CA		.	62	MISSIN
Female	Y	.		20231220		HP	US	US	63	.	GROUP3
Female	Y	.		20231228		Physician	US	US	.	.	MISSIN
Female	Y	.		20231208		Consumer	US	US	.	.	MISSIN
Male	Y	63	KG	20231218		Consumer	COUNTRY NOT SPECIFIED	CA	70	63	GROUP3
Female	Y	106.1	KG	20231110		Consumer	US	US	66	106.1	GROUP3
Female	Y	100.2	KG	20231129		Consumer	CA		53	100.2	GROUP3
Female	Y	.		20231028		Consumer	US	US	56	.	GROUP3
Male	Y	.		20231128		Physician	CA	CA	75	.	GROUP3
Male	Y	.		20231220		Lawyer	US	US	.	.	MISSIN
Female	Y	.		20231106		Consumer	US	US	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
122550212	12255021	2	Follow-up	.	20231101	20160411	20231109	Expedited	
122656474	12265647	4	Follow-up	20150918	20231005	20160413	20231010	Expedited	
122657802	12265780	2	Follow-up	20160214	20231026	20160413	20231030	Expedited	
1226963211	12269632	11	Follow-up	20160410	20231102	20160414	20231108	Expedited	
122815454	12281545	4	Follow-up	.	20231204	20160419	20231211	Expedited	
122844006	12284400	6	Follow-up	.	20231108	20160420	20231117	Expedited	
1229068117	12290681	17	Follow-up	.	20231022	20160421	20231101	Expedited	
1229378940	12293789	40	Follow-up	20150608	20231106	20160421	20231109	Expedited	
122975224	12297522	4	Follow-up	.	20230928	20160422	20231012	Expedited	
1230227453	12302274	53	Follow-up	20080101	20231127	20160425	20231205	Expedited	
123033744	12303374	4	Follow-up	20091001	20231213	20160426	20231224	Periodic	
123036974	12303697	4	Follow-up	20070813	20231025	20160426	20231030	Periodic	
123039903	12303990	3	Follow-up	.	20231211	20160426	20231218	Periodic	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending report</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
US-ANIPHARMA-2016-US-002191	ANI	Upala S, Wijarnpreecha K, Jaruvongvanich V, Bischof E, Sanguankeo A. Antipsychotics-induced ischemic colitis.. American Journal of Emergency Medicine. 2015;33(11):1716.	34	Year	
JP-B.I. Pharmaceuticals, Inc./ Ridgefield-2015-BI-53555NB	BOEHRINGER INGELHEIM		78	Year	Elderly
ES-BAXALTA-2016BLT001295	TAKEDA		52	Year	
CO-SHIRE-CO201604454	TAKEDA		17	Year	
US-SA-2016SA073610	SANOFI AVENTIS	Kord Valeshabad A, Mieler WF, Setlur V, Thomas M, Shahidi M.. Posterior segment toxicity after gemcitabine and docetaxel chemotherapy.. Optom Vis Sci: official publication of the American Academy of Optometry.. 2015;92(5):e110-3	78	Year	Elderly
US-AUROBINDO-AUR-APL-2016-04747	AUROBINDO	Wightman RS, Hoffman RS, Howland MA, Brain R, Lugassy DM, Biary R. Not your regular high: Potentially lethal cardiac dysrhythmias caused by loperamide. Clinical Toxicology. 2016;54(4):398	48	Year	
US-PFIZER INC-2016199630	PFIZER		60	Year	
CA-ROCHE-1591315	ROCHE		66	Year	
IN-INVALIDUS PHARMACEUTICALS LLC-IN-2016VAL001237	VALIDUS	Sasidharanpillai S, Sabitha S, Riyaz N, Binitha MP, Muhammed K, Riyaz A et al. Drug reaction with eosinophilia and systemic symptoms in children: A prospective study. Pediatric Dermatology. 2016;33(2):e162-5	.		
CA-PFIZER INC-2016221150	MYLAN		.		
US-JNJFOC-20160406965	JOHNSON AND JOHNSON		12	Year	Adolescent
US-JNJFOC-20160413005	JOHNSON AND JOHNSON		7	Year	Child
US-JNJFOC-20160411117	JOHNSON AND JOHNSON		.		



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Male	Y	.		20231109		Physician	US	US	34	.	GROUP2
Male	Y	47.9	KG	20231010		Physician	JP	JP	78	47.9	GROUP4
Male	Y	.		20231030		Physician	ES	ES	52	.	GROUP3
Male	Y	54	KG	20231108		Consumer	CO	CO	17	54	GROUP1
Female	Y	.		20231211		Physician	US	US	78	.	GROUP4
Female	Y	.		20231118		HP	US	US	48	.	GROUP2
Female	Y	.		20231101		Consumer	US	US	60	.	GROUP3
Female	Y	130	KG	20231109		Consumer	CA		66	130	GROUP3
	Y	.		20231012		Physician	IN	IN	.	.	MISSIN
Female	Y	.		20231205		Physician	CA	CA	.	.	MISSIN
Male	Y	.		20231224		Lawyer	US	US	12	.	GROUP1
Male	Y	.		20231030		Lawyer	US	US	7	.	GROUP1
Male	Y	.		20231216		Lawyer	US	US	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
123040872	12304087	2	Follow-up	20111014	20230929	20160426	20231005	Periodic	
1230456626	12304566	26	Follow-up	20150701	20231207	20160426	20231215	Expedited	
1230619217	12306192	17	Follow-up	20160701	20231116	20160426	20231128	Expedited	
123066303	12306630	3	Follow-up	.	20230927	20160426	20231103	Expedited	
123066314	12306631	4	Follow-up	.	20231003	20160426	20231103	Expedited	
123090303	12309030	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123090423	12309042	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123097115	12309711	5	Follow-up	20140401	20231003	20160427	20231013	Expedited	
123098207	12309820	7	Follow-up	.	20231009	20160427	20231023	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviatio n for patient's age</i>	<i>Patient Age Group code</i>
US-JNJFOC-20160412694	JOHNSON AND JOHNSON		8	Year	Child
PHHY2016CA055639	NOVARTIS		55	Year	
US-PFIZER INC-2016226395	PFIZER		57	Year	
NO-BAUSCH-BL-2016-009764	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	63	Year	
NO-BAUSCH-BL-2016-009731	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	64	Year	
NO-BAUSCH-BL-2016-009702	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	21	Year	
NO-BAUSCH-BL-2016-009709	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	29	Year	
AT-BIOGEN-2014BI016999	BIOGEN		33	Year	
DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-115548	RANBAXY	Hoeltzenbein M, Beck E, Meixner K, Schaefer C, Kreutz R. Pregnancy outcome after exposure to the novel oral anticoagulant rivaroxaban in women at suspected risk for thromboembolic events: a case series from the German Embryotox Pharmacovigilance Centre. Clin-Res-Cardiol. 2016;105(2):117-126	.		Neonate

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Male	Y	.		20231006		HP	US	US	8	.	GROUP1
Female	Y	.		20231215		Physician	CA	CA	55	.	GROUP3
Male	Y	113	KG	20231127		Consumer	US	US	57	113	GROUP3
Female	Y	.		20231103		HP	NO	NO	63	.	GROUP3
Female	Y	.		20231103		HP	NO	NO	64	.	GROUP3
Female	Y	.		20231103		HP	NO	NO	21	.	GROUP1
Male	Y	.		20231103		HP	NO	NO	29	.	GROUP2
Female	Y	50	KG	20231013		Physician	AT	AT	33	50	GROUP2
	Y	.		20231023		HP	DE	DE	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
123119083	12311908	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123119133	12311913	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123119193	12311919	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123119243	12311924	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123119253	12311925	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123119263	12311926	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123119286	12311928	6	Follow-up	.	20230927	20160427	20231103	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
NO-BAUSCH-BL-2016-009753	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	40	Year	
NO-BAUSCH-BL-2016-009682	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	50	Year	
NO-BAUSCH-BL-2016-009754	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	40	Year	
NO-BAUSCH-BL-2016-009761	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	54	Year	
NO-BAUSCH-BL-2016-009706	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	50	Year	
NO-BAUSCH-BL-2016-009763	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	47	Year	
NO-BAUSCH-BL-2016-009693	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	66	Year	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Demographic Listings**

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Male	Y	.		20231103		HP	NO	NO	40	.	GROUP2
Female	Y	.		20231103		HP	NO	NO	50	.	GROUP2
Male	Y	.		20231103		HP	NO	NO	40	.	GROUP2
Male	Y	.		20231103		HP	NO	NO	54	.	GROUP3
Male	Y	.		20231103		HP	NO	NO	50	.	GROUP2
Female	Y	.		20231103		HP	NO	NO	47	.	GROUP2
Female	Y	.		20231103		HP	NO	NO	66	.	GROUP3

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
123119353	12311935	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123119363	12311936	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123119443	12311944	3	Follow-up	.	20230927	20160427	20231102	Expedited	
123120013	12312001	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123121313	12312131	3	Follow-up	.	20230927	20160427	20231103	Expedited	
123333823	12333382	3	Follow-up	20130101	20230913	20160504	20231019	Periodic	
1233895913	12338959	13	Follow-up	20160502	20231206	20160505	20231218	Periodic	
123430863	12343086	3	Follow-up	.	20231204	20160506	20231208	Expedited	
1234722916	12347229	16	Follow-up	20160101	20230921	20160509	20231003	Expedited	
123507647	12350764	7	Follow-up	20160101	20231213	20160510	20231219	Expedited	



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
NO-BAUSCH-BL-2016-009715	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	59	Year	
NO-BAUSCH-BL-2016-009757	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	32	Year	
NO-BAUSCH-BL-2016-009711	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137.	48	Year	
NO-BAUSCH-BL-2016-009700	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	51	Year	
NO-BAUSCH-BL-2016-009738	BAUSCH AND LOMB	Frost J, Lokken T, Helland A, Nordrum I, Slordal L. Post-mortem levels and tissue distribution of codeine, codeine-6-glucuronide, norcodeine, morphine and morphine glucuronides in a series of codeine-related deaths. Forensic Science International. 2016 MAR 04;262:128-137. doi:10.1016/j.forsciint.2016.02.051	56	Year	
US-JAZZ-2016-US-007880	JAZZ		48	Year	
US-PFIZER INC-2016243931	PFIZER		59	Year	
US-SA-2016SA087667	SANOFI AVENTIS	Chapuy CI, Sahai I, Sharma R, Zhu AX, Kozyreva ON.. Hyperammonemic encephalopathy associated with fibrolamellar hepatocellular carcinoma: Case report, literature review, and proposed treatment algorithm.. The Oncologist. 2016;21(4):514-20.	31	Year	Adult
CA-PFIZER INC-2016243994	PFIZER		32	Year	
FR-JNJFOC-20160427151	JOHNSON AND JOHNSON		49	Year	Adult

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Male	Y	.		20231103		HP	NO	NO	59	.	GROUP3
Male	Y	.		20231103		HP	NO	NO	32	.	GROUP2
Male	Y	.		20231102		HP	NO	NO	48	.	GROUP2
Female	Y	.		20231103		HP	NO	NO	51	.	GROUP3
Male	Y	.		20231103		HP	NO	NO	56	.	GROUP3
Female	Y	.		20231019		Physician	US	US	48	.	GROUP2
Female	Y	71.67	KG	20231218		HP	US	US	59	71.67	GROUP3
Male	Y	.		20231208		Physician	US	US	31	.	GROUP2
Female	Y	.		20231003		Physician	CA	CA	32	.	GROUP2
Female	Y	67	KG	20231220		Physician	FR	FR	49	67	GROUP2

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report number</i>
1235162812	12351628	12	Follow-up	20160101	20231123	20160510	20231128	Expedited	
123563352	12356335	2	Follow-up	20130801	20231019	20160511	20231025	Expedited	
1235836630	12358366	30	Follow-up	20131029	20231130	20160512	20231212	Expedited	
123602163	12360216	3	Follow-up		20231019	20160512	20231222	Expedited	
123673573	12367357	3	Follow-up	20040101	20231120	20160513	20231128	Expedited	
123712795	12371279	5	Follow-up	20150909	20231218	20160516	20231221	Expedited	
1237277237	12372772	37	Follow-up	20160101	20230926	20160516	20231005	Expedited	
123828053	12382805	3	Follow-up	20160401	20231107	20160518	20231112	Expedited	
123865169	12386516	9	Follow-up		20231106	20160519	20231108	Expedited	
1238769515	12387695	15	Follow-up	20141201	20231219	20160520	20231230	Expedited	
123877733	12387773	3	Follow-up	20160311	20231120	20160520	20231123	Periodic	
123883414	12388341	4	Follow-up	20160430	20160531	20160520	20231122	Expedited	
1239199829	12391998	29	Follow-up	20150311	20231211	20160523	20231221	Expedited	
123928902	12392890	2	Follow-up	20151001	20230818	20160523	20231019	Periodic	
123988992	12398899	2	Follow-up		20231205	20160524	20231213	Periodic	
124058976	12405897	6	Follow-up		20231222	20160526	20231230	Expedited	
1241345017	12413450	17	Follow-up	20090207	20191204	20160527	20231123	Expedited	
1241683811	12416838	11	Follow-up		20230926	20160530	20231006	Expedited	
1241759015	12417590	15	Follow-up	20160412	20231017	20160530	20231026	Expedited	
124193252	12419325	2	Follow-up	20160401	20230928	20160531	20231004	Expedited	
1242381216	12423812	16	Follow-up	20160401	20231017	20160601	20231027	Expedited	
1242661017	12426610	17	Follow-up	20140528	20230510	20160601	20231128	Expedited	
124267893	12426789	3	Follow-up	20130501	20230731	20160601	20231019	Periodic	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviatio n for patient's age</i>	<i>Patient Age Group code</i>
CA-009507513-1603CAN002558	MERCK		.		
PT-PFIZER INC-2016243258	MYLAN	Beato, Joao et al. Elizabethkingia meningoseptica and Contact Lens Use. Acta Med Port. 2016;29 (4):287-289	47	Year	
CA-ROCHE-1756306	ROCHE		51	Year	
US-JAZZ-2016-US-008465	JAZZ		35	Year	
US-JNJFOC-20160501826	JOHNSON AND JOHNSON		3	Decade	Adult
US-JAZZ-2015-US-014172	JAZZ		75	Year	
PHHY2016CA007008	NOVARTIS		82	Year	
CA-BIOGEN-2016BI00236776	BIOGEN		43	Year	
US-JAZZ-2015-US-021618	JAZZ		.		
CA-ROCHE-1761274	ROCHE		46	Year	
US-BIOGEN-2016BI00215902	BIOGEN		49	Year	
FR-ROCHE-1760139	ROCHE		30	Year	
CA-ROCHE-1760511	ROCHE		53	Year	
US-JAZZ-2015-US-014793	JAZZ		32	Year	
US-JAZZ-2016-US-009254	JAZZ		.		
GB-ROCHE-1691591	ROCHE		57	Year	
US-009507513-1605USA010926	MERCK		.		
US-PFIZER INC-2016280298	PFIZER		76	Year	
CA-TAKEDA-2016TUS006496	TAKEDA		62	Year	
US-SUNOVION-2016SUN001327	SUNOVION		.		
CA-PFIZER INC-2016250580	PFIZER		62	Year	
PHHY2013CA144082	NOVARTIS		.		Elderly
US-JAZZ-2016-US-009753	JAZZ		42	Year	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Male	Y	92	KG	20231128		Pharmacist	CA	CA	.	92	MISSIN
Male	Y	.		20231025		Physician	PT	PT	47	.	GROUP2
Female	Y	.		20231212		Consumer	CA	CA	51	.	GROUP3
Female	Y	.		20231222		Consumer	US	US	35	.	GROUP2
Male	Y	.		20231129		HP	US	US	30	.	GROUP2
Female	Y	85.714	KG	20231221		Physician	US	US	75	85.714	GROUP3
Male	Y	.		20231005		Consumer	CA	CA	82	.	GROUP4
Male	Y	.		20231112		Consumer	CA	CA	43	.	GROUP2
Male	Y	.		20231108		Physician	US	US	.	.	MISSIN
Female	Y	.		20231230		Consumer	CA	CA	46	.	GROUP2
Male	Y	.		20231123		Consumer	US	US	49	.	GROUP2
Female	Y	53	KG	20231122		Physician	FR		30	53	GROUP2
Female	Y	.		20231221		Consumer	CA	CA	53	.	GROUP3
Female	Y	.		20231019		Consumer	US	US	32	.	GROUP2
Female	Y	.		20231214		Consumer	US	US	.	.	MISSIN
Male	Y	.		20231230		HP	GB	GB	57	.	GROUP3
Female	Y	87.982	KG	20231123		Physician	US	US	.	87.982	MISSIN
Female	Y	.		20231006		Consumer	US	US	76	.	GROUP4
Female	Y	.		20231026		Physician	CA	CA	62	.	GROUP3
	Y	.		20231004		Consumer	US	US	.	.	MISSIN
Female	Y	.		20231027		HP	CA	CA	62	.	GROUP3
Female	Y	.		20231127		HP	CA	CA	.	.	MISSIN
Female	Y	.		20231019		Physician	US	US	42	.	GROUP2

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

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1243188715	12431887	15	Follow-up	20160506	20231115	20160603	20231118	Expedited	
1244105814	12441058	14	Follow-up	20160316	20231003	20160607	20231013	Expedited	
1244109913	12441099	13	Follow-up	20170108	20231003	20160607	20231016	Expedited	
124454965	12445496	5	Follow-up	20040714	20231106	20160608	20231115	Periodic	
124455942	12445594	2	Follow-up	20090101	20231016	20160608	20231018	Periodic	
124519574	12451957	4	Follow-up	.	20230807	20160609	20231019	Periodic	
124557465	12455746	5	Follow-up	20160101	20231211	20160610	20231229	Expedited	
124576196	12457619	6	Follow-up	20160301	20231220	20160610	20231228	Expedited	
124647052	12464705	2	Follow-up	.	20231204	20160614	20231208	Expedited	
124656152	12465615	2	Follow-up	.	20231205	20160614	20231214	Expedited	
124658184	12465818	4	Follow-up	.	20231204	20160614	20231213	Expedited	
1246649231	12466492	31	Follow-up	20120801	20231012	20160615	20231023	Expedited	
124697266	12469726	6	Follow-up	20200526	20231213	20160615	20231218	Expedited	
124729263	12472926	3	Follow-up	.	20231019	20160616	20231031	Expedited	
1248414317	12484143	17	Follow-up	20150519	20231215	20160621	20231226	Expedited	
1248745116	12487451	16	Follow-up	20140605	20231214	20160622	20231226	Expedited	
1248777719	12487777	19	Follow-up	20160531	20231109	20160622	20231120	Expedited	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

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PHHY2016CO066331	NOVARTIS		48	Year	
CA-ROCHE-1769176	ROCHE		48	Year	
CA-ROCHE-1770745	ROCHE		43	Year	
US-JNJFOC-20160504496	JOHNSON AND JOHNSON		8	Year	Child
US-JNJFOC-20160419448	JOHNSON AND JOHNSON		3	Decade	Adult
US-JAZZ-2015-US-018971	JAZZ		.		
FR-B.I. Pharmaceuticals, Inc./Ridgefield-2016-BI-37012FF	BOEHRINGER INGELHEIM		49	Year	Adult
CA-TAKEDA-2016TUS006114	TAKEDA		38	Year	
US-drreddys-USA/USA/16/0080606	DR REDDYS	Chapuy C, Sahai I, Sharma R, Zhu A, Kozyreva O. Hyperammonemic Encephalopathy Associated With Fibrolamellar Hepatocellular Carcinoma: Case Report, Literature Review, and Proposed Treatment Algorithm. Oncologist. 2016;21(4):514-20. doi:Unknown	31	Year	Adult
US-ELI_LILLY_AND_COMPANY-US201606004225	ELI LILLY AND CO		31	Year	
US-PFIZER INC-2016297397	PFIZER	Chapuy, C.. Hyperammonemic encephalopathy associated with fibrolamellar hepatocellular carcinoma: Case report, literature review, and proposed treatment algorithm. Oncologist. 2016;21(4):514-520	31	Year	
CA-ROCHE-1775252	ROCHE		71	Year	
US-JAZZ-2016-US-010594	JAZZ		76	Year	
US-BAYER-2016-109879	BAYER	Choudhry WM; Nori US; Nadasdy T; Satoskar AA. An unexpected cause of acute kidney injury in a patient with ANCA associated vasculitis. Clinical Nephrology. 2016;85 (5):289-295	69	Year	Elderly
CA-ROCHE-1779410	ROCHE		38	Year	
CA-ROCHE-1778623	ROCHE		56	Year	
CA-ROCHE-1780228	ROCHE		56	Year	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Male	Y	70	KG	20231118		Consumer	CO	CO	48	70	GROUP2
Female	Y	110	KG	20231013		Consumer	CA	CA	48	110	GROUP2
Female	Y	.		20231016		Consumer	CA	CA	43	.	GROUP2
Male	Y	.		20231115		HP	US	US	8	.	GROUP1
Male	Y	.		20231018		Lawyer	US	US	30	.	GROUP2
Female	Y	117	KG	20231019		Consumer	US	US	.	117	MISSIN
Female	Y	67	KG	20231214		Physician	FR	FR	49	67	GROUP2
Female	Y	.		20231228		Consumer	CA	CA	38	.	GROUP2
Male	Y	.		20231208		Physician	US	US	31	.	GROUP2
Male	Y	.		20231214		Physician	US	US	31	.	GROUP2
Male	Y	.		20231213		Physician	US	US	31	.	GROUP2
Female	Y	.		20231023		Consumer	CA	CA	71	.	GROUP3
Female	Y	.		20231218		Consumer	US	US	76	.	GROUP4
Female	Y	.		20231031		Physician	US	US	69	.	GROUP3
Female	Y	.		20231226		Consumer	CA	CA	38	.	GROUP2
Female	Y	.		20231226		Physician	CA	CA	56	.	GROUP3
Male	Y	.		20231120		Consumer	CA	CA	56	.	GROUP3



## ADVERSE EVENT REPORTING SYSTEM (AERS)

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124879704	12487970	4	Follow-up	.	20231218	20160622	20231229	Expedited	
125035915	12503591	5	Follow-up	20160515	20231002	20160628	20231005	Expedited	
1251723528	12517235	28	Follow-up	20160101	20231122	20160630	20231130	Expedited	
1251759434	12517594	34	Follow-up	20160205	20231106	20160630	20231113	Expedited	
125236397	12523639	7	Follow-up	20140304	20231107	20160704	20231114	Expedited	
1252758731	12527587	31	Follow-up	20121001	20231108	20160705	20231117	Expedited	
125285222	12528522	2	Follow-up	.	20231031	20160705	20231109	Expedited	
125316252	12531625	2	Follow-up	20130801	20231019	20160706	20231030	Expedited	
1253212410	12532124	10	Follow-up	20160304	20231220	20160706	20231226	Expedited	
1253507817	12535078	17	Follow-up	20120101	20231212	20160707	20231222	Expedited	
125419252	12541925	2	Follow-up	20160621	20231130	20160708	20231206	Expedited	GB-MHRA-TPP10959200C517762YC1466496217202
1254806012	12548060	12	Follow-up	20160626	20220618	20160712	20231004	Expedited	
1254818510	12548185	10	Follow-up	.	20231101	20160712	20231115	Periodic	
125511353	12551135	3	Follow-up	.	20231004	20160713	20231011	Expedited	
125520368	12552036	8	Follow-up	20190901	20231208	20160713	20231218	Expedited	
125529493	12552949	3	Follow-up	20160101	20231019	20160713	20231130	Expedited	
125579484	12557948	4	Follow-up	20220101	20231010	20160714	20231013	Expedited	
125595734	12559573	4	Follow-up	20150720	20231213	20160715	20231218	Expedited	
125609252	12560925	2	Follow-up	20150101	20231127	20160715	20231209	Expedited	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
US-AUROBINDO-AUR-APL-2016-08106	AUROBINDO	Qureshi M, Catalasan G.. The use of high dose insulin euglycemia therapy in calcium channel blocker and beta blocker overdose. Journal of General Internal Medicine. 2016;31:2(1):S760-S761	48	Year
US-ABBVIE-16P-163-1661753-00	ABBVIE		42	Year
CA-ROCHE-1785228	ROCHE		68	Year
PHHY2016CL088658	NOVARTIS		59	Year
CA-ROCHE-1786585	ROCHE		55	Year
CA-ROCHE-1786206	ROCHE		70	Year
TR-PFIZER INC-2016326347	PFIZER	Yuksel, R.. Cabergoline-induced manic episode: case report. Therapeutic Advances in Psychopharmacology. 2016;6 (3):229-231	26	Year
PT-MYLANLABS-2016M1028043	MYLAN	Beato JN, Espinar MJ, Figueira L, Eremina YO, Ribeiro M, Moreira R, et al. Elizabethkingia meningoseptica and contact lens use. Acta-Med-Port 2016;29(4):287-289.	47	Year
CA-TAKEDA-2016TUS002594	TAKEDA		61	Year
CA-ROCHE-1789546	ROCHE		59	Year
GB-MYLANLABS-2016M1027964	MYLAN		75	Year
PHHY2016IN094130	NOVARTIS		41	Year
US-PFIZER INC-2015433513	PFIZER		70	Year
US-AUROBINDO-AUR-APL-2016-08784	AUROBINDO	Wiegand TJ, Chamberlin S. Toxin induced myocardial stunning with improvement in cardiac contractility after intravenous lipid emulsion administration. Clinical Toxicology. 2016;54(4):489	25	Year
PHHY2014CA094560	NOVARTIS		70	Year
US-JAZZ-2016-US-012667	JAZZ		41	Year
US-JAZZ-2016-US-000751	JAZZ		.	
PHHY2015CA076195	NOVARTIS		50	Year
JP-ELI_LILLY_AND_COMPANY-JP201607003016	ELI LILLY AND CO	Wada M, et al..Examination of cases treated with ramucirumab at our hospital - Focusing on the experience of perforation cases -.The 58th Annual Meeting of the Japanese Society of Gastroenterology 2016;..	75	Year

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Male	Y	.		20231229		Physician	US	US	48	.	GROUP2
	Male	Y	.		20231005		Physician	US	US	42	.	GROUP2
	Female	Y	.		20231201		Consumer	CA	CA	68	.	GROUP3
	Female	Y	69.5	KG	20231113		Physician	CL	CL	59	69.5	GROUP3
	Male	Y	68	KG	20231114		Consumer	CA	CA	55	68	GROUP3
	Male	Y	.		20231118		Consumer	CA	CA	70	.	GROUP3
	Female	Y	.		20231109		Physician	TR	TR	26	.	GROUP2
	Male	Y	.		20231030		HP	PT	PT	47	.	GROUP2
	Female	Y	.		20231226		HP	CA	CA	61	.	GROUP3
	Female	Y	.		20231222		Consumer	CA	CA	59	.	GROUP3
	Male	Y	105	KG	20231206		Physician	GB	GB	75	105	GROUP3
	Male	Y	.		20231004		Consumer	IN	IN	41	.	GROUP2
	Female	Y	61	KG	20231115		Consumer	US	US	70	61	GROUP3
	Female	Y	.		20231011		Physician	US	US	25	.	GROUP1
	Female	Y	.		20231216		Physician	CA	CA	70	.	GROUP3
	Female	Y	.		20231130		Consumer	US	US	41	.	GROUP2
	Male	Y	.		20231013		Consumer	US	US	.	.	MISSIN
	Female	Y	.		20231218		Physician	CA	CA	50	.	GROUP2
	Male	Y	.		20231209		Physician	JP	JP	75	.	GROUP3

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
125619276	12561927	6	Follow-up	20100101	20231205	20160715	20231211	Expedited	
1256504624	12565046	24	Follow-up	20151001	20231211	20160718	20231218	Expedited	
1258205211	12582052	11	Follow-up	20140921	20231024	20160722	20231106	Expedited	
1258253825	12582538	25	Follow-up	20160601	20231222	20160722	20231227	Expedited	
1258700623	12587006	23	Follow-up	20160401	20231115	20160725	20231122	Expedited	
1259605217	12596052	17	Follow-up	20200201	20231201	20160727	20231214	Expedited	
125972513	12597251	3	Follow-up	.	20231201	20160727	20231214	Expedited	
125974976	12597497	6	Follow-up	20230201	20231128	20160727	20231207	Periodic	
126018092	12601809	2	Follow-up	.	20231213	20160728	20231221	Expedited	
126027722	12602772	2	Follow-up	20160701	20231211	20160728	20231219	Expedited	
126052728	12605272	8	Follow-up	20160701	20231031	20160729	20231102	Expedited	
126079123	12607912	3	Follow-up	.	20231113	20160729	20231116	Periodic	
126083683	12608368	3	Follow-up	.	20231113	20160729	20231121	Periodic	
126083763	12608376	3	Follow-up	.	20231113	20160729	20231120	Periodic	
126102746	12610274	6	Follow-up	20160706	20231108	20160801	20231117	Expedited	
1261220638	12612206	38	Follow-up	20150510	20231115	20160801	20231122	Expedited	
126137718	12613771	8	Follow-up	.	20231106	20160802	20231120	Periodic	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending report</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
US-JAZZ-2016-US-012790	JAZZ		.		
CA-ROCHE-1727702	ROCHE		62	Year	
CA-ROCHE-1798750	ROCHE		37	Year	
PHHY2016CA086482	NOVARTIS		51	Year	
CA-ROCHE-1799664	ROCHE		60	Year	
CA-ROCHE-1801131	ROCHE		46	Year	
US-AUROBINDO-AUR-APL-2016-09810	AUROBINDO	Hoffmann MS, Overman MJ, Nates JL.. Acute benzodiazepine toxicity exacerbated by concomitant oral olanzapine. Journal of Community and Supportive Oncology. 2016;14(4):178-9	61	Year	
US-PFIZER INC-2016327397	PFIZER		58	Year	
GB-AUROBINDO-AUR-APL-2016-09604	AUROBINDO		57	Year	
KR-BAYER-2016-146802	BAYER		63	Year	Adult
FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-060754	BRISTOL MYERS SQUIBB		76	Year	Elderly
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-062694	BRISTOL MYERS SQUIBB	Naidoo J, Schindler K, Querfeld C, Busam K, Cunningham J, Page DB, et al. Autoimmune bullous skin disorders with immune checkpoint inhibitors targeting PD-1 and PD-L1. Cancer Immunology Research. 2016 Feb 29;4(5):383-9. doi:10.1158/2326-6066.CIR-15-0123.	80	Year	Elderly
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-062695	BRISTOL MYERS SQUIBB	Naidoo J, Schindler K, Querfeld C, Busam K, Cunningham J, Page DB, et al. Autoimmune bullous skin disorders with immune checkpoint inhibitors targeting PD-1 and PD-L1. Cancer Immunology Research. 2016 Feb 29;4(5):383-9. doi:10.1158/2326-6066.CIR-15-0123.	85	Year	Elderly
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-062302	BRISTOL MYERS SQUIBB	Naidoo J, Schindler K, Querfeld C, Busam K, Cunningham J, Page DB, et al. Autoimmune bullous skin disorders with immune checkpoint inhibitors targeting PD-1 and PD-L1. Cancer Immunology Research. 2016 Feb 29;4(5):383-9. doi:10.1158/2326-6066.CIR-15-0123.	80	Year	Elderly
CA-PFIZER INC-2016359008	PFIZER		62	Year	
PHHY2015CA089484	NOVARTIS		40	Year	
US-TAKEDA-2016MPI006683	TAKEDA		.		

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Female	Y	.		20231211		Consumer	US	US	.	.	MISSIN
Male	Y	69	KG	20231218		Consumer	CA	CA	62	69	GROUP3
Male	Y	.		20231106		Physician	CA	CA	37	.	GROUP2
Male	Y	.		20231227		Consumer	CA	CA	51	.	GROUP3
Female	Y	.		20231122		Consumer	CA	CA	60	.	GROUP3
Female	Y	.		20231214		Consumer	CA	CA	46	.	GROUP2
Female	Y	.		20231214		Physician	US	US	61	.	GROUP3
Female	Y	.		20231207		HP	US	US	58	.	GROUP3
Male	Y	.		20231221		HP	GB	GB	57	.	GROUP3
Male	Y	.		20231219		HP	KR	KR	63	.	GROUP3
Female	Y	.		20231103		Physician	FR	FR	76	.	GROUP4
Male	Y	.		20231116		HP	US	US	80	.	GROUP4
Male	Y	.		20231121		HP	US	US	85	.	GROUP4
Male	Y	.		20231120		HP	US	US	80	.	GROUP4
Male	Y	.		20231117		HP	CA	CA	62	.	GROUP3
Female	Y	88	KG	20231122		Physician	CA	CA	40	88	GROUP2
Male	Y	.		20231120		HP	US	US	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
126144642	12614464	2	Follow-up	.	20231130	20160802	20231208	Expedited	
1261461519	12614615	19	Follow-up	20160101	20231201	20160802	20231208	Expedited	
126146323	12614632	3	Follow-up	20150101	20230918	20160802	20231019	Periodic	
1262188810	12621888	10	Follow-up	20160701	20231107	20160804	20231115	Expedited	FR-PURDUE PHARMA-GBR-2016-0039405
1262194015	12621940	15	Follow-up	20160701	20231026	20160804	20231031	Expedited	
1262399912	12623999	12	Follow-up	20160701	20231009	20160804	20231011	Expedited	
126300813	12630081	3	Follow-up	.	20231013	20160808	20231020	Expedited	
126446453	12644645	3	Follow-up	20160727	20231208	20160811	20231214	Expedited	
1264583518	12645835	18	Follow-up	20151218	20231016	20160811	20231022	Expedited	
1264862010	12648620	10	Follow-up	20160701	20231213	20160812	20231218	Expedited	
1264877314	12648773	14	Follow-up	20180801	20231031	20160812	20231106	Periodic	
126510864	12651086	4	Follow-up	20140101	20230825	20160815	20231019	Periodic	
1265259319	12652593	19	Follow-up	20160805	20231124	20160815	20231204	Expedited	
126525949	12652594	9	Follow-up	.	20231109	20160815	20231115	Periodic	
126566772	12656677	2	Follow-up	.	20231009	20160816	20231013	Expedited	
1265982714	12659827	14	Follow-up	20220310	20231205	20160817	20231207	Expedited	
126599422	12659942	2	Follow-up	.	20231024	20160817	20231030	Expedited	
1266158617	12661586	17	Follow-up	20160819	20231113	20160817	20231120	Periodic	
126627513	12662751	3	Follow-up	20160101	20231108	20160818	20231114	Periodic	
126629514	12662951	4	Follow-up	20160801	20231011	20160818	20231016	Expedited	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
US-JAZZ-2016-US-003756	JAZZ		53	Year	
US-PFIZER INC-2016022099	PFIZER		66	Year	
US-JAZZ-2016-US-003209	JAZZ		60	Year	
FR-PURDUE PHARMA-GBR-2016-0039405	PURDUE		76	Year	
CA-PFIZER INC-2016366727	MYLAN		41	Year	
US-BIOGEN-2016BI00274394	BIOGEN		58	Year	
US-PFIZER INC-2016368912	PFIZER	Singh, A.. Transient left ventricular regional ballooning during dobutamine stress echocardiography. Journal of the American Society of Echocardiography. 2016;29 (6):B98	85	Year	
US-JAZZ-2016-US-010831	JAZZ		54	Year	
PHHY2016CA007779	NOVARTIS		45	Year	
US-INCYTE CORPORATION-2016IN004805	INCYTE		.		
US-PFIZER INC-2016374798	PFIZER		63	Year	
US-JAZZ-2016-US-005382	JAZZ		.		
US-PFIZER INC-2016387053	PFIZER		72	Year	
US-PFIZER INC-2016385767	PFIZER		66	Year	
GB-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-066552	BRISTOL MYERS SQUIBB	Ottensmeier C, Galea I, Cross N, Maishman T, Hamid D, Cave J, et al. A novel phase II trial of ipilimumab, carboplatin and etoposide (ice) for the first line treatment of extensive stage small cell lung cancer (SCLC). Annals of Oncology. 2014;25(Supplement 4):iv511-iv6.doi:10.1093/annonc/mdu355.15.	.		
US-SHIRE-2016DX000079	TAKEDA		17	Year	
US-SHIRE-2016DX000217	TAKEDA		.		
US-PFIZER INC-2016387665	PFIZER		62	Year	
US-BIOGEN-2016BI00278394	BIOGEN		.		
CA-ROCHE-1815675	ROCHE		26	Year	



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Female	Y	.		20231208		Consumer	US	US	53	.	GROUP3
Female	Y	86	KG	20231208		Consumer	US	US	66	86	GROUP3
Male	Y	.		20231019		HP	US	US	60	.	GROUP3
Female	Y	.		20231115		Physician	FR	FR	76	.	GROUP4
Female	Y	59	KG	20231031		Consumer	CA	CA	41	59	GROUP2
Male	Y	.		20231011		Consumer	US	US	58	.	GROUP3
Female	Y	.		20231020		HP	US	US	85	.	GROUP4
Female	Y	.		20231215		Physician	US	US	54	.	GROUP3
Male	Y	.		20231022		Physician	CA	CA	45	.	GROUP2
	Y	.		20231218		Consumer	US	US	.	.	MISSIN
Male	Y	.		20231106		Consumer	US	US	63	.	GROUP3
Male	Y	.		20231019		Consumer	US	US	.	.	MISSIN
Male	Y	95.5	KG	20231204		Consumer	US	US	72	95.5	GROUP3
Male	Y	.		20231115		Physician	US	US	66	.	GROUP3
	Y	.		20231013		HP	GB	GB	.	.	MISSIN
Female	Y	60.781	KG	20231207		HP	US	US	17	60.781	GROUP1
Female	Y	88	KG	20231030		Physician	US	US	.	88	MISSIN
Female	Y	70	KG	20231120		Physician	US	US	62	70	GROUP3
Female	Y	.		20231114		Consumer	US	US	.	.	MISSIN
Female	Y	88.5	KG	20231016		HP	CA		26	88.5	GROUP2

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>	<i>Manufacturer's unique report identifier.</i>
126636233	12663623	3	Follow-up	20160628	20231117	20160818	20231130	Expedited		US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000070
126661713	12666171	3	Follow-up	20160201	20230724	20160818	20231019	Periodic		US-JAZZ-2016-US-005715
126666384	12666638	4	Follow-up	.	20231009	20160819	20231016	Expedited		DE-ROCHE-1814842
1266682834	12666828	34	Follow-up	.	20231218	20160819	20231227	Expedited		CA-BAUSCH-BL-2016-019424
126694216	12669421	6	Follow-up	20160101	20231127	20160819	20231205	Expedited		PHHY2016CA021426
1267143810	12671438	10	Follow-up	20160810	20231130	20160822	20231208	Expedited		PHHY2016CA112272
1267308830	12673088	30	Follow-up	20160301	20231102	20160822	20231108	Expedited		PHHY2016CA038348
1267604333	12676043	33	Follow-up	.	20231127	20160823	20231129	Expedited		CA-SA-2015SA146389
126784766	12678476	6	Follow-up	20160101	20231107	20160823	20231113	Expedited		PHHY2016CA060905
1267970510	12679705	10	Follow-up	20160802	20231116	20160824	20231129	Expedited		CA-ROCHE-1818957
1268469220	12684692	20	Follow-up	20150515	20231106	20160825	20231112	Expedited		JP-JNJFOC-20160818269
126849622	12684962	2	Follow-up	20160803	20231214	20160825	20231221	Expedited		FR-PFIZER INC-2016397195
126865539	12686553	9	Follow-up	20160701	20231208	20160825	20231214	Expedited		FR-MYLANLABS-2016M1035188
126908303	12690830	3	Follow-up	.	20231201	20160826	20231208	Expedited		US-TAKEDA-2016TUS015026
126915713	12691571	3	Follow-up	20120101	20231106	20160826	20231108	Expedited		US-JAZZ-2016-US-015941
126946204	12694620	4	Follow-up	20150412	20170407	20160829	20231202	Expedited		US-BAYER-2016-103680
1269688715	12696887	15	Follow-up	.	20231020	20160830	20231025	Expedited		CA-Orion Corporation ORION PHARMA-TREX2016-1453
126982523	12698252	3	Follow-up	20030101	20231113	20160830	20231121	Periodic		US-JNJFOC-20160728228
1270466920	12704669	20	Follow-up	20160623	20231128	20160831	20231201	Expedited		CA-TAKEDA-2016TUS015019

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Coded name of manufacturer sending report</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviatio n for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient' s sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>
ACADIA PHARMACEUTICALS		61	Year		Male	Y	90.703
JAZZ		45	Year		Female	Y	.
ROCHE	Minckwitz G, Reimer T, Potenberg J, Conrad B, Schurer U, Eidtmann H, Just M, Paepke S and Stickeler E The phase III ICE study: Adjuvant Ibandronate with or without capecitabine in elderly patients with moderate or high risk early breast cancer. (Abstract S3-04). Cancer Research 2015 May 01;75(SUPP:9):-.	.				Y	.
BAUSCH AND LOMB	Farrell B, Merkley V, Thompson W. Managing polypharmacy in a 77-year-old woman with multiple prescribers. CMAJ. 2013 OCT 01;185(14):1240-1245. doi:10.1503 /cmaj.122012	77	Year		Female	Y	.
NOVARTIS		43	Year		Female	Y	.
NOVARTIS		56	Year		Male	Y	.
NOVARTIS		52	Year		Female	Y	.
SANOFI AVENTIS		43	Year	Adult	Female	Y	68
NOVARTIS		48	Year		Male	Y	.
ROCHE		66	Year		Male	Y	.
JOHNSON AND JOHNSON		55	Year	Adult	Male	Y	.
PFIZER		60	Year		Male	Y	104
MYLAN		76	Year		Female	Y	.
TAKEDA		.			Male	Y	.
JAZZ		.			Female	Y	.
BAYER		62	Year	Adult	Male	Y	101.4
ORION		60	Year	Adult	Female	Y	.
JOHNSON AND JOHNSON		1	Decade	Child	Male	Y	.
TAKEDA		37	Year		Male	Y	.

### ADVERSE EVENT REPORTING SYSTEM (AERS) Demographic Listings

<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
KG	20231130		Consumer	US	US	61	90.703	GROUP3
	20231019		HP	US	US	45	.	GROUP2
	20231016		HP	DE		.	.	MISSIN
	20231227		Physician	CA	CA	77	.	GROUP4
	20231205		Physician	CA	CA	43	.	GROUP2
KG	20231208		Consumer	CA	CA	56	.	GROUP3
	20231108		HP	CA	CA	52	.	GROUP3
	20231129		Physician	CA	CA	43	68	GROUP2
	20231113		Consumer	CA	CA	48	.	GROUP2
	20231129		Physician	CA	CA	66	.	GROUP3
KG	20231113		Physician	JP	JP	55	.	GROUP3
	20231221		Physician	FR	FR	60	104	GROUP3
	20231214		HP	FR	FR	76	.	GROUP4
	20231208		Consumer	US	US	.	.	MISSIN
	20231108		Physician	US	US	.	.	MISSIN
KG	20231202		Lawyer	US	US	62	101.4	GROUP3
	20231025		Physician	CA		60	.	GROUP3
	20231121		Lawyer	US	US	10	.	GROUP1
	20231201		Consumer	CA	CA	37	.	GROUP2

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>	<i>Manufacturer's unique report identifier.</i>
127133207	12713320	7	Follow-up	.	20231017	20160902	20231024	Expedited		CA-BAXTER-2016BAX045339
1271450712	12714507	12	Follow-up	20160101	20231027	20160905	20231031	Expedited		US-JAZZ-2016-US-008662
1271617516	12716175	16	Follow-up	20160101	20231205	20160906	20231212	Expedited		PHHY2011CA67594
1271619614	12716196	14	Follow-up	20140701	20221108	20160906	20231206	Expedited		PHHY2014CA097752
1272747538	12727475	38	Follow-up	20160609	20230922	20160909	20231003	Expedited		CA-ROCHE-1827432
127335812	12733581	2	Follow-up	.	20231012	20160912	20231020	Expedited		NO-AUROBINDO-AUR-APL-2016-11309
1273672134	12736721	34	Follow-up	20160101	20220325	20160913	20231129	Expedited		PHHY2016CA124821
127442575	12744257	5	Follow-up	20060801	20231117	20160914	20231124	Expedited		US-JAZZ-2016-US-017186
127476922	12747692	2	Follow-up	20160501	20230724	20160915	20231019	Periodic		US-JAZZ-2016-US-009620
1276662113	12766621	13	Follow-up	.	20231120	20160921	20231130	Expedited		PHHY2016CA129816
1276746115	12767461	15	Follow-up	.	20231119	20160921	20231120	Expedited		US-PFIZER INC-2016422273
127688913	12768891	3	Follow-up	20130601	20230724	20160921	20231019	Periodic		US-JAZZ-2016-US-010472
127688972	12768897	2	Follow-up	20160809	20231102	20160921	20231110	Periodic		US-INCYTE CORPORATION-2016IN005194
127739882	12773988	2	Follow-up	20131001	20231211	20160923	20231222	Expedited		IT-Accord-044231
127769588	12776958	8	Follow-up	20160101	20231124	20160923	20231128	Expedited		US-JAZZ-2016-US-018194
127795064	12779506	4	Follow-up	20160101	20230811	20160926	20231025	Expedited		GB-AUROBINDO-AUR-APL-2016-11618
1278946016	12789460	16	Follow-up	20160919	20231017	20160928	20231019	Expedited		PHHY2016CA132023
1279005821	12790058	21	Follow-up	20160101	20231017	20160928	20231023	Expedited		PHHY2016CA081553
127908472	12790847	2	Follow-up	.	20230925	20160929	20231002	Expedited		TR-BAUSCH-BL-2016-023893
127919063	12791906	3	Follow-up	20131001	20231211	20160929	20231220	Expedited		IT-PFIZER INC-2016449348

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviatio n for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient' s sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>
BAXTER		58	Year		Female	Y	.
JAZZ		.			Female	Y	.
NOVARTIS		62	Year		Male	Y	.
NOVARTIS		70	Year		Female	Y	68
ROCHE		62	Year		Female	Y	74
AUROBINDO		64	Year		Female	Y	.
NOVARTIS		78	Year		Male	Y	.
JAZZ		46	Year		Male	Y	.
JAZZ		51	Year		Female	Y	.
NOVARTIS		63	Year		Male	Y	.
PFIZER		74	Year		Female	Y	59.864
JAZZ		48	Year		Female	Y	.
INCYTE		.				Y	.
ACCORD	Talotta R, Atzeni F, Batticciotto A, Ventura D, Sarzi-Puttini P. Possible relationship between certolizumab pegol and arrhythmias: report of two cases. Reumatismo. 2016 Sep 9; 68(2):104-8.	60	Year	Adult	Male	Y	.
JAZZ		.			Male	Y	82.54
AUROBINDO		93	Year		Male	Y	.
NOVARTIS		68	Year		Female	Y	.
NOVARTIS		68	Year		Male	Y	.
BAUSCH AND LOMB	Ozturk Aktas O, Karabiber E, Ozdemir E, Celebioglu E, Ovunc K, Karakaya G, Kalyoncu F. Kounis syndrome (Allergic Angina and Allergic Myocardial Infarction): Two cases.. Allergy: European Journal of Allergy and Clinical Immunology. 2016 AUG 01;71(102):567-568. doi:10.1111/all.12978	35	Year		Male	Y	.
PFIZER	Talotta, R.. Possible relationship between certolizumab pegol and arrhythmias: Report of two cases. Reumatismo. 2016;68 (2):104-108	60	Year		Male	Y	.

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	20231024		Consumer	CA	CA	58	.	GROUP3
	20231031		Consumer	US	US	.	.	MISSIN
	20231212		Consumer	CA	CA	62	.	GROUP3
KG	20231206		HP	CA	CA	70	68	GROUP3
KG	20231003		Physician	CA	CA	62	74	GROUP3
	20231020		Consumer	NO	NO	64	.	GROUP3
	20231129		Physician	CA	CA	78	.	GROUP4
	20231124		Physician	US	US	46	.	GROUP2
	20231019		Physician	US	US	51	.	GROUP3
	20231130		Physician	CA	CA	63	.	GROUP3
KG	20231120		Physician	US	US	74	59.864	GROUP3
	20231019		HP	US	US	48	.	GROUP2
	20231110		Consumer	US	US	.	.	MISSIN
	20231222		HP	IT	IT	60	.	GROUP3
KG	20231128		Physician	US	US	.	82.54	MISSIN
	20231025		Physician	GB	GB	93	.	GROUP4
	20231019		HP	CA	CA	68	.	GROUP3
	20231023		Consumer	CA	CA	68	.	GROUP3
	20231002		HP	TR	TR	35	.	GROUP2
	20231220		HP	IT	IT	60	.	GROUP3

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
127919704	12791970	4	Follow-up	20100101	20231113	20160929	20231122	Periodic	
127923264	12792326	4	Follow-up	20030101	20231006	20160929	20231013	Periodic	
127925774	12792577	4	Follow-up	20060101	20231030	20160929	20231108	Periodic	
127925843	12792584	3	Follow-up	.	20231009	20160929	20231014	Periodic	
127928484	12792848	4	Follow-up	19950101	20231025	20160929	20231031	Periodic	
127932064	12793206	4	Follow-up	20020801	20231006	20160929	20231012	Periodic	
127932964	12793296	4	Follow-up	20021201	20231122	20160929	20231129	Periodic	
127934284	12793428	4	Follow-up	20000201	20230929	20160929	20231005	Periodic	
127970915	12797091	5	Follow-up	20120101	20230727	20160929	20231019	Periodic	
128111456	12811145	6	Follow-up	20160801	20231206	20161005	20231208	Expedited	
128125275	12812527	5	Follow-up	20150904	20231117	20161005	20231122	Expedited	
1281285321	12812853	21	Follow-up	20150101	20231123	20161005	20231204	Expedited	
1282456425	12824564	25	Follow-up	20110101	20231122	20161007	20231130	Expedited	
128337604	12833760	4	Follow-up	20161004	20231215	20161010	20231226	Expedited	
1283816224	12838162	24	Follow-up	20130501	20230926	20161012	20231004	Expedited	
1284001415	12840014	15	Follow-up	20140101	20231127	20161012	20231204	Expedited	
1284111422	12841114	22	Follow-up	20160926	20231129	20161012	20231204	Expedited	



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
US-JNJFOC-20160806444	JOHNSON AND JOHNSON		.	
US-JNJFOC-20160915325	JOHNSON AND JOHNSON		7	Year
US-JNJFOC-20160917935	JOHNSON AND JOHNSON		.	
US-JNJFOC-20160916830	JOHNSON AND JOHNSON		.	
US-JNJFOC-20160917052	JOHNSON AND JOHNSON		11	Year
US-JNJFOC-20160916485	JOHNSON AND JOHNSON		10	Year
US-JNJFOC-20160916829	JOHNSON AND JOHNSON		15	Year
US-JNJFOC-20160917910	JOHNSON AND JOHNSON		11	Year
US-JAZZ-2016-US-018062	JAZZ		.	
US-PFIZER INC-2016462800	PFIZER		58	Year
JP-JNJFOC-20160931151	JOHNSON AND JOHNSON	Saka Y. A case of systemic lupus erythematosus and rheumatoid arthritis in which lupus nephritis was rapidly aggravated after administration of golimumab. The Japanese Journal of Nephrology Aug-2016;58(6):909.	62	Year
CA-PFIZER INC-2016464804	PFIZER		60	Year
CA-PFIZER INC-2016464814	PFIZER		68	Year
CA-JNJFOC-20161006224	JOHNSON AND JOHNSON		56	Year
PHHY2009CA21616	NOVARTIS		68	Year
US-PFIZER INC-2016471039	PFIZER		83	Year
CA-TAKEDA-2016TUS014585	TAKEDA		26	Year

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Male	Y	.		20231122		HP	US	US	.	.	MISSIN
Child	Male	Y	.		20231013		Lawyer	US	US	7	.	GROUP1
Adolescent	Male	Y	.		20231108		HP	US	US	.	.	MISSIN
	Male	Y	.		20231014		HP	US	US	.	.	MISSIN
Child	Male	Y	.		20231031		HP	US	US	11	.	GROUP1
Child	Male	Y	.		20231012		HP	US	US	10	.	GROUP1
Adolescent	Male	Y	.		20231130		Lawyer	US	US	15	.	GROUP1
Child	Male	Y	.		20231006		Lawyer	US	US	11	.	GROUP1
	Female	Y	.		20231019		HP	US	US	.	.	MISSIN
	Male	Y	.		20231208		Consumer	US	US	58	.	GROUP3
Adult	Female	Y	45	KG	20231122		Physician	JP	JP	62	45	GROUP3
	Female	Y	64	KG	20231204		HP	CA	CA	60	64	GROUP3
	Female	Y	.		20231130		HP	CA	CA	68	.	GROUP3
Adult	Male	Y	72	KG	20231226		HP	CA	CA	56	72	GROUP3
	Female	Y	.		20231004		Consumer	CA	CA	68	.	GROUP3
	Female	Y	54.43	KG	20231204		Consumer	US	US	83	54.43	GROUP4
	Male	Y	.		20231204		HP	CA	CA	26	.	GROUP2

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
128418645	12841864	5	Follow-up	20160516	20231221	20161012	20231228	Expedited	
128428173	12842817	3	Follow-up	.	20231214	20161013	20231219	Expedited	
128452458	12845245	8	Follow-up	20170101	20231002	20161013	20231005	Expedited	
128455702	12845570	2	Follow-up	20100101	20230728	20161013	20231019	Periodic	
128533274	12853327	4	Follow-up	20160101	20230727	20161017	20231019	Periodic	
1285374010	12853740	10	Follow-up	20160101	20231213	20161017	20231219	Expedited	
128607137	12860713	7	Follow-up	20160801	20231005	20161019	20231011	Expedited	
128713873	12871387	3	Follow-up	.	20231122	20161020	20231201	Expedited	
128759653	12875965	3	Follow-up	20160101	20230727	20161024	20231019	Periodic	
128796683	12879668	3	Follow-up	20160501	20231025	20161025	20231031	Expedited	
128813852	12881385	2	Follow-up	20110101	20231011	20161025	20231020	Periodic	
128813963	12881396	3	Follow-up	20050101	20231009	20161025	20231018	Periodic	
128814004	12881400	4	Follow-up	20060109	20230927	20161025	20231004	Periodic	
128814102	12881410	2	Follow-up	20040330	20231213	20161025	20231224	Periodic	
128815644	12881564	4	Follow-up	.	20231122	20161025	20231130	Expedited	
128830863	12883086	3	Follow-up	20161001	20231017	20161025	20231023	Expedited	
128835772	12883577	2	Follow-up	.	20231003	20161025	20231006	Expedited	
1288783427	12887834	27	Follow-up	20150204	20231201	20161027	20231213	Expedited	
128896804	12889680	4	Follow-up	20160927	20231114	20161027	20231117	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
CA-TAKEDA-2016TUS008716	TAKEDA		28	Year
US-PFIZER INC-2016478445	PFIZER		71	Year
CA-TAKEDA-2016TUS013310	TAKEDA		.	
US-JAZZ-2016-US-013550	JAZZ		.	
US-JAZZ-2016-US-014244	JAZZ		.	
PHHY2016CO131817	NOVARTIS		.	
JP-009507513-1610JPN009964	MERCK	Yoneda et al.. A case of development of bullous pemphigoid and rapid progression of hepatocellular carcinoma which was suspected to be related to the administration of the DPP4 inhibitor. 109th Kyushu Regional Meeting of the Japanese Society of Gastroenterology. 2017;143	78	Year
CA-ROCHE-1844714	ROCHE		45	Year
US-JAZZ-2016-US-015179	JAZZ		.	
DE-ROCHE-1846197	ROCHE		61	Year
US-JNJFOC-20161006853	JOHNSON AND JOHNSON		.	
US-JNJFOC-20161005944	JOHNSON AND JOHNSON		1	Decade
US-JNJFOC-20161005406	JOHNSON AND JOHNSON		4	Year
US-JNJFOC-20161009727	JOHNSON AND JOHNSON		10	Year
US-JNJFOC-20161009728	JOHNSON AND JOHNSON		.	
CA-SHIRE-CA201615466	TAKEDA		31	Year
US-JAZZ-2016-US-020445	JAZZ		.	
CA-ROCHE-1846035	ROCHE		31	Year
GB-ABBVIE-16P-167-1762423-00	ABBVIE		11	Year

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Male	Y	.		20231228		Consumer	CA	CA	28	.	GROUP2
	Male	Y	.		20231219		Physician	US	US	71	.	GROUP3
	Male	Y	.		20231005		Physician	CA	CA	.	.	MISSIN
	Female	Y	.		20231019		HP	US	US	.	.	MISSIN
	Male	Y	.		20231019		Consumer	US	US	.	.	MISSIN
	Female	Y	72	KG	20231219		Consumer	CO	CO	.	72	MISSIN
	Male	Y	.		20231011		Physician	JP	JP	78	.	GROUP4
	Male	Y	81	KG	20231201		Consumer	CA		45	81	GROUP2
	Female	Y	.		20231019		HP	US	US	.	.	MISSIN
	Female	Y	.		20231031		Physician	DE		61	.	GROUP3
Child	Male	Y	71.8	KG	20231020		HP	US	US	.	71.8	MISSIN
Child	Male	Y	.		20231018		HP	US	US	10	.	GROUP1
Child	Male	Y	.		20231004		HP	US	US	4	.	GROUP1
Child	Male	Y	.		20231224		HP	US	US	10	.	GROUP1
	Male	Y	.		20231130		HP	US	US	.	.	MISSIN
	Male	Y	.		20231023		HP	CA	CA	31	.	GROUP2
	Female	Y	.		20231006		Consumer	US	US	.	.	MISSIN
	Male	Y	.		20231213		Physician	CA	CA	31	.	GROUP2
	Male	Y	.		20231116		Physician	GB	GB	11	.	GROUP1

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
128906342	12890634	2	Follow-up	20160801	20230818	20161027	20231019	Periodic	
129175148	12917514	8	Follow-up	20150701	20231127	20161107	20231203	Expedited	
1292916520	12929165	20	Follow-up	20161030	20231205	20161110	20231215	Expedited	
129309562	12930956	2	Follow-up	20130101	20230804	20161110	20231019	Periodic	
129381218	12938121	8	Follow-up	20160101	20231007	20161114	20231017	Expedited	
129382472	12938247	2	Follow-up	20160901	20231030	20161114	20231124	Periodic	
129392585	12939258	5	Follow-up	20161001	20230927	20161114	20231025	Periodic	
129401283	12940128	3	Follow-up	20160101	20231217	20161115	20231224	Periodic	
129407123	12940712	3	Follow-up	20050831	20231120	20161115	20231124	Periodic	
129411963	12941196	3	Follow-up	20000401	20231120	20161115	20231126	Periodic	
1294339813	12943398	13	Follow-up	20160727	20231115	20161115	20231122	Expedited	
1294445310	12944453	10	Follow-up	20110101	20231211	20161115	20231213	Expedited	
1294587413	12945874	13	Follow-up	20150527	20231030	20161116	20231101	Expedited	
1294608711	12946087	11	Follow-up	.	20231013	20161115	20231017	Expedited	
129482007	12948200	7	Follow-up	20110101	20231010	20161117	20231017	Expedited	
129534697	12953469	7	Follow-up	20160403	20230712	20161117	20231123	Expedited	
1295393127	12953931	27	Follow-up	20170101	20231023	20161118	20231101	Expedited	
1295753119	12957531	19	Follow-up	20111201	20231109	20161118	20231114	Expedited	
1295809811	12958098	11	Follow-up	20150901	20231019	20161120	20231027	Expedited	
129640184	12964018	4	Follow-up	20151016	20231207	20161122	20231215	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending report</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
US-JAZZ-2016-US-015803	JAZZ		33	Year	
PHHY2015CA089817	NOVARTIS		41	Year	
US-PFIZER INC-2016499536	PFIZER		80	Year	
US-JAZZ-2016-US-016948	JAZZ		.		
US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000889	ACADIA PHARMACEUTICALS		.		
US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000975	ACADIA PHARMACEUTICALS		78	Year	
US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001073	ACADIA PHARMACEUTICALS		56	Year	
US-JNJFOC-20161102410	JOHNSON AND JOHNSON		3	Decade	Adult
US-JNJFOC-20161103672	JOHNSON AND JOHNSON		8	Year	Child
US-JNJFOC-20161103821	JOHNSON AND JOHNSON		8	Year	Child
US-PFIZER INC-2016526407	PFIZER		60	Year	
US-JAZZ-2016-US-022111	JAZZ		33	Year	
CA-BAUSCH-BL-2016-027688	BAUSCH AND LOMB		60	Year	
US-JAZZ-2016-US-022236	JAZZ		.		
CA-Orion Corporation ORION PHARMA-TREX2016-2292	ORION		24	Year	Adult
ES-B.I. Pharmaceuticals, Inc./Ridgefield-2016-BI-21455II	BOEHRINGER INGELHEIM		57	Year	Adult
CA-ROCHE-1855931	ROCHE		46	Year	
US-SHIRE-US201617384	TAKEDA		1	Year	
CA-ROCHE-1856168	ROCHE		52	Year	
PHHY2016CA159840	NOVARTIS		54	Year	

# **ADVERSE EVENT REPORTING SYSTEM (AERS)** **Demographic Listings**

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Female	Y	.		20231019		Consumer	US	US	33	.	GROUP2
Female	Y	.		20231204		Consumer	CA	CA	41	.	GROUP2
Female	Y	51	KG	20231215		Physician	US	US	80	51	GROUP4
Female	Y	.		20231019		Consumer	US	US	.	.	MISSIN
Male	Y	88	KG	20231017		Consumer	US	US	.	88	MISSIN
Female	Y	.		20231124		Consumer	US	US	78	.	GROUP4
Female	Y	70	KG	20231025		Consumer	US	US	56	70	GROUP3
Male	Y	.		20231224		Lawyer	US	US	30	.	GROUP2
Male	Y	.		20231125		Lawyer	US	US	8	.	GROUP1
Male	Y	.		20231126		Lawyer	US	US	8	.	GROUP1
Male	Y	113.4	KG	20231122		Physician	US	US	60	113.4	GROUP3
Female	Y	113.4	KG	20231213		Physician	US	US	33	113.4	GROUP2
Female	Y	97	KG	20231101		Consumer	CA	CA	60	97	GROUP3
Male	Y	.		20231017		Physician	US	US	.	.	MISSIN
Female	Y	65	KG	20231017		Physician	CA		24	65	GROUP1
Female	Y	73	KG	20231123		Physician	ES	ES	57	73	GROUP3
Female	Y	.		20231101		HP	CA	CA	46	.	GROUP2
Male	Y	24	KG	20231114		HP	US	US	1	24	GROUP1
Female	Y	.		20231027		Physician	CA	CA	52	.	GROUP3
Female	Y	.		20231215		Physician	CA	CA	54	.	GROUP3



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
129661094	12966109	4	Follow-up	.	20231128	20161122	20231129	Expedited	
129702073	12970207	3	Follow-up	.	20230927	20161123	20231020	Periodic	
129710933	12971093	3	Follow-up	20120901	20231115	20161123	20231121	Expedited	
129756816	12975681	6	Follow-up	20161001	20231019	20161125	20231026	Expedited	
129758429	12975842	9	Follow-up	20160719	20230929	20161125	20231002	Expedited	
129797152	12979715	2	Follow-up	20130101	20231012	20161128	20231018	Expedited	
1298165819	12981658	19	Follow-up	20160927	20231128	20161129	20231207	Expedited	
1298245917	12982459	17	Follow-up	20161111	20231116	20161129	20231124	Expedited	
129832442	12983244	2	Follow-up	.	20231013	20161129	20231024	Expedited	
129879489	12987948	9	Follow-up	20160101	20231221	20161130	20231225	Expedited	
129887515	12988751	5	Follow-up	20120101	20231006	20161130	20231010	Expedited	
129895932	12989593	2	Follow-up	20160921	20231009	20161201	20231016	Expedited	
129913302	12991330	2	Follow-up	.	20231016	20161201	20231019	Expedited	
129929712	12992971	2	Follow-up	20160901	20231107	20161202	20231117	Expedited	
129936304	12993630	4	Follow-up	20090101	20231106	20161202	20231112	Periodic	
1299455329	12994553	29	Follow-up	20160101	20231207	20161202	20231214	Expedited	
129969329	12996932	9	Follow-up	20160902	20231031	20161205	20231107	Expedited	
1300378736	13003787	36	Follow-up	20161001	20231120	20161206	20231128	Expedited	
130099107	13009910	7	Follow-up	20140720	20231108	20161208	20231114	Expedited	
1301226125	13012261	25	Follow-up	20170823	20231025	20161209	20231030	Expedited	
1301373012	13013730	12	Follow-up	20160101	20231012	20161209	20231018	Expedited	
130167094	13016709	4	Follow-up	20151231	20231031	20161212	20231109	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
US-BAXALTA-2016BLT008492	TAKEDA		.	
US-PFIZER INC-2016542779	PFIZER		78	Year
US-JAZZ-2016-US-019064	JAZZ		22	Year
BE-TAKEDA-2016TUS021324	TAKEDA		22	Year
FR-ROCHE-1837678	ROCHE		74	Year
US-GLAXOSMITHKLINE-US2016172914	GLAXOSMITHKLINE		.	
CA-ROCHE-1860260	ROCHE		52	Year
PHHY2016CA156954	NOVARTIS		43	Year
CA-INCYTE CORPORATION-2016IN007466	INCYTE		.	
US-BAXALTA-2016BLT008577	TAKEDA		.	
US-JAZZ-2016-US-023156	JAZZ		60	Year
US-ROCHE-1849108	ROCHE		57	Year
CA-PURDUE PHARMA-CAN-2016-0007231	PURDUE		52	Year
GB-AUROBINDO-AUR-APL-2016-14434	AUROBINDO		84	Year
US-JNJFOC-20161115313	JOHNSON AND JOHNSON		22	Year
PHHY2016CA074240	NOVARTIS		72	Year
CA-ROCHE-1863451	ROCHE		69	Year
PHHY2016CA149013	NOVARTIS		61	Year
PHHY2014IN084165	NOVARTIS		34	Year
US-PFIZER INC-2016561839	PFIZER		57	Year
CA-TAKEDA-2016TUS018689	TAKEDA		.	
DE-AUROBINDO-AUR-APL-2016-15137	AUROBINDO	Hoeltzenbein M, Bartz I, Fietz A, Lohse L, Onken M, Dathe K et al. Antiepileptic treatment with levetiracetam during the first trimester and pregnancy outcome: an observational study. Epilepsia. 2023;1-52	8	Month

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Demographic Listings**

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Adult	Female	Y	.		20231129		HP	US	US	.	.	MISSIN
	Female	Y	.		20231020		Physician	US	US	78	.	GROUP4
	Male	Y	79.83	KG	20231121		Physician	US	US	22	79.83	GROUP1
	Male	Y	.		20231026		Physician	BE	BE	22	.	GROUP1
	Male	Y	85	KG	20231002		Physician	FR		74	85	GROUP3
		Y	.		20231018		Consumer	US	US	.	.	MISSIN
	Female	Y	.		20231207		Consumer	CA	CA	52	.	GROUP3
	Male	Y	.		20231124		Consumer	CA	CA	43	.	GROUP2
		Y	.		20231024		Consumer	CA	CA	.	.	MISSIN
	Female	Y	91	KG	20231225		HP	US	US	.	91	MISSIN
	Female	Y	.		20231010		Consumer	US	US	60	.	GROUP3
	Male	Y	.		20231016		Physician	US		57	.	GROUP3
	Female	Y	.		20231019		HP	CA	CA	52	.	GROUP3
	Male	Y	.		20231117		Consumer	GB	GB	84	.	GROUP4
	Male	Y	76.726	KG	20231112		Lawyer	US	US	22	76.726	GROUP1
	Male	Y	.		20231214		Consumer	CA	CA	72	.	GROUP3
	Female	Y	.		20231107		Physician	CA	CA	69	.	GROUP3
	Male	Y	91	KG	20231128		Consumer	CA	CA	61	91	GROUP3
	Female	Y	.		20231114		Consumer	IN	IN	34	.	GROUP2
	Female	Y	114	KG	20231030		Consumer	US	US	57	114	GROUP3
	Male	Y	.		20231018		Physician	CA	CA	.	.	MISSIN
	Male	Y	3.41	KG	20231109		Physician	DE	DE	0	3.41	GROUP1

### ADVERSE EVENT REPORTING SYSTEM (AERS) Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
1302401118	13024011	18	Follow-up	20161101	20231010	20161213	20231020	Expedited	
130260364	13026036	4	Follow-up	20050101	20231113	20161214	20231123	Periodic	
130297032	13029703	2	Follow-up	20161015	20231108	20161215	20231118	Expedited	
130314855	13031485	5	Follow-up	20160628	20231106	20161215	20231114	Expedited	
130320184	13032018	4	Follow-up	.	20231113	20161215	20231120	Periodic	
130357263	13035726	3	Follow-up	20150729	20231207	20161216	20231220	Periodic	
130375084	13037508	4	Follow-up	20120101	20231206	20161217	20231208	Expedited	
130455783	13045578	3	Follow-up	.	20231211	20161220	20231214	Periodic	
1305805713	13058057	13	Follow-up	.	20231207	20161223	20231222	Expedited	
1306707611	13067076	11	Follow-up	20161101	20231226	20161227	20231229	Expedited	
1306917111	13069171	11	Follow-up	20210101	20231010	20161228	20231019	Expedited	
130714024	13071402	4	Follow-up	20120101	20170710	20161229	20231202	Expedited	
130719762	13071976	2	Follow-up	20161221	20231218	20161229	20231227	Expedited	
1307598415	13075984	15	Follow-up	20161101	20231205	20161230	20231211	Expedited	
130765083	13076508	3	Follow-up	20161221	20231005	20161230	20231012	Expedited	
130799412	13079941	2	Follow-up	.	20231225	20170103	20231227	Periodic	
1308956011	13089560	11	Follow-up	20201123	20231129	20170105	20231211	Periodic	
130896044	13089604	4	Follow-up	.	20231012	20170105	20231020	Expedited	
130913686	13091368	6	Follow-up	20161223	20230927	20170106	20231004	Expedited	
130951602	13095160	2	Follow-up	.	20231221	20170107	20231226	Periodic	
1309831715	13098317	15	Follow-up	.	20231127	20170109	20231204	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
US-PFIZER INC-2016569208	PFIZER		40	Year
US-JNJFOC-20150808939	JOHNSON AND JOHNSON		6	Decade
IT-AUROBINDO-AUR-APL-2016-15196	AUROBINDO		70	Year
CA-TAKEDA-2016TUS012404	TAKEDA		59	Year
US-PFIZER INC-2016573228	PFIZER		.	
US-PFIZER INC-2016570983	PFIZER		70	Year
US-JAZZ-2016-US-023796	JAZZ		.	
US-BIOGEN-2016BI00329386	BIOGEN		.	
CA-APOTEX-2016AP015766	APOTEX		65	Year
US-JAZZ-2016-US-024377	JAZZ		45	Year
US-PFIZER INC-2016477642	PFIZER		67	Year
US-BAYER-2016-246337	BAYER		.	
CA-JNJFOC-20161222161	JOHNSON AND JOHNSON		38	Year
CA-TAKEDA-2016TUS021452	TAKEDA		40	Year
DE-SEATTLE GENETICS-2016SGN02067	SEATTLE GENETICS		.	
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-112048	BRISTOL MYERS SQUIBB	Basnet A, Saad N, Benjamin S. A case of vanishing brain metastasis in a melanoma patient on nivolumab. Anticancer Research. 2016;36:4795-8. doi:10.21873/anticancer.11038.	66	Year
US-PFIZER INC-2017004247	PFIZER		66	Year
US-PFIZER INC-2017004379	PFIZER	Koh, Eun Kyung. A case of adrenal insufficiency induced by topical ketoconazol. Endocrine Reviews. 2015;36(2)	38	Year
US-SHIRE-US201620166	TAKEDA		41	Year
US-AMGEN-USASL2017000831	AMGEN		81	Year
US-PFIZER INC-2017007900	PFIZER		17	Year

Patient Age Group	Code for patient's sex	Whether (Y/N) this report was submitted	Numeric value of patient's weight.	Unit abbreviation for patient's weight.	Date report was sent (YYYYMMDD format).	Whether (Y/N) voluntary reporter also no	Reporter's type of occupation.	The country of the reporter in the lates	The country where the event occurred.	Derived age in years.	Derived weight in kilograms.	Derived age group.
Adult	Female	Y	.		20231020		Consumer	US	US	40	.	GROUP2
	Male	Y	.		20231123		HP	US	US	60	.	GROUP3
	Female	Y	.		20231118		Physician	IT	IT	70	.	GROUP3
	Female	Y	.		20231114		Consumer	CA	CA	59	.	GROUP3
	Female	Y	.		20231120		Physician	US	US	.	.	MISSIN
	Female	Y	64.23	KG	20231220		Physician	US	US	70	64.23	GROUP3
	Female	Y	.		20231208		Physician	US	US	.	.	MISSIN
	Male	Y	.		20231214		Physician	US	US	.	.	MISSIN
	Female	Y	.		20231222		Physician	CA	CA	65	.	GROUP3
Adult	Female	Y	.		20231229		HP	US	US	45	.	GROUP2
	Female	Y	97.5	KG	20231019		Consumer	US	US	67	97.5	GROUP3
	Female	Y	72.562	KG	20231202		Physician	US	US	.	72.562	MISSIN
	Adult	Female	Y	.	20231227		HP	CA	CA	38	.	GROUP2
Adult	Female	Y	.		20231211		Consumer	CA	CA	40	.	GROUP2
	Female	Y	.		20231012		Physician	DE	DE	.	.	MISSIN
	Elderly	Male	Y	.	20231227		Physician	US	US	66	.	GROUP3
Elderly	Male	Y	71	KG	20231211		Consumer	US	US	66	71	GROUP3
	Female	Y	.		20231020		Physician	US	US	38	.	GROUP2
	Female	Y	.		20231004		Physician	US	US	41	.	GROUP2
	Female	Y	.		20231226		Consumer	US	US	81	.	GROUP4
		Male	Y	.	20231204		Consumer	US	US	17	.	GROUP1

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
1310972321	13109723	21	Follow-up	.	20231106	20170112	20231110	Expedited	
131179953	13117995	3	Follow-up	20080528	20231211	20170116	20231218	Expedited	
131181313	13118131	3	Follow-up	19990101	20230927	20170116	20231005	Periodic	
131181364	13118136	4	Follow-up	20061017	20230927	20170116	20231005	Periodic	
131181465	13118146	5	Follow-up	20130501	20231009	20170116	20231016	Periodic	
131181515	13118151	5	Follow-up	20050101	20231107	20170116	20231113	Periodic	
131181983	13118198	3	Follow-up	20070101	20231013	20170116	20231019	Periodic	
131182315	13118231	5	Follow-up	.	20231013	20170116	20231021	Periodic	
131182343	13118234	3	Follow-up	20061001	20231013	20170116	20231016	Periodic	
1312065018	13120650	18	Follow-up	20060301	20231130	20170117	20231212	Periodic	
1312448414	13124484	14	Follow-up	20180201	20231004	20170118	20231010	Expedited	
131271632	13127163	2	Follow-up	.	20230508	20170118	20231220	Expedited	
131273442	13127344	2	Follow-up	.	20230508	20170118	20231220	Expedited	
131300352	13130035	2	Follow-up	20160303	20231211	20170119	20231220	Expedited	
1313174010	13131740	10	Follow-up	20160701	20231116	20170119	20231128	Expedited	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending report</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
US-PFIZER INC-2016491928	PFIZER		43	Year
US-JNJFOC-20161208025	JOHNSON AND JOHNSON		15	Year
US-JNJFOC-20161217184	JOHNSON AND JOHNSON		9	Year
US-JNJFOC-20161217188	JOHNSON AND JOHNSON		16	Year
US-JNJFOC-20161217193	JOHNSON AND JOHNSON		22	Year
US-JNJFOC-20161217183	JOHNSON AND JOHNSON		.	
US-JNJFOC-20161218080	JOHNSON AND JOHNSON		11	Year
US-JNJFOC-20161218091	JOHNSON AND JOHNSON		.	
US-JNJFOC-20161218103	JOHNSON AND JOHNSON		15	Year
US-PFIZER INC-2017012640	PFIZER		57	Year
PHHY2016CA020887	NOVARTIS		36	Year
US-ROCHE-1845275	ROCHE	Raghavan D, Miller D, Penafiel M, Abraham J and Ahmed F. A Case of Recurrent Membranous Nephropathy in Transplant Presenting with Deep Vein Thrombosis-Abstract PUB431. Journal of the American Society of Nephrology 2016 Nov;27:1003A-.	58	Year
US-ROCHE-1845297	ROCHE	Daswatta D, Graves S and Ellis C. Recurrent Dense Deposit Disease: A Report of Two Cases with Varying Presentations, Pathologic Findings and Patient Outcomes [Abstract: PUB550].. Journal of the American Society of Nephrology 2016 Nov;27:1030A-.	.	
DE-AUROBINDO-AUR-APL-2017-01265	AUROBINDO		17	Year
US-PFIZER INC-2017024415	PFIZER		69	Year



ADVERSE EVENT REPORTING SYSTEM (AERS)  
Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Female	Y	84	KG	20231110		Consumer	US	US	43	84	GROUP2
Adolescent	Male	Y	.		20231218		HP	US	US	15	.	GROUP1
Child	Male	Y	.		20231005		Lawyer	US	US	9	.	GROUP1
Adolescent	Male	Y	.		20231005		HP	US	US	16	.	GROUP1
Adult	Male	Y	.		20231016		HP	US	US	22	.	GROUP1
Child	Male	Y	.		20231113		Lawyer	US	US	.	.	MISSIN
Child	Male	Y	.		20231019		HP	US	US	11	.	GROUP1
	Male	Y	.		20231021		Lawyer	US	US	.	.	MISSIN
Adolescent	Male	Y	.		20231017		Lawyer	US	US	15	.	GROUP1
	Female	Y	.		20231212		Physician	US	US	57	.	GROUP3
	Female	Y	.		20231010		Consumer	CA	CA	36	.	GROUP2
	Male	Y	.		20231221		Physician	US		58	.	GROUP3
	Female	Y	.		20231221		Physician	US		.	.	MISSIN
	Male	Y	60	KG	20231220		Physician	DE	DE	17	60	GROUP1
	Male	Y	.		20231127		Consumer	US	US	69	.	GROUP3

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
131346387	13134638	7	Follow-up	20170107	20231114	20170120	20231121	Expedited	
131396835	13139683	5	Follow-up	20161223	20231113	20170123	20231120	Periodic	
131408182	13140818	2	Follow-up	20161001	20161014	20170123	20231118	Periodic	
1314326413	13143264	13	Follow-up	20160101	20231017	20170124	20231031	Expedited	
131474342	13147434	2	Follow-up	.	20231024	20170125	20231101	Expedited	
1315318823	13153188	23	Follow-up	20160707	20231006	20170126	20231016	Expedited	
131584896	13158489	6	Follow-up	20161101	20231204	20170127	20231208	Expedited	
131614126	13161412	6	Follow-up	.	20231207	20170130	20231212	Expedited	
131674923	13167492	3	Follow-up	.	20231128	20170131	20231206	Periodic	
131675473	13167547	3	Follow-up	.	20231129	20170131	20231211	Periodic	
131717653	13171765	3	Follow-up	.	20231115	20170201	20231128	Periodic	
131717783	13171778	3	Follow-up	20170112	20231108	20170201	20231115	Periodic	
131720564	13172056	4	Follow-up	20160101	20231006	20170131	20231009	Expedited	
131836203	13183620	3	Follow-up	.	20231115	20170203	20231128	Periodic	
131884112	13188411	2	Follow-up	20160401	20170127	20170206	20231220	Expedited	
131948255	13194825	5	Follow-up	20120501	20231110	20170207	20231117	Expedited	
132012462	13201246	2	Follow-up	.	20231113	20170209	20231116	Periodic	
132256512	13225651	2	Follow-up	20170208	20231107	20170213	20231114	30 Day	
1322723239	13227232	39	Follow-up	.	20231213	20170213	20231222	Expedited	
132292854	13229285	4	Follow-up	20160101	20231117	20170214	20231129	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
CA-PFIZER INC-2017026615	PFIZER		49	Year
US-PFIZER INC-2017027316	PFIZER		59	Year
US-UNITED THERAPEUTICS-UNT-2016-016262	UNITED THERAPEUTICS		49	Year
FR-GLAXOSMITHKLINE-FR2016GSK093577	GLAXOSMITHKLINE		.	
US-SHIRE-US201701298	TAKEDA		.	
CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005845	BRISTOL MYERS SQUIBB		67	Year
CA-TAKEDA-2016TUS021205	TAKEDA		30	Year
CA-ROCHE-1885366	ROCHE	Acedillo R, Govind M, Kashgary A and Clark W. Treatment of severe, refractory and rapidly evolving thrombotic thrombocytopenic purpura. BMJ CASE REPORTS 2016;;-.	36	Year
US-PFIZER INC-2017039402	PFIZER		73	Year
US-PFIZER INC-2017040824	PFIZER		73	Year
US-PFIZER INC-2017038643	PFIZER		68	Year
US-PFIZER INC-2017038476	PFIZER		84	Year
PT-009507513-1611PRT002581	MERCK		70	Year
US-AMGEN-USASP2017015442	AMGEN		68	Year
US-NOVOPROD-529786	NOVO NORDISK		54	Year
US-JAZZ-2017-US-001138	JAZZ		42	Year
US-BIOGEN-2017BI00352184	BIOGEN		.	
US-GLAXOSMITHKLINE-US2017019594	GLAXOSMITHKLINE		58	Year
CA-PURDUE PHARMA-CAN-2017-0007437	PURDUE	Farrell B, Merkley V, Thompson W.. Managing polypharmacy in a 77-year-old woman with multiple prescribers. CMAJ. 2013;185(14):1240-1245	77	Year
US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002192	ACADIA PHARMACEUTICALS		.	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Female	Y	.		20231121		Consumer	CA	CA	49	.	GROUP2
	Female	Y	66	KG	20231120		Consumer	US	US	59	66	GROUP3
	Female	Y	102.95	KG	20231118		HP	US	US	49	102.95	GROUP2
		Y	.		20231031		HP	FR	FR	.	.	MISSIN
	Male	Y	.		20231101		Physician	US	US	.	.	MISSIN
Elderly	Female	Y	73	KG	20231016		Consumer	CA	CA	67	73	GROUP3
	Male	Y	.		20231208		Physician	CA	CA	30	.	GROUP2
	Male	Y	.		20231212		HP	CA		36	.	GROUP2
	Female	Y	.		20231206		Physician	US	US	73	.	GROUP3
	Female	Y	.		20231211		Consumer	US	US	73	.	GROUP3
	Female	Y	.		20231128		Consumer	US	US	68	.	GROUP3
	Female	Y	59	KG	20231115		Physician	US	US	84	59	GROUP4
	Male	Y	.		20231009		Physician	PT	PT	70	.	GROUP3
Elderly	Female	Y	.		20231127		Consumer	US	US	68	.	GROUP3
	Female	Y	.		20231220		Consumer	US	US	54	.	GROUP3
	Male	Y	.		20231117		Physician	US	US	42	.	GROUP2
	Female	Y	.		20231116		Consumer	US	US	.	.	MISSIN
	Female	Y	.		20231114		Consumer	US	US	58	.	GROUP3
	Female	Y	.		20231222		HP	CA	CA	77	.	GROUP4
	Male	Y	77	KG	20231129		Consumer	US	US	.	77	MISSIN

# **ADVERSE EVENT REPORTING SYSTEM (AERS)**

## **Demographic Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
1323008512	13230085	12	Follow-up	20200421	20231107	20170214	20231110	Expedited	
132340655	13234065	5	Follow-up	20160101	20231215	20170215	20231220	Expedited	
132357762	13235776	2	Follow-up	.	20231106	20170215	20231109	Periodic	
132446642	13244664	2	Follow-up	20160801	20230823	20170216	20231019	Periodic	
132535658	13253565	8	Follow-up	20161201	20230925	20170220	20231005	Expedited	
132573907	13257390	7	Follow-up	.	20231225	20170221	20231228	Expedited	
132594262	13259426	2	Follow-up	.	20231213	20170222	20231227	Periodic	
1326573916	13265739	16	Follow-up	20160707	20231208	20170223	20231215	Expedited	
132667138	13266713	8	Follow-up	20160809	20231204	20170224	20231213	Expedited	
1326925316	13269253	16	Follow-up	20170207	20231003	20170224	20231016	Expedited	
1327001616	13270016	16	Follow-up	20131201	20231101	20170224	20231103	Expedited	
132718234	13271823	4	Follow-up	.	20231219	20170227	20231226	Expedited	
1327789813	13277898	13	Follow-up	20170202	20231017	20170228	20231019	Expedited	
132807613	13280761	3	Follow-up	.	20231031	20170301	20231108	Expedited	
132818014	13281801	4	Follow-up	20160901	20231011	20170301	20231020	Expedited	
132846696	13284669	6	Follow-up	20161201	20231218	20170301	20231220	Expedited	
1328785317	13287853	17	Follow-up	20170220	20231218	20170302	20231219	Periodic	
1329621913	13296219	13	Follow-up	20161227	20230930	20170304	20231220	Expedited	
1330128110	13301281	10	Follow-up	.	20231206	20170307	20231218	Periodic	
133030383	13303038	3	Follow-up	20061001	20231020	20170307	20231025	Expedited	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
US-PFIZER INC-2017063888	PFIZER		74	Year	
PHHY2017CO010499	NOVARTIS		.		
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-013106	BRISTOL MYERS SQUIBB	Beckermann KE, Jolly PC, Kim JY, Bordeaux J, Puzanov I, Rathmell WK, et al. Clinical and immunologic correlates of response to PD-1 blockade in a patient with metastatic renal medullary carcinoma.. Journal for ImmunoTherapy of Cancer. 2017 Jan 17;5(1):1-5.doi:10.1186/s40425-016-0206-1.	29	Year	Adult
US-JAZZ-2017-US-000939	JAZZ		29	Year	
US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001926	ACADIA PHARMACEUTICALS		63	Year	
IT-MYLANLABS-2017M1009321	MYLAN	Greco P, Regolisti G, Antonioti R, Maccari C, Parenti E, Corrado S, et al.. Metformin-associated lactic acidosis and acute kidney injury.. Giornale Italiano di Nefrologia. 2016;33 (6):1-9	78	Year	
US-PFIZER INC-2017075661	PFIZER		63	Year	
PHHY2016CA100024	NOVARTIS		77	Year	
PHHY2016DE125377	NOVARTIS		3	Week	
GR-SA-2017SA031296	SANOFI AVENTIS		40	Year	Adult
US-JAZZ-2017-US-002361	JAZZ		65	Year	
CA-BAXTER-2017BAX007845	BAXTER		.		
CA-TAKEDA-2017TUS000823	TAKEDA		63	Year	
CA-BAXTER-2017BAX008935	BAXTER		36	Year	
US-PFIZER INC-2017086549	PFIZER		69	Year	
US-JAZZ-2017-US-002708	JAZZ		32	Year	
US-PFIZER INC-2016570442	PFIZER		17	Year	
FR-AUROBINDO-AUR-APL-2017-30496	AUROBINDO		71	Year	
US-PFIZER INC-2017094302	PFIZER		78	Year	
US-SHIRE-US201704894	TAKEDA		0	Year	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Female	Y	87	KG	20231110		Consumer	US	US	74	87	GROUP3
Female	Y	46	KG	20231220		Consumer	CO	CO	.	46	MISSIN
Male	Y	.		20231109		Physician	US	US	29	.	GROUP2
Female	Y	.		20231019		Consumer	US	US	29	.	GROUP2
Male	Y	108	KG	20231005		Consumer	US	US	63	108	GROUP3
Male	Y	.		20231228		HP	IT	IT	78	.	GROUP4
Female	Y	.		20231227		Consumer	US	US	63	.	GROUP3
Female	Y	.		20231215		HP	CA	CA	77	.	GROUP4
Male	Y	3.18	KG	20231213		Physician	DE	DE	0	3.18	GROUP1
Female	Y	57	KG	20231016		Physician	GR	GR	40	57	GROUP2
Male	Y	94.785	KG	20231103		Physician	US	US	65	94.785	GROUP3
	Y	.		20231226		HP	CA	CA	.	.	MISSIN
Female	Y	.		20231019		Consumer	CA	CA	63	.	GROUP3
Male	Y	.		20231108		Consumer	CA	CA	36	.	GROUP2
Female	Y	.		20231020		Consumer	US	US	69	.	GROUP3
Female	Y	.		20231220		Physician	US	US	32	.	GROUP2
Male	Y	59	KG	20231219		Physician	US	US	17	59	GROUP1
Male	Y	113.4	KG	20231220		Physician	FR	FR	71	113.4	GROUP3
Female	Y	75	KG	20231218		Consumer	US	US	78	75	GROUP4
Male	Y	36.281	KG	20231025		HP	US	US	0	36.281	GROUP1

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
1330367811	13303678	11	Follow-up	20170217	20231006	20170307	20231011	Expedited	
1330513013	13305130	13	Follow-up	20230228	20231227	20170308	20231230	Expedited	
133076635	13307663	5	Follow-up	20161226	20231018	20170308	20231026	Expedited	
133101574	13310157	4	Follow-up	.	20231023	20170309	20231026	Periodic	
133103732	13310373	2	Follow-up	.	20231217	20170309	20231220	Periodic	
133103943	13310394	3	Follow-up	.	20231006	20170309	20231010	Periodic	
133103962	13310396	2	Follow-up	.	20231025	20170309	20231030	Periodic	
133104072	13310407	2	Follow-up	20130101	20231115	20170309	20231124	Periodic	
133104092	13310409	2	Follow-up	20061201	20231122	20170309	20231130	Periodic	
133104383	13310438	3	Follow-up	20160601	20230927	20170309	20231006	Periodic	
133104633	13310463	3	Follow-up	20080101	20231113	20170309	20231122	Periodic	
133108513	13310851	3	Follow-up	20060101	20231108	20170309	20231116	Periodic	
133108794	13310879	4	Follow-up	20040726	20231023	20170309	20231026	Periodic	
133114453	13311445	3	Follow-up	.	20231115	20170309	20231124	Periodic	
133114834	13311483	4	Follow-up	.	20231106	20170309	20231111	Periodic	
133114943	13311494	3	Follow-up	.	20231122	20170309	20231129	Periodic	



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
CO-BAXALTA-2017BLT001601	TAKEDA		18	Year	
PHHY2017CA032617	NOVARTIS		40	Year	
BR-PFIZER INC-2017098140	PFIZER		.		
US-JNJFOC-20170224824	JOHNSON AND JOHNSON		.		
US-JNJFOC-20170202959	JOHNSON AND JOHNSON		.		
US-JNJFOC-20170202973	JOHNSON AND JOHNSON		.		
US-JNJFOC-20170202974	JOHNSON AND JOHNSON		.		
US-JNJFOC-20170202975	JOHNSON AND JOHNSON		.		Adolescent
US-JNJFOC-20170202976	JOHNSON AND JOHNSON		10	Year	Child
US-JNJFOC-20170202971	JOHNSON AND JOHNSON		15	Year	Adolescent
US-JNJFOC-20170204502	JOHNSON AND JOHNSON		.		Adolescent
US-JNJFOC-20170204474	JOHNSON AND JOHNSON		.		Child
US-JNJFOC-20170206245	JOHNSON AND JOHNSON		5	Year	Child
US-JNJFOC-20170300778	JOHNSON AND JOHNSON		.		
US-JNJFOC-20170300314	JOHNSON AND JOHNSON		.		
US-JNJFOC-20170300784	JOHNSON AND JOHNSON		.		

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Female	Y	48	KG	20231011		Consumer	CO	CO	18	48	GROUP1
Female	Y	.		20231230		Consumer	CA	CA	40	.	GROUP2
Female	Y	.		20231026		Physician	BR	BR	.	.	MISSIN
Male	Y	.		20231026		Lawyer	US	US	.	.	MISSIN
	Y	.		20231220		Lawyer	US	US	.	.	MISSIN
	Y	.		20231010		Lawyer	US	US	.	.	MISSIN
Male	Y	.		20231030		Lawyer	US	US	.	.	MISSIN
Male	Y	.		20231125		Lawyer	US	US	.	.	MISSIN
Male	Y	.		20231201		Lawyer	US	US	10	.	GROUP1
Male	Y	.		20231006		Lawyer	US	US	15	.	GROUP1
Male	Y	.		20231122		HP	US	US	.	.	MISSIN
Male	Y	.		20231116		HP	US	US	.	.	MISSIN
Male	Y	.		20231027		Lawyer	US	US	5	.	GROUP1
Male	Y	.		20231124		Lawyer	US	US	.	.	MISSIN
Male	Y	.		20231111		Lawyer	US	US	.	.	MISSIN
Male	Y	.		20231130		Lawyer	US	US	.	.	MISSIN

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Demographic Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
133116253	13311625	3	Follow-up	20160601	20230925	20170309	20231003	Periodic	
133116604	13311660	4	Follow-up	20070201	20231210	20170309	20231215	Periodic	
1331956117	13319561	17	Follow-up	20161206	20231117	20170310	20231128	Expedited	
133284553	13328455	3	Follow-up	.	20231006	20170313	20231010	Periodic	
1333644913	13336449	13	Follow-up	20160101	20231026	20170314	20231030	Expedited	
133365235	13336523	5	Follow-up	20180101	20230921	20170314	20231019	Periodic	
133429876	13342987	6	Follow-up	20170307	20231201	20170316	20231208	Expedited	
133473682	13347368	2	Follow-up	20170101	20230928	20170317	20231004	Expedited	
1335105016	13351050	16	Follow-up	20150101	20231013	20170320	20231020	Expedited	
133523655	13352365	5	Follow-up	20110101	20231208	20170320	20231213	Expedited	IT-MINISAL02-400110
133523846	13352384	6	Follow-up	.	20231016	20170320	20231023	Expedited	
1335529225	13355292	25	Follow-up	20170101	20231211	20170321	20231221	Expedited	
1335799321	13357993	21	Follow-up	20180101	20231020	20170322	20231026	Periodic	
133583395	13358339	5	Follow-up	20170301	20231020	20170322	20231027	Expedited	
133599388	13359938	8	Follow-up	20160423	20231220	20170322	20231228	Expedited	
1336515012	13365150	12	Follow-up	20120701	20231207	20170323	20231214	Expedited	
133701598	13370159	8	Follow-up	20160601	20231002	20170324	20231004	Expedited	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending report</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>
US-JNJFOC-20170303419	JOHNSON AND JOHNSON		21	Year	Adult
US-JNJFOC-20170216757	JOHNSON AND JOHNSON		17	Year	Adolescent
PHHY2017FR036980	NOVARTIS		.		Adult
US-JNJFOC-20170301604	JOHNSON AND JOHNSON		.		
US-JAZZ-2016-US-022127	JAZZ		.		
US-JAZZ-2016-US-025030	JAZZ		.		
DE-SEATTLE GENETICS-2017SGN00571	SEATTLE GENETICS		.		Adult
US-VERTEX PHARMACEUTICALS-2017-000326	VERTEX		.		
US-PFIZER INC-2017107202	PFIZER		78	Year	
IT-MYLANLABS-2017M1016663	MYLAN	Arena F, De Angelis LH, D Andrea MM, Cannatelli A, Fossati L, Di Pilato V, et al.. Infections caused by carbapenem-resistant Klebsiella pneumoniae with hypermucoviscous phenotype: A case report and literature review.. Virulence. 2017;8(8):1900-8	52	Year	
US-ARIAD PHARMACEUTICALS, INC-2014US004189	TAKEDA		.		
US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002653	ACADIA PHARMACEUTICALS		.		
US-PFIZER INC-2017124435	PFIZER		65	Year	
PHHY2017CA038044	NOVARTIS		48	Year	
FR-PFIZER INC-2017118142	PFIZER	Charpiat, B.. Respiratory depression related to multiple drug-drug interactions precipitated by a fluconazole loading dose in a patient treated with oxycodone. European Journal of Clinical Pharmacology. 2017;73(6):787-788	51	Year	
JP-MYLANLABS-2012S1015004	MYLAN		33	Year	
US-JAZZ-2017-US-003679	JAZZ		41	Year	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

Code for patient's sex	Whether (Y/N) this report was submitted	Numeric value of patient's weight.	Unit abbreviation for patient's weight.	Date report was sent (YYYYMMDD format).	Whether (Y/N) voluntary reporter also no	Reporter's type of occupation.	The country of the reporter in the lates	The country where the event occurred.	Derived age in years.	Derived weight in kilograms.	Derived age group.
Male	Y	.		20231003		Lawyer	US	US	21	.	GROUP1
Male	Y	116.8	KG	20231215		HP	US	US	17	116.8	GROUP1
Female	Y	65	KG	20231128		Physician	FR	FR	.	65	MISSIN
Male	Y	.		20231010		Lawyer	US	US	.	.	MISSIN
Female	Y	.		20231030		Consumer	US	US	.	.	MISSIN
Female	Y	.		20231019		Consumer	US	US	.	.	MISSIN
Female	Y	.		20231208		Physician	DE	DE	.	.	MISSIN
Female	Y	.		20231004		Consumer	US	US	.	.	MISSIN
Female	Y	73	KG	20231020		Consumer	US	US	78	73	GROUP4
Male	Y	.		20231213		HP	IT	IT	52	.	GROUP3
Female	Y	180	KG	20231023		Physician	US	US	.	180	MISSIN
Female	Y	.		20231221		Consumer	US	US	.	.	MISSIN
Male	Y	99.79	KG	20231026		Physician	US	US	65	99.79	GROUP3
Male	Y	.		20231027		Consumer	CA	CA	48	.	GROUP2
Male	Y	89	KG	20231228		Pharmacist	FR	FR	51	89	GROUP3
Male	Y	35.9	KG	20231214		Physician	JP	JP	33	35.9	GROUP2
Male	Y	.		20231004		Consumer	US	US	41	.	GROUP2

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>	<i>Manufacturer's unique report identifier.</i>
133748923	13374892	3	Follow-up	.	20231103	20170327	20231110	Expedited		KR-SA-2017SA049420
133761803	13376180	3	Follow-up	20150401	20231115	20170328	20231122	Expedited		US-AUROBINDO-AUR-APL-2017-31266
133829345	13382934	5	Follow-up	20161001	20231107	20170329	20231114	Expedited		US-JAZZ-2017-US-003754
133931897	13393189	7	Follow-up	20161006	20231128	20170331	20231204	Expedited		US-BAXALTA-2017BLT002403
1339532714	13395327	14	Follow-up	20170310	20231205	20170403	20231212	Periodic		US-PFIZER INC-2017140036
133959212	13395921	2	Follow-up	.	20231208	20170403	20231220	Expedited		US-AUROBINDO-AUR-APL-2017-31722
1339710411	13397104	11	Follow-up	20170322	20231205	20170403	20231206	Expedited		CA-TAKEDA-2017TUS006601
134010312	13401031	2	Follow-up	20130219	20231003	20170404	20231016	Expedited		AT-BIOGEN-2013BI019452
134018982	13401898	2	Follow-up	20141101	20231003	20170404	20231013	Expedited		AT-BIOGEN-2014BI124637
134019173	13401917	3	Follow-up	20100108	20231003	20170404	20231013	Expedited		AT-BIOGEN-2010BI014726
134033914	13403391	4	Follow-up	20170101	20230816	20170404	20231019	Periodic		US-JAZZ-2017-US-004065
134040983	13404098	3	Follow-up	20110601	20231003	20170405	20231017	Expedited		AT-BIOGEN-2011BI027513
134065693	13406569	3	Follow-up	20130801	20231003	20170405	20231017	Expedited		AT-BIOGEN-2013BI111631
134066473	13406647	3	Follow-up	20130301	20231003	20170405	20231017	Expedited		AT-BIOGEN-2013BI030044
134083324	13408332	4	Follow-up	.	20231013	20170406	20231017	Periodic		US-JNJFOC-20170206628
134083414	13408341	4	Follow-up	20070309	20231006	20170406	20231012	Expedited		US-JNJFOC-20161016309
134083585	13408358	5	Follow-up	20060421	20231115	20170406	20231201	Periodic		US-JNJFOC-20170206998

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeri c value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>
SANOFI AVENTIS	Kim E, Park Y, Ha H, Chung H.. Patterns of drugs + poisons in southern area of South Korea in 2014.. Forensic Science International.. 2016;269:50-5	62	Year	Adult	Male	Y	.	
AUROBINDO	Kawai Y, DeMonbrun AG, Chambers RS, Nolan DA, Dolcourt BA, Malas NM et al. A previously healthy adolescent with acute encephalopathy and decorticate posturing.. Pediatrics. 2017;139 (1):Article Number e20153779	14	Year		Female	Y	.	
JAZZ		47	Year		Female	Y	.	
TAKEDA		51	Year		Female	Y	114	KG
PFIZER		59	Year		Male	Y	125	KG
AUROBINDO	Bakhit M, McCarty TR, Park S, Njei B, Cho M, Karagozian R et al. Vanishing bile duct syndrome in Hodgkin?s lymphoma: A case report and literature review.. World J Gastroenterol. 2017;23 (2):366-372	25	Year		Male	Y	.	
TAKEDA		59	Year		Female	Y	.	
BIOGEN		43	Year		Male	Y	72	KG
BIOGEN		38	Year		Female	Y	.	
BIOGEN		41	Year		Female	Y	.	
JAZZ		.			Male	Y	.	
BIOGEN		26	Year		Female	Y	70	KG
BIOGEN		34	Year		Female	Y	58	KG
BIOGEN		39	Year		Male	Y	90	KG
JOHNSON AND JOHNSON		.			Male	Y	.	
JOHNSON AND JOHNSON		9	Year	Child	Male	Y	.	
JOHNSON AND JOHNSON		10	Year	Child	Male	Y	.	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
20231110		HP	KR	KR	62	.	GROUP3
20231122		Physician	US	US	14	.	GROUP1
20231115		Consumer	US	US	47	.	GROUP2
20231204		Consumer	US	US	51	114	GROUP3
20231212		Pharmacist	US	US	59	125	GROUP3
20231220		HP	US	US	25	.	GROUP1
20231206		Consumer	CA	CA	59	.	GROUP3
20231016		Physician	AT	AT	43	72	GROUP2
20231013		Physician	AT	AT	38	.	GROUP2
20231013		Physician	AT	AT	41	.	GROUP2
20231019		Physician	US	US	.	.	MISSIN
20231017		Physician	AT	AT	26	70	GROUP2
20231017		Physician	AT	AT	34	58	GROUP2
20231017		Physician	AT	AT	39	90	GROUP2
20231017		Lawyer	US	US	.	.	MISSIN
20231012		HP	US	US	9	.	GROUP1
20231201		HP	US	US	10	.	GROUP1



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
134083883	13408388	3	Follow-up	20160812	20231213	20170406	20231218	Periodic	
134084944	13408494	4	Follow-up	20020506	20231009	20170406	20231013	Periodic	
134085124	13408512	4	Follow-up	20011206	20230929	20170406	20231005	Periodic	
134085334	13408533	4	Follow-up	20000525	20231213	20170406	20231219	Periodic	
134085342	13408534	2	Follow-up	20021211	20231206	20170406	20231215	Expedited	
134085873	13408587	3	Follow-up		20231206	20170406	20231213	Periodic	
134085894	13408589	4	Follow-up	20011205	20231128	20170406	20231201	Periodic	
134085953	13408595	3	Follow-up	20050301	20231122	20170406	20231130	Periodic	
134088083	13408808	3	Follow-up	20011203	20230927	20170406	20231006	Expedited	
134088094	13408809	4	Follow-up	20070801	20231115	20170406	20231121	Expedited	
134088254	13408825	4	Follow-up	20010601	20231101	20170406	20231107	Periodic	
134088884	13408888	4	Follow-up	20031213	20231115	20170406	20231123	Periodic	
134089644	13408964	4	Follow-up	20130624	20231009	20170406	20231014	Periodic	
134090483	13409048	3	Follow-up	20130801	20231115	20170406	20231123	Expedited	
134091664	13409166	4	Follow-up	20130625	20230929	20170406	20231005	Periodic	
134091734	13409173	4	Follow-up	20050101	20230927	20170406	20231005	Expedited	
134091874	13409187	4	Follow-up	20080101	20231011	20170406	20231020	Periodic	
134091934	13409193	4	Follow-up	20120502	20231006	20170406	20231010	Periodic	
134092324	13409232	4	Follow-up	20140609	20231013	20170406	20231017	Periodic	
134092425	13409242	5	Follow-up	20051028	20231121	20170406	20231129	Periodic	
134092954	13409295	4	Follow-up	20020314	20231206	20170406	20231213	Periodic	
134092974	13409297	4	Follow-up	20080403	20231011	20170406	20231016	Expedited	
134093924	13409392	4	Follow-up	20070817	20231213	20170406	20231218	Periodic	
134094144	13409414	4	Follow-up	20040806	20231217	20170406	20231227	Periodic	
134094214	13409421	4	Follow-up	20100101	20231011	20170406	20231017	Periodic	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>
US-JNJFOC-20170208093	JOHNSON AND JOHNSON		19	Year	Adult	Male	Y	.	
US-JNJFOC-20161005760	JOHNSON AND JOHNSON		9	Year	Child	Male	Y	.	
US-JNJFOC-20170223474	JOHNSON AND JOHNSON		9	Year	Child	Male	Y	.	
US-JNJFOC-20170223489	JOHNSON AND JOHNSON		9	Year	Child	Male	Y	.	
US-JNJFOC-20150703044	JOHNSON AND JOHNSON		3	Year	Child	Male	Y	.	
US-JNJFOC-20170225232	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170224779	JOHNSON AND JOHNSON		12	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170225277	JOHNSON AND JOHNSON		8	Year	Child	Male	Y	.	
US-JNJFOC-20170109027	JOHNSON AND JOHNSON		5	Year	Child	Male	Y	.	
US-JNJFOC-20170109141	JOHNSON AND JOHNSON		16	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170223534	JOHNSON AND JOHNSON		8	Year	Child	Male	Y	.	
US-JNJFOC-20170224936	JOHNSON AND JOHNSON		16	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170110015	JOHNSON AND JOHNSON		12	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170112928	JOHNSON AND JOHNSON		10	Year	Child	Male	Y	.	
US-JNJFOC-20170116645	JOHNSON AND JOHNSON		14	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170116632	JOHNSON AND JOHNSON		1	Decade	Child	Male	Y	.	
US-JNJFOC-20170116654	JOHNSON AND JOHNSON		7	Year	Child	Male	Y	.	
US-JNJFOC-20170116710	JOHNSON AND JOHNSON		15	Year	Adolescent	Male	Y	.	
US-JNJFOC-20161009043	JOHNSON AND JOHNSON		24	Year	Adult	Male	Y	.	
US-JNJFOC-20170117293	JOHNSON AND JOHNSON		6	Year	Child	Male	Y	.	
US-JNJFOC-20170124492	JOHNSON AND JOHNSON		3	Year	Child	Male	Y	.	
US-JNJFOC-20170124440	JOHNSON AND JOHNSON		13	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170124614	JOHNSON AND JOHNSON		8	Year	Child	Male	Y	.	
US-JNJFOC-20170124905	JOHNSON AND JOHNSON		4	Year	Child	Male	Y	.	
US-JNJFOC-20170124439	JOHNSON AND JOHNSON		.		Adolescent	Male	Y	.	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
20231218		Lawyer	US	US	19	.	GROUP1
20231013		HP	US	US	9	.	GROUP1
20231005		Lawyer	US	US	9	.	GROUP1
20231219		Lawyer	US	US	9	.	GROUP1
20231215		HP	US	US	3	.	GROUP1
20231213		Lawyer	US	US	.	.	MISSIN
20231201		HP	US	US	12	.	GROUP1
20231130		Lawyer	US	US	8	.	GROUP1
20231006		HP	US	US	5	.	GROUP1
20231121		Lawyer	US	US	16	.	GROUP1
20231108		Lawyer	US	US	8	.	GROUP1
20231123		Lawyer	US	US	16	.	GROUP1
20231014		Lawyer	US	US	12	.	GROUP1
20231124		HP	US	US	10	.	GROUP1
20231006		Lawyer	US	US	14	.	GROUP1
20231005		HP	US	US	10	.	GROUP1
20231020		HP	US	US	7	.	GROUP1
20231010		HP	US	US	15	.	GROUP1
20231017		Lawyer	US	US	24	.	GROUP1
20231129		HP	US	US	6	.	GROUP1
20231214		HP	US	US	3	.	GROUP1
20231017		HP	US	US	13	.	GROUP1
20231218		Lawyer	US	US	8	.	GROUP1
20231227		Lawyer	US	US	4	.	GROUP1
20231017		Lawyer	US	US	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
134094673	13409467	3	Follow-up	20030307	20231122	20170406	20231130	Periodic	
134095363	13409536	3	Follow-up	.	20231217	20170406	20231225	Periodic	
134095584	13409558	4	Follow-up	20070115	20231113	20170406	20231121	Periodic	
134095674	13409567	4	Follow-up	20070101	20231115	20170406	20231122	Periodic	
134095753	13409575	3	Follow-up	20111001	20231213	20170406	20231219	Periodic	
134096113	13409611	3	Follow-up	.	20231009	20170406	20231013	Periodic	
134096323	13409632	3	Follow-up	20030121	20231211	20170406	20231215	Periodic	
134097154	13409715	4	Follow-up	20031216	20231106	20170406	20231111	Periodic	
134097294	13409729	4	Follow-up	.	20231009	20170406	20231013	Periodic	
1340999011	13409990	11	Follow-up	20201216	20231127	20170406	20231129	Expedited	
134103104	13410310	4	Follow-up	20040401	20231211	20170406	20231218	Periodic	
134103174	13410317	4	Follow-up	20081017	20231106	20170406	20231112	Periodic	
134103482	13410348	2	Follow-up	.	20231106	20170406	20231111	Periodic	
134103524	13410352	4	Follow-up	.	20231213	20170406	20231224	Periodic	
134103552	13410355	2	Follow-up	20120601	20231106	20170406	20231113	Periodic	
134103662	13410366	2	Follow-up	.	20231122	20170406	20231130	Periodic	
134103722	13410372	2	Follow-up	20131011	20231009	20170406	20231013	Periodic	
134103752	13410375	2	Follow-up	.	20231206	20170406	20231215	Periodic	
134104485	13410448	5	Follow-up	20040301	20231115	20170406	20231123	Periodic	
134104624	13410462	4	Follow-up	20020101	20231006	20170406	20231011	Periodic	
134105073	13410507	3	Follow-up	.	20231013	20170406	20231023	Periodic	
134105123	13410512	3	Follow-up	.	20231013	20170406	20231020	Periodic	
134105833	13410583	3	Follow-up	.	20231025	20170406	20231105	Periodic	
134106344	13410634	4	Follow-up	.	20231220	20170406	20231229	Periodic	
134106674	13410667	4	Follow-up	.	20231227	20170406	20231229	Periodic	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>
US-JNJFOC-20170109306	JOHNSON AND JOHNSON		6	Year	Child	Male	Y	.	
US-JNJFOC-20170127257	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20161016648	JOHNSON AND JOHNSON		9	Year	Child	Male	Y	.	
US-JNJFOC-20170127409	JOHNSON AND JOHNSON		.		Child	Male	Y	.	
US-JNJFOC-20160412106	JOHNSON AND JOHNSON		14	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170205646	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170205847	JOHNSON AND JOHNSON		7	Year	Child	Male	Y	.	
US-JNJFOC-20170224842	JOHNSON AND JOHNSON		14	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170225150	JOHNSON AND JOHNSON		.			Male	Y	.	
US-BAXALTA-2017BLT002697	TAKEDA		69	Year		Female	Y	96	KG
US-JNJFOC-20170226935	JOHNSON AND JOHNSON		10	Year	Child	Male	Y	.	
US-JNJFOC-20170304239	JOHNSON AND JOHNSON		11	Year	Child	Male	Y	.	
US-JNJFOC-20170306603	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306088	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306609	JOHNSON AND JOHNSON		12	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170306421	JOHNSON AND JOHNSON		.				Y	.	
US-JNJFOC-20170306602	JOHNSON AND JOHNSON		19	Year	Adult	Male	Y	.	
US-JNJFOC-20170306474	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170226435	JOHNSON AND JOHNSON		12	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170226567	JOHNSON AND JOHNSON		4	Year	Child	Male	Y	.	
US-JNJFOC-20170227604	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170227218	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170300313	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170301288	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170301322	JOHNSON AND JOHNSON		.		Adult	Male	Y	.	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
20231201		Lawyer	US	US	6	.	GROUP1
20231225		Lawyer	US	US	.	.	MISSIN
20231121		Lawyer	US	US	9	.	GROUP1
20231122		HP	US	US	.	.	MISSIN
20231219		Lawyer	US	US	14	.	GROUP1
20231013		Lawyer	US	US	.	.	MISSIN
20231214		Lawyer	US	US	7	.	GROUP1
20231111		HP	US	US	14	.	GROUP1
20231013		Lawyer	US	US	.	.	MISSIN
20231129		Consumer	US	US	69	96	GROUP3
20231218		Lawyer	US	US	10	.	GROUP1
20231112		Lawyer	US	US	11	.	GROUP1
20231111		Lawyer	US	US	.	.	MISSIN
20231224		Lawyer	US	US	.	.	MISSIN
20231113		Lawyer	US	US	12	.	GROUP1
20231201		Lawyer	US	US	.	.	MISSIN
20231013		Lawyer	US	US	19	.	GROUP1
20231214		Lawyer	US	US	.	.	MISSIN
20231123		Lawyer	US	US	12	.	GROUP1
20231011		Lawyer	US	US	4	.	GROUP1
20231023		Lawyer	US	US	.	.	MISSIN
20231020		HP	US	US	.	.	MISSIN
20231105		Lawyer	US	US	.	.	MISSIN
20231229		Lawyer	US	US	.	.	MISSIN
20231229		Lawyer	US	US	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
134106743	13410674	3	Follow-up	20080118	20231025	20170406	20231103	Periodic	
134107453	13410745	3	Follow-up	.	20231115	20170406	20231122	Expedited	
134108014	13410801	4	Follow-up	20110601	20231113	20170406	20231120	Expedited	
134108254	13410825	4	Follow-up	20030716	20231006	20170406	20231009	Periodic	
134108264	13410826	4	Follow-up	20070606	20231030	20170406	20231105	Periodic	
134108573	13410857	3	Follow-up	20151221	20231213	20170406	20231221	Expedited	
134109433	13410943	3	Follow-up	20080604	20231211	20170406	20231218	Periodic	
134109483	13410948	3	Follow-up	20120926	20231211	20170406	20231218	Periodic	
134110303	13411030	3	Follow-up	20080211	20231101	20170406	20231108	Periodic	
134110324	13411032	4	Follow-up	.	20231106	20170406	20231112	Periodic	
134110833	13411083	3	Follow-up	.	20231211	20170406	20231218	Periodic	
134110902	13411090	2	Follow-up	20110131	20231106	20170406	20231113	Periodic	
134110923	13411092	3	Follow-up	.	20231206	20170406	20231213	Periodic	
134111123	13411112	3	Follow-up	.	20230929	20170406	20231007	Periodic	
134111202	13411120	2	Follow-up	.	20231009	20170406	20231015	Periodic	
134111323	13411132	3	Follow-up	.	20231213	20170406	20231220	Periodic	
134111423	13411142	3	Follow-up	.	20230929	20170406	20231009	Periodic	
134111692	13411169	2	Follow-up	19961001	20231129	20170406	20231206	Periodic	
134111723	13411172	3	Follow-up	.	20231030	20170406	20231109	Periodic	
134112042	13411204	2	Follow-up	20090101	20230927	20170406	20231006	Periodic	
134112052	13411205	2	Follow-up	20010101	20230929	20170406	20231007	Periodic	
134112122	13411212	2	Follow-up	20071004	20231115	20170406	20231123	Periodic	
134112272	13411227	2	Follow-up	20130101	20231013	20170406	20231020	Periodic	
134112282	13411228	2	Follow-up	20010301	20231213	20170406	20231221	Periodic	
134112302	13411230	2	Follow-up	.	20231101	20170406	20231110	Periodic	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>
US-JNJFOC-20161009679	JOHNSON AND JOHNSON		3	Year	Child	Male	Y	.	
US-JNJFOC-20170307587	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170227356	JOHNSON AND JOHNSON		19	Year	Adult	Male	Y	.	
US-JNJFOC-20170300530	JOHNSON AND JOHNSON		5	Year	Child	Male	Y	.	
US-JNJFOC-20170301487	JOHNSON AND JOHNSON		12	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170300053	JOHNSON AND JOHNSON		21	Year	Adult	Male	Y	.	
US-JNJFOC-20170302830	JOHNSON AND JOHNSON		14	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170304641	JOHNSON AND JOHNSON		19	Year	Adult	Male	Y	.	
US-JNJFOC-20170304331	JOHNSON AND JOHNSON		17	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170304332	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306655	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306549	JOHNSON AND JOHNSON		11	Year	Child	Male	Y	.	
US-JNJFOC-20170306657	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306689	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306597	JOHNSON AND JOHNSON		.		Child	Male	Y	.	
US-JNJFOC-20170306638	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306641	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306436	JOHNSON AND JOHNSON		12	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170306684	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306459	JOHNSON AND JOHNSON		20	Year	Adult	Male	Y	.	
US-JNJFOC-20170306460	JOHNSON AND JOHNSON		14	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170306759	JOHNSON AND JOHNSON		14	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170306594	JOHNSON AND JOHNSON		18	Year	Adult	Male	Y	.	
US-JNJFOC-20170306570	JOHNSON AND JOHNSON		12	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170306572	JOHNSON AND JOHNSON		.			Male	Y	.	



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
20231103		HP	US	US	3	.	GROUP1
20231122		Lawyer	US	US	.	.	MISSIN
20231120		HP	US	US	19	.	GROUP1
20231009		HP	US	US	5	.	GROUP1
20231105		Lawyer	US	US	12	.	GROUP1
20231222		Lawyer	US	US	21	.	GROUP1
20231216		Lawyer	US	US	14	.	GROUP1
20231218		HP	US	US	19	.	GROUP1
20231108		Lawyer	US	US	17	.	GROUP1
20231112		Lawyer	US	US	.	.	MISSIN
20231218		Lawyer	US	US	.	.	MISSIN
20231113		Lawyer	US	US	11	.	GROUP1
20231213		Lawyer	US	US	.	.	MISSIN
20231007		Lawyer	US	US	.	.	MISSIN
20231015		Lawyer	US	US	.	.	MISSIN
20231220		Lawyer	US	US	.	.	MISSIN
20231009		Lawyer	US	US	.	.	MISSIN
20231206		Lawyer	US	US	12	.	GROUP1
20231109		Lawyer	US	US	.	.	MISSIN
20231006		Lawyer	US	US	20	.	GROUP1
20231007		Lawyer	US	US	14	.	GROUP1
20231123		Lawyer	US	US	14	.	GROUP1
20231020		Lawyer	US	US	18	.	GROUP1
20231222		Lawyer	US	US	12	.	GROUP1
20231110		Lawyer	US	US	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
134112342	13411234	2	Follow-up	.	20231220	20170406	20231228	Periodic	
134112402	13411240	2	Follow-up	.	20231213	20170406	20231220	Periodic	
134112662	13411266	2	Follow-up	.	20231006	20170406	20231012	Periodic	
134112722	13411272	2	Follow-up	.	20231213	20170406	20231224	Periodic	
134112744	13411274	4	Follow-up	20080101	20231101	20170406	20231108	Expedited	
134112834	13411283	4	Follow-up	20110101	20230927	20170406	20231004	Periodic	
134113004	13411300	4	Follow-up	20130411	20231030	20170406	20231031	Periodic	
134113063	13411306	3	Follow-up	.	20231006	20170406	20231010	Periodic	
134113124	13411312	4	Follow-up	20060101	20231011	20170406	20231017	Periodic	
134113163	13411316	3	Follow-up	20070101	20231101	20170406	20231108	Periodic	
134113423	13411342	3	Follow-up	20070402	20231025	20170406	20231031	Periodic	
134113433	13411343	3	Follow-up	.	20231129	20170406	20231206	Periodic	
134113454	13411345	4	Follow-up	.	20231206	20170406	20231215	Periodic	
134113942	13411394	2	Follow-up	20150101	20231106	20170406	20231112	Periodic	
134114023	13411402	3	Follow-up	.	20231117	20170406	20231122	Expedited	
134114165	13411416	5	Follow-up	.	20231108	20170406	20231115	Periodic	
134114792	13411479	2	Follow-up	.	20231030	20170406	20231108	Periodic	
134114872	13411487	2	Follow-up	.	20231013	20170406	20231017	Periodic	
134114942	13411494	2	Follow-up	.	20231013	20170406	20231018	Periodic	
134114992	13411499	2	Follow-up	.	20231115	20170406	20231123	Periodic	
134115182	13411518	2	Follow-up	.	20230927	20170406	20231005	Periodic	
134115754	13411575	4	Follow-up	.	20231115	20170406	20231124	Periodic	
134116013	13411601	3	Follow-up	20020608	20231213	20170406	20231224	Periodic	
134116074	13411607	4	Follow-up	.	20231106	20170406	20231111	Periodic	
134116323	13411632	3	Follow-up	20110405	20231030	20170406	20231105	Periodic	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>
US-JNJFOC-20170306718	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306724	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306428	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170306430	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170307029	JOHNSON AND JOHNSON		17	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170307031	JOHNSON AND JOHNSON		.		Adolescent	Male	Y	.	
US-JNJFOC-20170307186	JOHNSON AND JOHNSON		19	Year	Adult	Male	Y	.	
US-JNJFOC-20170307036	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170307179	JOHNSON AND JOHNSON		17	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170307192	JOHNSON AND JOHNSON		14	Year	Adolescent	Male	Y	.	
US-JNJFOC-20160411879	JOHNSON AND JOHNSON		11	Year	Child	Male	Y	.	
US-JNJFOC-20170306645	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170307883	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170304912	JOHNSON AND JOHNSON		23	Year	Adult	Male	Y	.	
US-JNJFOC-20170304921	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170304928	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170304891	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170304863	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170304949	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170304977	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170304962	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170302829	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170301657	JOHNSON AND JOHNSON		8	Year	Child	Male	Y	.	
US-JNJFOC-20170303243	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170302828	JOHNSON AND JOHNSON		17	Year	Adolescent	Male	Y	.	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

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20231228		Lawyer	US	US	.	.	MISSIN
20231220		Lawyer	US	US	.	.	MISSIN
20231012		Lawyer	US	US	.	.	MISSIN
20231224		Lawyer	US	US	.	.	MISSIN
20231108		HP	US	US	17	.	GROUP1
20231004		HP	US	US	.	.	MISSIN
20231031		HP	US	US	19	.	GROUP1
20231010		Lawyer	US	US	.	.	MISSIN
20231017		HP	US	US	17	.	GROUP1
20231108		HP	US	US	14	.	GROUP1
20231031		HP	US	US	11	.	GROUP1
20231206		HP	US	US	.	.	MISSIN
20231215		Lawyer	US	US	.	.	MISSIN
20231112		Lawyer	US	US	23	.	GROUP1
20231122		Lawyer	US	US	.	.	MISSIN
20231115		Lawyer	US	US	.	.	MISSIN
20231108		Lawyer	US	US	.	.	MISSIN
20231017		Lawyer	US	US	.	.	MISSIN
20231018		Lawyer	US	US	.	.	MISSIN
20231123		Lawyer	US	US	.	.	MISSIN
20231005		Lawyer	US	US	.	.	MISSIN
20231124		Lawyer	US	US	.	.	MISSIN
20231224		Lawyer	US	US	8	.	GROUP1
20231111		Lawyer	US	US	.	.	MISSIN
20231105		Lawyer	US	US	17	.	GROUP1

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
134116633	13411663	3	Follow-up	20061010	20231101	20170406	20231110	Periodic	
134116954	13411695	4	Follow-up	.	20231211	20170406	20231218	Periodic	
134117563	13411756	3	Follow-up	.	20231013	20170406	20231017	Periodic	
134117574	13411757	4	Follow-up	.	20231128	20170406	20231201	Periodic	
134117702	13411770	2	Follow-up	20071201	20231129	20170406	20231207	Periodic	
134118053	13411805	3	Follow-up	.	20231115	20170406	20231123	Periodic	
134118133	13411813	3	Follow-up	.	20231211	20170406	20231218	Periodic	
134118434	13411843	4	Follow-up	20010907	20231206	20170406	20231213	Periodic	
134118605	13411860	5	Follow-up	.	20231006	20170406	20231013	Periodic	
134118773	13411877	3	Follow-up	20080901	20231009	20170406	20231017	Periodic	
134120823	13412082	3	Follow-up	20131202	20231025	20170406	20231103	Periodic	
134121044	13412104	4	Follow-up	.	20231030	20170406	20231109	Periodic	
134121334	13412133	4	Follow-up	20090101	20231101	20170406	20231109	Expedited	
134121494	13412149	4	Follow-up	20061201	20231013	20170406	20231020	Expedited	
134121804	13412180	4	Follow-up	20110101	20230927	20170406	20231006	Periodic	
134121844	13412184	4	Follow-up	20131009	20230929	20170406	20231005	Periodic	
134123292	13412329	2	Follow-up	20050901	20231011	20170406	20231019	Periodic	
134123484	13412348	4	Follow-up	20130805	20230927	20170406	20231004	Periodic	
134123494	13412349	4	Follow-up	20121116	20231011	20170406	20231015	Periodic	
134124233	13412423	3	Follow-up	20130101	20231030	20170406	20231102	Periodic	
134124273	13412427	3	Follow-up	.	20231115	20170406	20231124	Periodic	
134124703	13412470	3	Follow-up	.	20231101	20170406	20231109	Periodic	
134124934	13412493	4	Follow-up	20130124	20231013	20170406	20231018	Periodic	
134125224	13412522	4	Follow-up	20140403	20231129	20170406	20231206	Periodic	
134125265	13412526	5	Follow-up	.	20230928	20170406	20231004	Periodic	

### ADVERSE EVENT REPORTING SYSTEM (AERS) Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>
US-JNJFOC-20170303257	JOHNSON AND JOHNSON		16	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170303298	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170303430	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170303431	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20161008996	JOHNSON AND JOHNSON		13	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170303441	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170304267	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170303090	JOHNSON AND JOHNSON		4	Year	Child	Male	Y	.	
US-JNJFOC-20170304319	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170304320	JOHNSON AND JOHNSON		10	Year	Child	Male	Y	.	
US-JNJFOC-20170314118	JOHNSON AND JOHNSON		27	Year	Adult	Male	Y	.	
US-JNJFOC-20170315925	JOHNSON AND JOHNSON		.		Adult	Male	Y	72.64	KG
US-JNJFOC-20170313823	JOHNSON AND JOHNSON		.		Adolescent	Male	Y	.	
US-JNJFOC-20170314434	JOHNSON AND JOHNSON		22	Year	Adult	Male	Y	.	
US-JNJFOC-20170314645	JOHNSON AND JOHNSON		3	Decade	Adult	Male	Y	.	
US-JNJFOC-20170314467	JOHNSON AND JOHNSON		15	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170308337	JOHNSON AND JOHNSON		20	Year	Adult	Male	Y	.	
US-JNJFOC-20170315459	JOHNSON AND JOHNSON		22	Year	Adult	Male	Y	.	
US-JNJFOC-20170315460	JOHNSON AND JOHNSON		24	Year	Adult	Male	Y	.	
US-JNJFOC-20170310761	JOHNSON AND JOHNSON		18	Year	Adult	Male	Y	.	
US-JNJFOC-20170310762	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170309323	JOHNSON AND JOHNSON		.			Male	Y	.	
US-JNJFOC-20170309489	JOHNSON AND JOHNSON		22	Year	Adult	Male	Y	.	
US-JNJFOC-20160412103	JOHNSON AND JOHNSON		17	Year	Adolescent	Male	Y	.	
US-JNJFOC-20170307845	JOHNSON AND JOHNSON		.			Male	Y	.	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
20231110		Lawyer	US	US	16	.	GROUP1
20231216		Lawyer	US	US	.	.	MISSIN
20231017		Lawyer	US	US	.	.	MISSIN
20231201		Lawyer	US	US	.	.	MISSIN
20231207		Lawyer	US	US	13	.	GROUP1
20231123		Lawyer	US	US	.	.	MISSIN
20231216		Lawyer	US	US	.	.	MISSIN
20231213		Lawyer	US	US	4	.	GROUP1
20231013		Lawyer	US	US	.	.	MISSIN
20231017		HP	US	US	10	.	GROUP1
20231103		Lawyer	US	US	27	.	GROUP2
20231110		HP	US	US	.	72.64	MISSIN
20231109		Lawyer	US	US	.	.	MISSIN
20231020		Lawyer	US	US	22	.	GROUP1
20231006		Lawyer	US	US	30	.	GROUP2
20231005		Lawyer	US	US	15	.	GROUP1
20231019		Lawyer	US	US	20	.	GROUP1
20231004		HP	US	US	22	.	GROUP1
20231015		Lawyer	US	US	24	.	GROUP1
20231102		HP	US	US	18	.	GROUP1
20231124		Lawyer	US	US	.	.	MISSIN
20231109		HP	US	US	.	.	MISSIN
20231018		Lawyer	US	US	22	.	GROUP1
20231206		HP	US	US	17	.	GROUP1
20231004		Lawyer	US	US	.	.	MISSIN

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Demographic Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>
134125873	13412587	3	Follow-up	20060401	20231101	20170406	20231107	Periodic
134126262	13412626	2	Follow-up	20080101	20230929	20170406	20231006	Periodic
134126382	13412638	2	Follow-up	.	20231129	20170406	20231206	Periodic
134126863	13412686	3	Follow-up	.	20231217	20170406	20231225	Periodic
134127613	13412761	3	Follow-up	20021028	20231211	20170406	20231218	Periodic
134127913	13412791	3	Follow-up	.	20231213	20170406	20231224	Periodic
134128594	13412859	4	Follow-up	20090615	20231211	20170406	20231218	Periodic
134128773	13412877	3	Follow-up	20110901	20231115	20170406	20231121	Expedited
134130324	13413032	4	Follow-up	20030911	20231211	20170406	20231213	Periodic
134130353	13413035	3	Follow-up	20120101	20231030	20170406	20231107	Periodic
134131113	13413111	3	Follow-up	.	20231217	20170406	20231225	Periodic
134132583	13413258	3	Follow-up	20061109	20231115	20170406	20231123	Periodic
134132774	13413277	4	Follow-up	20151222	20231122	20170406	20231129	Periodic
134132793	13413279	3	Follow-up	.	20231211	20170406	20231218	Periodic
134132973	13413297	3	Follow-up	20120228	20231206	20170406	20231213	Periodic



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Regulatory Authority's case report numbe</i>	<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviatio n for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>
	US-JNJFOC-20170308429	JOHNSON AND JOHNSON		5	Year	Child	Male
	US-JNJFOC-20170308330	JOHNSON AND JOHNSON		.		Adolescent	Male
	US-JNJFOC-20170308185	JOHNSON AND JOHNSON		.			Male
	US-JNJFOC-20170309509	JOHNSON AND JOHNSON		.			Male
	US-JNJFOC-20170310809	JOHNSON AND JOHNSON		15	Year	Adolescent	Male
	US-JNJFOC-20170308546	JOHNSON AND JOHNSON		.			Male
	US-JNJFOC-20170312474	JOHNSON AND JOHNSON		9	Year	Child	Male
	US-JNJFOC-20170312417	JOHNSON AND JOHNSON		21	Year	Adult	Male
	US-JNJFOC-20170316757	JOHNSON AND JOHNSON		16	Year	Adolescent	Male
	US-JNJFOC-20170316791	JOHNSON AND JOHNSON		3	Decade	Adult	Male
	US-JNJFOC-20170310822	JOHNSON AND JOHNSON		.			Male
	US-JNJFOC-20170312291	JOHNSON AND JOHNSON		2	Year	Child	Male
	US-JNJFOC-20170312542	JOHNSON AND JOHNSON		31	Year	Adult	Male
	US-JNJFOC-20170312544	JOHNSON AND JOHNSON		.			Male
	US-JNJFOC-20170312556	JOHNSON AND JOHNSON		10	Year	Child	Male

### ADVERSE EVENT REPORTING SYSTEM (AERS)

#### Demographic Listings

<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Y	.		20231108		Lawyer	US	US	5	.	GROUP1
Y	.		20231006		Lawyer	US	US	.	.	MISSIN
Y	.		20231206		Lawyer	US	US	.	.	MISSIN
Y	.		20231225		Lawyer	US	US	.	.	MISSIN
Y	.		20231216		Lawyer	US	US	15	.	GROUP1
Y	.		20231224		Lawyer	US	US	.	.	MISSIN
Y	.		20231216		Lawyer	US	US	9	.	GROUP1
Y	.		20231121		HP	US	US	21	.	GROUP1
Y	.		20231213		Lawyer	US	US	16	.	GROUP1
Y	.		20231107		HP	US	US	30	.	GROUP2
Y	.		20231225		Lawyer	US	US	.	.	MISSIN
Y	.		20231124		HP	US	US	2	.	GROUP1
Y	.		20231129		Lawyer	US	US	31	.	GROUP2
Y	.		20231216		Lawyer	US	US	.	.	MISSIN
Y	.		20231213		HP	US	US	10	.	GROUP1

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
134132993	13413299	3	Follow-up	20050829	20231211	20170406	20231218	Periodic	
134133304	13413330	4	Follow-up	.	20231009	20170406	20231012	Periodic	
134133329	13413332	9	Follow-up	20100916	20231116	20170406	20231124	Periodic	
134136225	13413622	5	Follow-up	20150511	20231030	20170406	20231106	Periodic	
134136262	13413626	2	Follow-up	20131202	20230927	20170406	20231004	Periodic	
134136362	13413636	2	Follow-up	20061216	20231013	20170406	20231019	Periodic	
134136665	13413666	5	Follow-up	20080714	20231117	20170406	20231124	Periodic	
134137264	13413726	4	Follow-up	20130429	20231006	20170406	20231016	Expedited	
134138382	13413838	2	Follow-up	.	20231006	20170406	20231010	Periodic	
134138514	13413851	4	Follow-up	20100201	20231211	20170406	20231218	Periodic	
134138573	13413857	3	Follow-up	.	20231101	20170406	20231108	Periodic	
134141165	13414116	5	Follow-up	.	20231222	20170407	20231229	Expedited	
134145813	13414581	3	Follow-up	.	20231115	20170406	20231124	Periodic	
134145863	13414586	3	Follow-up	.	20231106	20170406	20231112	Periodic	
134146293	13414629	3	Follow-up	.	20231113	20170406	20231121	Periodic	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending report</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>
US-JNJFOC-20170312590	JOHNSON AND JOHNSON		19	Year	Adult	Male	Y
US-JNJFOC-20170317037	JOHNSON AND JOHNSON		.			Male	Y
US-JNJFOC-20170316555	JOHNSON AND JOHNSON		18	Year	Adult	Male	Y
US-JNJFOC-20170317725	JOHNSON AND JOHNSON		26	Year	Adult	Male	Y
US-JNJFOC-20170318152	JOHNSON AND JOHNSON		24	Year	Adult	Male	Y
US-JNJFOC-20170317958	JOHNSON AND JOHNSON		20	Year	Adult	Male	Y
US-JNJFOC-20170311631	JOHNSON AND JOHNSON		18	Year	Adult	Male	Y
US-JNJFOC-20170313895	JOHNSON AND JOHNSON		19	Year	Adult	Male	Y
US-JNJFOC-20170318338	JOHNSON AND JOHNSON		.			Male	Y
US-JNJFOC-20170318341	JOHNSON AND JOHNSON		22	Year	Adult	Male	Y
US-JNJFOC-20170318348	JOHNSON AND JOHNSON		.			Male	Y
CA-SA-2017SA058442	SANOFI AVENTIS		49	Year	Adult	Male	Y
US-JNJFOC-20170319114	JOHNSON AND JOHNSON		.			Male	Y
US-JNJFOC-20170319423	JOHNSON AND JOHNSON		.			Male	Y
US-JNJFOC-20170319666	JOHNSON AND JOHNSON		.			Male	Y

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Demographic Listings**

<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
.		20231216		Lawyer	US	US	19	.	GROUP1
.		20231012		Lawyer	US	US	.	.	MISSIN
.		20231124		Lawyer	US	US	18	.	GROUP1
.		20231106		Lawyer	US	US	26	.	GROUP2
.		20231004		Lawyer	US	US	24	.	GROUP1
.		20231019		Lawyer	US	US	20	.	GROUP1
.		20231124		HP	US	US	18	.	GROUP1
83.99	KG	20231016		HP	US	US	19	83.99	GROUP1
.		20231010		Lawyer	US	US	.	.	MISSIN
.		20231216		Lawyer	US	US	22	.	GROUP1
.		20231108		Lawyer	US	US	.	.	MISSIN
.		20231229		HP	CA	CA	49	.	GROUP2
.		20231124		Lawyer	US	US	.	.	MISSIN
.		20231112		Lawyer	US	US	.	.	MISSIN
.		20231121		Lawyer	US	US	.	.	MISSIN

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
134148314	13414831	4	Follow-up	.	20231025	20170406	20231031	Periodic	
134148654	13414865	4	Follow-up	20070406	20231211	20170406	20231223	Periodic	
134190143	13419014	3	Follow-up	20060809	20231106	20170407	20231112	Periodic	
134190213	13419021	3	Follow-up	20141112	20231106	20170407	20231111	Periodic	
134190294	13419029	4	Follow-up	.	20231217	20170407	20231225	Expedited	
134190364	13419036	4	Follow-up	.	20231213	20170407	20231218	Periodic	
134191844	13419184	4	Follow-up	20131112	20231106	20170407	20231112	Periodic	
134194003	13419400	3	Follow-up	20081212	20231106	20170407	20231114	Periodic	
134194094	13419409	4	Follow-up	20060101	20230929	20170407	20231007	Periodic	
1341979423	13419794	23	Follow-up	20170201	20231207	20170407	20231218	Expedited	
134281817	13428181	7	Follow-up	20170331	20231214	20170411	20231220	Expedited	
1342967213	13429672	13	Follow-up	20180101	20230929	20170412	20231004	Expedited	
134333438	13433343	8	Follow-up	.	20231019	20170412	20231026	Expedited	
134410227	13441022	7	Follow-up	20170101	20231018	20170413	20231023	Expedited	
1344289218	13442892	18	Follow-up	20170202	20231017	20170414	20231023	Expedited	
1345284711	13452847	11	Follow-up	20161206	20231201	20170418	20231208	Expedited	
134551344	13455134	4	Follow-up	20130618	20231219	20170419	20231229	Expedited	IT-UCBSA-2017014518
134631473	13463147	3	Follow-up	20170411	20231110	20170420	20231115	Expedited	
134674795	13467479	5	Follow-up	20170207	20231214	20170421	20231221	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>	<i>Patient Age Group code</i>	<i>Code for patient's sex</i>
US-JNJFOC-20170319764	JOHNSON AND JOHNSON		.			Male
US-JNJFOC-20170319766	JOHNSON AND JOHNSON		21	Year	Adult	Male
US-JNJFOC-20170319729	JOHNSON AND JOHNSON		12	Year	Adolescent	Male
US-JNJFOC-20170319228	JOHNSON AND JOHNSON		18	Year	Adult	Male
US-JNJFOC-20170319303	JOHNSON AND JOHNSON		.			Male
US-JNJFOC-20170319730	JOHNSON AND JOHNSON		.			Male
US-JNJFOC-20170316691	JOHNSON AND JOHNSON		25	Year	Adult	Male
US-JNJFOC-20170316146	JOHNSON AND JOHNSON		31	Year	Adult	Male
US-JNJFOC-20170316627	JOHNSON AND JOHNSON		3	Decade	Adult	Male
US-PFIZER INC-2017154081	PFIZER		57	Year		Female
US-PFIZER INC-2017152369	PFIZER		66	Year		Female
BR-TAKEDA-2017TUS007298	TAKEDA		.			Male
PHHY2017CA043743	NOVARTIS		50	Year		Female
US-JAZZ-2017-US-004639	JAZZ		.			Male
PHHY2017CA021453	NOVARTIS		45	Year		Male
FR-BIOGEN-2017BI00387028	BIOGEN		54	Year		Female
IT-UCBSA-2017014518	UCB		53	Year		Male
AU-AMGEN-AUSCT2017059393	AMGEN		67	Year	Elderly	Male
GB-MYLANLABS-2017M1023794	MYLAN		.		Adult	Female

# **ADVERSE EVENT REPORTING SYSTEM (AERS)**

## **Demographic Listings**

<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Y	.		20231031		Lawyer	US	US	.	.	MISSIN
Y	.		20231224		Lawyer	US	US	21	.	GROUP1
Y	.		20231112		Lawyer	US	US	12	.	GROUP1
Y	.		20231111		Lawyer	US	US	18	.	GROUP1
Y	.		20231226		HP	US	US	.	.	MISSIN
Y	.		20231219		Lawyer	US	US	.	.	MISSIN
Y	.		20231112		Lawyer	US	US	25	.	GROUP1
Y	.		20231114		Lawyer	US	US	31	.	GROUP2
Y	.		20231007		HP	US	US	30	.	GROUP2
Y	47	KG	20231218		Consumer	US	US	57	47	GROUP3
Y	94.3	KG	20231220		HP	US	US	66	94.3	GROUP3
Y	67	KG	20231004		Consumer	BR	BR	.	67	MISSIN
Y	.		20231026		Pharmacist	CA	CA	50	.	GROUP2
Y	.		20231023		Physician	US	US	.	.	MISSIN
Y	.		20231023		Consumer	CA	CA	45	.	GROUP2
Y	65	KG	20231208		Physician	FR	FR	54	65	GROUP3
Y	.		20231229		Physician	IT	IT	53	.	GROUP3
Y	.		20231115		Physician	AU	AU	67	.	GROUP3
Y	65	KG	20231221		Pharmacist	GB	GB	.	65	MISSIN



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
134678273	13467827	3	Follow-up	20141201	20200730	20170421	20231017	Periodic	
134844377	13484437	7	Follow-up	20140101	20231027	20170426	20231103	Expedited	
1348445812	13484458	12	Follow-up	20160927	20231017	20170426	20231025	Expedited	
134851012	13485101	2	Follow-up	20120611	20231108	20170425	20231116	Periodic	
134860119	13486011	9	Follow-up	20150101	20231101	20170426	20231107	Expedited	
1348660214	13486602	14	Follow-up	20170201	20231101	20170426	20231103	Expedited	
134892662	13489266	2	Follow-up	.	20231220	20170427	20231228	Periodic	
134896563	13489656	3	Follow-up	20020201	20231217	20170427	20231225	Periodic	
134903532	13490353	2	Follow-up	20020101	20231220	20170427	20231229	Periodic	
134903692	13490369	2	Follow-up	.	20231220	20170427	20231228	Periodic	
134921864	13492186	4	Follow-up	20060101	20231217	20170427	20231226	Expedited	
134922032	13492203	2	Follow-up	.	20231217	20170427	20231225	Periodic	
134947526	13494752	6	Follow-up	20211013	20230929	20170428	20231007	Expedited	
135068785	13506878	5	Follow-up	20231118	20231122	20170502	20231124	Expedited	
135213614	13521361	4	Follow-up	.	20231024	20170508	20231106	Periodic	
1352442019	13524420	19	Follow-up	20170101	20231129	20170508	20231204	Expedited	
135289153	13528915	3	Follow-up	20161204	20170630	20170509	20231017	Periodic	
135316108	13531610	8	Follow-up	20170201	20231003	20170510	20231009	Expedited	
135360507	13536050	7	Follow-up	20170415	20170627	20170511	20231227	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
US-NAPPMUNDI-USA-2017-0137000	PURDUE		26	Year
PHHY2011CA47089	NOVARTIS		60	Year
PHHY2016CA148710	NOVARTIS		65	Year
US-JNJFOC-20170419289	JOHNSON AND JOHNSON		9	Year
PHHY2015CA103813	NOVARTIS		18	Year
JP-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-015277	BRISTOL MYERS SQUIBB		75	Year
US-JNJFOC-20170427419	JOHNSON AND JOHNSON		.	
US-JNJFOC-20170427534	JOHNSON AND JOHNSON		6	Year
US-JNJFOC-20170427529	JOHNSON AND JOHNSON		.	
US-JNJFOC-20170427554	JOHNSON AND JOHNSON		.	
US-JNJFOC-20170427317	JOHNSON AND JOHNSON		.	
US-JNJFOC-20170427445	JOHNSON AND JOHNSON		.	
US-SHIRE-US201709149	TAKEDA		72	Year
US-SHIRE-US201709484	TAKEDA		73	Year
US-PFIZER INC-2017199352	PFIZER		68	Year
CA-TAKEDA-2017TUS009530	TAKEDA		.	
US-ALEXION PHARMACEUTICALS INC.-A201704560	ALEXION		68	Year
PHHY2017CA025217	NOVARTIS		49	Year
US-ACORDA-ACO_137319_2017	ACORDA		27	Year

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Demographic Listings**

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Child	Male	Y	.		20231018		Consumer	US	US	26	.	GROUP2
	Female	Y	.		20231103		HP	CA	CA	60	.	GROUP3
	Female	Y	.		20231025		Consumer	CA	CA	65	.	GROUP3
	Male	Y	.		20231116		HP	US	US	9	.	GROUP1
Elderly	Female	Y	.		20231107		HP	CA	CA	18	.	GROUP1
	Male	Y	46	KG	20231103		Physician	JP	JP	75	46	GROUP3
	Male	Y	.		20231228		Lawyer	US	US	.	.	MISSIN
Child	Male	Y	.		20231225		Lawyer	US	US	6	.	GROUP1
Adolescent	Male	Y	.		20231229		Lawyer	US	US	.	.	MISSIN
	Male	Y	.		20231228		Lawyer	US	US	.	.	MISSIN
Child	Male	Y	.		20231226		HP	US	US	.	.	MISSIN
	Male	Y	.		20231225		Lawyer	US	US	.	.	MISSIN
	Female	Y	.		20231007		Consumer	US	US	72	.	GROUP3
	Female	Y	.		20231124		Consumer	US	US	73	.	GROUP3
	Female	Y	.		20231106		Consumer	US	US	68	.	GROUP3
	Female	Y	.		20231204		Consumer	CA	CA	.	.	MISSIN
	Female	Y	63	KG	20231017		Physician	US	US	68	63	GROUP3
	Female	Y	.		20231009		Physician	CA	CA	49	.	GROUP2
	Female	Y	51.701	KG	20231227		Physician	US	US	27	51.701	GROUP2

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
135388083	13538808	3	Follow-up	20131001	20231101	20170512	20231108	Periodic	
135388104	13538810	4	Follow-up	.	20231013	20170512	20231018	Periodic	
135388184	13538818	4	Follow-up	.	20231106	20170512	20231113	Periodic	
135388403	13538840	3	Follow-up	20110101	20231129	20170512	20231203	Periodic	
135403142	13540314	2	Follow-up	20150520	20231212	20170512	20231214	Expedited	
135404313	13540431	3	Follow-up	20170503	20180908	20170512	20231222	Expedited	
1354156015	13541560	15	Follow-up	20110612	20231120	20170512	20231128	Expedited	
135456789	13545678	9	Follow-up	20211201	20231110	20170515	20231120	Expedited	
135501352	13550135	2	Follow-up	20150523	20180905	20170516	20231214	Expedited	
135512305	13551230	5	Follow-up	20110612	20231121	20170516	20231129	Expedited	
135557787	13555778	7	Follow-up	20170201	20231201	20170517	20231218	Expedited	
135557947	13555794	7	Follow-up	20170216	20231024	20170517	20231121	Periodic	
135581292	13558129	2	Follow-up	20231101	20231128	20170517	20231210	Expedited	
135598512	13559851	2	Follow-up	20160101	20230928	20170518	20231002	Periodic	
1356075629	13560756	29	Follow-up	20170310	20231031	20170518	20231115	Expedited	
1356231521	13562315	21	Follow-up	20150821	20231129	20170519	20231212	Expedited	
135653454	13565345	4	Follow-up	20170504	20231114	20170519	20231124	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
US-JNJFOC-20170313997	JOHNSON AND JOHNSON		23	Year
US-JNJFOC-20170314129	JOHNSON AND JOHNSON		.	
US-JNJFOC-20170314655	JOHNSON AND JOHNSON		.	
US-JNJFOC-20170315918	JOHNSON AND JOHNSON		3	Decade
AR-SA-2017SA083831	SANOFI AVENTIS		34	Year
AR-SA-2017SA083004	SANOFI AVENTIS		34	Year
PHHY2017HR067523	NOVARTIS	Kovacic S, Roginic S, Nemrava J, Gospocic K, Seferovic Saric M et al. Acute pancreatitis in two patients with Parkinson?s disease. COGENT MEDICINE. 2017;4 (1):1-12	76	Year
US-PFIZER INC-2017213028	PFIZER		74	Year
AR-SA-2017SA083829	SANOFI AVENTIS		33	Year
HR-SA-2017SA081418	SANOFI AVENTIS	Kovacic S, Roginic S, Nemrava J, Gospocic K, Seferovic Saric M, Luetic K.. Acute pancreatitis in two patients with Parkinsons disease. Cogent Medicine. 2017;4(1):1-12	76	Year
US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002305	ACADIA PHARMACEUTICALS		57	Year
US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002384	ACADIA PHARMACEUTICALS		56	Year
US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003079	ACADIA PHARMACEUTICALS		93	Year
US-AMGEN-USASP2017074167	AMGEN		57	Year
JP-ABBVIE-17K-087-1977405-00	ABBVIE		70	Year
CA-ROCHE-1936490	ROCHE		55	Year
CA-TAKEDA-2017TUS011016	TAKEDA		48	Year

# ADVERSE EVENT REPORTING SYSTEM (AERS) Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Adult	Male	Y	.		20231108		HP	US	US	23	.	GROUP1
Adult	Male	Y	.		20231018		Lawyer	US	US	.	.	MISSIN
Adult	Male	Y	.		20231113		HP	US	US	.	.	MISSIN
Adult	Male	Y	.		20231204		Lawyer	US	US	30	.	GROUP2
Adult	Female	Y	.		20231214		HP	AR	AR	34	.	GROUP2
Adult	Female	Y	.		20231222		HP	AR	AR	34	.	GROUP2
	Male	Y	.		20231127		HP	HR	HR	76	.	GROUP4
	Female	Y	72.12	KG	20231120		Physician	US	US	74	72.12	GROUP3
Adult	Female	Y	.		20231214		Physician	AR	AR	33	.	GROUP2
Elderly	Male	Y	.		20231129		Physician	HR	HR	76	.	GROUP4
	Female	Y	.		20231214		Consumer	US	US	57	.	GROUP3
	Female	Y	62	KG	20231121		Consumer	US	US	56	62	GROUP3
	Female	Y	.		20231210		Consumer	US	US	93	.	GROUP4
Adult	Female	Y	.		20231002		Consumer	US	US	57	.	GROUP3
	Female	Y	49	KG	20231115		Physician	JP	JP	70	49	GROUP3
	Female	Y	.		20231212		Consumer	CA	CA	55	.	GROUP3
	Male	Y	.		20231124		Consumer	CA	CA	48	.	GROUP2

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
135655683	13565568	3	Follow-up	20000101	20230131	20170519	20231005	Expedited	
135684412	13568441	2	Follow-up	20170401	20231206	20170522	20231215	Expedited	
135688168	13568816	8	Follow-up	.	20231205	20170522	20231218	Periodic	
135699084	13569908	4	Follow-up	20170101	20231017	20170522	20231020	Expedited	
135704317	13570431	7	Follow-up	20180201	20231003	20170522	20231015	Expedited	
135737695	13573769	5	Follow-up	20170515	20231109	20170523	20231117	Expedited	
135814722	13581472	2	Follow-up	.	20231109	20170525	20231115	Expedited	
135815149	13581514	9	Follow-up	20180201	20231031	20170525	20231103	Expedited	
135983634	13598363	4	Follow-up	20170501	20231127	20170531	20231204	Periodic	
136004232	13600423	2	Follow-up	.	20231201	20170601	20231208	Periodic	
1360172115	13601721	15	Follow-up	20170517	20231025	20170601	20231031	Expedited	
136030473	13603047	3	Follow-up	20170516	20231113	20170601	20231123	Expedited	
1360873920	13608739	20	Follow-up	20170101	20231102	20170602	20231110	Expedited	
136097694	13609769	4	Follow-up	20060101	20231002	20170602	20231004	Expedited	
136144782	13614478	2	Follow-up	.	20231127	20170606	20231210	Expedited	
136145633	13614563	3	Follow-up	.	20231003	20170606	20231011	Expedited	
136226523	13622652	3	Follow-up	.	20231117	20170607	20231127	Expedited	
1362330512	13623305	12	Follow-up	20170327	20231019	20170607	20231023	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
FR-ABBVIE-15P-056-1432038-00	ABBVIE		.	
US-PFIZER INC-2017218238	PFIZER		65	Year
US-PFIZER INC-2017216926	PFIZER		55	Year
US-BAXALTA-2017BLT004484	TAKEDA		.	
PHFR2017GB003798	NOVARTIS		75	Year
DE-JNJFOC-20170519202	JOHNSON AND JOHNSON		14	Year
ES-GLAXOSMITHKLINE-ES2017GSK076913	GLAXOSMITHKLINE	Gutierrez LS. Iatrogenic Cushing Syndrome and Secondary Adrenal Insufficiency Due to an Interaction Between Fluticasone and Ritonavir. Journal of the Endocrine Society. 2021;5(S 1):A136	.	
GB-GLAXOSMITHKLINE-GB2017GSK077248	GLAXOSMITHKLINE		.	
US-PFIZER INC-2017235428	PFIZER		72	Year
US-PFIZER INC-2017236907	PFIZER		.	
CA-TAKEDA-2017TUS011439	TAKEDA		18	Year
DE-SEATTLE GENETICS-2017SGN01341	SEATTLE GENETICS		43	Year
US-PFIZER INC-2017240409	PFIZER		60	Year
US-JAZZ-2017-US-006969	JAZZ		.	
IT-AUROBINDO-AUR-APL-2014-07965	AUROBINDO	Rapetti Rachele. Severe statin-induced rhabdomyolysis following cholestatic hepatitis induced by amoxicillin-clavulanate. European Journal of Case Reports in internal Medicine -10.12890/2014_000065. 2014;10.12890/2014:000065	86	Year
US-AUROBINDO-AUR-APL-2017-34291	AUROBINDO	Khalid MM, Waring ED, Vearrier D, McKeever R, Greenberg MI.. Symptomatic elevation of antiepileptic drug concentrations after addition of hemp oil extract to a therapeutic regimen.. Clinical Toxicology. 2017;55(5):467-8	7	Year
US-AUROBINDO-AUR-APL-2017-35018	AUROBINDO	Rao S.. Rao S. Can we avoid aggressive and burdensome option of feeding tubes?. Journal of the American Geriatrics Society. 2017;65(1):S30	79	Year
US-GLAXOSMITHKLINE-US2017GSK069550	GLAXOSMITHKLINE		.	



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Female	Y	.		20231004		HP	FR	FR	.	.	MISSIN
	Female	Y	.		20231215		HP	US	US	65	.	GROUP3
	Female	Y	72.562	KG	20231218		Physician	US	US	55	72.562	GROUP3
	Male	Y	90	KG	20231020		Physician	US	US	.	90	MISSIN
	Male	Y	90	KG	20231015		Consumer	GB	GB	75	90	GROUP3
Adolescent	Female	Y	41.4	KG	20231117		Physician	DE	DE	14	41.4	GROUP1
		Y	.		20231115		Physician	ES	ES	.	.	MISSIN
		Y	.		20231103		Physician	GB	GB	.	.	MISSIN
	Female	Y	86	KG	20231204		HP	US	US	72	86	GROUP3
	Male	Y	.		20231208		Consumer	US	US	.	.	MISSIN
	Female	Y	.		20231031		Physician	CA	CA	18	.	GROUP1
	Female	Y	.		20231123		Physician	DE	DE	43	.	GROUP2
	Female	Y	91	KG	20231110		Consumer	US	US	60	91	GROUP3
	Female	Y	.		20231004		Consumer	US	US	.	.	MISSIN
	Male	Y	.		20231210		HP	IT	IT	86	.	GROUP4
	Female	Y	.		20231011		HP	US	US	7	.	GROUP1
	Male	Y	.		20231127		Physician	US	US	79	.	GROUP4
		Y	.		20231023		Physician	US	US	.	.	MISSIN

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

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136250703	13625070	3	Follow-up	20110801	20231213	20170607	20231224	Periodic	
136251072	13625107	2	Follow-up	20050101	20231213	20170607	20231224	Periodic	
136256464	13625646	4	Follow-up	20020101	20231217	20170607	20231226	Expedited	
136256752	13625675	2	Follow-up	.	20231220	20170607	20231228	Periodic	
136256883	13625688	3	Follow-up	20011220	20231115	20170607	20231123	Periodic	
136257352	13625735	2	Follow-up	20130301	20231108	20170607	20231115	Periodic	
136263763	13626376	3	Follow-up	20071203	20231113	20170607	20231121	Periodic	
136264304	13626430	4	Follow-up	20100319	20231115	20170607	20231123	Periodic	
136265752	13626575	2	Follow-up	.	20231220	20170607	20231227	Periodic	
136401706	13640170	6	Follow-up	.	20231122	20170609	20231124	Expedited	
1364104913	13641049	13	Follow-up	20170101	20231213	20170612	20231225	Expedited	
136425604	13642560	4	Follow-up	.	20231020	20170612	20231030	Expedited	
1364544612	13645446	12	Follow-up	20211201	20231211	20170612	20231218	Expedited	
1364827740	13648277	40	Follow-up	20170402	20231019	20170613	20231027	Expedited	
136492084	13649208	4	Follow-up	20170501	20231019	20170613	20231222	Expedited	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
US-JNJFOC-20170424984	JOHNSON AND JOHNSON		9	Year
US-JNJFOC-20161009193	JOHNSON AND JOHNSON		.	
US-JNJFOC-20170400091	JOHNSON AND JOHNSON		.	
US-JNJFOC-20170503051	JOHNSON AND JOHNSON		.	
US-JNJFOC-20170503435	JOHNSON AND JOHNSON		9	Year
US-JNJFOC-20170505365	JOHNSON AND JOHNSON		10	Year
US-JNJFOC-20170416687	JOHNSON AND JOHNSON		13	Year
US-JNJFOC-20170416716	JOHNSON AND JOHNSON		12	Year
US-JNJFOC-20170427557	JOHNSON AND JOHNSON		.	
US-BAXALTA-2017BLT005408	TAKEDA		.	
CA-ROCHE-1948683	ROCHE		72	Year
US-AUROBINDO-AUR-APL-2017-35270	AUROBINDO	Sinno MG,Rosen D,Wittler R.. Concomitant Presentation of Hemophagocytic Lymphohistiocytosis and Posttransplant Lymphoproliferative Disease-Like Lymphoma in a Mildly Immunosuppressed Leukemia Patient: An Unusual Association.. Pediatric Blood and Cancer. 2016;63 (8):1474-6	4	Year
US-ARIAD PHARMACEUTICALS, INC-2017US008050	TAKEDA		32	Year
CA-CELLTRION INC.-2017CA004746	CELLTRION		.	
US-JAZZ-2017-US-007409	JAZZ		52	Year

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Demographic Listings**

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Child	Male	Y	.		20231224		Lawyer	US	US	9	.	GROUP1
Child	Male	Y	.		20231224		HP	US	US	.	.	MISSIN
Child	Male	Y	.		20231226		HP	US	US	.	.	MISSIN
	Male	Y	.		20231228		Lawyer	US	US	.	.	MISSIN
Child	Male	Y	.		20231123		Lawyer	US	US	9	.	GROUP1
Child		Y	.		20231115		Lawyer	US	US	10	.	GROUP1
Adolescent	Male	Y	.		20231121		Lawyer	US	US	13	.	GROUP1
Adolescent	Male	Y	.		20231124		Lawyer	US	US	12	.	GROUP1
	Male	Y	.		20231227		Lawyer	US	US	.	.	MISSIN
	Female	Y	134	KG	20231124		Consumer	US	US	.	134	MISSIN
	Female	Y	.		20231225		Physician	CA	CA	72	.	GROUP3
	Female	Y	.		20231030		Physician	US	US	4	.	GROUP1
	Female	Y	.		20231218		Consumer	US	US	32	.	GROUP2
		Y	.		20231027		HP	CA	CA	.	.	MISSIN
	Female	Y	79.3	KG	20231222		Consumer	US	US	52	79.3	GROUP3

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

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136509072	13650907	2	Follow-up	20160423	20231204	20170614	20231205	Expedited	
136553689	13655368	9	Follow-up	20170522	20230925	20170615	20231005	Expedited	IT-MINISAL02-412521
136574623	13657462	3	Follow-up	20160501	20221221	20170615	20231030	30 Day	
136603483	13660348	3	Follow-up	20170615	20230831	20170616	20231019	Periodic	
136641333	13664133	3	Follow-up	19990521	20231205	20170619	20231208	Expedited	
1366846010	13668460	10	Follow-up	20170501	20210531	20170620	20231109	Expedited	
136695112	13669511	2	Follow-up	.	20231106	20170620	20231113	Expedited	
136720014	13672001	4	Follow-up	20150601	20231122	20170620	20231128	Expedited	
136720135	13672013	5	Follow-up	20170601	20231115	20170620	20231121	Periodic	
136748363	13674836	3	Follow-up	.	20231206	20170621	20231218	Periodic	
136754955	13675495	5	Follow-up	.	20230927	20170621	20231004	Expedited	
1367789622	13677896	22	Follow-up	20170206	20231130	20170622	20231205	Expedited	
1368793837	13687938	37	Follow-up	20121226	20231219	20170626	20231221	Expedited	
136957812	13695781	2	Follow-up	20170101	20231028	20170627	20231101	Periodic	
1369684240	13696842	40	Follow-up	20160914	20230921	20170628	20231004	Expedited	
136971772	13697177	2	Follow-up	20170608	20231129	20170628	20231206	Expedited	
136999614	13699961	4	Follow-up	.	20231206	20170629	20231215	Expedited	
137009446	13700944	6	Follow-up	20170101	20231031	20170629	20231108	Expedited	
1370558410	13705584	10	Follow-up	20180101	20231207	20170630	20231219	Expedited	
137066912	13706691	2	Follow-up	20110101	20231213	20170630	20231224	Periodic	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
FR-MYLANLABS-2017M1035162	MYLAN	Charpiat B, Tod M, Darnis B, Boulay G, Gagnieu M-C, Mabrut J-Y. Respiratory depression related to multiple drug-drug interactions precipitated by a fluconazole loading dose in a patient treated with oxycodone. Eur-J-Clin-Pharmacol 2017;73(6):787-788.	51	Year
IT-Accord-052517	ACCORD		10	Year
US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-047286	BRISTOL MYERS SQUIBB		58	Year
US-JAZZ-2017-US-007707	JAZZ		20	Year
DE-PFIZER INC-HQ7480319JUN2000	PFIZER		55	Year
IN-INCYTE CORPORATION-2017IN004783	INCYTE		.	
US-VERTEX PHARMACEUTICALS-2017-003182	VERTEX	McKinzie CJ, Goralski JL, Noah TL, Retsch-Bogart GZ, Prieur MB. Worsening anxiety and depression after initiation of lumacaftor/ivacaftor combination therapy in adolescent females with cystic fibrosis. J Cyst Fibros. 2017	17	Year
US-JAZZ-2017-US-007760	JAZZ		58	Year
US-JAZZ-2017-US-007830	JAZZ		47	Year
US-PFIZER INC-2017267470	PFIZER		55	Year
CA-BAUSCH-BL-2017-018663	BAUSCH AND LOMB		58	Year
AU-SA-2017SA039168	SANOFI AVENTIS		46	Year
CA-ROCHE-1196834	ROCHE		45	Year
US-BIOGEN-2017BI00420689	BIOGEN		.	
CO-INCYTE CORPORATION-2017IN005035	INCYTE		.	
FR-NAPPMUNDI-GBR-2017-0046218	PURDUE		86	Year
CA-APOTEX-2017AP013369	APOTEX		52	Year
US-PFIZER INC-2017279882	PFIZER		57	Year
US-ROCHE-1955880	ROCHE		55	Year
US-JNJFOC-20151018764	JOHNSON AND JOHNSON		.	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Demographic Listings**

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
	Male	Y	89	KG	20231205		HP	FR	FR	51	89	GROUP3
Child	Male	Y	.		20231005		Physician	IT	IT	10	.	GROUP1
Adult	Female	Y	98.865	KG	20231030		Consumer	US	US	58	98.865	GROUP3
	Male	Y	.		20231019		Physician	US	US	20	.	GROUP1
	Female	Y	71	KG	20231208		HP	DE	DE	55	71	GROUP3
		Y	.		20231109		Consumer	IN	IN	.	.	MISSIN
	Female	Y	.		20231113		Pharmacist	US	US	17	.	GROUP1
	Female	Y	.		20231128		Consumer	US	US	58	.	GROUP3
	Female	Y	.		20231121		Physician	US	US	47	.	GROUP2
	Female	Y	65.77	KG	20231218		Consumer	US	US	55	65.77	GROUP3
	Female	Y	52	KG	20231004		Consumer	CA	CA	58	52	GROUP3
Adult	Female	Y	102.5	KG	20231205		HP	AU	AU	46	102.5	GROUP2
	Female	Y	75	KG	20231221		HP	CA		45	75	GROUP2
	Female	Y	.		20231101		HP	US	US	.	.	MISSIN
		Y	.		20231005		Consumer	CO	CO	.	.	MISSIN
	Male	Y	75	KG	20231206		Physician	FR	FR	86	75	GROUP4
	Female	Y	.		20231215		HP	CA	CA	52	.	GROUP3
	Male	Y	.		20231108		Consumer	US	US	57	.	GROUP3
	Female	Y	63.56	KG	20231219		Consumer	US		55	63.56	GROUP3
Child	Male	Y	.		20231224		HP	US	US	.	.	MISSIN

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Demographic Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
137068223	13706822	3	Follow-up	20131101	20231030	20170630	20231108	Periodic	
1370783914	13707839	14	Follow-up	.	20231114	20170630	20231123	Expedited	
1370841319	13708413	19	Follow-up	20170601	20231215	20170630	20231225	Expedited	
137101862	13710186	2	Follow-up	.	20231003	20170703	20231011	Expedited	
137109882	13710988	2	Follow-up	20170601	20231201	20170703	20231206	Expedited	
1371451212	13714512	12	Follow-up	20170601	20231115	20170704	20231120	Expedited	
1371785214	13717852	14	Follow-up	.	20231127	20170705	20231204	Expedited	
1372081420	13720814	20	Follow-up	20170628	20231208	20170706	20231220	Expedited	
137211834	13721183	4	Follow-up	.	20230921	20170706	20231003	Expedited	IT-MERCK KGAA-8166573
137218048	13721804	8	Follow-up	20170401	20231206	20170706	20231213	Periodic	
1372180710	13721807	10	Follow-up	20150601	20231211	20170706	20231220	Expedited	
137279573	13727957	3	Follow-up	20070101	20231106	20170707	20231112	Periodic	
137290084	13729008	4	Follow-up	.	20231207	20170707	20231220	Periodic	
137312403	13731240	3	Follow-up	.	20231030	20170707	20231107	Periodic	
137386173	13738617	3	Follow-up	20090123	20230926	20170710	20231005	Expedited	
137386794	13738679	4	Follow-up	20140505	20171026	20170710	20231109	Expedited	
137409038	13740903	8	Follow-up	20170423	20231031	20170711	20231106	Expedited	
1374176710	13741767	10	Follow-up	20170601	20231110	20170711	20231120	Periodic	
1374265414	13742654	14	Follow-up	20170508	20231113	20170711	20231123	Expedited	



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
US-JNJFOC-20170616810	JOHNSON AND JOHNSON		19	Year
US-PFIZER INC-2017284135	PFIZER		71	Year
NL-ABBVIE-17P-114-2020924-00	ABBVIE		63	Year
US-AUROBINDO-AUR-APL-2017-36216	AUROBINDO	Tait L, et al. Worsening agitation and hallucinations: Could it be PTSD?. Current Psychiatry. 2017;16:50-58	57	Year
US-SHIRE-2017BLT005889	TAKEDA		80	Year
PHHY2017CA097764	NOVARTIS		44	Year
BR-GLAXOSMITHKLINE-BR2017GSK060417	GLAXOSMITHKLINE		.	
CA-ROCHE-1959396	ROCHE		45	Year
IT-EMD Serono-8166573	EMD SERONO INC	Croese T, Cascavilla M, Truci G, Comi G, Colombo B. A case of intracranial hypertension due to anabolic and polivitaminic abuse. Neurological Sciences. 2017;38(1): 209-	36	Year
US-JAZZ-2017-US-008482	JAZZ		41	Year
US-JAZZ-2017-US-008632	JAZZ		73	Year
US-JNJFOC-20150713762	JOHNSON AND JOHNSON		1	Decade
US-PFIZER INC-2017295753	PFIZER		79	Year
US-JNJFOC-20150708455	JOHNSON AND JOHNSON		.	
US-SAOL THERAPEUTICS-2017SAO00261	AMNEAL		19	Year
US-SAOL THERAPEUTICS-0700641524	SAOL THERAPEUTICS		63	Year
JP-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-061398	BRISTOL MYERS SQUIBB		50	Year
US-PFIZER INC-2017296776	PFIZER		74	Year
IT-PFIZER INC-2017297815	PFIZER		93	Year

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Demographic Listings**

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Adult	Male	Y	.		20231108		Lawyer	US	US	19	.	GROUP1
	Female	Y	.		20231123		Consumer	US	US	71	.	GROUP3
	Male	Y	80	KG	20231225		HP	NL	NL	63	80	GROUP3
	Male	Y	.		20231011		Physician	US	US	57	.	GROUP3
	Female	Y	.		20231206		Consumer	US	US	80	.	GROUP4
	Male	Y	.		20231120		Consumer	CA	CA	44	.	GROUP2
		Y	.		20231204		HP	BR	BR	.	.	MISSIN
	Female	Y	86	KG	20231220		Consumer	CA	CA	45	86	GROUP2
Adult	Male	Y	.		20231003		Physician	IT	IT	36	.	GROUP2
	Female	Y	52.6	KG	20231213		Consumer	US	US	41	52.6	GROUP2
	Male	Y	.		20231220		Physician	US	US	73	.	GROUP3
Child	Male	Y	.		20231112		HP	US	US	10	.	GROUP1
	Female	Y	.		20231220		HP	US	US	79	.	GROUP4
	Male	Y	.		20231107		Lawyer	US	US	.	.	MISSIN
	Female	Y	56.236	KG	20231005		HP	US	US	19	56.236	GROUP1
	Female	Y	72.562	KG	20231109		Physician	US	US	63	72.562	GROUP3
Adult	Male	Y	67	KG	20231106		Physician	JP	JP	50	67	GROUP2
	Male	Y	.		20231120		Consumer	US	US	74	.	GROUP3
	Female	Y	.		20231123		Physician	IT	IT	93	.	GROUP4

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Demographic Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Safety Report Version Number.</i>	<i>Code for initial or follow-up status of</i>	<i>Date the adverse event occurred or began</i>	<i>Date manufacturer first received initial</i>	<i>Date FDA received first version (Initial</i>	<i>Date FDA received Case(YYYYMMDD format).</i>	<i>Code for the type of report submitted</i>	<i>Regulatory Authority's case report numbe</i>
137466033	13746603	3	Follow-up	20170705	20231113	20170712	20231122	Expedited	
137487108	13748710	8	Follow-up	20170512	20231003	20170713	20231013	Expedited	
137522382	13752238	2	Follow-up	20170511	20230802	20170713	20231019	Periodic	

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Demographic Listings

<i>Manufacturer's unique report identifier.</i>	<i>Coded name of manufacturer sending repor</i>	<i>Literature Reference information.</i>	<i>Numeric value of patient's age at event.</i>	<i>Unit abbreviation for patient's age</i>
DE-SEATTLE GENETICS-2017SGN01722	SEATTLE GENETICS		.	
AT-BIOGEN-2017BI00428444	BIOGEN		34	Year
US-JAZZ-2017-US-006056	JAZZ		25	Year

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Demographic Listings**

<i>Patient Age Group code</i>	<i>Code for patient's sex</i>	<i>Whether (Y/N) this report was submitted</i>	<i>Numeric value of patient's weight.</i>	<i>Unit abbreviation for patient's weight.</i>	<i>Date report was sent (YYYYMMDD format).</i>	<i>Whether (Y/N) voluntary reporter also no</i>	<i>Reporter's type of occupation.</i>	<i>The country of the reporter in the lates</i>	<i>The country where the event occurred.</i>	<i>Derived age in years.</i>	<i>Derived weight in kilograms.</i>	<i>Derived age group.</i>
Adult	Female	Y	.		20231122		Physician	DE	DE	.	.	MISSIN
	Female	Y	.		20231013		Physician	AT	AT	34	.	GROUP2
	Female	Y	.		20231019		Physician	US	US	25	.	GROUP1

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
100144838	10014483	1	Primary Suspect Drug	ISENTRESS	RALTEGRAVIR POTASSIUM	Validated trade name used	Transplacental	400 mg, bid	.
100144838	10014483	2	Secondary Suspect Drug	ISENTRESS	RALTEGRAVIR POTASSIUM	Validated trade name used	Transplacental	400 mg	.
100144838	10014483	3	Secondary Suspect Drug	ISENTRESS	RALTEGRAVIR POTASSIUM	Validated trade name used	Transplacental	UNK	.
100144838	10014483	4	Secondary Suspect Drug	ABACAVIR	ABACAVIR	Validated trade name used	Transplacental	300 mg, bid	.
100144838	10014483	5	Secondary Suspect Drug	ABACAVIR	ABACAVIR	Validated trade name used	Transplacental	300 mg	.
100144838	10014483	6	Secondary Suspect Drug	ABACAVIR	ABACAVIR	Validated trade name used	Transplacental	300.0 Milligram 1 every 1 Days	.
100144838	10014483	7	Secondary Suspect Drug	ACYCLOVIR	ACYCLOVIR	Validated trade name used	Transplacental	UNK	.
100144838	10014483	8	Secondary Suspect Drug	ACYCLOVIR	ACYCLOVIR	Validated trade name used			.
100144838	10014483	9	Secondary Suspect Drug	AZITHROMYCIN	AZITHROMYCIN	Validated trade name used	Transplacental	2 every 1 days	.
100144838	10014483	10	Secondary Suspect Drug	AZITHROMYCIN	AZITHROMYCIN	Validated trade name used	Transplacental	UNK	.

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
	Does not apply				22145	400	Milligram(s)	Tablet	Twice a day
	Does not apply				22145	400	Milligram(s)	Tablet	
	Does not apply				22145	.		Tablet	
	Does not apply				.	300	Milligram(s)	Capsule	Twice a day
	Does not apply				.	300	Milligram(s)	Capsule	
	Does not apply				.	300	Milligram(s)	Capsule	Daily
	Does not apply				.	.			
	Does not apply				.	.			
	Does not apply				.	.			Twice a day
	Does not apply				.	.			

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
100144838	10014483	11	Secondary Suspect Drug	BACTRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM	Validated trade name used	Transplacental	400 mg, bid	.
100144838	10014483	12	Secondary Suspect Drug	BACTRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM	Validated trade name used	Transplacental	UNK	.
100144838	10014483	13	Secondary Suspect Drug	INTELENCE	ETRAVIRINE	Validated trade name used	Transplacental	200 mg, bid	.
100144838	10014483	14	Secondary Suspect Drug	INTELENCE	ETRAVIRINE	Validated trade name used	Transplacental	200 mg	.
100144838	10014483	15	Secondary Suspect Drug	INTELENCE	ETRAVIRINE	Validated trade name used	Transplacental	200 mg, 1 every 1 Days	.
100144838	10014483	16	Secondary Suspect Drug	LAMIVUDINE	LAMIVUDINE	Validated trade name used	Transplacental	150 mg, bid	.
100144838	10014483	17	Secondary Suspect Drug	LAMIVUDINE	LAMIVUDINE	Validated trade name used	Transplacental	150 mg	.
100144838	10014483	18	Secondary Suspect Drug	PREZISTA	DARUNAVIR ETHANOLATE	Validated trade name used	Transplacental	600 mg, bid	.
100144838	10014483	19	Secondary Suspect Drug	PREZISTA	DARUNAVIR ETHANOLATE	Validated trade name used	Transplacental	600 mg, qd	.
100144838	10014483	20	Secondary Suspect Drug	PREZISTA	DARUNAVIR ETHANOLATE	Validated trade name used	Transplacental	600 mg	.
100144838	10014483	21	Secondary Suspect Drug	RITONAVIR	RITONAVIR	Validated trade name used	Transplacental	100 mg, bid	.



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
	Does not apply				.	400	Milligram(s)		Twice a day
	Does not apply				.	.			
	Does not apply				.	200	Milligram(s)	Tablet	Twice a day
	Does not apply				.	200	Milligram(s)	Tablet	Daily
	Does not apply				.	200	Milligram(s)	Tablet	Daily
	Does not apply				.	150	Milligram(s)		Twice a day
	Does not apply				.	150	Milligram(s)		
	Does not apply				.	600	Milligram(s)	Tablet	Twice a day
	Does not apply				.	600	Milligram(s)	Tablet	Daily
	Does not apply				.	600	Milligram(s)	Tablet	
	Does not apply				.	100	Milligram(s)		Twice a day

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
100144838	10014483	22	Secondary Suspect Drug	RITONAVIR	RITONAVIR	Validated trade name used	Transplacental	100 mg	.	
100144838	10014483	23	Secondary Suspect Drug	VIREAD	TENOFOVIR DISOPROXIL FUMARATE	Validated trade name used	Transplacental	300 mg, qd	.	
100144838	10014483	24	Secondary Suspect Drug	VIREAD	TENOFOVIR DISOPROXIL FUMARATE	Validated trade name used	Transplacental	300 mg	.	
100144838	10014483	25	Secondary Suspect Drug	VIREAD	TENOFOVIR DISOPROXIL FUMARATE	Validated trade name used	Transdermal	300 mg, qd	.	
100144838	10014483	26	Secondary Suspect Drug	VIREAD	TENOFOVIR DISOPROXIL FUMARATE	Validated trade name used	Transdermal	300 mg	.	
100144838	10014483	27	Secondary Suspect Drug	ZIDOVUDINE	ZIDOVUDINE	Validated trade name used	Transplacental	300 mg, bid	.	
100144838	10014483	28	Secondary Suspect Drug	ZIDOVUDINE	ZIDOVUDINE	Validated trade name used	Transplacental	300 mg	.	
100144838	10014483	29	Concomitant	FOLIC ACID	FOLIC ACID	Validated trade name used	Transplacental		.	
100144838	10014483	30	Concomitant	IRON	IRON	Validated trade name used	Transplacental	UNK	.	
100144838	10014483	31	Concomitant	MAGNESIUM GLUCONATE	MAGNESIUM GLUCONATE	Validated trade name used	Transplacental		.	
100144838	10014483	32	Concomitant	IRON;MINERALS NOS;VITAMINS NOS		Validated trade name used	Transplacental		.	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Does not apply				.	100	Milligram(s)		
Does not apply				.	300	Milligram(s)		Daily
Does not apply				.	300	Milligram(s)		
Does not apply				.	300	Milligram(s)		Daily
Does not apply				.	300	Milligram(s)		
Does not apply				.	300	Milligram(s)		Twice a day
Does not apply				.	300	Milligram(s)		
				.	.			
				.	.			
				.	.		Tablet	
Unknown				.	.		Tablet	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
100144838	10014483	33	Concomitant	CALCIUM CARBONATE	CALCIUM CARBONATE	Validated trade name used	Unknown	.	
100144838	10014483	34	Concomitant	CALCIUM PANTOTHENATE	CALCIUM PANTOTHENATE	Validated trade name used	Unknown	.	
100144838	10014483	35	Concomitant	ERGOCALCIFEROL	ERGOCALCIFEROL	Validated trade name used	Unknown	.	
100144838	10014483	36	Concomitant	FERROUS FUMARATE	FERROUS FUMARATE	Validated trade name used	Unknown	.	
100144838	10014483	37	Concomitant	NICOTINAMIDE	NIACINAMIDE	Validated trade name used	Unknown	.	
100144838	10014483	38	Concomitant	PYRIDOXINE HYDROCHLORIDE	PYRIDOXINE HYDROCHLORIDE	Validated trade name used	Unknown	.	
100144838	10014483	39	Concomitant	VITAMIN A PALMITATE	VITAMIN A PALMITATE	Validated trade name used	Unknown	.	
100144838	10014483	40	Concomitant	RIBOFLAVIN	RIBOFLAVIN	Validated trade name used	Unknown	.	
100144838	10014483	41	Concomitant	THIAMINE MONONITRATE	THIAMINE MONONITRATE	Validated trade name used	Unknown	.	
100144838	10014483	42	Concomitant	VITAMIN B12	CYANOCOBALAMIN	Validated trade name used	Unknown	.	
100144838	10014483	43	Concomitant	VITAMIN C	ASCORBIC ACID	Validated trade name used	Unknown	.	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

[illegible]

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1001678124	10016781	1	Primary Suspect Drug	SANDOSTATIN	OCTREOTIDE ACETATE	Validated trade name used	Subcutaneous	UNK, TID (cont 02 weeks post 01st LAR)	.
1001678124	10016781	2	Secondary Suspect Drug	SANDOSTATIN	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, QMO	.
1001678124	10016781	3	Secondary Suspect Drug	SANDOSTATIN	OCTREOTIDE ACETATE	Validated trade name used			.
1001678124	10016781	4	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, QMO (once a month)	.
1001678124	10016781	5	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, QMO (once a month)	.
1001678124	10016781	6	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, QMO (every 4 weeks)	.
1001678124	10016781	7	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, QMO (once a month)	.
1001678124	10016781	8	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Unknown	UNK	.
1001678124	10016781	9	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, QMO	.
1001678124	10016781	10	Concomitant	SANDOSTATIN	OCTREOTIDE ACETATE	Validated trade name used	Subcutaneous	UNK, TID	.
1001678124	10016781	11	Concomitant	AFINITOR	EVEROLIMUS	Validated trade name used	Oral	10 mg, QD	.

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
	Positive dechallenge	Unknown			19667	.			3 times a day
	Positive dechallenge	Unknown			19667	20	Milligram(s)		/MONTH
	Positive dechallenge	Unknown			19667	.			
	Unknown				19667	20	Milligram(s)		/MONTH
	Unknown				19667	30	Milligram(s)		/MONTH
	Unknown				19667	20	Milligram(s)		/MONTH
	Unknown				19667	20	Milligram(s)		/MONTH
	Unknown		SMR01		19667	.			
	Unknown				19667	20	Milligram(s)		/MONTH
	Positive dechallenge				.	.			3 times a day
	Positive dechallenge				.	10	Milligram(s)		Daily

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
1001678124	10016781	12	Concomitant	AFINITOR	EVEROLIMUS	Validated trade name used	Oral	UNK
1001678124	10016781	13	Concomitant	DEXILANT	DEXLANSOPRAZOLE	Validated trade name used	Oral	UNK
1001678124	10016781	14	Concomitant	INSULIN NOS	INSULIN NOS	Validated trade name used	Unknown	UNK
1001678124	10016781	15	Concomitant	VITAMIN D	VITAMIN D NOS	Validated trade name used	Oral	UNK (10000 units)
1001678124	10016781	16	Concomitant	CRESTOR	ROSUVASTATIN CALCIUM	Validated trade name used	Oral	
1001678124	10016781	17	Concomitant	ASPIRIN	ASPIRIN	Validated trade name used	Oral	UNK
1001678124	10016781	18	Concomitant	BUPROPION	BUPROPION	Validated trade name used	Oral	UNK
1001678124	10016781	19	Concomitant	FERROUS SULFATE	FERROUS SULFATE	Validated trade name used	Oral	UNK
1001678124	10016781	20	Concomitant	CALCIUM	CALCIUM	Validated trade name used	Oral	UNK
1001678124	10016781	21	Concomitant	ABILIFY	ARIPIPRAZOLE	Validated trade name used	Unknown	UNK
1002130539	10021305	1	Primary Suspect Drug	SANDOSTATIN	OCTREOTIDE ACETATE	Validated trade name used	Subcutaneous	50 ug (test dose)



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.		Positive dechallenge					.	.		
.		Unknown					.	.		
.		Positive dechallenge					.	.		
.		Unknown					.	.		
.		Unknown					.	.		
.		Unknown					.	.		
.		Unknown					.	.		
.		Unknown					.	.		
.		Unknown					.	.		
.		Does not apply				19667	50	Microgram(s) (µg)		

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
1002130539	10021305	2	Secondary Suspect Drug	SANDOSTATIN	OCTREOTIDE ACETATE	Validated trade name used		
1002130539	10021305	3	Secondary Suspect Drug	SANDOSTATIN	OCTREOTIDE ACETATE	Validated trade name used		
1002130539	10021305	4	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, QMO (every 4 weeks)
1002130539	10021305	5	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, QMO (every 4 weeks)
1002130539	10021305	6	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, Q4W
1002130539	10021305	7	Concomitant	FRAGMIN	DALTEPARIN SODIUM	Validated trade name used	Subcutaneous	1 ml, QD
100293662	10029366	1	Primary Suspect Drug	CYCLOSPORINE	CYCLOSPORINE	Validated trade name used	Unknown	UNK
100293662	10029366	2	Secondary Suspect Drug	CYCLOSPORINE	CYCLOSPORINE	Validated trade name used		
100293662	10029366	3	Secondary Suspect Drug	BASILIXIMAB	BASILIXIMAB	Validated trade name used	Unknown	UNK
100293662	10029366	4	Secondary Suspect Drug	BASILIXIMAB	BASILIXIMAB	Validated trade name used		
100293662	10029366	5	Secondary Suspect Drug	PREDNISOLONE	PREDNISOLONE	Validated trade name used	Oral	UNK

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.		Does not apply				19667	.			
.		Does not apply				19667	.			
.						19667	30	Milligram(s)		/MONTH
.						19667	30	Milligram(s)		/MONTH
.						19667	30	Milligram(s)		
.						.	1	Millilitre(s)		Daily
.		Positive dechallenge				50574	.			
.		Positive dechallenge				50574	.			
.		Unknown				.	.			
.		Unknown				.	.			
.		Unknown				.	.			

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
100293662	10029366	6	Secondary Suspect Drug	PREDNISOLONE	PREDNISOLONE	Validated trade name used		
100293662	10029366	7	Secondary Suspect Drug	MYCOPHENOLATE MOFETIL	MYCOPHENOLATE MOFETIL	Validated trade name used	Unknown	UNK
100293662	10029366	8	Secondary Suspect Drug	MYCOPHENOLATE MOFETIL	MYCOPHENOLATE MOFETIL	Validated trade name used		
100356167	10035616	1	Primary Suspect Drug	DABIGATRAN ETEXILATE MESYLATE	DABIGATRAN ETEXILATE MESYLATE	Validated trade name used	Oral	
100356167	10035616	2	Concomitant	CARVEDILOL	CARVEDILOL	Validated trade name used	Oral	
100356167	10035616	3	Concomitant	ENALAPRIL	ENALAPRIL	Validated trade name used	Oral	
100356167	10035616	4	Concomitant	PILSICAINIDE HYDROCHLORIDE	PILSICAINIDE HYDROCHLORIDE	Validated trade name used	Oral	
100356167	10035616	5	Concomitant	ADALAT	NIFEDIPINE	Validated trade name used	Oral	
100356167	10035616	6	Concomitant	SPIRONOLACTONE	SPIRONOLACTONE	Validated trade name used	Oral	
100356167	10035616	7	Concomitant	AMMONIUM GLYCYRRHIZATE	AMMONIUM GLYCYRRHIZATE	Validated trade name used	Oral	
100356167	10035616	8	Concomitant	URSO	URSODIOL	Validated trade name used	Oral	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.		Unknown					.	.		
.		Unknown					.	.		
.		Unknown					.	.		
.		Does not apply		Unknown		22512	75	Milligram(s)	Capsule	Every 12 hours
.		Does not apply				.	10	Milligram(s)		
.		Positive dechallenge				.	5	Milligram(s)		
.		Positive dechallenge				.	50	Milligram(s)		Every 12 hours
.		Positive dechallenge				.	20	Milligram(s)		
.		Positive dechallenge				.	25	Milligram(s)		
.		Positive dechallenge				.	.	.	Tablet	Every 8 hours
.		Positive dechallenge				.	50	Milligram(s)		Every 8 hours

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
1006401878	10064018	1	Primary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	Unknown dose?Received outside RPAP, clinical research. No details provided, batch/lot not included
1006401878	10064018	2	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	1st RPAP dose
1006401878	10064018	3	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	Though PIRs were received, batch/lot numbers were not provided.
1006401878	10064018	4	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1006401878	10064018	5	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	Received outside RPAP, dosing and frequency not available
1006401878	10064018	6	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	Though PIRs were received
1006401878	10064018	7	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1006401878	10064018	8	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1006401878	10064018	9	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1006401878	10064018	10	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	.		Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	570.4	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	560	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	616	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	.		Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	568	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	576	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	584	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	560	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	600	Milligram(s)	Infusion, Solution	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
1006401878	10064018	11	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	Though PIRs were received, batch/lot numbers were not provided.
1006401878	10064018	12	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1006401878	10064018	13	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1006401878	10064018	14	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1006401878	10064018	15	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1006401878	10064018	16	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1006401878	10064018	17	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1006401878	10064018	18	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1006401878	10064018	19	Secondary Suspect Drug	METHOTREXATE	METHOTREXATE	Validated trade name used	Unknown	
1006401878	10064018	20	Secondary Suspect Drug	CELEBREX	CELECOXIB	Validated trade name used	Unknown	



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	571	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	616	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	640	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	648	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	640	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	632	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	640	Milligram(s)	Infusion, Solution	
.		Unknown		B20282,B20172,B20343,B20162,B20213,		125276	632	Milligram(s)	Infusion, Solution	
.		Does not apply		UNKNOWN		.	.			
.		Unknown		UNKNOWN		.	.		Foam	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
1006401878	10064018	21	Concomitant	FOLIC ACID	FOLIC ACID	Validated trade name used		
1006401878	10064018	22	Concomitant	HYDROCHLOROTHIAZIDE	HYDROCHLOROTHIAZIDE	Validated trade name used		
1006401878	10064018	23	Concomitant	DICLOFENAC	DICLOFENAC	Validated trade name used		
1006401878	10064018	24	Concomitant	CRESTOR	ROSUVASTATIN CALCIUM	Validated trade name used		
1006401878	10064018	25	Concomitant	PLAVIX	CLOPIDOGREL BISULFATE	Validated trade name used		
1006401878	10064018	26	Concomitant	ASPIRIN	ASPIRIN	Validated trade name used		
1006401878	10064018	27	Concomitant	NITROGLYCERIN	NITROGLYCERIN	Validated trade name used		
1006401878	10064018	28	Concomitant	LOPRESSOR	METOPROLOL TARTRATE	Validated trade name used		
1006401878	10064018	29	Concomitant	METAMUCIL	PLANTAGO SEED	Validated trade name used		
1006401878	10064018	30	Concomitant	METOPROLOL	METOPROLOL	Validated trade name used		

[illegible]

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
1006401878	10064018	31	Concomitant	CLONAZEPAM	CLONAZEPAM	Validated trade name used		
1006401878	10064018	32	Concomitant	FOLIC ACID	FOLIC ACID	Validated trade name used		
1007468610	10074686	1	Primary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	
1007468610	10074686	2	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	
1007468610	10074686	3	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	
1007468610	10074686	4	Concomitant	ALVESCO	CICLESONIDE	Validated trade name used	Respiratory (inhalation)	2 dosage form, BID
1007468610	10074686	5	Concomitant	SPIRIVA	TIOTROPIUM BROMIDE MONOHYDRATE	Validated trade name used	Respiratory (inhalation)	1 dosage form, QD
1007468610	10074686	6	Concomitant	SYMBICORT	BUDESONIDE\FORMOTEROL FUMARATE DIHYDRATE	Validated trade name used	Respiratory (inhalation)	2 dosage form, BID (200 ug, budesonide, 6 ug, formoterol fumarate
1007468610	10074686	7	Concomitant	ALBUTEROL	ALBUTEROL	Validated trade name used		(4 puffs)
1007468610	10074686	8	Concomitant	VENTOLIN	ALBUTEROL SULFATE	Validated trade name used		2 dosage form, PRN

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.	.	.	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	.	.	.
.	.	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN	.	103976	225	Milligram(s)	INJECTION, SOLUTION	Every other week	.
.	.	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN	.	103976	225	Milligram(s)	INJECTION, SOLUTION	Every other week	.
.	.	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN	.	103976	225	Milligram(s)	INJECTION, SOLUTION	Every other week	.
.	.	.	.	.	.	.	.	.	.	Twice a day
.	.	Unknown	.	.	.	.	.	.	.	Daily
.	.	Unknown	.	.	.	.	.	.	.	Twice a day
.	.	Unknown	UNKNOWN	.	.	.	.	.	.	.
.	.	Unknown	UNKNOWN,UNKNOWN,UNKNOWN	.	.	.	.	.	.	.

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
1007468610	10074686	9	Concomitant	VENTOLIN	ALBUTEROL SULFATE	Validated trade name used		(2 puffs at 6 a3) }24 hours prior to testing
1007468610	10074686	10	Concomitant	VENTOLIN	ALBUTEROL SULFATE	Validated trade name used		(2 puffs at 6 a3) greater than 24 hours prior to testing
100764782	10076478	1	Primary Suspect Drug	LEVETIRACETAM	LEVETIRACETAM	Validated trade name used		500 milligram, Once Daily (qd)
1008408132	10084081	1	Primary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, QMO (every 4 weeks)
1008408132	10084081	2	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	60 mg, QMO (every 4 weeks)
1008408132	10084081	3	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, QMO (every 4 weeks)
1008408132	10084081	4	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Unknown	UNK
1008408132	10084081	5	Concomitant	JARDIANCE	EMPAGLIFLOZIN	Validated trade name used	Oral	25 mg, QD
1008408132	10084081	6	Concomitant	PERINDOPRIL	PERINDOPRIL	Validated trade name used	Oral	8 mg
1008408132	10084081	7	Concomitant	ROSUVASTATIN	ROSUVASTATIN	Validated trade name used	Oral	20 mg

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.		Unknown		UNKNOWN,UNKNOWN,UNKNOWN			.	.		Daily
.		Unknown		UNKNOWN,UNKNOWN,UNKNOWN			.	.		Daily
.		Unknown	Unknown				.	500	Milligram(s)	Daily
.		Positive dechallenge				21008	30	Milligram(s)		/MONTH
.		Positive dechallenge				21008	60	Milligram(s)		/MONTH
.		Positive dechallenge		S0091, 350475		21008	30	Milligram(s)		/MONTH
.		Positive dechallenge				21008	.			
.		Unknown					.	25	Milligram(s)	Daily
.		Unknown					.	8	Milligram(s)	
.		Unknown					.	20	Milligram(s)	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
100941024	10094102	1	Primary Suspect Drug	LEVETIRACETAM	LEVETIRACETAM	Validated trade name used		500 milligram, qd (IN THE FIRST TRIMESTER)
1009418019	10094180	1	Primary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	8 mg/kg
1009418019	10094180	2	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1009418019	10094180	3	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1009418019	10094180	4	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1009418019	10094180	5	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
1009418019	10094180	6	Secondary Suspect Drug	RITUXAN	RITUXIMAB	Validated trade name used	Intravenous (not otherwise specified)	Most recent dose of infusion was received on 02/May/2013
1009418019	10094180	7	Secondary Suspect Drug	METHOTREXATE	METHOTREXATE	Validated trade name used	Unknown	
1009418019	10094180	8	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Subcutaneous	
1009418019	10094180	9	Concomitant	NAPROXEN	NAPROXEN	Validated trade name used		



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.		Unknown				90843	500	Milligram(s)		
.		Positive dechallenge		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125276	460	Milligram(s)	Infusion, Solution	
.		Positive dechallenge		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125276	480	Milligram(s)	Infusion, Solution	
.		Positive dechallenge		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125276	560	Milligram(s)	Infusion, Solution	
.		Positive dechallenge		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125276	360	Milligram(s)	Infusion, Solution	Every other week
.		Positive dechallenge		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125276	360	Milligram(s)	Infusion, Solution	
.		Unknown		ASKED BUT UNKNOWN		103705	1000	Milligram(s)	Infusion, Solution	
.		Unknown		UNKNOWN		.	.			
.		Unknown		ASKED BUT UNKNOWN		125472	162	Milligram(s)	Pre-filled syringe	/WK
.						.	.			

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1009418019	10094180	10	Concomitant	TYLENOL	ACETAMINOPHEN	Validated trade name used			.
1009418019	10094180	11	Concomitant	FOSAMAX	ALENDRONATE SODIUM	Validated trade name used			.
1009418019	10094180	12	Concomitant	ANAKINRA	ANAKINRA	Validated trade name used			.
1009418019	10094180	13	Concomitant	OMEPRAZOLE	OMEPRAZOLE	Validated trade name used			.
1009418019	10094180	14	Concomitant	VALACYCLOVIR	VALACYCLOVIR HYDROCHLORIDE	Validated trade name used		2 week course	.
1009418019	10094180	15	Concomitant	PERCOCET	ACETAMINOPHEN\OXYCODONE HYDROCHLORIDE	Validated trade name used			.
1009418019	10094180	16	Concomitant	CYCLOSPORINE	CYCLOSPORINE	Validated trade name used			.
1009418019	10094180	17	Concomitant	FOLIC ACID	FOLIC ACID	Validated trade name used			.
1009418019	10094180	18	Concomitant	PREDNISONE	PREDNISONE	Validated trade name used			.
1014222251	10142222	1	Primary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1014222251	10142222	2	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.

Cumulative dose to first reaction unit C	Dechallenge code, indicating if reaction	Rechallenge code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported).	NDA number.	Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
					.	.			
					.	.			
					.	.			
					.	.			
					.	.			
					.	.			
					.	.			
					.	.			
			B2052,B2035,B2059,B2039,B2041,B206,		125276	350	Milligram(s)	Infusion, Solution	
			B2052,B2035,B2059,B2039,B2041,B206,		125276	552	Milligram(s)	Infusion, Solution	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1014222251	10142222	3	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1014222251	10142222	4	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1014222251	10142222	5	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1014222251	10142222	6	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1014222251	10142222	7	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	On hold	.
1014222251	10142222	8	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1014222251	10142222	9	Concomitant	ZOPICLONE	ZOPICLONE	Validated trade name used		AT BED TIME	.
1014222251	10142222	10	Concomitant	MELOXICAM	MELOXICAM	Validated trade name used			.
1014222251	10142222	11	Concomitant	LYRICA	PREGABALIN	Validated trade name used			.
1014222251	10142222	12	Concomitant	TEGRETOL	CARBAMAZEPINE	Validated trade name used			.
1014222251	10142222	13	Concomitant	ROSUVASTATIN	ROSUVASTATIN	Validated trade name used			.

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
			B2052,B2035,B2059,B2039,B2041,B206,		125276	522	Milligram(s)	Infusion, Solution	
			B2052,B2035,B2059,B2039,B2041,B206,		125276	752	Milligram(s)	Infusion, Solution	
			B2052,B2035,B2059,B2039,B2041,B206,		125276	.		Infusion, Solution	
			B2052,B2035,B2059,B2039,B2041,B206,		125276	752	Milligram(s)	Infusion, Solution	
			B2052,B2035,B2059,B2039,B2041,B206,		125276	720	Milligram(s)	Infusion, Solution	
			B2052,B2035,B2059,B2039,B2041,B206,		125276	.		Infusion, Solution	
					.	7.5	Milligram(s)		Daily
					.	.			
					.	.			
					.	.			
					.	.			
					.	20	Milligram(s)		Daily

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1014222251	10142222	14	Concomitant	PREGABALIN	PREGABALIN	Validated trade name used			.
1014222251	10142222	15	Concomitant	HYDROXYCHLOROQUINE	HYDROXYCHLOROQUINE	Validated trade name used			.
1014222251	10142222	16	Concomitant	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used		Uncertain if it is twice a day as per physician	.
1014222251	10142222	17	Concomitant	PANTOPRAZOLE SODIUM	PANTOPRAZOLE SODIUM	Validated trade name used			.
1014222251	10142222	18	Concomitant	ADVAIR HFA	FLUTICASONE PROPIONATE\SALMETEROL XINAFOATE	Validated trade name used			.
1014222251	10142222	19	Concomitant	ATROVENT	IPRATROPIUM BROMIDE	Validated trade name used			.
1014222251	10142222	20	Concomitant	PREDNISONE	PREDNISONE	Validated trade name used			.
1014222251	10142222	21	Concomitant	PREDNISONE	PREDNISONE	Validated trade name used			.
1014222251	10142222	22	Concomitant	ATROVENT	IPRATROPIUM BROMIDE	Validated trade name used			.
1014222251	10142222	23	Concomitant	CRESTOR	ROSUVASTATIN CALCIUM	Validated trade name used			.

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Cumulative dose to first reaction unit C	Dechallenge code, indicating if reaction	Rechallenge code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported).	NDA number.	Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
					.	150	Milligram(s)		Daily
					.	200	Milligram(s)		Daily
					.	60	Milligram(s)		
					.	40	Milligram(s)		Daily
					.	.			
					.	.			
					.	7.5	Milligram(s)		
					.	5	Milligram(s)		Daily
					.	.			
					.	.			

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1014222251	10142222	24	Concomitant	LEVETIRACETAM	LEVETIRACETAM	Validated trade name used			.
1014222251	10142222	25	Concomitant	PLAQUENIL	HYDROXYCHLOROQUINE SULFATE	Validated trade name used			.
1014222251	10142222	26	Concomitant	SULFASALAZINE	SULFASALAZINE	Validated trade name used			.
1014222251	10142222	27	Concomitant	MELOXICAM	MELOXICAM	Validated trade name used			.
1014222251	10142222	28	Concomitant	XARELTO	RIVAROXABAN	Validated trade name used			.
101451672	10145167	1	Primary Suspect Drug	ENBREL	ETANERCEPT	Validated trade name used	Unknown	50 milligram, qwk	.
1015212331	10152123	1	Primary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1015212331	10152123	2	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1015212331	10152123	3	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1015212331	10152123	4	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1015212331	10152123	5	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
						.	.		
						.	.		
						.	.		
						.	.		
						.	.		
						.	15	Milligram(s)	Twice a day
			1044814		103795	50	Milligram(s)	Solution for injection	/WK
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	300	Milligram(s)	INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	.		INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	.		INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	.		INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	.		INJECTION, SOLUTION	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1015212331	10152123	6	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	7	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	8	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	9	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	10	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	11	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	12	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	13	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	14	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	15	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	16	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Unknown	.	.

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	.		INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	300	Milligram(s)	INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	300	Milligram(s)	INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	300	Milligram(s)	INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	300	Milligram(s)	INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	300	Milligram(s)	INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	300	Milligram(s)	INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	300	Milligram(s)	INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	300	Milligram(s)	INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	300	Milligram(s)	INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	.		INJECTION, SOLUTION	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1015212331	10152123	17	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	18	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1015212331	10152123	19	Secondary Suspect Drug	COSENTYX	SECUKINUMAB	Validated trade name used	Unknown	.	.
1015212331	10152123	20	Concomitant	ADVAIR HFA	FLUTICASONE PROPIONATE\SALMETEROL XINAFOATE	Validated trade name used	Unknown	1 DF (500/50)	.
1015212331	10152123	21	Concomitant	ADVAIR HFA	FLUTICASONE PROPIONATE\SALMETEROL XINAFOATE	Validated trade name used	Unknown	1 DF, QD	.
1015212331	10152123	22	Concomitant	ADVAIR HFA	FLUTICASONE PROPIONATE\SALMETEROL XINAFOATE	Validated trade name used	Unknown	1 DF, BID	.
1015212331	10152123	23	Concomitant	OMNARIS	CICLESONIDE	Validated trade name used	Nasal	2 DF, each nostril	.
1015212331	10152123	24	Concomitant	ALVESCO	CICLESONIDE	Validated trade name used	Unknown	puff	.
1015212331	10152123	25	Concomitant	RABEPRAZOLE	RABEPRAZOLE	Validated trade name used	Oral	.	.
1015212331	10152123	26	Concomitant	RANITIDINE	RANITIDINE	Validated trade name used	.	.	.

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	.		INJECTION, SOLUTION	
Unknown			SUR62,S0004,SE068,SAD52,SEJ08,SJY86		103976	300	Milligram(s)	INJECTION, SOLUTION	
Unknown			UNKNOWN		.	.			
			UNKNOWN		.	.			Twice a day
			UNKNOWN		.	.			Daily
			UNKNOWN		.	.			Twice a day
			UNKNOWN		.	.		SPRAY	
			UNKNOWN		.	.			Daily
					.	150	Milligram(s)		Twice a day
					.	.			

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1015212331	10152123	27	Concomitant	CETIRIZINE HYDROCHLORIDE	CETIRIZINE HYDROCHLORIDE	Validated trade name used	Oral	20 mg, UNK	.
1015212331	10152123	28	Concomitant	SINGULAIR	MONTELUKAST SODIUM	Validated trade name used	Oral	10 mg, daily	.
1015212331	10152123	29	Concomitant	ZOLOFT	SERTRALINE HYDROCHLORIDE	Validated trade name used	Oral	50 mg, QHS	.
1015212331	10152123	30	Concomitant	BENADRYL	DIPHENHYDRAMINE HYDROCHLORIDE	Validated trade name used	Oral	2 DF, OTHER	.
101621574	10162157	1	Primary Suspect Drug	AFLIBERCEPT	AFLIBERCEPT	Validated trade name used	Intravenous drip	234 mg,QCY	.
101621574	10162157	2	Secondary Suspect Drug	FLUOROURACIL	FLUOROURACIL	Validated trade name used	Intravenous bolus	660 mg,QCY	.
101621574	10162157	3	Secondary Suspect Drug	FLUOROURACIL	FLUOROURACIL	Validated trade name used	Intravenous drip	3960 mg,QCY	.
101621574	10162157	4	Secondary Suspect Drug	IRINOTECAN	IRINOTECAN	Validated trade name used	Intravenous drip	300 mg,QCY	.
101621574	10162157	5	Secondary Suspect Drug	LEUCOVORIN	LEUCOVORIN\LEUCOVORIN CALCIUM	Validated trade name used	Intravenous drip	660 mg,QCY	.
101621574	10162157	6	Concomitant	TYLENOL	ACETAMINOPHEN	Validated trade name used		UNK	.

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
			UNKNOWN		.	20	Milligram(s)		
			UNKNOWN		.	10	Milligram(s)		Daily
			UNKNOWN		.	50	Milligram(s)		
			UNKNOWN		.	.			
					125418	234	Milligram(s)	Solution for infusion	/CYCLE
					.	660	Milligram(s)	Solution for infusion	/CYCLE
					.	3960	Milligram(s)	Solution for infusion	/CYCLE
					.	300	Milligram(s)	Concentrate for solution for infusion	/CYCLE
					.	660	Milligram(s)	Solution for infusion	/CYCLE
Unknown					.	.			

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
101621574	10162157	7	Concomitant	CALCIUM CHLORIDE\POTASSIUM CHLORIDE\SODIUM CHLORIDE	CALCIUM CHLORIDE\POTASSIUM CHLORIDE\SODIUM CHLORIDE	Validated trade name used		UNK	.
1016611037	10166110	1	Primary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1016611037	10166110	2	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1016611037	10166110	3	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1016611037	10166110	4	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1016611037	10166110	5	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	UNK	.
1016611037	10166110	6	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	UNK	.
1016611037	10166110	7	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	UNK	.
1016611037	10166110	8	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	UNK	.
1016611037	10166110	9	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Unknown						.	.		
Unknown			ASKED BUT UNKNOWN,SN262,SAD52,SLL42		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
Unknown			ASKED BUT UNKNOWN,SN262,SAD52,SLL42		103976	75	Milligram(s)	INJECTION, SOLUTION	
Unknown			ASKED BUT UNKNOWN,SN262,SAD52,SLL42		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
Unknown			ASKED BUT UNKNOWN,SN262,SAD52,SLL42		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
Unknown			ASKED BUT UNKNOWN,SN262,SAD52,SLL42		103976	.		INJECTION, SOLUTION	
Unknown			ASKED BUT UNKNOWN,SN262,SAD52,SLL42		103976	.		INJECTION, SOLUTION	
Unknown			ASKED BUT UNKNOWN,SN262,SAD52,SLL42		103976	.		INJECTION, SOLUTION	
Unknown			ASKED BUT UNKNOWN,SN262,SAD52,SLL42		103976	.		INJECTION, SOLUTION	
Unknown			ASKED BUT UNKNOWN,SN262,SAD52,SLL42		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>
1016611037	10166110	10	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used
1016611037	10166110	11	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used
1016611037	10166110	12	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used
1016611037	10166110	13	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used
1016611037	10166110	14	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used
1016611037	10166110	15	Secondary Suspect Drug	PREDNISONE	PREDNISONE	Validated trade name used
1016611037	10166110	16	Secondary Suspect Drug	PREDNISONE	PREDNISONE	Validated trade name used
1016611037	10166110	17	Secondary Suspect Drug	PREDNISONE	PREDNISONE	Validated trade name used
1016611037	10166110	18	Secondary Suspect Drug	PREDNISONE	PREDNISONE	Validated trade name used
1016611037	10166110	19	Concomitant	ADVAIR HFA	FLUTICASONE PROPIONATE\SALMETEROL XINAFOATE	Validated trade name used
1016611037	10166110	20	Concomitant	LOSEC	OMEPRAZOLE	Validated trade name used
1016611037	10166110	21	Concomitant	ALVESCO	CICLESONIDE	Validated trade name used
1016611037	10166110	22	Concomitant	ALVESCO	CICLESONIDE	Validated trade name used
1016611037	10166110	23	Concomitant	VENTOLIN	ALBUTEROL SULFATE	Validated trade name used
1016611037	10166110	24	Concomitant	METERGOLINE	METERGOLINE	Validated trade name used

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

The route of drug administration	Verbatim text for dose, frequency, and r	Cumulative dose to first reaction	Cumulative dose to first reaction unit C	Dechallenge code, indicating if reaction	Rechallenge code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported).
Subcutaneous		.		Unknown		ASKED BUT UNKNOWN,SN262,SAD52,SLL42	
Subcutaneous		.		Unknown		ASKED BUT UNKNOWN,SN262,SAD52,SLL42	
Subcutaneous		.		Unknown		ASKED BUT UNKNOWN,SN262,SAD52,SLL42	
Subcutaneous		.		Unknown		ASKED BUT UNKNOWN,SN262,SAD52,SLL42	
Subcutaneous		.		Unknown		ASKED BUT UNKNOWN,SN262,SAD52,SLL42	
Unknown		.		Positive dechallenge		UNKNOWN,UNKNOWN,UNKNOWN,UNKNOWN	
Unknown		.		Positive dechallenge		UNKNOWN,UNKNOWN,UNKNOWN,UNKNOWN	
Unknown	UNK	.		Positive dechallenge		UNKNOWN,UNKNOWN,UNKNOWN,UNKNOWN	
Unknown	(1 course for 3 weeks)	.		Positive dechallenge		UNKNOWN,UNKNOWN,UNKNOWN,UNKNOWN	
Unknown	250 OT, UNK	.					
Unknown		.					
Unknown		.					
Unknown		.					
Unknown	200 ug	.		Unknown		UNKNOWN	
Unknown	UNK	.		Unknown		UNKNOWN	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
103976	.		INJECTION, SOLUTION	
103976	.		INJECTION, SOLUTION	
.	50	Milligram(s)		
.	25	Milligram(s)		
.	.			
.	.			
.	.			
.	.			
.	100	Microgram(s) (µg)		
.	.			
.	200	Microgram(s) (µg)		
.	.			

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>
1016611037	10166110	25	Concomitant	CLINDAMYCIN	CLINDAMYCIN	Validated trade name used
1016611037	10166110	26	Concomitant	ATROVENT	IPRATROPIUM BROMIDE	Validated trade name used
101676303	10167630	1	Primary Suspect Drug	EFAVIRENZ	EFAVIRENZ	Validated trade name used
101676303	10167630	2	Concomitant	STAVUDINE	STAVUDINE	Validated trade name used
101676303	10167630	3	Concomitant	RIFAMPIN	RIFAMPIN	Validated trade name used
101676303	10167630	4	Concomitant	RIFAMPIN	RIFAMPIN	Validated trade name used
101676303	10167630	5	Concomitant	ETHAMBUTOL HYDROCHLORIDE	ETHAMBUTOL HYDROCHLORIDE	Validated trade name used
101676303	10167630	6	Concomitant	PYRAZINAMIDE	PYRAZINAMIDE	Validated trade name used
101676303	10167630	7	Concomitant	LAMIVUDINE	LAMIVUDINE	Validated trade name used
101676313	10167631	1	Primary Suspect Drug	EFAVIRENZ	EFAVIRENZ	Validated trade name used
101676313	10167631	2	Concomitant	STAVUDINE	STAVUDINE	Validated trade name used
101676313	10167631	3	Concomitant	RIFAMPIN	RIFAMPIN	Validated trade name used
101676313	10167631	4	Concomitant	ISONIAZID	ISONIAZID	Validated trade name used
101676313	10167631	5	Concomitant	ETHAMBUTOL HYDROCHLORIDE	ETHAMBUTOL HYDROCHLORIDE	Validated trade name used
101676313	10167631	6	Concomitant	PYRAZINAMIDE	PYRAZINAMIDE	Validated trade name used

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>
	UNK	.		Unknown		UNKNOWN	
Unknown		.					
Oral	600 mg, qd	.		Unknown	Unknown	Unknown	
	30 mg, UNK	.		Unknown			
		.		Unknown			
		.		Unknown			
		.		Unknown			
		.		Unknown			
	150 mg, UNK	.		Unknown			
Oral		.		Unknown		Unknown	
	30 mg, bid	.		Unknown			
	1DF:8-10 mg/kg/day	.		Unknown			
	1DF:4-5 mg/kg/day	.		Unknown			
	1Df:15-20 mg/kg/day	.		Unknown			
	1DF:20-30 mg/kg/day	.		Unknown			

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.	.			
.	20	Microgram(s) (µg)		
21360	600	Milligram(s)	Unknown	Daily
20412	30	Milligram(s)	Unknown	
.	.			
.	.		Unknown	
.	.			
.	.		Unknown	
.	150	Milligram(s)	Unknown	
20972	600	Milligram(s)	Film-coated tablet	Daily
20412	30	Milligram(s)		
.	.			
.	.			
.	.			
.	.			

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>
101676313	10167631	7	Concomitant	LAMIVUDINE	LAMIVUDINE	Validated trade name used
101678657	10167865	1	Primary Suspect Drug	BELIMUMAB	BELIMUMAB	Validated trade name used
101678657	10167865	2	Concomitant	PREDNISONE	PREDNISONE	Validated trade name used
101678657	10167865	3	Concomitant	NEUPOGEN	FILGRASTIM	Validated trade name used
101678657	10167865	4	Concomitant	NEUPOGEN	FILGRASTIM	Validated trade name used
101678657	10167865	5	Concomitant	NEUPOGEN	FILGRASTIM	Validated trade name used
101678657	10167865	6	Concomitant	NEUPOGEN	FILGRASTIM	Validated trade name used
101678657	10167865	7	Concomitant	NEUPOGEN	FILGRASTIM	Validated trade name used
101678657	10167865	8	Concomitant	VANCOMYCIN	VANCOMYCIN	Validated trade name used
101678657	10167865	9	Concomitant	VANCOMYCIN	VANCOMYCIN	Validated trade name used
101678657	10167865	10	Concomitant	VANCOMYCIN	VANCOMYCIN	Validated trade name used
101678657	10167865	11	Concomitant	VANCOMYCIN	VANCOMYCIN	Validated trade name used
101678657	10167865	12	Concomitant	FLAGYL	METRONIDAZOLE\METRONIDAZOLE HYDROCHLORIDE	Validated trade name used
101678657	10167865	13	Concomitant	FLAGYL	METRONIDAZOLE\METRONIDAZOLE HYDROCHLORIDE	Validated trade name used
101678657	10167865	14	Concomitant	FLAGYL	METRONIDAZOLE\METRONIDAZOLE HYDROCHLORIDE	Validated trade name used



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>
	150 mg, UNK	.		Unknown			
Intravenous (not otherwise specified)	10 mg/kg, CYC	.		Does not apply			
Oral	5 mg, qd	.		Unknown			
Subcutaneous	300 ug, qd	8040	Microgram(s) (µg)	Unknown			
Subcutaneous	300 ug, qd	8040	Microgram(s) (µg)	Unknown			
Subcutaneous	480 ug, qd	8040	Microgram(s) (µg)	Unknown			
Subcutaneous	300 ug, bid	8040	Microgram(s) (µg)	Unknown			
Subcutaneous	480 ug, qd	8040	Microgram(s) (µg)	Unknown			
Intravenous (not otherwise specified)	1 g, bid	.		Unknown			
Intravenous (not otherwise specified)	1 g, bid	.		Unknown			
Intravenous (not otherwise specified)	750 mg, bid	.		Unknown			
Intravenous (not otherwise specified)	125 mg, qid	.		Unknown			
Intravenous (not otherwise specified)	500 mg, tid	9000	Milligram(s)	Unknown			
Intravenous (not otherwise specified)	500 UNK	9000	Milligram(s)	Unknown			
Intravenous (not otherwise specified)	500 mg, tid	9000	Milligram(s)	Unknown			

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.	150	Milligram(s)		
125	10	Milligram(s)/Kilogram	Powder for infusion	
.	5	Milligram(s)		Daily
.	300	Microgram(s) (µg)		Daily
.	300	Microgram(s) (µg)		Daily
.	480	Microgram(s) (µg)		Daily
.	300	Microgram(s) (µg)		Every 12 hours
.	480	Microgram(s) (µg)		Daily
.	1	Gram(s)		Every 12 hours
.	1	Gram(s)		Every 12 hours
.	750	Milligram(s)		Every 12 hours
.	125	Milligram(s)		Every 6 hours
.	500	Milligram(s)		Every 8 hours
.	500	Milligram(s)		Every 8 hours
.	500	Milligram(s)		Every 8 hours

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

Unique number for identifying a FAERS re	Number for identifying a FAERS case.	Unique number for identifying a drug for	Code for drug's reported role in event.	Name of medicinal product.	Product Active Ingredient.	Code for source of DRUGNAME.	The route of drug administration	Verbatim text for dose, frequency, and r	Cumulative dose to first reaction
101678657	10167865	15	Concomitant	VORICONAZOLE	VORICONAZOLE	Validated trade name used	Intravenous (not otherwise specified)	250 mg, bid	14500
1017130214	10171302	1	Primary Suspect Drug	XELJANZ	TOFACITINIB CITRATE	Validated trade name used		5 mg, 2x/day	.
1017130214	10171302	2	Secondary Suspect Drug	XELJANZ	TOFACITINIB CITRATE	Validated trade name used		5 mg, 1x/day	.
1017572232	10175722	1	Primary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1017572232	10175722	2	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1017572232	10175722	3	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1017572232	10175722	4	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1017572232	10175722	5	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1017572232	10175722	6	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1017572232	10175722	7	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1017572232	10175722	8	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Cumulative dose to first reaction unit C	Dechallenge code, indicating if reaction	Rechallenge code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported).	NDA number.	Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
Milligram(s)	Unknown					250	Milligram(s)		Every 12 hours
					203214	5	Milligram(s)	Tablet	Twice a day
					203214	5	Milligram(s)	Tablet	Daily
	Positive dechallenge		B20141,B20071,B20262,B20152,B20071,		125276	228	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20141,B20071,B20262,B20152,B20071,		125276	456	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20141,B20071,B20262,B20152,B20071,		125276	436	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20141,B20071,B20262,B20152,B20071,		125276	440	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20141,B20071,B20262,B20152,B20071,		125276	456	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20141,B20071,B20262,B20152,B20071,		125276	220	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20141,B20071,B20262,B20152,B20071,		125276	400	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20141,B20071,B20262,B20152,B20071,		125276	440	Milligram(s)	Infusion, Solution	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1017572232	10175722	9	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1017572232	10175722	10	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1017572232	10175722	11	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1017572232	10175722	12	Concomitant	FOLIC ACID	FOLIC ACID	Validated trade name used			.
1017572232	10175722	13	Concomitant	RAMIPRIL	RAMIPRIL	Validated trade name used			.
1017572232	10175722	14	Concomitant	CRESTOR	ROSUVASTATIN CALCIUM	Validated trade name used			.
1017572232	10175722	15	Concomitant	METHOTREXATE	METHOTREXATE	Validated trade name used			.
1017572232	10175722	16	Concomitant	HYDROXYCHLOROQUINE	HYDROXYCHLOROQUINE	Validated trade name used			.
1017572232	10175722	17	Concomitant	CALCIUM	CALCIUM	Validated trade name used			.
1017572232	10175722	18	Concomitant	METFORMIN	METFORMIN HYDROCHLORIDE	Validated trade name used			.
101780773	10178077	1	Primary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Cumulative dose to first reaction unit C	Dechallenge code, indicating if reaction	Rechallenge code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported).	NDA number.	Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
	Positive dechallenge		B20141,B20071,B20262,B20152,B20071,		125276	400	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20141,B20071,B20262,B20152,B20071,		125276	400	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20141,B20071,B20262,B20152,B20071,		125276	.		Infusion, Solution	
					.	.			
					.	.			
					.	.			
					.	.			
					.	.			
					.	.			
					.	.			
					.	.		Tablet	
	Unknown		ASKED BUT UNKNOWN		125276	.		Infusion, Solution	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
101780773	10178077	2	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Subcutaneous	.	
101780773	10178077	3	Concomitant	AMITRIPTYLINE	AMITRIPTYLINE	Validated trade name used		.	
101780773	10178077	4	Concomitant	ESTROGENS	ESTROGENS	Validated trade name used		.	
101780773	10178077	5	Concomitant	PLAQUENIL	HYDROXYCHLOROQUINE SULFATE	Validated trade name used		.	
101780773	10178077	6	Concomitant	PROGESTERONE	PROGESTERONE	Validated trade name used		.	
101780773	10178077	7	Concomitant	ERGOCALCIFEROL	ERGOCALCIFEROL	Validated trade name used		.	
101916392	10191639	1	Primary Suspect Drug	VALPROATE SODIUM	VALPROATE SODIUM	Validated trade name used	Unknown	.	
101916392	10191639	2	Secondary Suspect Drug	VALPROATE SODIUM	VALPROATE SODIUM	Validated trade name used	Unknown	.	
101916392	10191639	3	Secondary Suspect Drug	VALPROATE SODIUM	VALPROATE SODIUM	Validated trade name used	Unknown	.	
101916392	10191639	4	Secondary Suspect Drug	RISPERIDONE	RISPERIDONE	Validated trade name used	Unknown	.	
101916392	10191639	5	Secondary Suspect Drug	RISPERIDONE	RISPERIDONE	Validated trade name used	Unknown	.	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
	Unknown		ASKED BUT UNKNOWN		125472	162	Milligram(s)	Pre-filled syringe	Every other week
					.	.			
					.	.		Gel	
					.	.			
					.	.			
					.	.			
	Does not apply		Not Available		18723	400	Milligram(s)		Daily
	Does not apply		Not Available		18723	400	Milligram(s)		
	Does not apply		Not Available		18723	400	Milligram(s)		
	Positive dechallenge		Not Available		.	4	Milligram(s)		
	Positive dechallenge		Not Available		.	4	Milligram(s)		Daily



# ADVERSE EVENT REPORTING SYSTEM (AERS) Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
101916392	10191639	6	Secondary Suspect Drug	RISPERIDONE	RISPERIDONE	Validated trade name used	Unknown		.
101916392	10191639	7	Secondary Suspect Drug	RISPERIDONE	RISPERIDONE	Validated trade name used	Unknown	take at bedtime	.
101916392	10191639	8	Secondary Suspect Drug	LORAZEPAM	LORAZEPAM	Validated trade name used	Oral		.
101916392	10191639	9	Concomitant	HALOPERIDOL	HALOPERIDOL	Validated trade name used	Unknown		.
1020642923	10206429	1	Primary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	2	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	3	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	4	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	5	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	6	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	7	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.

[illegible]

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1020642923	10206429	8	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	9	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	10	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	11	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	12	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	13	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	14	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	15	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	16	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1020642923	10206429	17	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	UNK	.
1020642923	10206429	18	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	.		INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	.		INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	.		INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	.		INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	.		INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	.		INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	.		INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	.		INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	.		INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	.		INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	300	Milligram(s)	INJECTION, SOLUTION	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1020642923	10206429	19	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1020642923	10206429	20	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1020642923	10206429	21	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1020642923	10206429	22	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1020642923	10206429	23	Concomitant	PULMICORT TURBUHALER	BUDESONIDE	Validated trade name used	Unknown	UNK	.
1020642923	10206429	24	Concomitant	IBUPROFEN	IBUPROFEN	Validated trade name used	Unknown	UNK, QD	.
1020642923	10206429	25	Concomitant	BRICANYL	TERBUTALINE SULFATE	Validated trade name used	Unknown	UNK	.
1020642923	10206429	26	Concomitant	FORMOTEROL FUMARATE	FORMOTEROL FUMARATE	Validated trade name used	Unknown	2 dosage form, BID	.
1020642923	10206429	27	Concomitant	ZADITOR	KETOTIFEN FUMARATE	Validated trade name used	Unknown	1 dosage form, BID	.
1020642923	10206429	28	Concomitant	MONTELUKAST SODIUM	MONTELUKAST SODIUM	Validated trade name used		1 dosage form, QD	.
1020642923	10206429	29	Concomitant	ALVESCO	CICLESONIDE	Validated trade name used	Unknown		.

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Cumulative dose to first reaction unit C	Dechallenge code, indicating if reaction	Rechallenge code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported).	NDA number.	Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	300	Milligram(s)	INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	300	Milligram(s)	INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	300	Milligram(s)	INJECTION, SOLUTION	
			S0072F,S0004,SD875,SL043,ASKED BUT		103976	300	Milligram(s)	INJECTION, SOLUTION	
			UNKNOWN		.	.			
			UNKNOWN		.	.			Daily
			UNKNOWN		.	.			
			UNKNOWN		.	.			Twice a day
	Unknown		UNKNOWN		.	.			Daily
	Unknown		UNKNOWN		.	.			Daily
					.	6	Milligram(s)		

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1020642923	10206429	30	Concomitant	ALVESCO	CICLESONIDE	Validated trade name used	Unknown	.	.
1020642923	10206429	31	Concomitant	CROMOLYN SODIUM	CROMOLYN SODIUM	Validated trade name used		.	.
102371704	10237170	1	Primary Suspect Drug	VALPROATE SODIUM	VALPROATE SODIUM	Validated trade name used	Unknown	2000 mg	.
102371704	10237170	2	Secondary Suspect Drug	CLARITHROMYCIN	CLARITHROMYCIN	Validated trade name used	Other		.
102371704	10237170	3	Secondary Suspect Drug	LEVETIRACETAM	LEVETIRACETAM	Validated trade name used	Unknown		.
102371704	10237170	4	Secondary Suspect Drug	CELECOXIB	CELECOXIB	Validated trade name used	Unknown		.
102371704	10237170	5	Secondary Suspect Drug	PHENOBARBITAL	PHENOBARBITAL	Validated trade name used	Unknown	100 mg QD	.
102371704	10237170	6	Secondary Suspect Drug	AMOXICILLIN\CLAVULANIC ACID	AMOXICILLIN\CLAVULANIC ACID	Validated trade name used	Unknown		.
1027487983	10274879	1	Primary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1027487983	10274879	2	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1027487983	10274879	3	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	Clinical trial	.

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
					.	8	Milligram(s)		
	Positive dechallenge		Not available		18723	.			
	Positive dechallenge		Not available		50662	.			
	Positive dechallenge		Not available		.	500	Milligram(s)	Tablet	Every 12 hours
	Positive dechallenge		Not available		.	.			
	Unknown		Not available		.	.			
	Positive dechallenge		Not available		.	.			
		Unknown	B2055,B2058,B2059,B2060,B2062,B2063		125276	800	Milligram(s)	Infusion, Solution	
		Unknown	B2055,B2058,B2059,B2060,B2062,B2063		125276	800	Milligram(s)	Infusion, Solution	
		Unknown	B2055,B2058,B2059,B2060,B2062,B2063		125276	800	Milligram(s)	Infusion, Solution	



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1027487983	10274879	4	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	.	.
1027487983	10274879	5	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	.	.
1027487983	10274879	6	Concomitant	METHOTREXATE	METHOTREXATE	Validated trade name used		.	.
1027487983	10274879	7	Concomitant	FOLIC ACID	FOLIC ACID	Validated trade name used		.	.
1027487983	10274879	8	Concomitant	NEXIUM	ESOMEPRAZOLE MAGNESIUM	Validated trade name used		.	.
1027487983	10274879	9	Concomitant	PROCHLORPERAZINE	PROCHLORPERAZINE	Validated trade name used		.	.
1027487983	10274879	10	Concomitant	NAPROXEN	NAPROXEN	Validated trade name used		.	.
1028518546	10285185	1	Primary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	.	.
1028518546	10285185	2	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	.	.
1028518546	10285185	3	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	.	.
1028518546	10285185	4	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	.	.

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
		Unknown	B2055,B2058,B2059,B2060,B2062,B2063		125276	700	Milligram(s)	Infusion, Solution	
		Unknown	B2055,B2058,B2059,B2060,B2062,B2063		125276	800	Milligram(s)	Infusion, Solution	
					.	.			
					.	.			
					.	.			
					.	.			
					.	.			
	Positive dechallenge		B20262,B20142,B20152,B20303,B20383,		125276	632	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20262,B20142,B20152,B20303,B20383,		125276	675	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20262,B20142,B20152,B20303,B20383,		125276	507.6	Milligram(s)	Infusion, Solution	
	Positive dechallenge		B20262,B20142,B20152,B20303,B20383,		125276	407	Milligram(s)	Infusion, Solution	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1028518546	10285185	5	Secondary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1028518546	10285185	6	Secondary Suspect Drug	RITUXAN	RITUXIMAB	Validated trade name used	Intravenous drip	Day 1; 15	.
1028518546	10285185	7	Concomitant	PREVACID	LANSOPRAZOLE	Validated trade name used			.
1028518546	10285185	8	Concomitant	NAPROXEN	NAPROXEN	Validated trade name used			.
1028518546	10285185	9	Concomitant	SULFASALAZINE	SULFASALAZINE	Validated trade name used			.
1028518546	10285185	10	Concomitant	DIPHENHYDRAMINE	DIPHENHYDRAMINE	Validated trade name used	Oral		.
1028518546	10285185	11	Concomitant	ACETAMINOPHEN	ACETAMINOPHEN	Validated trade name used	Oral		.
1028518546	10285185	12	Concomitant	METHYLPREDNISOLONE	METHYLPREDNISOLONE	Validated trade name used	Intravenous (not otherwise specified)		.
1028518546	10285185	13	Concomitant	LEUCOVORIN	LEUCOVORIN LEUCOVORIN CALCIUM	Validated trade name used			.
1028518546	10285185	14	Concomitant	TYLENOL	ACETAMINOPHEN	Validated trade name used	Oral		.
1028518546	10285185	15	Concomitant	BENADRYL	DIPHENHYDRAMINE HYDROCHLORIDE	Validated trade name used	Oral		.

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Cumulative dose to first reaction unit C	Dechallenge code, indicating if reaction	Rechallenge code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported).	NDA number.	Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
	Positive dechallenge		B20262,B20142,B20152,B20303,B20383,		125276	.		Infusion, Solution	
			N7220,N7258,N7294,H0971,H0992,H0994		103705	1000	Milligram(s)	Infusion, Solution	Every other week
					.	.			
					.	.			
					.	.			
					.	50	Milligram(s)		
					.	650	Milligram(s)		
					.	100	Milligram(s)		
					.	.			
					.	650	Milligram(s)		
					.	50	Milligram(s)		

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1028518546	10285185	16	Concomitant	SOLU-MEDROL	METHYLPREDNISOLONE SODIUM SUCCINATE	Validated trade name used	Intravenous (not otherwise specified)		.
1028518546	10285185	17	Concomitant	METHOTREXATE	METHOTREXATE	Validated trade name used			.
1028518546	10285185	18	Concomitant	PANTOPRAZOLE SODIUM	PANTOPRAZOLE SODIUM	Validated trade name used			.
1030948614	10309486	1	Primary Suspect Drug	LUCENTIS	RANIBIZUMAB	Validated trade name used	Intraocular		.
1030948614	10309486	2	Secondary Suspect Drug	LUCENTIS	RANIBIZUMAB	Validated trade name used	Other		.
1030948614	10309486	3	Secondary Suspect Drug	LUCENTIS	RANIBIZUMAB	Validated trade name used	Unknown		.
1030948614	10309486	4	Secondary Suspect Drug	LUCENTIS	RANIBIZUMAB	Validated trade name used	Intraocular	UNK (solution intravitreal)	.
1030948614	10309486	5	Secondary Suspect Drug	LUCENTIS	RANIBIZUMAB	Validated trade name used	Intraocular	UNK (solution injection)	.
1030948614	10309486	6	Secondary Suspect Drug	AVASTIN	BEVACIZUMAB	Validated trade name used	Intraocular		.
1030948614	10309486	7	Secondary Suspect Drug	AVASTIN	BEVACIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.
1030948614	10309486	8	Secondary Suspect Drug	BEVACIZUMAB	BEVACIZUMAB	Validated trade name used	Intraocular		.

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Cumulative dose to first reaction unit C	Dechallenge code, indicating if reaction	Rechallenge code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported).	NDA number.	Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
						.	100	Milligram(s)	
						.	.		
						.	.		
	Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125156	.		INJECTION, SOLUTION	
	Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125156	.		INJECTION, SOLUTION	
	Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125156	.		INJECTION, SOLUTION	
	Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125156	.		INJECTION, SOLUTION	
	Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125156	.		INJECTION, SOLUTION	
	Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125085	.		Infusion, Solution	
	Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125085	.		Infusion, Solution	
	Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125085	.		Infusion, Solution	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
1030948614	10309486	9	Secondary Suspect Drug	BEVACIZUMAB	BEVACIZUMAB	Validated trade name used	Intravenous (not otherwise specified)	
103443973	10344397	1	Primary Suspect Drug	XGEVA	DENOSUMAB	Validated trade name used	Subcutaneous	1.7 milliliter, q2wk (1.7 ml (70 mg/ml))
103443973	10344397	2	Concomitant	ANASTROZOLE	ANASTROZOLE	Validated trade name used	Oral	1 mg, qd (1 piece (s) once a day)
103443973	10344397	3	Concomitant	OMEPRAZOLE	OMEPRAZOLE	Validated trade name used	Oral	20 mg, qd (1 piece once a day)
103443973	10344397	4	Concomitant	NAPROXEN	NAPROXEN	Validated trade name used	Oral	500 mg, bid (1 piece (s) twice a day)
1035913611	10359136	1	Primary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	
1035913611	10359136	2	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	
1035913611	10359136	3	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	
1035913611	10359136	4	Secondary Suspect Drug	VALSARTAN	VALSARTAN	Validated trade name used	Oral	
1035913611	10359136	5	Secondary Suspect Drug	CORTISONE	CORTISONE	Validated trade name used	Unknown	
1035913611	10359136	6	Secondary Suspect Drug	LANOLIN	LANOLIN	Validated trade name used	Unknown	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

Cumulative dose to first reaction	Cumulative dose to first reaction unit C	Dechallenge code, indicating if reaction	Rechallenge code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported).	NDA number.	Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
.		Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		125085	.		Infusion, Solution	
.				1045804A		125320	1.7	Millilitre(s)	Solution for injection	Every other week
.						.	1	Milligram(s)	Tablet	Daily
.						.	20	Milligram(s)	Capsule	Daily
.						.	500	Milligram(s)	Tablet	Twice a day
.		Positive dechallenge		UNKNOWN,UNKNOWN,UNKNOWN		103976	300	Milligram(s)	INJECTION, SOLUTION	
.		Positive dechallenge		UNKNOWN,UNKNOWN,UNKNOWN		103976	300	Milligram(s)	INJECTION, SOLUTION	Every other week
.		Positive dechallenge		UNKNOWN,UNKNOWN,UNKNOWN		103976	300	Milligram(s)	INJECTION, SOLUTION	Every other week
.		Unknown		UNKNOWN		.	160	Milligram(s)		Daily
.		Unknown		UNKNOWN		.	.			
.		Unknown	Unknown	UNKNOWN		.	.			



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
1035913611	10359136	7	Secondary Suspect Drug	NEOMYCIN	NEOMYCIN	Validated trade name used	Unknown	
1035913611	10359136	8	Concomitant	ALVESCO	CICLESONIDE	Validated trade name used	Unknown	
1035913611	10359136	9	Concomitant	PREDNISONE	PREDNISONE	Validated trade name used	Unknown	
1035913611	10359136	10	Concomitant	SPIRIVA	TIOTROPIUM BROMIDE MONOHYDRATE	Validated trade name used	Unknown	
1035913611	10359136	11	Concomitant	SYMBICORT	BUDESONIDE/FORMOTEROL FUMARATE DIHYDRATE	Validated trade name used	Unknown	
1035913611	10359136	12	Concomitant	VENTOLIN	ALBUTEROL SULFATE	Validated trade name used	Unknown	PRN
1035913611	10359136	13	Concomitant	FLOVENT	FLUTICASONE PROPIONATE	Validated trade name used	Unknown	
103687216	10368721	1	Primary Suspect Drug	ZYKADIA	CERITINIB	Validated trade name used	Oral	750 mg, QD
103687216	10368721	2	Secondary Suspect Drug	ZYKADIA	CERITINIB	Validated trade name used	Oral	600 mg, QD
103687216	10368721	3	Concomitant	DEXTROSE	DEXTROSE/DEXTROSE MONOHYDRATE	Validated trade name used	Unknown	5 %, 500 cc bid ev
103749689	10374968	1	Primary Suspect Drug	AFLIBERCEPT	AFLIBERCEPT	Validated trade name used	Intravenous drip	324 mg,QCY

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.		Unknown	Unknown	UNKNOWN			.	.		
.		Unknown					.	.		Twice a day
.		Unknown					.	.		Daily
.		Unknown					.	.		Daily
.		Unknown					.	.		Daily
.		Unknown					.	.		
.		Unknown					.	.		Twice a day
29400	Milligram(s)					205755	750	Milligram(s)	Capsule	Daily
29400	Milligram(s)					205755	600	Milligram(s)	Capsule	Daily
.							5	Percent (%)		
.		Positive dechallenge				125418	324	Milligram(s)	Solution for infusion	/CYCLE

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
103749689	10374968	2	Secondary Suspect Drug	AFLIBERCEPT	AFLIBERCEPT	Validated trade name used	Intravenous drip	324 mg,QCY
103749689	10374968	3	Secondary Suspect Drug	FLUOROURACIL	FLUOROURACIL	Validated trade name used	Intravenous drip	2232 mg,QCY
103749689	10374968	4	Secondary Suspect Drug	FLUOROURACIL	FLUOROURACIL	Validated trade name used	Intravenous bolus	1488 mg,QCY
103749689	10374968	5	Secondary Suspect Drug	FLUOROURACIL	FLUOROURACIL	Validated trade name used	Intravenous bolus	1488 mg,UNK
103749689	10374968	6	Secondary Suspect Drug	FLUOROURACIL	FLUOROURACIL	Validated trade name used	Intravenous drip	2232 mg,QCY
103749689	10374968	7	Secondary Suspect Drug	IRINOTECAN	IRINOTECAN	Validated trade name used	Intravenous drip	334.8 mg,QCY
103749689	10374968	8	Secondary Suspect Drug	IRINOTECAN	IRINOTECAN	Validated trade name used	Intravenous drip	334.8 mg,QCY
103749689	10374968	9	Secondary Suspect Drug	LEUCOVORIN	LEUCOVORINLEUCOVORIN CALCIUM	Validated trade name used	Intravenous drip	744 mg,QCY
103749689	10374968	10	Secondary Suspect Drug	LEUCOVORIN	LEUCOVORINLEUCOVORIN CALCIUM	Validated trade name used	Intravenous drip	744 mg,QCY
103749689	10374968	11	Concomitant	GRANISETRON	GRANISETRON	Validated trade name used		UNK
103749689	10374968	12	Concomitant	ATROPINE	ATROPINE	Validated trade name used	Unknown	UNK

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.		Positive dechallenge				125418	324	Milligram(s)	Solution for infusion	/CYCLE
.		Positive dechallenge				.	2232	Milligram(s)	Solution for infusion	/CYCLE
.		Positive dechallenge				.	1488	Milligram(s)	Solution for infusion	/CYCLE
.		Positive dechallenge				.	1488	Milligram(s)	Solution for infusion	/CYCLE
.		Positive dechallenge				.	2232	Milligram(s)	Solution for infusion	/CYCLE
.		Positive dechallenge		UNKNOWN		.	334.8	Milligram(s)	Concentrate for solution for infusion	/CYCLE
.		Positive dechallenge		UNKNOWN		.	334.8	Milligram(s)	Concentrate for solution for infusion	/CYCLE
.		Positive dechallenge		UNKNOWN		.	744	Milligram(s)	Solution for infusion	/CYCLE
.		Positive dechallenge		UNKNOWN		.	744	Milligram(s)	Solution for infusion	/CYCLE
.		Unknown				.	.	.		
.		Unknown				.	.	.		

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
103749689	10374968	13	Concomitant	METOCLOPRAMIDE	METOCLOPRAMIDE	Validated trade name used	Unknown	UNK UNK,UNK
103749689	10374968	14	Concomitant	METOCLOPRAMIDE	METOCLOPRAMIDE	Validated trade name used	Unknown	UNK UNK,UNK
103749689	10374968	15	Concomitant	MEGESTROL ACETATE	MEGESTROL ACETATE	Validated trade name used	Unknown	UNK UNK,UNK
103749689	10374968	16	Concomitant	LOPERAMIDE	LOPERAMIDE	Validated trade name used		UNK
103749689	10374968	17	Concomitant	OCTREOTIDE	OCTREOTIDE	Validated trade name used	Unknown	UNK UNK,UNK
103749689	10374968	18	Concomitant	MEGESTROL ACETATE	MEGESTROL ACETATE	Validated trade name used	Unknown	UNK UNK,UNK
103749689	10374968	19	Concomitant	PRIMPERAN	METOCLOPRAMIDE HYDROCHLORIDE	Validated trade name used	Unknown	UNK UNK,UNK
103749689	10374968	20	Concomitant	GRANULOCYTE COLONY-STIMULATING FACTOR NOS	GRANULOCYTE COLONY-STIMULATING FACTOR NOS	Validated trade name used	Unknown	UNK UNK,UNK
103749689	10374968	21	Concomitant	DOPAMINE	DOPAMINE HYDROCHLORIDE	Validated trade name used	Unknown	UNK
103749689	10374968	22	Concomitant	HALOPERIDOL	HALOPERIDOL	Validated trade name used	Unknown	UNK UNK,UNK
103749689	10374968	23	Concomitant	MIDAZOLAM	MIDAZOLAM	Validated trade name used		UNK

[illegible]

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>
103749689	10374968	24	Concomitant	OMEPRazole	OMEPRazole	Validated trade name used	Unknown	UNK
103892335	10389233	1	Secondary Suspect Drug	DOXORUBICIN	DOXORUBICIN	Validated trade name used	Unknown	liposome injection, Cyclic
103892335	10389233	2	Secondary Suspect Drug	VINCristine	VINCristine	Validated trade name used	Unknown	UNK, Cyclic
103892335	10389233	3	Primary Suspect Drug	PREDNISOLONE	PREDNISOLONE	Validated trade name used	Unknown	UNK, Cyclic
103892335	10389233	4	Secondary Suspect Drug	CYCLOPHOSPHAMIDE	CYCLOPHOSPHAMIDE	Validated trade name used	Unknown	UNK, Cyclic
103892335	10389233	5	Secondary Suspect Drug	RITUXIMAB	RITUXIMAB	Validated trade name used	Unknown	UNK, Cyclic
103892335	10389233	6	Concomitant	TENOFOVIR	TENOFOVIR	Validated trade name used	Unknown	UNK
103892335	10389233	7	Concomitant	TENOFOVIR	TENOFOVIR	Validated trade name used	Unknown	UNK
103892335	10389233	8	Concomitant	HUMAN HEPATITIS B VIRUS IMMUNE GLOBULIN	HUMAN HEPATITIS B VIRUS IMMUNE GLOBULIN	Validated trade name used	Unknown	UNK
103892335	10389233	9	Concomitant	HUMAN HEPATITIS B VIRUS IMMUNE GLOBULIN	HUMAN HEPATITIS B VIRUS IMMUNE GLOBULIN	Validated trade name used	Unknown	UNK
103928076	10392807	1	Primary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.		Unknown					.	.		
.		Unknown					.	.	Solution for injection	
.		Unknown					.	.		
.		Unknown				17469	.	.		
.		Unknown					.	.		
.		Unknown					.	.	Concentrate for solution for infusion	
.		Unknown					.	.		
.		Unknown					.	.		
.		Unknown					.	.		
.		Unknown					.	.		
.			Unknown			20272	.	.	Film-coated tablet	



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
103928076	10392807	2	Secondary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral	0.5 to 1 mg	.
103928076	10392807	3	Secondary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral		.
103928375	10392837	1	Primary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral	varying doses of 0.25 mg and 0.5 mg three times a day	.
103928375	10392837	2	Secondary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral	therapy start date: //2009; varying doses of 0.5 mg three times a day and 5 mg daily	.
103928375	10392837	3	Secondary Suspect Drug	RISPERIDONE	RISPERIDONE	Validated trade name used	Oral		.
103928375	10392837	4	Secondary Suspect Drug	RISPERDAL M-TAB	RISPERIDONE	Validated trade name used	Oral		.
103928375	10392837	5	Secondary Suspect Drug	RISPERIDONE	RISPERIDONE	Validated trade name used	Oral		.
103985405	10398540	1	Primary Suspect Drug	GILENYA	FINGOLIMOD HYDROCHLORIDE	Validated trade name used	Oral	0.5 mg, QD	.
103985405	10398540	2	Secondary Suspect Drug	GILENYA	FINGOLIMOD HYDROCHLORIDE	Validated trade name used	Unknown	UNK	.
104003092	10400309	1	Secondary Suspect Drug	ENALAPRIL MALEATE	ENALAPRIL MALEATE	Validated trade name used		UNK	.

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
		Unknown			20272	.		Film-coated tablet	
		Unknown			20272	.		Film-coated tablet	
		Unknown			20272	.		Unknown	
		Unknown			20272	.		Unknown	
	Unknown	Unknown			20272	.		Film-coated tablet	
	Unknown	Unknown			21444	1	Milligram(s)	Orodispersible tablet	Daily
	Unknown				.	.		Tablet	
	Positive dechallenge				22527	0.5	Milligram(s)	Capsule, hard	Daily
	Positive dechallenge				22527	.		Capsule, hard	
					.	.		Tablet	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
104003092	10400309	2	Primary Suspect Drug	CLOPIDOGREL BISULFATE	CLOPIDOGREL BISULFATE	Validated trade name used	Oral	75 mg,QD	.	
104003092	10400309	3	Secondary Suspect Drug	ASPIRIN	ASPIRIN	Validated trade name used	Oral	75 mg,QD	.	
104003092	10400309	4	Concomitant	DOXAZOSIN	DOXAZOSIN MESYLATE	Validated trade name used	Oral	2 mg,QD	.	
104003092	10400309	5	Concomitant	FUROSEMIDE	FUROSEMIDE	Validated trade name used	Oral	40 mg,QD	.	
104003092	10400309	6	Concomitant	ISOSORBIDE MONONITRATE	ISOSORBIDE MONONITRATE	Validated trade name used	Oral	20 mg,QD	.	
104003092	10400309	7	Concomitant	NEBIVOLOL	NEBIVOLOL	Validated trade name used	Oral	10 mg,QD	.	
104003092	10400309	8	Concomitant	RAMIPRIL	RAMIPRIL	Validated trade name used	Oral	10 mg,QD	.	
1040513313	10405133	1	Primary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.	
1040513313	10405133	2	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.	
1040513313	10405133	3	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.	
1040513313	10405133	4	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Negative dechallenge				20839	75	Milligram(s)		Daily
Negative dechallenge				.	75	Milligram(s)		Daily
Unknown				.	2	Milligram(s)		Daily
Unknown				.	40	Milligram(s)		Daily
Unknown				.	20	Milligram(s)		Daily
Unknown				.	10	Milligram(s)		Daily
Unknown				.	10	Milligram(s)		Daily
Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	150	Milligram(s)	INJECTION, SOLUTION	
Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	150	Milligram(s)	INJECTION, SOLUTION	
Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	150	Milligram(s)	INJECTION, SOLUTION	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
1040513313	10405133	5	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.
1040513313	10405133	6	Concomitant	SYMBICORT	BUDESONIDE\FORMOTEROL FUMARATE DIHYDRATE	Validated trade name used	Unknown	.	.	.
1040513313	10405133	7	Concomitant	BRICANYL	TERBUTALINE SULFATE	Validated trade name used	Unknown	.	.	.
1040513313	10405133	8	Concomitant	ADVAIR HFA	FLUTICASONE PROPIONATE\SALMETEROL XINAFOATE	Validated trade name used	Unknown	.	.	.
1040513313	10405133	9	Concomitant	VENTOLIN	ALBUTEROL SULFATE	Validated trade name used	Unknown	4 puffs daily	.	.
1040513313	10405133	10	Concomitant	SPIRIVA	TIOTROPIUM BROMIDE MONOHYDRATE	Validated trade name used	.	.	.	.
1040513313	10405133	11	Concomitant	ZENHALE	FORMOTEROL FUMARATE\MOMETASONE FUROATE	Validated trade name used	.	strength: 200 mcg	.	.
1041491125	10414911	1	Primary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, Q4W (every 4 weeks)	.	.
1041491125	10414911	2	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, Q4W (every 4 weeks)	.	.
1041491125	10414911	3	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, QMO (once a month)	.	.

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Unknown		ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	150	Milligram(s)	INJECTION, SOLUTION	
				.	.			
				.	.			
				.	.			
				.	.			Daily
Unknown		UNKNOWN		.	.			
Unknown		UNKNOWN		.	.			
				21008	20	Milligram(s)		
		368833		21008	30	Milligram(s)		
				21008	30	Milligram(s)		/MONTH

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
1041491125	10414911	4	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg,Q4W (every 4 weeks)	.	
1041491125	10414911	5	Secondary Suspect Drug	SYNTHROID	LEVOTHYROXINE SODIUM	Validated trade name used	Unknown	UNK	.	
1041491125	10414911	6	Concomitant	CRESTOR	ROSUVASTATIN CALCIUM	Validated trade name used	Unknown	UNK	.	
1041491125	10414911	7	Concomitant	VITAMINS	VITAMINS	Validated trade name used	Unknown	UNK	.	
1041491125	10414911	8	Concomitant	VITAMIN D	VITAMIN D NOS	Validated trade name used	Unknown	UNK	.	
1041491125	10414911	9	Concomitant	CALCIUM	CALCIUM	Validated trade name used	Unknown	UNK	.	
1041491125	10414911	10	Concomitant	METOPROLOL	METOPROLOL	Validated trade name used	Unknown	UNK UNK, PRN	.	
104232052	10423205	1	Primary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral		.	
104232052	10423205	2	Secondary Suspect Drug	INVEGA	PALIPERIDONE	Validated trade name used	Oral		.	
104232195	10423219	1	Primary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral		.	
104232195	10423219	2	Secondary Suspect Drug	INVEGA	PALIPERIDONE	Validated trade name used	Oral		.	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
				21008	30	Milligram(s)		
Unknown				.	.			
Unknown				.	.			
Unknown				.	.			
Unknown				.	.			
Unknown				.	.			
Unknown				.	.			
Unknown	Unknown			20272	.		Film-coated tablet	
Unknown	Unknown			21999	.		Prolonged-release tablet	
Unknown	Unknown			20272	.		Film-coated tablet	
Does not apply	Unknown			21999	.		Prolonged-release tablet	



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
104232195	10423219	3	Secondary Suspect Drug	RISPERDAL CONSTA	RISPERIDONE	Validated trade name used	Intramuscular		.	
104232195	10423219	4	Secondary Suspect Drug	RISPERDAL CONSTA	RISPERIDONE	Validated trade name used			.	
104232195	10423219	5	Secondary Suspect Drug	RISPERDAL CONSTA	RISPERIDONE	Validated trade name used			.	
104232195	10423219	6	Secondary Suspect Drug	RISPERDAL CONSTA	RISPERIDONE	Validated trade name used			.	
104232195	10423219	7	Secondary Suspect Drug	RISPERIDONE	RISPERIDONE	Validated trade name used	Oral		.	
104232203	10423220	1	Primary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral		.	
104232203	10423220	2	Secondary Suspect Drug	INVEGA	PALIPERIDONE	Validated trade name used	Oral		.	
104266473	10426647	1	Primary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral		.	
104266473	10426647	2	Secondary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used			.	
104266473	10426647	3	Secondary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used			.	
104266473	10426647	4	Secondary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used			.	

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Unknown	Unknown			21346	.		Prolonged-release suspension for injection	
Unknown	Unknown			21346	.			
Unknown	Unknown			21346	.			
Unknown	Unknown			21346	.			
Unknown				.	.		Tablets	
Unknown	Unknown			20272	.		Film-coated tablet	
Unknown	Unknown			21999	.		Prolonged-release tablet	
Unknown	Unknown			20272	.		Unknown	
Unknown	Unknown			20272	.			
Unknown	Unknown			20272	.			
Unknown	Unknown			20272	.			

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
104266473	10426647	5	Secondary Suspect Drug	INVEGA	PALIPERIDONE	Validated trade name used	Oral		.	
104266473	10426647	6	Secondary Suspect Drug	INVEGA	PALIPERIDONE	Validated trade name used			.	
104266473	10426647	7	Secondary Suspect Drug	RISPERDAL M-TAB	RISPERIDONE	Validated trade name used	Oral		.	
104266473	10426647	8	Secondary Suspect Drug	RISPERIDONE	RISPERIDONE	Validated trade name used	Unknown		.	
104490482	10449048	1	Primary Suspect Drug	TRAMADOL	TRAMADOL\TRAMADOL HYDROCHLORIDE	Validated trade name used	Unknown	UNK	.	
104490482	10449048	2	Secondary Suspect Drug	CODEINE	CODEINE	Validated trade name used	Unknown	UNK	.	
104490482	10449048	3	Secondary Suspect Drug	LYRICA	PREGABALIN	Validated trade name used	Unknown	UNK	.	
104490482	10449048	4	Concomitant	MORPHINE	MORPHINE	Validated trade name used	Unknown	UNK	.	
104490482	10449048	5	Concomitant	ALCOHOL	ALCOHOL	Validated trade name used	Unknown	UNK	.	
104580772	10458077	1	Primary Suspect Drug	TRAMADOL	TRAMADOL\TRAMADOL HYDROCHLORIDE	Validated trade name used	Unknown	UNK	.	
104580772	10458077	2	Secondary Suspect Drug	LYRICA	PREGABALIN	Validated trade name used	Unknown	UNK	.	

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Unknown	Unknown			21999	.		Prolonged-release tablet	
Unknown	Unknown			21999	.			
Unknown	Unknown			21444	.		Orodispersible tablet	
Unknown				.	.		Tablets	
Does not apply				203494	.			
Does not apply				.	.			
Does not apply				.	.			
Does not apply				.	.			
Does not apply				.	.			
Does not apply				203494	.			
Does not apply				.	.			

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
104580772	10458077	3	Secondary Suspect Drug	OXYCODONE	OXYCODONE	Validated trade name used	Unknown	UNK	.	
104580772	10458077	4	Secondary Suspect Drug	DULOXETINE	DULOXETINE	Validated trade name used	Unknown	UNK	.	
104580883	10458088	1	Primary Suspect Drug	ACETAMINOPHEN	ACETAMINOPHEN	Validated trade name used	Unknown	UNK	.	
104580883	10458088	2	Secondary Suspect Drug	TRAMADOL	TRAMADOL\TRAMADOL HYDROCHLORIDE	Validated trade name used	Unknown	UNK	.	
104580883	10458088	3	Secondary Suspect Drug	LYRICA	PREGABALIN	Validated trade name used	Unknown	UNK	.	
104580883	10458088	4	Secondary Suspect Drug	AMITRIPTYLINE	AMITRIPTYLINE	Validated trade name used	Unknown	UNK	.	
104580883	10458088	5	Secondary Suspect Drug	NORTRIPTYLINE	NORTRIPTYLINE	Validated trade name used	Unknown	UNK	.	
104580883	10458088	6	Secondary Suspect Drug	ALCOHOL	ALCOHOL	Validated trade name used	Unknown	UNK	.	
104635823	10463582	1	Primary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral		.	
104635823	10463582	2	Secondary Suspect Drug	INVEGA	PALIPERIDONE	Validated trade name used	Oral		.	
104665748	10466574	1	Primary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral	varying doses of 0.5 mg, 1 mg and 2 mg	.	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Does not apply					.	.		
Does not apply					.	.		
Does not apply				207229		.		
Does not apply				203494		.		
Does not apply					.	.		
Does not apply					.	.		
Does not apply					.	.		
Does not apply					.	.		
Unknown	Unknown			20588	0.5	Milligram(s)	Oral solution	Daily
Unknown	Unknown			21999	.		Prolonged-release tablet	
Unknown	Unknown			20272	.		Film-coated tablet	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
104665748	10466574	2	Secondary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral	.	.	.
104665748	10466574	3	Secondary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used		.	.	.
104665748	10466574	4	Secondary Suspect Drug	INVEGA	PALIPERIDONE	Validated trade name used	Oral	.	.	.
104665748	10466574	5	Secondary Suspect Drug	INVEGA	PALIPERIDONE	Validated trade name used	Oral	.	.	.
104825157	10482515	1	Primary Suspect Drug	LIPITOR	ATORVASTATIN CALCIUM	Validated trade name used	Unknown	10 mg, 1x/day	.	.
104825157	10482515	2	Secondary Suspect Drug	LIPITOR	ATORVASTATIN CALCIUM	Validated trade name used	Unknown	20 milligram	.	.
104825157	10482515	3	Concomitant	ATENOLOL	ATENOLOL	Validated trade name used	Unknown	50 milligram, qd	.	.
104825157	10482515	4	Concomitant	QUINAPRIL	QUINAPRIL	Validated trade name used	Unknown	UNK	.	.
105144244	10514424	1	Primary Suspect Drug	STELARA	USTEKINUMAB	Validated trade name used	Subcutaneous	.	.	.
105144244	10514424	2	Secondary Suspect Drug	STELARA	USTEKINUMAB	Validated trade name used		.	.	.
1051596718	10515967	1	Primary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, QMO (every 4 weeks)	.	.

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Unknown	Unknown			20272	.		Film-coated tablet	
Unknown	Unknown			20272	.			
Unknown	Unknown			21999	6	Milligram(s)	Prolonged-release tablet	
Unknown	Unknown			21999	6	Milligram(s)	Prolonged-release tablet	
Unknown	Unknown			20702	10	Milligram(s)	Film-coated tablet	Daily
Unknown	Unknown			20702	20	Milligram(s)	Film-coated tablet	
				.	50	Milligram(s)	Unknown	Daily
				.	.		Unknown	
				125261	45	Milligram(s)	Solution for injection in pre-filled syringe	
				125261	.			
Unknown				21008	30	Milligram(s)		/MONTH



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
1051596718	10515967	2	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, Q4W	.	
1051596718	10515967	3	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, Q3W	.	
1051596718	10515967	4	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, Q3W	.	
1051596718	10515967	5	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, Q4W	.	
1052690058	10526900	1	Primary Suspect Drug	ACTEMRA	TOCILIZUMAB	Validated trade name used	Intravenous (not otherwise specified)		.	
1052690058	10526900	2	Concomitant	FOSINOPRIL	FOSINOPRIL	Validated trade name used			.	
1052690058	10526900	3	Concomitant	NORVASC	AMLODIPINE BESYLATE	Validated trade name used			.	
1052690058	10526900	4	Concomitant	OXYCODONE	OXYCODONE	Validated trade name used			.	
1052690058	10526900	5	Concomitant	FOLIC ACID	FOLIC ACID	Validated trade name used			.	
1052690058	10526900	6	Concomitant	PANTOPRAZOLE	PANTOPRAZOLE	Validated trade name used			.	
1052690058	10526900	7	Concomitant	AMLODIPINE	AMLODIPINE BESYLATE	Validated trade name used			.	

[illegible]

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
1052690058	10526900	8	Concomitant	ROSUVASTATIN	ROSUVASTATIN	Validated trade name used			.	
1052690058	10526900	9	Concomitant	DICLOFENAC	DICLOFENAC	Validated trade name used			.	
1052690058	10526900	10	Concomitant	ASPIRIN	ASPIRIN	Validated trade name used			.	
1052690058	10526900	11	Concomitant	CEPHALEXIN	CEPHALEXIN	Validated trade name used		for 7 day.	.	
1054038738	10540387	1	Primary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, QMO (every 4 week)	.	
1054038738	10540387	2	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	30 mg, QMO	.	
1054038738	10540387	3	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	40 mg, QMO	.	
1054038738	10540387	4	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, QMO	.	
1054038738	10540387	5	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, QMO (every 4 weeks)	.	
1054038738	10540387	6	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, QMO	.	
1054038738	10540387	7	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, Q4W	.	

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
				.	.			
				.	.			
				.	.			
				.	500	Milligram(s)		4 times a day
				21008	20	Milligram(s)		/MONTH
				21008	30	Milligram(s)		/MONTH
				21008	40	Milligram(s)		/MONTH
				21008	20	Milligram(s)		/MONTH
				21008	20	Milligram(s)		/MONTH
				21008	20	Milligram(s)		/MONTH
				21008	20	Milligram(s)		/MONTH

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
1054038738	10540387	8	Secondary Suspect Drug	SANDOSTATIN LAR DEPOT	OCTREOTIDE ACETATE	Validated trade name used	Intramuscular	20 mg, QMO	.	
1054038738	10540387	9	Secondary Suspect Drug	SANDOSTATIN	OCTREOTIDE ACETATE	Validated trade name used	Subcutaneous	UNK UNK, ONCE/SINGLE (Test dose)	.	
1054038738	10540387	10	Secondary Suspect Drug	SANDOSTATIN	OCTREOTIDE ACETATE	Validated trade name used			.	
1054038738	10540387	11	Secondary Suspect Drug	SANDOSTATIN	OCTREOTIDE ACETATE	Validated trade name used			.	
1054038738	10540387	12	Concomitant	CRESTOR	ROSUVASTATIN CALCIUM	Validated trade name used	Unknown	UNK	.	
1054038738	10540387	13	Concomitant	ASPIRIN	ASPIRIN	Validated trade name used	Unknown		.	
1054038738	10540387	14	Concomitant	XARELTO	RIVAROXABAN	Validated trade name used	Unknown	UNK	.	
1054038738	10540387	15	Concomitant	FLOMAX	TAMSULOSIN HYDROCHLORIDE	Validated trade name used	Unknown	UNK	.	
105481232	10548123	1	Primary Suspect Drug	LEVETIRACETAM	LEVETIRACETAM	Validated trade name used	Unknown	daily dose: 3250 (units unspecified)	.	
105481232	10548123	2	Secondary Suspect Drug	LEVETIRACETAM	LEVETIRACETAM	Validated trade name used	Unknown	unk	.	
105524185	10552418	1	Primary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral		.	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
				21008	20	Milligram(s)		/MONTH
Unknown				21008	.			
Unknown				21008	.			
Unknown				21008	.			
Unknown				.	.			
Unknown				.	.			
Unknown				.	.			
Unknown				.	.			
	Unknown	Unk		203059	.			
	Unknown	Unk		203059	.			
Unknown				20272	.		Film-coated tablet	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
105524185	10552418	2	Secondary Suspect Drug	INVEGA	PALIPERIDONE	Validated trade name used	Oral	.	.	.
105524185	10552418	3	Secondary Suspect Drug	ZYPREXA	OLANZAPINE	Validated trade name used	Oral	.	.	.
105524185	10552418	4	Secondary Suspect Drug	SEROQUEL	QUETIAPINE FUMARATE	Validated trade name used	Unknown	.	.	.
105741013	10574101	1	Primary Suspect Drug	CYCLOSPORINE	CYCLOSPORINE	Validated trade name used	Unknown	UNK, target blood level: 280-320 ng/ml	.	.
105741013	10574101	2	Secondary Suspect Drug	CYCLOSPORINE	CYCLOSPORINE	Validated trade name used	.	.	.	.
105741013	10574101	3	Secondary Suspect Drug	MYCOPHENOLATE MOFETIL	MYCOPHENOLATE MOFETIL	Validated trade name used	Unknown	2 g, QD	.	.
105741013	10574101	4	Secondary Suspect Drug	MYCOPHENOLATE MOFETIL	MYCOPHENOLATE MOFETIL	Validated trade name used	.	.	.	.
105741013	10574101	5	Secondary Suspect Drug	PREDNISOLONE	PREDNISOLONE	Validated trade name used	Unknown	20 mg, QD	.	.
105741013	10574101	6	Secondary Suspect Drug	PREDNISOLONE	PREDNISOLONE	Validated trade name used	.	.	.	.
1058928657	10589286	1	Primary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Unknown				21999	.		Prolonged-release tablet	
Unknown				.	.		Tablet	
Unknown				.	.		Unknown	
Unknown				50574	.			
Unknown				50574	.			
Unknown				.	2	Gram(s)		Daily
Unknown				.	.			
Unknown				.	20	Milligram(s)		Daily
Unknown				.	.			
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
1058928657	10589286	2	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.
1058928657	10589286	3	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.
1058928657	10589286	4	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.
1058928657	10589286	5	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.
1058928657	10589286	6	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.
1058928657	10589286	7	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.
1058928657	10589286	8	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.
1058928657	10589286	9	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.
1058928657	10589286	10	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.
1058928657	10589286	11	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.
1058928657	10589286	12	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.	.

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1058928657	10589286	13	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	UNK	.
1058928657	10589286	14	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	15	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	16	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	17	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	18	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	19	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	20	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	21	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	22	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	23	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1058928657	10589286	24	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1058928657	10589286	25	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1058928657	10589286	26	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1058928657	10589286	27	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1058928657	10589286	28	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1058928657	10589286	29	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1058928657	10589286	30	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1058928657	10589286	31	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1058928657	10589286	32	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1058928657	10589286	33	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.
1058928657	10589286	34	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous	.	.

# **ADVERSE EVENT REPORTING SYSTEM (AERS)** **Drug Listings**

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1058928657	10589286	35	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	36	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	37	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	38	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	39	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	40	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	41	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	42	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	43	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Unknown	UNK	.
1058928657	10589286	44	Secondary Suspect Drug	XOLAIR	OMALIZUMAB	Validated trade name used	Subcutaneous		.
1058928657	10589286	45	Secondary Suspect Drug	PNEUMOVAX 23	PNEUMOCOCCAL VACCINE, POLYVALENT 23	Validated trade name used	Unknown		.

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	.		INJECTION, SOLUTION	
	Positive dechallenge	Unknown	ASKED BUT UNKNOWN,ASKED BUT UNKNOWN		103976	375	Milligram(s)	INJECTION, SOLUTION	Every other week
	Does not apply		ASKED BUT UNKNOWN		.	.			



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>
1058928657	10589286	46	Concomitant	SPIRIVA	TIOTROPIUM BROMIDE MONOHYDRATE	Validated trade name used	Unknown	UNK	.
1058928657	10589286	47	Concomitant	ADVAIR HFA	FLUTICASONE PROPIONATE/SALMETEROL XINAFOATE	Validated trade name used	Unknown	UNK	.
1058928657	10589286	48	Concomitant	SINGULAIR	MONTELUKAST SODIUM	Validated trade name used	Unknown	UNK	.
1058928657	10589286	49	Concomitant	NASONEX	MOMETASONE FUROATE	Validated trade name used	Unknown	UNK	.
1058928657	10589286	50	Concomitant	VENTOLIN	ALBUTEROL SULFATE	Validated trade name used	Unknown	UNK UNK, BID	.
1058928657	10589286	51	Concomitant	SYMBICORT	BUDESONIDE/FORMOTEROL FUMARATE DIHYDRATE	Validated trade name used	Unknown	UNK	.
1058928657	10589286	52	Concomitant	PREDNISONE	PREDNISONE	Validated trade name used			.
105947013	10594701	1	Primary Suspect Drug	TRAMADOL HYDROCHLORIDE	TRAMADOL HYDROCHLORIDE	Validated trade name used	Oral	1.5 g, UNK	.
105947013	10594701	2	Secondary Suspect Drug	NAPROXEN	NAPROXEN	Validated trade name used	Oral	UNK	.
105947013	10594701	3	Secondary Suspect Drug	METAXALONE	METAXALONE	Validated trade name used	Oral	12 g, UNK	.
1060157312	10601573	1	Primary Suspect Drug	RUXOLITINIB	RUXOLITINIB	Validated trade name used	Oral	10 mg, BID (twice daily)	.

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Cumulative dose to first reaction unit C	Dechallenge code, indicating if reaction	Rechallenge code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported).	NDA number.	Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
	Unknown		unknown			.	.		
	Unknown		UNKNOWN			.	.		
	Unknown		UNKNOWN			.	.		
	Unknown		UNKNOWN			.	.		
	Unknown		UNKNOWN			.	.		Twice a day
	Unknown		UNKNOWN			.	.		
						.	.		
	Does not apply	Unknown			203494	1.5	Gram(s)	Tablet	
	Does not apply	Unknown			200629	.			
	Does not apply	Unknown			.	12	Gram(s)		
	Does not apply				202192	10	Milligram(s)	Tablet	Twice a day

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
1060157312	10601573	2	Secondary Suspect Drug	RUXOLITINIB	RUXOLITINIB	Validated trade name used	Oral	10 mg, QD	.	
1060157312	10601573	3	Secondary Suspect Drug	RUXOLITINIB	RUXOLITINIB	Validated trade name used	Oral	10 mg, BID	.	
1060157312	10601573	4	Secondary Suspect Drug	RUXOLITINIB	RUXOLITINIB	Validated trade name used	Oral	5 mg, BID	.	
1060157312	10601573	5	Concomitant	EPREX	ERYTHROPOIETIN	Validated trade name used	Unknown	UNK	.	
1060157312	10601573	6	Concomitant	RAMIPRIL	RAMIPRIL	Validated trade name used	Unknown	UNK	.	
106091663	10609166	1	Primary Suspect Drug	LEVETIRACETAM	LEVETIRACETAM	Validated trade name used	Unknown	3000 mg, Daily	.	
106091663	10609166	2	Secondary Suspect Drug	LEVETIRACETAM	LEVETIRACETAM	Validated trade name used			.	
106091663	10609166	3	Secondary Suspect Drug	LACOSAMIDE	LACOSAMIDE	Validated trade name used	Oral	200 mg, single loading dose	.	
106091663	10609166	4	Secondary Suspect Drug	LACOSAMIDE	LACOSAMIDE	Validated trade name used	Oral	100 mg, Two Times a Day	.	
106091663	10609166	5	Secondary Suspect Drug	LACOSAMIDE	LACOSAMIDE	Validated trade name used	Oral	200 mg, Two Times a Day	.	
106091663	10609166	6	Secondary Suspect Drug	PREGABALIN	PREGABALIN	Validated trade name used	Unknown	300 milligram, Once a Day	.	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Does not apply				202192	10	Milligram(s)	Tablet	Daily
Does not apply				202192	10	Milligram(s)	Tablet	Twice a day
Does not apply				202192	5	Milligram(s)	Tablet	Twice a day
Does not apply				.	.			
Does not apply				.	.			
Does not apply	Unknown			78993	3000	Milligram(s)		
Does not apply	Unknown			78993	.			
Does not apply	Unknown			204994	200	Milligram(s)		
Does not apply	Unknown			204994	100	Milligram(s)		Twice a day
Does not apply	Unknown			204994	200	Milligram(s)		Twice a day
Does not apply				205321	300	Milligram(s)		Daily

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>
106091663	10609166	7	Secondary Suspect Drug	PHENOBARBITAL	PHENOBARBITAL	Validated trade name used	Unknown	50 mg, Once a Day	.	
106091663	10609166	8	Secondary Suspect Drug	PHENOBARBITAL	PHENOBARBITAL	Validated trade name used			.	
106336646	10633664	1	Primary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral		.	
106336646	10633664	2	Secondary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral	at varying doses of 0.5 mg to 1 mg	.	
106336646	10633664	3	Secondary Suspect Drug	RISPERDAL	RISPERIDONE	Validated trade name used	Oral	At varying doses of 1 mg to 2 mg	.	
106336646	10633664	4	Secondary Suspect Drug	INVEGA	PALIPERIDONE	Validated trade name used	Oral		.	
106352232	10635223	1	Primary Suspect Drug	LACOSAMIDE	LACOSAMIDE	Validated trade name used	Oral	200 mg, One time Dose, loading dose	.	
106352232	10635223	2	Secondary Suspect Drug	LACOSAMIDE	LACOSAMIDE	Validated trade name used	Oral	100 mg twice daily upto 200 mg twice a day maintenance dose	.	
106352232	10635223	3	Secondary Suspect Drug	LEVETIRACETAM	LEVETIRACETAM	Validated trade name used		Up to 3000 mg per day	.	
106352232	10635223	4	Concomitant	PREGABALIN	PREGABALIN	Validated trade name used		upto 150 mg twice daily	.	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
Does not apply	Unknown				.	50	Milligram(s)	Daily
Does not apply	Unknown				.	.		
Unknown	Unknown			20272	.		Film-coated tablet	
Unknown	Unknown			20272	.		Film-coated tablet	
Unknown	Unknown			20272	.		Film-coated tablet	
Unknown	Unknown			21999	.		Prolonged-release tablet	
Does not apply					.	200	Milligram(s)	Once or one time
Does not apply					.	.		Twice a day
Does not apply					.	.		
Does not apply					.	.		

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>
106352232	10635223	5	Concomitant	PHENOBARBITAL	PHENOBARBITAL
106520463	10652046	1	Primary Suspect Drug	PRISTIQ EXTENDED-RELEASE	DESVENLAFAXINE SUCCINATE
1069198853	10691988	1	Primary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	2	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	3	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	4	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	5	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	6	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	7	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	8	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	9	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	10	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	11	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	12	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	13	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	14	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	15	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	16	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	17	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	18	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	19	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	20	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	21	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	22	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	23	Secondary Suspect Drug	XOLAIR	OMALIZUMAB

[illegible]



[illegible]

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>
1069198853	10691988	24	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	25	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	26	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	27	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	28	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	29	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	30	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	31	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	32	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	33	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	34	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	35	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	36	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	37	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	38	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	39	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	40	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	41	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	42	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	43	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	44	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	45	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	46	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	47	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	48	Secondary Suspect Drug	XOLAIR	OMALIZUMAB

[illegible]

[illegible]

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>
1069198853	10691988	49	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	50	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	51	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	52	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	53	Secondary Suspect Drug	XOLAIR	OMALIZUMAB
1069198853	10691988	54	Concomitant	PREDNISON	PREDNISON
1069198853	10691988	55	Concomitant	SINGULAIR	MONTELUKAST SODIUM
1069198853	10691988	56	Concomitant	VENTOLIN	ALBUTEROL SULFATE
1069198853	10691988	57	Concomitant	ADVAIR HFA	FLUTICASONE PROPIONATE\SALMETEROL XINAFOATE
1069198853	10691988	58	Concomitant	ZENHALE	FORMOTEROL FUMARATE\MOMETASONE FUROATE
1069198853	10691988	59	Concomitant	SPIRIVA	TIOTROPIUM BROMIDE MONOHYDRATE
1069198853	10691988	60	Concomitant	ALVESCO	CICLESONIDE
1069198853	10691988	61	Concomitant	INSULIN NOS	INSULIN NOS
1070483325	10704833	1	Secondary Suspect Drug	SULFAMETHOXAZOLE\TRIMETHOPRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	2	Secondary Suspect Drug	SULFATRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	3	Secondary Suspect Drug	SULFATRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	4	Secondary Suspect Drug	SULFATRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	5	Secondary Suspect Drug	SULFATRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	6	Secondary Suspect Drug	SULFATRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	7	Secondary Suspect Drug	SULFATRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	8	Secondary Suspect Drug	SULFATRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	9	Secondary Suspect Drug	SULFATRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	10	Secondary Suspect Drug	BACLOFEN	BACLOFEN
1070483325	10704833	11	Secondary Suspect Drug	HYDROMORPHONE	HYDROMORPHONE
1070483325	10704833	12	Secondary Suspect Drug	CALCIUM CARBONATE	CALCIUM CARBONATE

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>
Validated trade name used	Subcutaneous	.	.	.	Unknown	.	S0053A,S0060A,S0061D,S0062,S0065E,S
Validated trade name used	Subcutaneous	.	.	.	Unknown	.	S0053A,S0060A,S0061D,S0062,S0065E,S
Validated trade name used	Subcutaneous	.	.	.	Unknown	.	S0053A,S0060A,S0061D,S0062,S0065E,S
Validated trade name used	Subcutaneous	.	.	.	Unknown	.	S0053A,S0060A,S0061D,S0062,S0065E,S
Validated trade name used	Subcutaneous	.	.	.	Unknown	.	S0053A,S0060A,S0061D,S0062,S0065E,S
Validated trade name used		30 mg, QD	.	.	Unknown	.	UNKNOWN
Validated trade name used	Unknown	.	.	.	Unknown	.	
Validated trade name used	Unknown	.	.	.	Unknown	.	
Validated trade name used	Unknown	1 DF, TID	.	.	Positive dechallenge	.	
Validated trade name used	Unknown	.	.	.	Unknown	.	
Validated trade name used	Unknown	.	.	.	Unknown	.	
Validated trade name used	Unknown	.	.	.	Unknown	.	
Validated trade name used	Unknown	.	.	.	Unknown	.	
Validated trade name used	Oral	60 milligram	.	.	Unknown	.	
Validated trade name used	Oral	3 milligram, qd	.	.	Unknown	.	
Validated trade name used	Oral	1 dosage form, qd	.	.	Unknown	.	
Validated trade name used	Oral	60 milligram	.	.	Unknown	.	
Validated trade name used	Oral	UNK	.	.	Unknown	.	
Validated trade name used	Unknown	3 milligram, qd	.	.	Unknown	.	
Validated trade name used	Unknown	60 milligram	.	.	Unknown	.	
Validated trade name used	Oral	1 milligram, qd	.	.	Unknown	.	
Validated trade name used	Unknown	UNK	.	.	Unknown	.	
Validated trade name used	Oral	UNK	.	.	Unknown	.	
Validated trade name used	Unknown	UNK	.	.	Unknown	.	
Validated trade name used	Unknown	UNK	.	.	Unknown	.	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
	103976	.		INJECTION, SOLUTION	
	103976	.		INJECTION, SOLUTION	
	103976	.		INJECTION, SOLUTION	
	103976	300	Milligram(s)	INJECTION, SOLUTION	Every other week
	103976	300	Milligram(s)	INJECTION, SOLUTION	Every other week
	.	30	Milligram(s)		Daily
	.	.			
	.	.			
	.	.			3 times a day
	.	.			
	.	.			
	.	.			
	.	.			
	.	60	Milligram(s)		
	.	3	Milligram(s)		
	.	.			
	.	60	Milligram(s)		
	.	.			
	.	3	Milligram(s)		
	.	60	Milligram(s)		
	.	1	Milligram(s)		
	.	.			
	.	.		Tablet	
	.	.		Tablet	
	.	.		Tablet	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>
1070483325	10704833	13	Primary Suspect Drug	POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	Validated trade name used	Unknown
1070483325	10704833	14	Secondary Suspect Drug	POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	Validated trade name used	Unknown
1070483325	10704833	15	Secondary Suspect Drug	POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	Validated trade name used	Unknown
1070483325	10704833	16	Secondary Suspect Drug	POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	Validated trade name used	Unknown
1070483325	10704833	17	Secondary Suspect Drug	FUROSEMIDE	FUROSEMIDE	Validated trade name used	Unknown
1070483325	10704833	18	Secondary Suspect Drug	ZOPICLONE	ZOPICLONE	Validated trade name used	Oral
1070483325	10704833	19	Secondary Suspect Drug	ZOPICLONE	ZOPICLONE	Validated trade name used	Unknown
1070483325	10704833	20	Secondary Suspect Drug	CALCIUM CARBONATE	CALCIUM CARBONATE	Validated trade name used	Unknown
1070483325	10704833	21	Secondary Suspect Drug	ALENDRONATE SODIUM	ALENDRONATE SODIUM	Validated trade name used	Unknown
1070483325	10704833	22	Secondary Suspect Drug	ALENDRONATE	ALENDRONATE SODIUM	Validated trade name used	Oral
1070483325	10704833	23	Secondary Suspect Drug	ALENDRONATE	ALENDRONATE SODIUM	Validated trade name used	Buccal



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
600 milligram	.		Unknown				211067	600	Milligram(s)	TABLET, EXTENDED RELEASE	
60 milligram, UNK	.		Unknown				211067	60	Milligram(s)	Tablet	
600 milligram	.		Unknown				211067	600	Milligram(s)	Tablet	
UNK	.		Unknown				211067	.		Tablet	
UNK	.		Unknown				.	.		Tablet	
UNK	.		Unknown				.	.		Tablet	
UNK	.		Unknown				.	.		Tablet	
UNK	.		Unknown				.	.		Tablet	
UNK	.		Unknown				77982	.		Tablet	
UNK	.		Unknown				77982	.		Tablet	
UNK	.		Unknown				77982	.		Tablet	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>
1070483325	10704833	24	Secondary Suspect Drug	NORTRIPTYLINE	NORTRIPTYLINE	Validated trade name used	Unknown
1070483325	10704833	25	Secondary Suspect Drug	MYCOPHENOLIC ACID	MYCOPHENOLIC ACID	Validated trade name used	Unknown
1070483325	10704833	26	Secondary Suspect Drug	NORTRIPTYLINE	NORTRIPTYLINE	Validated trade name used	Oral
1070483325	10704833	27	Secondary Suspect Drug	WARFARIN SODIUM	WARFARIN SODIUM	Validated trade name used	Unknown
1070483325	10704833	28	Secondary Suspect Drug	TIZANIDINE HYDROCHLORIDE	TIZANIDINE HYDROCHLORIDE	Validated trade name used	Oral
1070483325	10704833	29	Secondary Suspect Drug	PREDNISONE	PREDNISONE	Validated trade name used	Unknown
1070483325	10704833	30	Secondary Suspect Drug	TIZANIDINE	TIZANIDINE	Validated trade name used	Oral
1070483325	10704833	31	Secondary Suspect Drug	TIZANIDINE	TIZANIDINE	Validated trade name used	Unknown
1070483325	10704833	32	Secondary Suspect Drug	MOMETASONE	MOMETASONE	Validated trade name used	Unknown
1070483325	10704833	33	Secondary Suspect Drug	NAPROXEN SODIUM	NAPROXENNAPROXEN SODIUM	Validated trade name used	Unknown
1070483325	10704833	34	Secondary Suspect Drug	BACLOFEN	BACLOFEN	Validated trade name used	Unknown

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
UNK	.		Unknown					.	.	Capsule	
UNK	.		Unknown				91558	.			
UNK	.		Unknown					.	.	Capsule	
UNK	.		Unknown				91386	.		Tablet	
UNK	.		Unknown				76533	.		Tablet	
UNK	.		Unknown					.	.		
UNK	.		Unknown				76533	.		Tablet, Immediate Release	
UNK	.		Unknown				76533	.		Tablet, Immediate Release	
UNK	.		Unknown				91161	.			
UNK	.		Unknown					.	.		
UNK	.		Unknown					.	.		

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>
1070483325	10704833	35	Secondary Suspect Drug	BACLOFEN	BACLOFEN	Validated trade name used	Oral
1070483325	10704833	36	Secondary Suspect Drug	CALCIUM CARBONATE	CALCIUM CARBONATE	Validated trade name used	Unknown
1070483325	10704833	37	Secondary Suspect Drug	FOLIC ACID	FOLIC ACID	Validated trade name used	Oral
1070483325	10704833	38	Secondary Suspect Drug	FOLIC ACID	FOLIC ACID	Validated trade name used	Unknown
1070483325	10704833	39	Secondary Suspect Drug	GLICLAZIDE	GLICLAZIDE	Validated trade name used	Unknown
1070483325	10704833	40	Secondary Suspect Drug	DULOXETINE	DULOXETINE	Validated trade name used	Oral
1070483325	10704833	41	Secondary Suspect Drug	DULOXETINE	DULOXETINE	Validated trade name used	Oral
1070483325	10704833	42	Secondary Suspect Drug	DULOXETINE	DULOXETINE	Validated trade name used	Oral
1070483325	10704833	43	Secondary Suspect Drug	DULOXETINE	DULOXETINE	Validated trade name used	Oral
1070483325	10704833	44	Secondary Suspect Drug	DULOXETINE	DULOXETINE	Validated trade name used	Unknown
1070483325	10704833	45	Secondary Suspect Drug	DULOXETINE	DULOXETINE	Validated trade name used	Unknown

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
UNK	.		Unknown					.	.		
UNK	.		Unknown					.	.	Tablet	
UNK	.		Unknown					.	.		
UNK	.		Unknown					.	.		
10 milligram	.		Unknown					.	10 Milligram(s)	Tablet	
UNK	.		Unknown				202045	.		CAPSULE, DELAYED RELEASE	
3 milligram, qd	.		Unknown				202045	3	Milligram(s)	CAPSULE, DELAYED RELEASE	
1 dosage form, qd	.		Unknown				202045	.		CAPSULE, DELAYED RELEASE	
1 milligram, qd	.		Unknown				202045	1	Milligram(s)	CAPSULE, DELAYED RELEASE	
1 milligram	.		Unknown				202045	1	Milligram(s)	CAPSULE, DELAYED RELEASE	
1 dosage form, qd	.		Unknown				202045	.		CAPSULE, DELAYED RELEASE	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>
1070483325	10704833	46	Secondary Suspect Drug	LORATADINE	LORATADINE	Validated trade name used	Oral
1070483325	10704833	47	Secondary Suspect Drug	LORATADINE	LORATADINE	Validated trade name used	Oral
1070483325	10704833	48	Secondary Suspect Drug	LORATADINE	LORATADINE	Validated trade name used	Unknown
1070483325	10704833	49	Secondary Suspect Drug	MYCOPHENOLATE MOFETIL	MYCOPHENOLATE MOFETIL	Validated trade name used	Unknown
1070483325	10704833	50	Secondary Suspect Drug	TRIMIPRAMINE	TRIMIPRAMINE	Validated trade name used	Unknown
1070483325	10704833	51	Secondary Suspect Drug	ALENDRONATE SODIUM\CHOLECALCIFEROL	ALENDRONATE SODIUM\CHOLECALCIFEROL	Validated trade name used	Unknown
1070483325	10704833	52	Secondary Suspect Drug	DOCUSATE SODIUM	DOCUSATE SODIUM	Validated trade name used	Unknown
1070483325	10704833	53	Secondary Suspect Drug	DOCUSATE SODIUM	DOCUSATE SODIUM	Validated trade name used	Unknown
1070483325	10704833	54	Secondary Suspect Drug	LORATADINE	LORATADINE	Validated trade name used	Unknown
1070483325	10704833	55	Secondary Suspect Drug	HYDROCHLOROTHIAZIDE	HYDROCHLOROTHIAZIDE	Validated trade name used	Oral
1070483325	10704833	56	Secondary Suspect Drug	CLARITHROMYCIN	CLARITHROMYCIN	Validated trade name used	Unknown

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
10 milligram	.		Unknown				999999	10	Milligram(s)	Tablet	
UNK	.		Unknown				999999	.		Tablet	
UNK	.		Unknown				999999	.		Tablet	
UNK	.		Unknown				91558	.			
UNK	.		Unknown				.	.			
UNK	.		Unknown				.	.			
UNK	.		Unknown				.	.			
3 milliliter, qd	.		Unknown				.	3	Millilitre(s)		
10 mg, UNK	.		Unknown				.	10	Milligram(s)	Capsule	
UNK	.		Unknown				40774	.		Tablet	
10 milligram	.		Unknown				.	10	Milligram(s)		

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>
1070483325	10704833	57	Secondary Suspect Drug	RANITIDINE	RANITIDINE	Validated trade name used	Unknown
1070483325	10704833	58	Secondary Suspect Drug	SULFAMETHOXAZOLE\TRIMETHOPRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM	Validated trade name used	Oral
1070483325	10704833	59	Secondary Suspect Drug	ASPIRIN	ASPIRIN	Validated trade name used	Unknown
1070483325	10704833	60	Secondary Suspect Drug	TRIMETHOPRIM	TRIMETHOPRIM	Validated trade name used	Unknown
1070483325	10704833	61	Secondary Suspect Drug	POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	Validated trade name used	Intravenous (not otherwise specified)
1070483325	10704833	62	Secondary Suspect Drug	POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	Validated trade name used	Intravenous (not otherwise specified)
1070483325	10704833	63	Secondary Suspect Drug	POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	Validated trade name used	Intravenous (not otherwise specified)
1070483325	10704833	64	Secondary Suspect Drug	POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	Validated trade name used	Unknown
1070483325	10704833	65	Secondary Suspect Drug	POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	Validated trade name used	Unknown
1070483325	10704833	66	Secondary Suspect Drug	POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	Validated trade name used	Unknown
1070483325	10704833	67	Secondary Suspect Drug	ACIDOPHILUS	LACTOBACILLUS ACIDOPHILUS	Validated trade name used	Oral



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
UNK	.		Unknown				79127	.			
UNK	.		Unknown				.	.			
UNK	.		Unknown				.	.			
UNK	.		Unknown				.	.		Tablet, Immediate Release	
600 milligram	.		Unknown				.	600	Milligram(s)	Solution for injection	
600 milliequivalent	.		Unknown				.	600	Milliequivalent(s)	Solution for injection	
UNK	.		Unknown				.	.		Solution for injection	
600 milligram	.		Unknown				.	600	Milligram(s)	Solution for injection	
60 milligram	.		Unknown				.	60	Milligram(s)	Solution for injection	
600 milliequivalent	.		Unknown				.	600	Milliequivalent(s)	Solution for injection	
UNK	.		Unknown				.	.		Capsule	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>
1070483325	10704833	68	Secondary Suspect Drug	LORATADINE	LORATADINE	Validated trade name used	Intravenous (not otherwise specified)
1070483325	10704833	69	Secondary Suspect Drug	LORATADINE	LORATADINE	Validated trade name used	Intravenous (not otherwise specified)
1070483325	10704833	70	Secondary Suspect Drug	LORATADINE	LORATADINE	Validated trade name used	Intravenous (not otherwise specified)
1070483325	10704833	71	Secondary Suspect Drug	THYMOCYTE IMMUNE GLOBULIN NOS	THYMOCYTE IMMUNE GLOBULIN NOS	Validated trade name used	Intravenous (not otherwise specified)
1070483325	10704833	72	Secondary Suspect Drug	SULFATRIM	SULFAMETHOXAZOLE\TRIMETHOPRIM	Validated trade name used	Intravenous (not otherwise specified)
1070483325	10704833	73	Secondary Suspect Drug	ATIVAN	LORAZEPAM	Validated trade name used	Unknown
1070483325	10704833	74	Secondary Suspect Drug	CELLCEPT	MYCOPHENOLATE MOFETIL	Validated trade name used	Unknown
1070483325	10704833	75	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used	Oral
1070483325	10704833	76	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used	Oral
1070483325	10704833	77	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used	Oral
1070483325	10704833	78	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used	Oral

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
UNK	.		Unknown				.	.		Tablet	
600 milligram	.		Unknown				.	600	Milligram(s)	Tablet	
10 milligram	.		Unknown				.	10	Milligram(s)	Tablet	
UNK	.		Unknown				.	.		Solution for injection	
UNK	.		Unknown				.	.			
UNK	.		Unknown				.	.		Tablet	
UNK	.		Unknown				.	.		Tablet	
3 milligram, qd	.		Unknown				.	3	Milligram(s)	Capsule XR	
3 milligram, qd	.		Unknown				.	3	Milligram(s)	Capsule XR	
UNK, qd	.		Unknown				.	.		Capsule XR	
1 dosage form, qd	.		Unknown				.	.		Capsule XR	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>
1070483325	10704833	79	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used	Oral
1070483325	10704833	80	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used	Oral
1070483325	10704833	81	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used	Unknown
1070483325	10704833	82	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used	Oral
1070483325	10704833	83	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used	Unknown
1070483325	10704833	84	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used	Oral
1070483325	10704833	85	Secondary Suspect Drug	IMODIUM	LOPERAMIDE HYDROCHLORIDE	Validated trade name used	Intravenous (not otherwise specified)
1070483325	10704833	86	Secondary Suspect Drug	IMODIUM	LOPERAMIDE HYDROCHLORIDE	Validated trade name used	Unknown
1070483325	10704833	87	Secondary Suspect Drug	B100	CITRIC ACID MONOHYDRATE\SODIUM CHLORITE	Validated trade name used	Unknown
1070483325	10704833	88	Secondary Suspect Drug	LYRICA	PREGABALIN	Validated trade name used	Oral
1070483325	10704833	89	Secondary Suspect Drug	MELATONIN	MELATONIN	Validated trade name used	Unknown

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
1 dosage form, qd	.		Unknown					.	.	Capsule XR	
UNK UNK, qd	.		Unknown					.	.	Capsule XR	
3 milligram, qd	.		Unknown					.	3 Milligram(s)	Capsule XR	
1 milligram, qd	.		Unknown					.	1 Milligram(s)	Capsule XR	
1 dosage form, qd	.		Unknown					.	.	Capsule XR	
UNK	.		Unknown					.	.	Capsule XR	
UNK	.		Unknown					.	.		
UNK	.		Unknown					.	.		
UNK	.		Unknown					.	.	Tablet	
UNK	.		Unknown					.	.	Capsule	
5 milligram	.		Unknown					.	5 Milligram(s)	Tablet	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>
1070483325	10704833	90	Secondary Suspect Drug	NASONEX	MOMETASONE FUROATE	Validated trade name used	Unknown
1070483325	10704833	91	Secondary Suspect Drug	HYDROCHLOROTHIAZIDE	HYDROCHLOROTHIAZIDE	Validated trade name used	Oral
1070483325	10704833	92	Secondary Suspect Drug	HYDROCHLOROTHIAZIDE	HYDROCHLOROTHIAZIDE	Validated trade name used	Unknown
1070483325	10704833	93	Secondary Suspect Drug	FISH OIL	FISH OIL	Validated trade name used	Oral
1070483325	10704833	94	Secondary Suspect Drug	FISH OIL	FISH OIL	Validated trade name used	Unknown
1070483325	10704833	95	Secondary Suspect Drug	SENNOSIDES A AND B	SENNOSIDES A AND B	Validated trade name used	Unknown
1070483325	10704833	96	Secondary Suspect Drug	SENOKOT	SENNOSIDES	Validated trade name used	Unknown
1070483325	10704833	97	Secondary Suspect Drug	VITAMIN B12	CYANOCOBALAMIN	Validated trade name used	Unknown
1070483325	10704833	98	Secondary Suspect Drug	VITAMIN C	ASCORBIC ACID	Validated trade name used	Unknown
1070483325	10704833	99	Secondary Suspect Drug	VITAMIN D	VITAMIN D NOS	Validated trade name used	Unknown
1070483325	10704833	100	Secondary Suspect Drug	ZANTAC	RANITIDINE HYDROCHLORIDE	Validated trade name used	Oral

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
UNK	.		Unknown					.	.	SPRAY, METERED	
UNK	.		Unknown					.	.	Tablet	
UNK	.		Unknown					.	.	Tablet	
UNK	.		Unknown					.	.	Capsule	
UNK	.		Unknown					.	.	Capsule	
UNK	.		Unknown					.	.	Tablet	
UNK	.		Unknown					.	.	Tablet	
UNK	.		Unknown					.	.	Injection	
UNK	.		Unknown					.	.	Capsule	
UNK	.		Unknown					.	.	Tablet	
UNK	.		Unknown					.	.		

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>
1070483325	10704833	101	Secondary Suspect Drug	VITAMIN B12	CYANOCOBALAMIN	Validated trade name used	Unknown
1070483325	10704833	102	Secondary Suspect Drug	NIACINAMIDE\PYRIDOXINE HYDROCHLORIDE\RIBOFLAVIN\THIAMINE HYDROCHLORIDE	NIACINAMIDE\PYRIDOXINE HYDROCHLORIDE\RIBOFLAVIN\THIAMINE HYDROCHLORIDE	Validated trade name used	Unknown
1070483325	10704833	103	Secondary Suspect Drug	DOCONEXENT\ICOSAPENT	DOCONEXENT\ICOSAPENT	Validated trade name used	Unknown
1070483325	10704833	104	Secondary Suspect Drug	BIFIDOBACTERIUM ANIMALIS LACTIS	BIFIDOBACTERIUM ANIMALIS LACTIS	Validated trade name used	Unknown
1070483325	10704833	105	Secondary Suspect Drug	VITAMINS	VITAMINS	Validated trade name used	Unknown
1070483325	10704833	106	Secondary Suspect Drug	NIACINAMIDE\PYRIDOXINE HYDROCHLORIDE\RIBOFLAVIN\THIAMINE HYDROCHLORIDE	NIACINAMIDE\PYRIDOXINE HYDROCHLORIDE\RIBOFLAVIN\THIAMINE HYDROCHLORIDE	Validated trade name used	Unknown
1070483325	10704833	107	Secondary Suspect Drug	SENNA LEAF	SENNA LEAF	Validated trade name used	Oral
1070483325	10704833	108	Secondary Suspect Drug	DEXPANTHENOL	DEXPANTHENOL	Validated trade name used	Unknown
1070483325	10704833	109	Secondary Suspect Drug	ERGOCALCIFEROL	ERGOCALCIFEROL	Validated trade name used	Unknown
1070483325	10704833	110	Secondary Suspect Drug	PYRIDOXINE HYDROCHLORIDE	PYRIDOXINE HYDROCHLORIDE	Validated trade name used	Unknown
1070483325	10704833	111	Secondary Suspect Drug	RIBOFLAVIN	RIBOFLAVIN	Validated trade name used	Unknown



ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
UNK	.		Unknown					.	.	Tablet	
UNK, Unknown	.		Unknown					.	.	Tablet	
1000 mg, UNK	.		Unknown					.	1000 Milligram(s)	Capsule	
UNK	.		Unknown					.	.	Powder	
	.		Unknown					.	.		
UNK	.		Unknown					.	.		
	.		Unknown					.	.	Oral drops	
UNK	.		Unknown					.	.		
UNK	.		Unknown					.	.		
UNK	.		Unknown					.	.		
UNK	.		Unknown					.	.		

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>
1070483325	10704833	112	Secondary Suspect Drug	THIAMINE HYDROCHLORIDE
1070483325	10704833	113	Secondary Suspect Drug	RETINOL
1070483325	10704833	114	Secondary Suspect Drug	RETINOL
1070483325	10704833	115	Secondary Suspect Drug	RETINOL
1070483325	10704833	116	Secondary Suspect Drug	RETINOL
1070483325	10704833	117	Secondary Suspect Drug	RETINOL
1070483325	10704833	118	Secondary Suspect Drug	RETINOL
1070483325	10704833	119	Secondary Suspect Drug	RETINOL
1070483325	10704833	120	Secondary Suspect Drug	RETINOL
1070483325	10704833	121	Secondary Suspect Drug	RETINOL
1070483325	10704833	122	Secondary Suspect Drug	NICOTINAMIDE
1070483325	10704833	123	Secondary Suspect Drug	CALCIUM
1070483325	10704833	124	Secondary Suspect Drug	CYANOCOBALAMIN
1070483325	10704833	125	Secondary Suspect Drug	SENNAL LEAF
1070483325	10704833	126	Secondary Suspect Drug	LOPERAMIDE

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulativ e dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>
THIAMINE HYDROCHLORIDE	Validated trade name used	Oral	UNK	.		Unknown
RETINOL	Validated trade name used	Oral	3 mg, qd	.		Unknown
RETINOL	Validated trade name used	Oral	1 DF, qd	.		Unknown
RETINOL	Validated trade name used	Unknown	600 mEq, UNK	.		Unknown
RETINOL	Validated trade name used	Oral	UNK	.		Unknown
RETINOL	Validated trade name used	Unknown	1 DF, qd	.		Unknown
RETINOL	Validated trade name used	Unknown	3 mg, qd	.		Unknown
RETINOL	Validated trade name used	Unknown	UNK, 600 MU	.		Unknown
RETINOL	Validated trade name used	Unknown	600 milligram	.		Unknown
RETINOL	Validated trade name used	Unknown	UNK	.		Unknown
NIACINAMIDE	Validated trade name used	Unknown		.		Unknown
CALCIUM	Validated trade name used	Unknown	UNK	.		Unknown
CYANOCOBALAMIN	Validated trade name used	Unknown	UNK	.		Unknown
SENNAL LEAF	Validated trade name used	Unknown	UNK	.		Unknown
LOPERAMIDE	Validated trade name used	Intravenous (not otherwise specified)	UNK milligram	.		Unknown

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.	.	.	.	.	.	Tablet	.
.	.	.	.	3	Milligram(s)	Gel	.
.	.	.	.	.	.	Gel	.
.	.	.	.	600	Milliequivalent(s)	Gel	.
.	.	.	.	.	.	Gel	.
.	.	.	.	.	.	Gel	.
.	.	.	.	3	Milligram(s)	Gel	.
.	.	.	.	.	.	Gel	.
.	.	.	.	600	Milligram(s)	Gel	.
.	.	.	.	.	.	Gel	.
.	.	.	.	.	.	.	.
.	.	.	.	.	.	Capsule	.
.	.	.	.	.	.	Injection	.
.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>
1070483325	10704833	127	Secondary Suspect Drug	CLARITIN
1070483325	10704833	128	Secondary Suspect Drug	CLARITIN
1070483325	10704833	129	Secondary Suspect Drug	BIFIDOBACTERIUM ANIMALIS LACTIS
1070483325	10704833	130	Secondary Suspect Drug	FISH OIL
1070483325	10704833	131	Secondary Suspect Drug	HUMAN IMMUNOGLOBULIN G
1070483325	10704833	132	Secondary Suspect Drug	HORSE CHESTNUT
1070483325	10704833	133	Secondary Suspect Drug	FOSAMAX
1070483325	10704833	134	Secondary Suspect Drug	FISH OIL\TOCOPHEROL
1070483325	10704833	135	Secondary Suspect Drug	FISH OIL\TOCOPHEROL
1070483325	10704833	136	Secondary Suspect Drug	BACLOFEN
1070483325	10704833	137	Secondary Suspect Drug	ASCORBIC ACID
1070483325	10704833	138	Secondary Suspect Drug	CALCIUM CARBONATE
1070483325	10704833	139	Secondary Suspect Drug	FISH OIL
1070483325	10704833	140	Secondary Suspect Drug	FISH OIL
1070483325	10704833	141	Secondary Suspect Drug	SULFATRIM

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulativ e dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>
LORATADINE	Validated trade name used	Unknown	10 mg, UNK	.		Unknown
LORATADINE	Validated trade name used	Intravenous (not otherwise specified)	600 mg, UNK	.		Unknown
BIFIDOBACTERIUM ANIMALIS LACTIS	Validated trade name used	Unknown	UNK	.		Unknown
FISH OIL	Validated trade name used	Unknown	UNK	.		Unknown
HUMAN IMMUNOGLOBULIN G	Validated trade name used	Intravenous (not otherwise specified)	UNK	.		Unknown
HORSE CHESTNUT	Validated trade name used	Unknown	UNK	.		Unknown
ALENDRONATE SODIUM	Validated trade name used	Unknown	UNK	.		Unknown
FISH OIL\TOCOPHEROL	Validated trade name used	Unknown	UNK	.		Unknown
FISH OIL\TOCOPHEROL	Validated trade name used	Oral	UNK	.		Unknown
BACLOFEN	Validated trade name used	Unknown	UNK	.		Unknown
ASCORBIC ACID	Validated trade name used	Unknown	UNK	.		Unknown
CALCIUM CARBONATE	Validated trade name used	Unknown	UNK	.		Unknown
FISH OIL	Validated trade name used	Oral	UNK	.		Unknown
FISH OIL	Validated trade name used	Unknown	UNK	.		Unknown
SULFAMETHOXAZOLE\TRIMETHOPRIM	Validated trade name used	Intravenous (not otherwise specified)	UNK	.		Unknown

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
			.	10	Milligram(s)	Tablet SR	
			.	600	Milligram(s)	Tablet SR	
			.	.			
			.	.		Capsule	
			.	.		Solution for injection/infusion	
			.	.		Capsule	
			.	.		Tablet	
			.	.		CAPSULE, COATED	
			.	.		CAPSULE, COATED	
			.	.		Solution for injection	
			.	.		Capsule	
			.	.		Enteric Tablet	
			.	.		Capsule	
			.	.		Capsule	
			.	.			

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>
1070483325	10704833	142	Secondary Suspect Drug	BIOTIN
1070483325	10704833	143	Secondary Suspect Drug	COD LIVER OIL
1070483325	10704833	144	Secondary Suspect Drug	INSULIN NOS
1070483325	10704833	145	Secondary Suspect Drug	LACTOBACILLUS CASEI
1070483325	10704833	146	Secondary Suspect Drug	OMEGA-3-ACID ETHYL ESTERS
1070483325	10704833	147	Secondary Suspect Drug	VITAMIN D3
1070483325	10704833	148	Secondary Suspect Drug	TRIAMTERENE
1070483325	10704833	149	Secondary Suspect Drug	SULFADIAZINE\TRIMETHOPRIM
1070483325	10704833	150	Secondary Suspect Drug	SULFADIAZINE\TRIMETHOPRIM
1070483325	10704833	151	Secondary Suspect Drug	SULFADIAZINE\TRIMETHOPRIM
1070483325	10704833	152	Secondary Suspect Drug	SULFADIAZINE\TRIMETHOPRIM
1070483325	10704833	153	Secondary Suspect Drug	SULFADIAZINE\TRIMETHOPRIM
1070483325	10704833	154	Secondary Suspect Drug	SULFADIAZINE\TRIMETHOPRIM
1070483325	10704833	155	Secondary Suspect Drug	SULFADIAZINE\TRIMETHOPRIM
1070483325	10704833	156	Secondary Suspect Drug	DOCONEXENT



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulativ e dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>
BIOTIN	Validated trade name used	Unknown	UNK	.		Unknown
COD LIVER OIL	Validated trade name used	Oral	UNK	.		Unknown
INSULIN NOS	Validated trade name used	Unknown	UNK	.		Unknown
LACTOBACILLUS CASEI	Validated trade name used	Unknown	UNK	.		Unknown
OMEGA-3-ACID ETHYL ESTERS	Validated trade name used	Unknown	UNK	.		Unknown
CHOLECALCIFEROL	Validated trade name used	Unknown	400 IU, UNK	.		Unknown
TRIAMTERENE	Validated trade name used	Unknown	UNK	.		Unknown
SULFADIAZINE\TRIMETHOPRIM	Validated trade name used	Oral	60 milligram	.		Unknown
SULFADIAZINE\TRIMETHOPRIM	Validated trade name used	Oral	1 dosage form, qd	.		Unknown
SULFADIAZINE\TRIMETHOPRIM	Validated trade name used	Oral	3 milligram, qd	.		Unknown
SULFADIAZINE\TRIMETHOPRIM	Validated trade name used	Oral	UNK	.		Unknown
SULFADIAZINE\TRIMETHOPRIM	Validated trade name used	Oral	3 dosage form	.		Unknown
SULFADIAZINE\TRIMETHOPRIM	Validated trade name used	Unknown	UNK	.		Unknown
SULFADIAZINE\TRIMETHOPRIM	Validated trade name used	Oral	1 milligram, qd	.		Unknown
DOCONEXENT	Validated trade name used	Unknown	UNK	.		Unknown

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
.	.	.	.	.	.	.	.
.	.	.	.	.	.	Capsule	.
.	.	.	.	.	.	Capsule, hard	.
.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.
.	.	.	.	400	International Unit(s)	Capsule	.
.	.	.	.	.	.	.	.
.	.	.	.	60	Milligram(s)	.	.
.	.	.	.	.	.	.	.
.	.	.	.	3	Milligram(s)	.	.
.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.
.	.	.	.	1	Milligram(s)	.	.
.	.	.	.	.	.	.	.

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>
1070483325	10704833	157	Secondary Suspect Drug	SULFAMETHOXAZOLE
1070483325	10704833	158	Secondary Suspect Drug	BIFIDOBACTERIUM LONGUM\LACTOBACILLUS ACIDOPHILUS
1070483325	10704833	159	Secondary Suspect Drug	LAPINE T-LYMPHOCYTE IMMUNE GLOBULIN
1070483325	10704833	160	Secondary Suspect Drug	AMINOBENZOIC ACID
1070483325	10704833	161	Secondary Suspect Drug	EQUINE THYMOCYTE IMMUNE GLOBULIN
1070483325	10704833	162	Secondary Suspect Drug	BIFIDOBACTERIUM BIFIDUM
1070483325	10704833	163	Secondary Suspect Drug	CHOLINE BITARTRATE
1070483325	10704833	164	Secondary Suspect Drug	GAMASTAN
1070483325	10704833	165	Secondary Suspect Drug	INOSITOL
1070483325	10704833	166	Secondary Suspect Drug	LACTOBACILLUS ACIDOPHILUS
1070483325	10704833	167	Secondary Suspect Drug	LECITHIN
1070483325	10704833	168	Secondary Suspect Drug	NASONEX
1070483325	10704833	169	Secondary Suspect Drug	SENNOSIDES A AND B
1070483325	10704833	170	Secondary Suspect Drug	DOCUSATE SODIUM\SENNOSIDES A AND B
1070483325	10704833	171	Secondary Suspect Drug	.ALPHA.-TOCOPHEROL, D-

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulativ e dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>
SULFAMETHOXAZOLE	Validated trade name used	Intravenous (not otherwise specified)	UNK	.		Unknown
BIFIDOBACTERIUM LONGUM\LACTOBACILLUS ACIDOPHILUS	Validated trade name used	Oral	UNK	.		Unknown
LAPINE T-LYMPHOCYTE IMMUNE GLOBULIN	Validated trade name used	Unknown	UNK	.		Unknown
AMINO BENZOIC ACID	Validated trade name used	Unknown	UNK	.		Unknown
EQUINE THYMOCYTE IMMUNE GLOBULIN	Validated trade name used	Intravenous (not otherwise specified)	UNK	.		Unknown
BIFIDOBACTERIUM BIFIDUM	Validated trade name used	Unknown	UNK	.		Unknown
CHOLINE BITARTRATE	Validated trade name used	Unknown	UNK	.		Unknown
HUMAN IMMUNOGLOBULIN G	Validated trade name used	Intravenous (not otherwise specified)	UNK	.		Unknown
INOSITOL	Validated trade name used	Unknown	UNK	.		Unknown
LACTOBACILLUS ACIDOPHILUS	Validated trade name used	Oral	UNK	.		Unknown
LECITHIN	Validated trade name used	Unknown	UNK	.		Unknown
MOMETASONE FUROATE	Validated trade name used	Intravenous (not otherwise specified)	UNK	.		Unknown
SENNOSIDES A AND B	Validated trade name used	Unknown	UNK	.		Unknown
DOCUSATE SODIUM\SENNOSIDES A AND B	Validated trade name used	Unknown	UNK	.		Unknown
.ALPHA.-TOCOPHEROL, D-	Validated trade name used	Oral	UNK	.		Unknown

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
			.	.			
			.	.		Capsule CR	
			.	.			
			.	.			
			.	.		Injection	
			.	.			
			.	.		Solution for injection	
			.	.			
			.	.		Capsule	
			.	.			
			.	.			
			.	.			
			.	.			
			.	.			

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>
1070483325	10704833	172	Secondary Suspect Drug	GUAIFENESIN\SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	173	Secondary Suspect Drug	BIFIDOBACTERIUM LONGUM
1070483325	10704833	174	Secondary Suspect Drug	CHOLECALCIFEROL
1070483325	10704833	175	Secondary Suspect Drug	CHOLECALCIFEROL
1070483325	10704833	176	Secondary Suspect Drug	CREATINE
1070483325	10704833	177	Secondary Suspect Drug	FRUCTOSE
1070483325	10704833	178	Secondary Suspect Drug	.ALPHA.-TOCOPHEROL ACETATE, D-EVENING PRIMROSE OIL\FISH OIL
1070483325	10704833	179	Secondary Suspect Drug	VITAMINS
1070483325	10704833	180	Secondary Suspect Drug	MYCOPHENOLATE MOFETIL HYDROCHLORIDE
1070483325	10704833	181	Secondary Suspect Drug	BIFIDOBACTERIUM BIFIDUM\LYSOZYME
1070483325	10704833	182	Secondary Suspect Drug	INULIN
1070483325	10704833	183	Secondary Suspect Drug	VITAMIN B1
1070483325	10704833	184	Secondary Suspect Drug	HORSE CHESTNUT
1070483325	10704833	185	Secondary Suspect Drug	LORATADINE\PSEUDOEPHEDRINE SULFATE
1070483325	10704833	186	Secondary Suspect Drug	VITAMIN B12

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulativ e dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>
GUAIFENESIN\SULFAMETHOXAZOLE\TRIMETHOPRIM	Validated trade name used	Unknown	UNK	.		Unknown
BIFIDOBACTERIUM LONGUM	Validated trade name used	Unknown	UNK	.		Unknown
CHOLECALCIFEROL	Validated trade name used	Unknown	400 international unit	.		Unknown
CHOLECALCIFEROL	Validated trade name used	Unknown	1000 international unit	.		Unknown
CREATINE	Validated trade name used	Unknown	UNK	.		Unknown
FRUCTOSE	Validated trade name used	Unknown	UNK	.		Unknown
.ALPHA.-TOCOPHEROL ACETATE, D-EVENING PRIMROSE OIL\FISH OIL	Validated trade name used	Unknown	UNK	.		Unknown
VITAMINS	Validated trade name used	Unknown	UNK	.		Unknown
MYCOPHENOLATE MOFETIL HYDROCHLORIDE	Validated trade name used	Unknown	UNK	.		Unknown
BIFIDOBACTERIUM BIFIDUM\LYSOZYME	Validated trade name used	Unknown	UNK	.		Unknown
INULIN	Validated trade name used	Unknown	UNK	.		Unknown
THIAMINE HYDROCHLORIDE	Validated trade name used	Unknown	UNK	.		Unknown
HORSE CHESTNUT	Validated trade name used	Unknown	UNK	.		Unknown
LORATADINE\PSEUDOEPHEDRINE SULFATE	Validated trade name used	Unknown	10 mg, UNK	.		Unknown
CYANOCOBALAMIN	Validated trade name used	Unknown	UNK	.		Unknown

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Rechallenge code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported).	NDA number.	Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
			.	.			
			.	.			
			.	400	International Unit(s)		
			.	1000	International Unit(s)		
			.	.			
			.	.			
			.	.			
			.	.			
			.	.			
			.	.			
			.	.		Capsule, hard	
			.	.			
			.	.		Cream	
			.	10	Milligram(s)	Tablet	
			.	.		Capsule	



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>
1070483325	10704833	187	Secondary Suspect Drug	SULFADIAZINE\TRIMETHOPRIM
1070483325	10704833	188	Secondary Suspect Drug	HYDROXOCOBALAMIN
1070483325	10704833	189	Secondary Suspect Drug	VACCINIA IMMUNE GLOBULIN HUMAN
1070483325	10704833	190	Secondary Suspect Drug	VITAMIN B1
1070483325	10704833	191	Secondary Suspect Drug	CYANOCOBALAMIN
1070483325	10704833	192	Secondary Suspect Drug	LACTOBACILLUS REUTERI
1070483325	10704833	193	Secondary Suspect Drug	LACTOBACILLUS REUTERI
1070483325	10704833	194	Secondary Suspect Drug	DOCUSATE SODIUM\SENNA LEAF
1070483325	10704833	195	Secondary Suspect Drug	CREATININE
1070483325	10704833	196	Secondary Suspect Drug	SODIUM CHLORIDE
1070483325	10704833	197	Secondary Suspect Drug	MAGNESIUM CARBONATE
1070483325	10704833	198	Secondary Suspect Drug	CALCIUM GLUCONATE
1070483325	10704833	199	Secondary Suspect Drug	DOCUSATE CALCIUM
1070483325	10704833	200	Secondary Suspect Drug	CALCIUM PANTOTHENATE
1070483325	10704833	201	Secondary Suspect Drug	SENNOSIDES A AND B

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulativ e dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>
SULFADIAZINE/TRIMETHOPRIM	Validated trade name used	Intravenous (not otherwise specified)	UNK	.		Unknown
HYDROXOCOBALAMIN	Validated trade name used	Unknown	UNK	.		Unknown
VACCINIA IMMUNE GLOBULIN HUMAN	Validated trade name used	Intravenous (not otherwise specified)	UNK	.		Unknown
THIAMINE HYDROCHLORIDE	Validated trade name used	Unknown	UNK	.		Unknown
CYANOCOBALAMIN	Validated trade name used	Unknown	UNK	.		Unknown
LACTOBACILLUS REUTERI	Validated trade name used	Unknown	UNK	.		Unknown
LACTOBACILLUS REUTERI	Validated trade name used	Unknown	3 milliliter	.		Unknown
DOCUSATE SODIUM/SENNA LEAF	Validated trade name used	Unknown	UNK	.		Unknown
CREATININE	Validated trade name used	Unknown	UNK	.		Unknown
SODIUM CHLORIDE	Validated trade name used	Unknown	UNK	.		Unknown
MAGNESIUM CARBONATE	Validated trade name used	Unknown	UNK	.		Unknown
CALCIUM GLUCONATE	Validated trade name used	Unknown	UNK	.		Unknown
DOCUSATE CALCIUM	Validated trade name used	Unknown	UNK	.		Unknown
CALCIUM PANTOTHENATE	Validated trade name used	Unknown	UNK	.		Unknown
SENNOSIDES A AND B	Validated trade name used	Unknown	UNK	.		Unknown

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
			.	.			
			.	.			
			.	.			
			.	.		Capsule	
			.	.			
			.	.			
			.	3	Millilitre(s)		
			.	.			
			.	.			
			.	.			
			.	.			
			.	.			
			.	.		Capsule	
			.	.			
			.	.			

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>
1070483325	10704833	202	Secondary Suspect Drug	LACTOBACILLUS CASEI
1070483325	10704833	203	Secondary Suspect Drug	DOCUSATE SODIUM\SENNOSIDES A AND B
1070483325	10704833	204	Secondary Suspect Drug	GAMMAGARD
1070483325	10704833	205	Secondary Suspect Drug	GAMMAGARD
1070483325	10704833	206	Secondary Suspect Drug	TETANUS IMMUNE GLOBULIN (HUMAN)
1070483325	10704833	207	Secondary Suspect Drug	SULFADIAZINE
1070483325	10704833	208	Secondary Suspect Drug	SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	209	Secondary Suspect Drug	SULFADIAZINE
1070483325	10704833	210	Secondary Suspect Drug	SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	211	Secondary Suspect Drug	SULFADIAZINE
1070483325	10704833	212	Secondary Suspect Drug	CLORPRENALINE HYDROCHLORIDE
1070483325	10704833	213	Secondary Suspect Drug	BROMHEXINE\SULFAMETHOXAZOLE\TRIMETHOPRIM
1070483325	10704833	214	Secondary Suspect Drug	POTASSIUM CHLORIDE\SODIUM CHLORIDE
1070483325	10704833	215	Secondary Suspect Drug	SULFADIAZINE\TETROXOPRIM
1070483325	10704833	216	Secondary Suspect Drug	SULFADIAZINE\TETROXOPRIM

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>	<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulativ e dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>
LACTOBACILLUS CASEI	Validated trade name used	Unknown	UNK	.		Unknown
DOCUSATE SODIUM\SENNOSIDES A AND B	Validated trade name used	Unknown	UNK	.		Unknown
HUMAN IMMUNOGLOBULIN G	Validated trade name used	Unknown	UNK	.		Unknown
HUMAN IMMUNOGLOBULIN G	Validated trade name used	Intravenous (not otherwise specified)	UNK	.		Unknown
HUMAN CLOSTRIDIUM TETANI TOXOID IMMUNE GLOBULIN	Validated trade name used	Unknown	UNK	.		Unknown
SULFADIAZINE	Validated trade name used	Oral	1 dosage form, qd	.		Unknown
SULFAMETHOXAZOLE\TRIMETHOPRIM	Validated trade name used	Oral	60 milligram	.		Unknown
SULFADIAZINE	Validated trade name used	Oral	3 milligram, qd	.		Unknown
SULFAMETHOXAZOLE\TRIMETHOPRIM	Validated trade name used	Oral	UNK	.		Unknown
SULFADIAZINE	Validated trade name used	Intravenous (not otherwise specified)	UNK	.		Unknown
CLOPRENALINE HYDROCHLORIDE	Validated trade name used	Unknown	UNK	.		Unknown
BROMHEXINE\SULFAMETHOXAZOLE\TRIMETHOPRIM	Validated trade name used	Unknown	UNK	.		Unknown
POTASSIUM CHLORIDE\SODIUM CHLORIDE	Validated trade name used	Intravenous (not otherwise specified)	UNK	.		Unknown
SULFADIAZINE\TETROXOPRIM	Validated trade name used	Oral	60 milligram	.		Unknown
SULFADIAZINE\TETROXOPRIM	Validated trade name used	Oral	3 milligram, qd	.		Unknown

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported).</i>	<i>NDA number.</i>	<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
			.	.			
			.	.		Film-coated tablet	
			.	.		Powder for solution for injection or infusion	
			.	.		Powder for solution for injection or infusion	
			.	.			
			.	.			
			.	60	Milligram(s)		
			.	3	Milligram(s)		
			.	.			
			.	.			
			.	.			
			.	.			
			.	.			
			.	.		Solution for injection	
			.	60	Milligram(s)		
			.	3	Milligram(s)		

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>
1070483325	10704833	217	Secondary Suspect Drug	SULFADIAZINE\TETROXOPRIM	SULFADIAZINE\TETROXOPRIM	Validated trade name used
1070483325	10704833	218	Secondary Suspect Drug	SULFADIAZINE\TETROXOPRIM	SULFADIAZINE\TETROXOPRIM	Validated trade name used
1070483325	10704833	219	Secondary Suspect Drug	CREATINE	CREATINE	Validated trade name used
1070483325	10704833	220	Secondary Suspect Drug	ALENDRONIC ACID	ALENDRONIC ACID	Validated trade name used
1070483325	10704833	221	Secondary Suspect Drug	DULOXETINE HYDROCHLORIDE	DULOXETINE HYDROCHLORIDE	Validated trade name used
1070483325	10704833	222	Secondary Suspect Drug	DULOXETINE HYDROCHLORIDE	DULOXETINE HYDROCHLORIDE	Validated trade name used
1070483325	10704833	223	Secondary Suspect Drug	DULOXETINE HYDROCHLORIDE	DULOXETINE HYDROCHLORIDE	Validated trade name used
1070483325	10704833	224	Secondary Suspect Drug	DULOXETINE HYDROCHLORIDE	DULOXETINE HYDROCHLORIDE	Validated trade name used
1070483325	10704833	225	Secondary Suspect Drug	NORTRIPTYLINE	NORTRIPTYLINE	Validated trade name used
1070483325	10704833	226	Secondary Suspect Drug	HYDROMORPHONE HYDROCHLORIDE	HYDROMORPHONE HYDROCHLORIDE	Validated trade name used
1070483325	10704833	227	Secondary Suspect Drug	ASCORBIC ACID	ASCORBIC ACID	Validated trade name used
1070483325	10704833	228	Secondary Suspect Drug	SULFAMETHOXAZOLE	SULFAMETHOXAZOLE	Validated trade name used
1070483325	10704833	229	Secondary Suspect Drug	SENNOSIDES	SENNOSIDES	Validated trade name used
1070483325	10704833	230	Secondary Suspect Drug	DOCUSATE SODIUM\SENNOSIDES A AND B	DOCUSATE SODIUM\SENNOSIDES A AND B	Validated trade name used

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulativ e dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechalleng e code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported) .</i>	<i>NDA number.</i>
Oral	1 dosage form, qd	.		Unknown				.
Intravenous (not otherwise specified)	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Oral	3 milliliter, qd	.		Unknown				.
Unknown	3 dosage form, qd	.		Unknown				.
Oral	1 dosage form, qd	.		Unknown				.
Oral	3 milligram	.		Unknown				.
Oral		.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Oral	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.



ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
.			
.			
.			
.			
3	Millilitre(s)		
.			
.			
3	Milligram(s)		
.		Capsule	
.		TABLET, EXTENDED RELEASE	
.		Tablet	
.			
.			
.			

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>
1070483325	10704833	231	Secondary Suspect Drug	IMODIUM	LOPERAMIDE HYDROCHLORIDE	Validated trade name used
1070483325	10704833	232	Secondary Suspect Drug	MOMETASONE FUROATE	MOMETASONE FUROATE	Validated trade name used
1070483325	10704833	233	Secondary Suspect Drug	HORSE CHESTNUT	HORSE CHESTNUT	Validated trade name used
1070483325	10704833	234	Secondary Suspect Drug	TETANUS IMMUNE GLOBULIN (HUMAN)	HUMAN CLOSTRIDIUM TETANI TOXOID IMMUNE GLOBULIN	Validated trade name used
1070483325	10704833	235	Secondary Suspect Drug	NIACINAMIDE	NIACINAMIDE	Validated trade name used
1070483325	10704833	236	Secondary Suspect Drug	SULFADIAZINE	SULFADIAZINE	Validated trade name used
1070483325	10704833	237	Secondary Suspect Drug	VITAMIN E	.ALPHA.-TOCOPHEROL	Validated trade name used
1070483325	10704833	238	Secondary Suspect Drug	ATLANTIC SALMON OIL	ATLANTIC SALMON OIL	Validated trade name used
1070483325	10704833	239	Secondary Suspect Drug	ATLANTIC SALMON OIL	ATLANTIC SALMON OIL	Validated trade name used
1070483325	10704833	240	Secondary Suspect Drug	LACTOBACILLUS REUTERI	LACTOBACILLUS REUTERI	Validated trade name used
1070483325	10704833	241	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used
1070483325	10704833	242	Secondary Suspect Drug	CYMBALTA	DULOXETINE HYDROCHLORIDE	Validated trade name used
1070483325	10704833	243	Secondary Suspect Drug	PREDNISOLONE	PREDNISOLONE	Validated trade name used
1070483325	10704833	244	Secondary Suspect Drug	VITAMIN C	ASCORBIC ACID	Validated trade name used

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

The route of drug administration	Verbatim text for dose, frequency, and r	Cumulativ e dose to first reaction	Cumulativ e dose to first reaction unit C	Dechallenge code, indicating if reaction	Rechalleng e code, indicating if reaction	Expiration date of the drug. (YYYYMMDD f	Lot number of the drug (as reported) .	NDA number.
Oral		.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Oral	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Oral	3 milliliter, qd	.		Unknown				.
		.		Unknown				.
Unknown	UNK	.		Unknown				.
Oral	3 milliliter, qd	.		Unknown				.

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
.			
.			
.		Oral liquid	
.		Solution for injection	
.			
.			
.		Capsule	
.		Capsule	
.		Capsule	
.		Oral suspension	
3	Millilitre(s)		
.			
.			
3	Millilitre(s)	Tablet	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>
1070483325	10704833	245	Secondary Suspect Drug	SULFAMETHOXAZOLE\TRIMETHOPRIM	SULFAMETHOXAZOLETRIMETHOPRIM	Validated trade name used
1070483325	10704833	246	Secondary Suspect Drug	BROMHEXINE HYDROCHLORIDE	BROMHEXINE HYDROCHLORIDE	Validated trade name used
1070483325	10704833	247	Secondary Suspect Drug	RETINOL	RETINOL	Validated trade name used
1070483325	10704833	248	Secondary Suspect Drug	3-DEHYDRORETINOL	3-DEHYDRORETINOL	Validated trade name used
1070483325	10704833	249	Secondary Suspect Drug	3-DEHYDRORETINOL	3-DEHYDRORETINOL	Validated trade name used
1070483325	10704833	250	Secondary Suspect Drug	3-DEHYDRORETINOL	3-DEHYDRORETINOL	Validated trade name used
1070483325	10704833	251	Secondary Suspect Drug	3-DEHYDRORETINOL	3-DEHYDRORETINOL	Validated trade name used
1070483325	10704833	252	Secondary Suspect Drug	3-DEHYDRORETINOL	3-DEHYDRORETINOL	Validated trade name used
1070483325	10704833	253	Secondary Suspect Drug	PROBIOTICS NOS	PROBIOTICS NOS	Validated trade name used
1070483325	10704833	254	Secondary Suspect Drug	PROBIOTICS NOS	PROBIOTICS NOS	Validated trade name used
1070483325	10704833	255	Secondary Suspect Drug	HUMAN IMMUNOGLOBULIN G	HUMAN IMMUNOGLOBULIN G	Validated trade name used
1070483325	10704833	256	Secondary Suspect Drug	VITAMIN A	VITAMIN A	Validated trade name used
1070483325	10704833	257	Secondary Suspect Drug	VITAMIN A	VITAMIN A	Validated trade name used
1070483325	10704833	258	Secondary Suspect Drug	VITAMIN A	VITAMIN A	Validated trade name used

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Drug Listings

<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported)</i>	<i>NDA number.</i>
Intravenous (not otherwise specified)	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Intravenous (not otherwise specified)	600 milliequivalent	.		Unknown				.
Oral	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Oral	1 dosage form, qd	.		Unknown				.
Unknown	600 international unit	.		Unknown				.
Oral	3 milligram	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Intravenous (not otherwise specified)	UNK	.		Unknown				.
Oral	3 dosage form, qd	.		Unknown				.
Oral	1 dosage form	.		Unknown				.
Oral	UNK	.		Unknown				.

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
.			
.			
600	Milliequivalent(s)		
.			
.			
.			
600	International Unit(s)		
3	Milligram(s)		
.			
.			
.			
.		Capsule, soft gel	
.		Capsule, soft gel	
.		Capsule, soft gel	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>
1070483325	10704833	259	Secondary Suspect Drug	VITAMIN A	VITAMIN A	Validated trade name used
1070483325	10704833	260	Secondary Suspect Drug	VITAMIN A	VITAMIN A	Validated trade name used
1070483325	10704833	261	Secondary Suspect Drug	VITAMIN A	VITAMIN A	Validated trade name used
1070483325	10704833	262	Secondary Suspect Drug	VITAMIN A	VITAMIN A	Validated trade name used
1070483325	10704833	263	Secondary Suspect Drug	CHOLECALCIFEROL	CHOLECALCIFEROL	Validated trade name used
1070483325	10704833	264	Secondary Suspect Drug	.ALPHA.-TOCOPHEROL	.ALPHA.-TOCOPHEROL	Validated trade name used
1070483325	10704833	265	Secondary Suspect Drug	BIFIDOBACTERIUM LONGUM	BIFIDOBACTERIUM LONGUM	Validated trade name used
1070483325	10704833	266	Secondary Suspect Drug	DIETARY SUPPLEMENT\PROBIOTICS	DIETARY SUPPLEMENT\PROBIOTICS NOS	Validated trade name used
1070483325	10704833	267	Secondary Suspect Drug	COBAMAMIDE	COBAMAMIDE	Validated trade name used
1070483325	10704833	268	Secondary Suspect Drug	POTASSIUM CHLORIDE\SODIUM CHLORIDE	POTASSIUM CHLORIDE\SODIUM CHLORIDE	Validated trade name used
1070483325	10704833	269	Secondary Suspect Drug	NASONEX	MOMETASONE FUROATE	Validated trade name used
1070483325	10704833	270	Concomitant	RANITIDINE	RANITIDINE	Validated trade name used
1070483325	10704833	271	Concomitant	MAGNESIUM CITRATE	MAGNESIUM CITRATE	Validated trade name used
107314353	10731435	1	Primary Suspect Drug	DEXMETHYLPHENIDATE HYDROCHLORIDE	DEXMETHYLPHENIDATE HYDROCHLORIDE	Validated trade name used



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported)</i>	<i>NDA number.</i>
Unknown	600 international unit	.		Unknown				.
Unknown	UNK	.		Unknown				.
Oral	1 dosage form, qd	.		Unknown				.
Oral	3 milligram, qd	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Intravenous (not otherwise specified)	UNK	.		Unknown				.
Unknown	UNK	.		Unknown				.
Unknown	UNK	.		Does not apply				.
Unknown	UNK	.		Does not apply				.
Unknown	20 mg, in the morning	.		Does not apply				204266

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
600	International Unit(s)	Capsule, soft gel	
.		Capsule, soft gel	
.		Capsule, soft gel	
3	Milligram(s)	Capsule, soft gel	
.		Tablet	
.			
.			
.			
.		Tablet	
.			
.		Nasal spray, suspension	
.			
.			
20	Milligram(s)		

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>
107314353	10731435	2	Interacting	DEXMETHYLPHENIDATE HYDROCHLORIDE	DEXMETHYLPHENIDATE HYDROCHLORIDE	Validated trade name used
107314353	10731435	3	Interacting	GUANFACINE HYDROCHLORIDE	GUANFACINE HYDROCHLORIDE	Validated trade name used
107314353	10731435	4	Interacting	GUANFACINE HYDROCHLORIDE	GUANFACINE HYDROCHLORIDE	Validated trade name used
107314353	10731435	5	Interacting	RISPERIDONE	RISPERIDONE	Validated trade name used
107316442	10731644	1	Primary Suspect Drug	FLUCONAZOLE	FLUCONAZOLE	Validated trade name used
107316442	10731644	2	Interacting	FISH OIL	FISH OIL	Validated trade name used
1074008517	10740085	1	Primary Suspect Drug	RITUXAN	RITUXIMAB	Validated trade name used
1074008517	10740085	2	Secondary Suspect Drug	RITUXAN	RITUXIMAB	Validated trade name used
1074008517	10740085	3	Secondary Suspect Drug	RITUXAN	RITUXIMAB	Validated trade name used
1074008517	10740085	4	Secondary Suspect Drug	RITUXAN	RITUXIMAB	Validated trade name used
1074008517	10740085	5	Secondary Suspect Drug	RITUXAN	RITUXIMAB	Validated trade name used
1074008517	10740085	6	Secondary Suspect Drug	BRICANYL	TERBUTALINE SULFATE	Validated trade name used
1074008517	10740085	7	Concomitant	SYMBICORT	BUDESONIDE\FORMOTEROL FUMARATE DIHYDRATE	Validated trade name used
1074008517	10740085	8	Concomitant	ALBUTEROL	ALBUTEROL	Validated trade name used

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Drug Listings

<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulative dose to first reaction</i>	<i>Cumulative dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechallenge code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported)</i>	<i>NDA number.</i>
Unknown	5 mg, at noon	.		Does not apply				204266
Unknown	3 mg, Every morning	.		Does not apply				74796
Oral	5 mg at noon	.		Does not apply				74796
Unknown	0.25 mg, in the evening	.		Does not apply				78269
Unknown	3 DF, 1/week	.		Unknown				.
Unknown	8000 mg, Daily	.		Unknown				.
Intravenous (not otherwise specified)	Day 1 and Day 15, 24/Jun/2016 (previous rituximab infusion)	.				H06553,H0985,H0768,N3728,H0882,UNKN		103705
Intravenous (not otherwise specified)		.				H06553,H0985,H0768,N3728,H0882,UNKN		103705
Intravenous (not otherwise specified)	500 mg once	.				H06553,H0985,H0768,N3728,H0882,UNKN		103705
Intravenous (not otherwise specified)	500 mg once	.				H06553,H0985,H0768,N3728,H0882,UNKN		103705
Intravenous (not otherwise specified)	day 1 and 15	.				H06553,H0985,H0768,N3728,H0882,UNKN		103705
Unknown	As required	.		Unknown		UNKNOWN		.
Unknown		.				UNKNOWN		.
Unknown		.				UNKNOWN		.

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Amount of drug reported.</i>	<i>Unit of drug dose.</i>	<i>Form of dose reported.</i>	<i>Code for Frequency.</i>
5	Milligram(s)		
3	Milligram(s)		
5	Milligram(s)		
0.25	Milligram(s)		
.		Capsule	/WK
8000	Milligram(s)		
1000	Milligram(s)	Infusion, Solution	
.		Infusion, Solution	
500	Milligram(s)	Infusion, Solution	
500	Milligram(s)	Infusion, Solution	
1000	Milligram(s)	Infusion, Solution	
.			
.			
.			

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Drug Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Unique number for identifying a drug for</i>	<i>Code for drug's reported role in event.</i>	<i>Name of medicinal product.</i>	<i>Product Active Ingredient.</i>	<i>Code for source of DRUGNAME.</i>
1074008517	10740085	9	Concomitant	ACETAMINOPHEN	ACETAMINOPHEN	Validated trade name used
1074008517	10740085	10	Concomitant	ACETAMINOPHEN	ACETAMINOPHEN	Validated trade name used
1074008517	10740085	11	Concomitant	SOLU-MEDROL	METHYLPREDNISOLONE SODIUM SUCCINATE	Validated trade name used
1074008517	10740085	12	Concomitant	SOLU-MEDROL	METHYLPREDNISOLONE SODIUM SUCCINATE	Validated trade name used
1074008517	10740085	13	Concomitant	METHOTREXATE	METHOTREXATE	Validated trade name used

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

<i>The route of drug administration</i>	<i>Verbatim text for dose, frequency, and r</i>	<i>Cumulativ e dose to first reaction</i>	<i>Cumulativ e dose to first reaction unit C</i>	<i>Dechallenge code, indicating if reaction</i>	<i>Rechalleng e code, indicating if reaction</i>	<i>Expiration date of the drug. (YYYYMMDD f</i>	<i>Lot number of the drug (as reported) .</i>	<i>NDA number.</i>
Oral		.						.
Oral		.						.
Intravenous (not otherwise specified)		.						.
Intravenous (not otherwise specified)		.						.
Oral		.						.

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Drug Listings

Amount of drug reported.	Unit of drug dose.	Form of dose reported.	Code for Frequency.
625	Milligram(s)		
650	Milligram(s)		
100	Milligram(s)		
100	Milligram(s)		
.			



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
100144838	10014483	Foetal exposure during pregnancy	
100144838	10014483	Toxicity to various agents	
100144838	10014483	Anaemia	
1001678124	10016781	Dizziness	
1001678124	10016781	Rash	
1001678124	10016781	Anaemia	
1001678124	10016781	Oedema peripheral	
1001678124	10016781	Swelling	
1001678124	10016781	Proctalgia	
1001678124	10016781	Dyspepsia	
1001678124	10016781	Weight decreased	
1001678124	10016781	Haemorrhoidal haemorrhage	
1001678124	10016781	Erythema	
1001678124	10016781	Skin irritation	
1001678124	10016781	Eye pruritus	
1001678124	10016781	Pruritus	
1001678124	10016781	Sensitisation	
1001678124	10016781	Needle issue	
1001678124	10016781	Paronychia	
1001678124	10016781	Disturbance in attention	
1001678124	10016781	Blood creatine increased	
1001678124	10016781	Illness	
1001678124	10016781	Nasopharyngitis	
1001678124	10016781	Nausea	
1001678124	10016781	Pain in extremity	
1001678124	10016781	Nasal congestion	
1001678124	10016781	Haemorrhoids	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1001678124	10016781	Metastasis	
1001678124	10016781	Hypertension	
1001678124	10016781	Scab	
1001678124	10016781	Periorbital oedema	
1001678124	10016781	Tendonitis	
1001678124	10016781	Skin sensitisation	
1001678124	10016781	Mass	
1001678124	10016781	Cyst	
1001678124	10016781	Acne	
1001678124	10016781	Miliaria	
1001678124	10016781	Fall	
1001678124	10016781	Secretion discharge	
1001678124	10016781	COVID-19	
1001678124	10016781	Hypersensitivity	
1001678124	10016781	Cellulitis	
1001678124	10016781	Fatigue	
1001678124	10016781	Tremor	
1001678124	10016781	Oedema	
1001678124	10016781	Cough	
1001678124	10016781	Crying	
1001678124	10016781	Induration	
1001678124	10016781	Product use issue	
1001678124	10016781	Anxiety	
1001678124	10016781	Balance disorder	
1001678124	10016781	Dry skin	
1001678124	10016781	Rectal fissure	
1001678124	10016781	Injection site haematoma	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1001678124	10016781	Rosacea	
1001678124	10016781	Vitamin B12 deficiency	
1001678124	10016781	Abdominal pain	
1001678124	10016781	Pain	
1001678124	10016781	Bone pain	
1001678124	10016781	Urinary tract infection	
1001678124	10016781	Injection site mass	
1001678124	10016781	Hypoglycaemia	
1001678124	10016781	Pneumonia	
1001678124	10016781	Sputum discoloured	
1001678124	10016781	Injection site pain	
1001678124	10016781	Injection site pain	
1001678124	10016781	Metastases to liver	
1001678124	10016781	Ovarian cyst	
1001678124	10016781	Rash	
1001678124	10016781	Bronchitis	
1001678124	10016781	Peripheral swelling	
1001678124	10016781	Sinusitis	
1001678124	10016781	Injection site hypersensitivity	
1001678124	10016781	Arthralgia	
1001678124	10016781	Headache	
1001678124	10016781	Protein urine	
1001678124	10016781	Localised infection	
1001678124	10016781	Musculoskeletal pain	
1001678124	10016781	Mobility decreased	
1001678124	10016781	Blood pressure systolic increased	
1001678124	10016781	Hypersomnia	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1002130539	10021305	Infection	
1002130539	10021305	Blood pressure increased	
1002130539	10021305	Diarrhoea	
1002130539	10021305	Heart rate increased	
1002130539	10021305	Blood glucose increased	
1002130539	10021305	Product availability issue	
1002130539	10021305	Dyspnoea	
1002130539	10021305	Injection site haemorrhage	
1002130539	10021305	Wrist fracture	
1002130539	10021305	Nephrolithiasis	
1002130539	10021305	Haemorrhage	
1002130539	10021305	White blood cell count increased	
1002130539	10021305	White blood cell count decreased	
1002130539	10021305	Hypopituitarism	
1002130539	10021305	Pulmonary embolism	
1002130539	10021305	Injection site pain	
1002130539	10021305	Pain	
1002130539	10021305	Post procedural complication	
100293662	10029366	Staphylococcal infection	
100293662	10029366	Wound infection staphylococcal	
100293662	10029366	Mycobacterium haemophilum infection	
100293662	10029366	Toxicity to various agents	
100356167	10035616	Cardiac arrest	
100356167	10035616	Aortic dissection	
100356167	10035616	Haemorrhage	
100356167	10035616	Disseminated intravascular coagulation	
100356167	10035616	Shock haemorrhagic	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1006401878	10064018	Hyperhidrosis	
1006401878	10064018	Loss of consciousness	
1006401878	10064018	Haemorrhage	
1006401878	10064018	Sinusitis	
1006401878	10064018	Blood pressure systolic increased	
1006401878	10064018	Breast pain	
1006401878	10064018	Pain in extremity	
1006401878	10064018	Arthritis	
1006401878	10064018	Abdominal discomfort	
1006401878	10064018	Swelling	
1006401878	10064018	Weight increased	
1006401878	10064018	Musculoskeletal stiffness	
1006401878	10064018	Blister	
1006401878	10064018	Depression	
1006401878	10064018	Heart rate decreased	
1006401878	10064018	Blood pressure diastolic abnormal	
1006401878	10064018	Chest discomfort	
1006401878	10064018	Infusion related reaction	
1006401878	10064018	Blood pressure diastolic increased	
1006401878	10064018	Hypotension	
1006401878	10064018	Abdominal pain upper	
1006401878	10064018	Body temperature decreased	
1006401878	10064018	Mobility decreased	
1006401878	10064018	Malaise	
1006401878	10064018	Blood pressure increased	
1006401878	10064018	Gastroenteritis	
1006401878	10064018	Product dispensing error	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1006401878	10064018	Blood pressure systolic abnormal	
1006401878	10064018	Nervousness	
1006401878	10064018	Fatigue	
1006401878	10064018	Hypertension	
1006401878	10064018	Arthralgia	
1006401878	10064018	Back pain	
1006401878	10064018	Weight decreased	
1006401878	10064018	Respiratory rate increased	
1006401878	10064018	Hypersomnia	
1006401878	10064018	Oxygen saturation decreased	
1006401878	10064018	Haematoma	
1006401878	10064018	Osteoarthritis	
1006401878	10064018	Dehydration	
1006401878	10064018	Heart rate increased	
1006401878	10064018	Neck pain	
1006401878	10064018	Feeling hot	
1006401878	10064018	Infection	
1006401878	10064018	Nasopharyngitis	
1006401878	10064018	Influenza	
1007468610	10074686	Expiratory reserve volume decreased	
1007468610	10074686	Weight decreased	
1007468610	10074686	Wheezing	
1007468610	10074686	Asthma	
1007468610	10074686	Heart rate increased	
1007468610	10074686	Total lung capacity decreased	
1007468610	10074686	Middle insomnia	
1007468610	10074686	Allergy test positive	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Reaction Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1007468610	10074686	Forced expiratory volume decreased	
1007468610	10074686	Dyspnoea	
1007468610	10074686	Restrictive pulmonary disease	
1007468610	10074686	Obstructive airways disorder	
1007468610	10074686	Productive cough	
100764782	10076478	Maternal exposure during pregnancy	
100764782	10076478	Abortion spontaneous	
1008408132	10084081	Body temperature decreased	
1008408132	10084081	White blood cell count increased	
1008408132	10084081	Malaise	
1008408132	10084081	Headache	
1008408132	10084081	Fatigue	
1008408132	10084081	Injection site haemorrhage	
1008408132	10084081	Abdominal pain upper	
1008408132	10084081	Abdominal pain	
1008408132	10084081	Needle issue	
1008408132	10084081	Limb injury	
1008408132	10084081	Cough	
1008408132	10084081	Arthralgia	
1008408132	10084081	Blood pressure increased	
1008408132	10084081	Nausea	
1008408132	10084081	Blood glucose increased	
1008408132	10084081	Malignant neoplasm progression	
1008408132	10084081	Diarrhoea	
1008408132	10084081	Nasal congestion	
1008408132	10084081	Underdose	
1008408132	10084081	Injection site pain	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1008408132	10084081	Vomiting	
1008408132	10084081	Weight increased	
1008408132	10084081	Pruritus	
1008408132	10084081	Hepatic enzyme increased	
1008408132	10084081	Wrong technique in product usage process	
1008408132	10084081	Small intestine carcinoma	
100941024	10094102	Maternal exposure during pregnancy	
100941024	10094102	Abortion spontaneous	
1009418019	10094180	Organ failure	
1009418019	10094180	Knee arthroplasty	
1009418019	10094180	Heart rate increased	
1009418019	10094180	Drug ineffective	
1009418019	10094180	Arthropathy	
1009418019	10094180	Sepsis syndrome	
1009418019	10094180	Weight decreased	
1009418019	10094180	Musculoskeletal disorder	
1009418019	10094180	Infection	
1009418019	10094180	Nasopharyngitis	
1009418019	10094180	Hypotension	
1009418019	10094180	Herpes zoster	
1009418019	10094180	Weight increased	
1009418019	10094180	Haemophagocytic lymphohistiocytosis	
1009418019	10094180	Drug hypersensitivity	
1009418019	10094180	COVID-19	
1009418019	10094180	Fall	
1009418019	10094180	Arthritis infective	
1014222251	10142222	Blood pressure systolic abnormal	



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1014222251	10142222	Weight increased	
1014222251	10142222	Contusion	
1014222251	10142222	Blood pressure increased	
1014222251	10142222	Joint swelling	
1014222251	10142222	Synovial cyst	
1014222251	10142222	Pain	
1014222251	10142222	Blood pressure diastolic abnormal	
1014222251	10142222	Dizziness	
1014222251	10142222	Rheumatoid arthritis	
1014222251	10142222	Asthenia	
1014222251	10142222	Paraesthesia oral	
1014222251	10142222	Headache	
1014222251	10142222	Malaise	
1014222251	10142222	Abdominal pain	
1014222251	10142222	Loss of consciousness	
1014222251	10142222	Seizure	
1014222251	10142222	Arthralgia	
1014222251	10142222	Peripheral swelling	
1014222251	10142222	Fall	
1014222251	10142222	Nystagmus	
1014222251	10142222	Limb injury	
1014222251	10142222	Head injury	
1014222251	10142222	Infection	
1014222251	10142222	Nausea	
1014222251	10142222	Infusion related reaction	
1014222251	10142222	Cerebrovascular accident	
1014222251	10142222	Ill-defined disorder	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1014222251	10142222	Loss of consciousness	
1014222251	10142222	Blood pressure fluctuation	
1014222251	10142222	Pneumonia	
1014222251	10142222	Arthropathy	
1014222251	10142222	Pulse absent	
1014222251	10142222	Blood pressure diastolic decreased	
1014222251	10142222	Oxygen saturation decreased	
1014222251	10142222	Road traffic accident	
1014222251	10142222	Body temperature decreased	
1014222251	10142222	Visual impairment	
1014222251	10142222	Myalgia	
1014222251	10142222	Dry mouth	
1014222251	10142222	Fatigue	
1014222251	10142222	Wound infection	
1014222251	10142222	Blood pressure systolic increased	
1014222251	10142222	Blood creatine phosphokinase increased	
1014222251	10142222	Hypoaesthesia oral	
1014222251	10142222	Somnolence	
1014222251	10142222	Resuscitation	
1014222251	10142222	Hypoaesthesia oral	
1014222251	10142222	Pulmonary artery aneurysm	
1014222251	10142222	Blood pressure diastolic increased	
1014222251	10142222	Erythema	
1014222251	10142222	Skin laceration	
101451672	10145167	Diabetes mellitus	
1015212331	10152123	Anaphylactic reaction	
1015212331	10152123	Diarrhoea	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1015212331	10152123	Middle insomnia	
1015212331	10152123	Blood pressure increased	
1015212331	10152123	Forced expiratory volume decreased	
1015212331	10152123	Influenza	
1015212331	10152123	Pneumonia	
1015212331	10152123	Total lung capacity decreased	
1015212331	10152123	Weight decreased	
1015212331	10152123	Sensitivity to weather change	
1015212331	10152123	Malaise	
1015212331	10152123	Nasopharyngitis	
1015212331	10152123	Psoriatic arthropathy	
1015212331	10152123	Anaphylactic reaction	
1015212331	10152123	Oropharyngeal pain	
1015212331	10152123	Cardiac failure congestive	
1015212331	10152123	Weight increased	
1015212331	10152123	Sinusitis	
1015212331	10152123	Asthma	
1015212331	10152123	Swelling	
1015212331	10152123	Asthma	
1015212331	10152123	Glomerular filtration rate decreased	
1015212331	10152123	Pruritus	
1015212331	10152123	Pain	
1015212331	10152123	Product dose omission issue	
1015212331	10152123	Obstructive airways disorder	
1015212331	10152123	Swelling face	
1015212331	10152123	Body mass index increased	
1015212331	10152123	Pyrexia	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1015212331	10152123	Blood urea decreased	
1015212331	10152123	Body temperature decreased	
1015212331	10152123	Respiratory disorder	
1015212331	10152123	Arthralgia	
1015212331	10152123	Drug hypersensitivity	
1015212331	10152123	Obesity	
1015212331	10152123	Reversible airways obstruction	
101621574	10162157	Pneumonia	
101621574	10162157	Gastrointestinal perforation	
1016611037	10166110	Weight increased	
1016611037	10166110	Lymphadenitis	
1016611037	10166110	Nasopharyngitis	
1016611037	10166110	Cough	
1016611037	10166110	Blood glucose decreased	
1016611037	10166110	Anaphylactic shock	
1016611037	10166110	Vocal cord dysfunction	
1016611037	10166110	Lower respiratory tract infection	
1016611037	10166110	Presyncope	
1016611037	10166110	Dizziness	
1016611037	10166110	Headache	
1016611037	10166110	Concomitant disease aggravated	
1016611037	10166110	Abdominal pain	
1016611037	10166110	Dyspnoea	
1016611037	10166110	Anaphylactic reaction	
1016611037	10166110	Endometriosis	
1016611037	10166110	Hypersensitivity	
1016611037	10166110	Nausea	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1016611037	10166110	Palpitations	
1016611037	10166110	Malaise	
1016611037	10166110	Blood immunoglobulin E increased	
1016611037	10166110	Asthma	
1016611037	10166110	Somnolence	
1016611037	10166110	Abdominal pain upper	
101676303	10167630	Delirium	
101676313	10167631	Insomnia	
101678657	10167865	Klebsiella sepsis	
1017130214	10171302	Arthropathy	
1017130214	10171302	Influenza	
1017130214	10171302	COVID-19	
1017130214	10171302	Product dose omission in error	
1017130214	10171302	Hip surgery	
1017130214	10171302	Ear infection	
1017130214	10171302	Infection	
1017130214	10171302	Memory impairment	
1017130214	10171302	Sinusitis	
1017130214	10171302	Nasopharyngitis	
1017130214	10171302	Illness	
1017130214	10171302	Dysphonia	
1017130214	10171302	Bronchitis	
1017130214	10171302	Immune system disorder	
1017572232	10175722	Pyrexia	
1017572232	10175722	Blood pressure fluctuation	
1017572232	10175722	Lung disorder	
1017572232	10175722	Illness	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1017572232	10175722	Pyrexia	
1017572232	10175722	Body temperature increased	
1017572232	10175722	Pain	
1017572232	10175722	Blood pressure diastolic increased	
1017572232	10175722	Ill-defined disorder	
1017572232	10175722	Hepatic enzyme increased	
1017572232	10175722	Neutrophil count increased	
1017572232	10175722	Influenza	
1017572232	10175722	Nasopharyngitis	
1017572232	10175722	Drug ineffective	
1017572232	10175722	Malaise	
1017572232	10175722	Hypertension	
1017572232	10175722	Cough	
1017572232	10175722	Fatigue	
1017572232	10175722	Weight decreased	
1017572232	10175722	Blood pressure increased	
101780773	10178077	Retinal detachment	
101916392	10191639	Extrapyramidal disorder	
101916392	10191639	Inappropriate schedule of product administration	
101916392	10191639	Somnolence	
101916392	10191639	Hypothermia	
1020642923	10206429	Upper respiratory tract congestion	
1020642923	10206429	Pain in extremity	
1020642923	10206429	Breath sounds abnormal	
1020642923	10206429	Injection site swelling	
1020642923	10206429	Wheezing	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS re case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1020642923	10206429	Muscle injury	
1020642923	10206429	Bronchitis	
1020642923	10206429	Nasopharyngitis	
1020642923	10206429	Skeletal injury	
1020642923	10206429	Pain	
1020642923	10206429	Oedema	
1020642923	10206429	Food allergy	
1020642923	10206429	Progesterone decreased	
1020642923	10206429	Skin abrasion	
1020642923	10206429	Gastrointestinal disorder	
1020642923	10206429	Erythema	
1020642923	10206429	Wrong technique in product usage process	
1020642923	10206429	Chest discomfort	
1020642923	10206429	Gait disturbance	
1020642923	10206429	Candida infection	
1020642923	10206429	Oesophageal candidiasis	
1020642923	10206429	Hypotension	
1020642923	10206429	Urinary tract infection	
1020642923	10206429	Body temperature decreased	
1020642923	10206429	Limb injury	
1020642923	10206429	Anxiety	
1020642923	10206429	Scratch	
1020642923	10206429	Upper respiratory tract infection	
1020642923	10206429	Road traffic accident	
1020642923	10206429	Rhonchi	
1020642923	10206429	Gastroenteritis viral	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1020642923	10206429	Mouth injury	
102371704	10237170	Oedema peripheral	
102371704	10237170	Face oedema	
102371704	10237170	Cardio-respiratory arrest	
102371704	10237170	Drug intolerance	
102371704	10237170	Drug reaction with eosinophilia and systemic symptoms	
102371704	10237170	Generalised tonic-clonic seizure	
102371704	10237170	Lymphadenopathy	
102371704	10237170	Status epilepticus	
102371704	10237170	Aspartate aminotransferase increased	
102371704	10237170	Pyrexia	
102371704	10237170	Oedema peripheral	
102371704	10237170	Alanine aminotransferase increased	
102371704	10237170	Erythema	
1027487983	10274879	Cough	
1027487983	10274879	Rheumatoid lung	
1027487983	10274879	Heart rate increased	
1027487983	10274879	Haemoptysis	
1027487983	10274879	Dyspnoea	
1027487983	10274879	Arthralgia	
1027487983	10274879	Influenza	
1027487983	10274879	Umbilical hernia	
1027487983	10274879	Gait disturbance	
1027487983	10274879	Drug ineffective	
1027487983	10274879	Road traffic accident	
1027487983	10274879	Weight increased	



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1027487983	10274879	Blood pressure systolic increased	
1027487983	10274879	Testicular mass	
1027487983	10274879	Grip strength decreased	
1027487983	10274879	Panic disorder	
1027487983	10274879	Blood pressure increased	
1027487983	10274879	Musculoskeletal stiffness	
1027487983	10274879	Weight decreased	
1027487983	10274879	Blood pressure diastolic abnormal	
1027487983	10274879	Cataract	
1027487983	10274879	Hypertension	
1027487983	10274879	Oxygen saturation decreased	
1027487983	10274879	Lower respiratory tract infection	
1027487983	10274879	Nasopharyngitis	
1027487983	10274879	Rheumatoid arthritis	
1027487983	10274879	Pneumonia	
1028518546	10285185	Blood pressure increased	
1028518546	10285185	Heart rate increased	
1028518546	10285185	Blood pressure systolic increased	
1028518546	10285185	Oedema peripheral	
1028518546	10285185	Cough	
1028518546	10285185	Blood pressure fluctuation	
1028518546	10285185	Abdominal hernia	
1028518546	10285185	Oxygen saturation decreased	
1028518546	10285185	Bronchitis viral	
1028518546	10285185	Wound	
1028518546	10285185	Hernia	
1028518546	10285185	Blood pressure diastolic decreased	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1028518546	10285185	Blood pressure diastolic abnormal	
1028518546	10285185	Oxygen saturation decreased	
1028518546	10285185	Blood pressure increased	
1028518546	10285185	Rheumatoid nodule	
1028518546	10285185	Arthritis infective	
1028518546	10285185	Pain in extremity	
1028518546	10285185	Asthma	
1028518546	10285185	Blood pressure systolic abnormal	
1028518546	10285185	Nasopharyngitis	
1028518546	10285185	Nodule	
1028518546	10285185	Bursitis	
1028518546	10285185	Ovarian fibroma	
1028518546	10285185	Diverticulitis	
1028518546	10285185	Pyrexia	
1028518546	10285185	Nasopharyngitis	
1028518546	10285185	Respiratory rate increased	
1028518546	10285185	Oedema	
1028518546	10285185	Blood pressure diastolic increased	
1030948614	10309486	Macular oedema	
1030948614	10309486	Product use issue	
1030948614	10309486	Haemorrhage	
1030948614	10309486	Off label use	
103443973	10344397	Deformity thorax	
103443973	10344397	Metastases to bone	
103443973	10344397	Osteomalacia	
1035913611	10359136	Cataract	
1035913611	10359136	Drug hypersensitivity	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1035913611	10359136	Decreased activity	
1035913611	10359136	Wheezing	
1035913611	10359136	Pneumonia	
1035913611	10359136	General physical health deterioration	
1035913611	10359136	Fatigue	
1035913611	10359136	Chest discomfort	
1035913611	10359136	Dyspnoea	
1035913611	10359136	Illness	
1035913611	10359136	Gait disturbance	
1035913611	10359136	Cough	
1035913611	10359136	Asthmatic crisis	
1035913611	10359136	Pain	
103687216	10368721	General physical health deterioration	
103749689	10374968	Diarrhoea	
103749689	10374968	Flatulence	
103749689	10374968	Asthenia	
103749689	10374968	Diarrhoea	
103749689	10374968	Dyspnoea	
103749689	10374968	Sepsis	
103749689	10374968	Stomatitis	
103749689	10374968	Abdominal pain	
103749689	10374968	Pyrexia	
103892335	10389233	Acute hepatic failure	
103892335	10389233	Jaundice	
103892335	10389233	Hepatitis B	
103892335	10389233	Hepatic encephalopathy	
103928076	10392807	Depression	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
103928076	10392807	Abnormal weight gain	
103928076	10392807	Off label use	
103928076	10392807	Product use in unapproved indication	
103928076	10392807	Abdominal discomfort	
103928076	10392807	Gynaecomastia	
103928076	10392807	Emotional disorder	
103928375	10392837	Off label use	
103928375	10392837	Hyperprolactinaemia	
103928375	10392837	Product use in unapproved indication	
103928375	10392837	Galactorrhoea	
103928375	10392837	Abnormal weight gain	
103928375	10392837	Gynaecomastia	
103985405	10398540	Visual acuity reduced	
103985405	10398540	Pain in extremity	
103985405	10398540	Lymphocyte count decreased	
103985405	10398540	Expanded disability status scale score increased	
103985405	10398540	Nephrolithiasis	
103985405	10398540	Visual impairment	
103985405	10398540	Musculoskeletal stiffness	
103985405	10398540	Fatigue	
103985405	10398540	Eye pain	
103985405	10398540	Drug intolerance	
103985405	10398540	Headache	
104003092	10400309	Epistaxis	
104003092	10400309	Dementia	
1040513313	10405133	Oropharyngeal pain	
1040513313	10405133	Forced expiratory volume decreased	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1040513313	10405133	Asthma	
1040513313	10405133	Pyrexia	
1040513313	10405133	Dyspnoea	
1040513313	10405133	Fatigue	
1040513313	10405133	Middle insomnia	
1040513313	10405133	Obstructive airways disorder	
1041491125	10414911	Anxiety	
1041491125	10414911	Nausea	
1041491125	10414911	Malignant neoplasm progression	
1041491125	10414911	Product use complaint	
1041491125	10414911	Kidney infection	
1041491125	10414911	Palpitations	
1041491125	10414911	Hypertension	
1041491125	10414911	Herpes zoster	
1041491125	10414911	Incorrect dose administered	
1041491125	10414911	Drug dose omission by device	
1041491125	10414911	Injection site haemorrhage	
1041491125	10414911	Carcinoid tumour	
1041491125	10414911	Blood pressure systolic increased	
1041491125	10414911	Blood pressure increased	
1041491125	10414911	Syncope	
1041491125	10414911	Rubber sensitivity	
1041491125	10414911	Vertigo	
1041491125	10414911	Dizziness	
1041491125	10414911	Stress	
1041491125	10414911	Hyperparathyroidism	
1041491125	10414911	Vomiting	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Reaction Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1041491125	10414911	Cystitis	
1041491125	10414911	Blood pressure diastolic increased	
1041491125	10414911	Body temperature decreased	
1041491125	10414911	Injection site pain	
104232052	10423205	Hyperprolactinaemia	
104232052	10423205	Gynaecomastia	
104232052	10423205	Abnormal weight gain	
104232195	10423219	Gynaecomastia	
104232195	10423219	Hyperglycaemia	
104232195	10423219	Increased appetite	
104232195	10423219	Hyperprolactinaemia	
104232195	10423219	Galactorrhoea	
104232195	10423219	Obesity	
104232195	10423219	Extrapyramidal disorder	
104232203	10423220	Abnormal weight gain	
104232203	10423220	Hyperprolactinaemia	
104232203	10423220	Hyperglycaemia	
104232203	10423220	Gynaecomastia	
104266473	10426647	Obesity	
104266473	10426647	Hyperprolactinaemia	
104266473	10426647	Gynaecomastia	
104490482	10449048	Completed suicide	
104490482	10449048	Toxicity to various agents	
104490482	10449048	Overdose	
104490482	10449048	Death	
104580772	10458077	Completed suicide	
104580772	10458077	Overdose	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Reaction Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
104580883	10458088	Overdose	
104580883	10458088	Completed suicide	
104580883	10458088	Death	
104635823	10463582	Appetite disorder	
104635823	10463582	Gynaecomastia	
104635823	10463582	Overweight	
104635823	10463582	Hyperprolactinaemia	
104635823	10463582	Off label use	
104635823	10463582	Emotional disorder	
104665748	10466574	Emotional distress	
104665748	10466574	Diabetes mellitus	
104665748	10466574	Weight increased	
104665748	10466574	Gynaecomastia	
104825157	10482515	Muscle spasms	
104825157	10482515	Muscular weakness	
104825157	10482515	Tremor	
104825157	10482515	Diabetes mellitus	
104825157	10482515	Limb discomfort	
104825157	10482515	Myalgia	
104825157	10482515	Limb discomfort	
105144244	10514424	Inappropriate schedule of product administration	
105144244	10514424	Product dose omission issue	
105144244	10514424	Pituitary tumour benign	
1051596718	10515967	Groin pain	
1051596718	10515967	Blood pressure systolic increased	
1051596718	10515967	Flushing	
1051596718	10515967	Anxiety	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1051596718	10515967	Back pain	
1051596718	10515967	Lower respiratory tract infection	
1051596718	10515967	Constipation	
1051596718	10515967	Diarrhoea	
1051596718	10515967	Blood pressure increased	
1051596718	10515967	Arthralgia	
1051596718	10515967	Sinusitis	
1051596718	10515967	Arthralgia	
1051596718	10515967	Flank pain	
1051596718	10515967	Asthenia	
1051596718	10515967	Abdominal pain lower	
1051596718	10515967	Needle issue	
1051596718	10515967	Hyperhidrosis	
1051596718	10515967	Depression	
1051596718	10515967	Weight increased	
1051596718	10515967	Limb mass	
1051596718	10515967	Nausea	
1051596718	10515967	Malaise	
1051596718	10515967	Renal pain	
1051596718	10515967	Incorrect dose administered by device	
1051596718	10515967	Abdominal pain	
1051596718	10515967	Gait disturbance	
1051596718	10515967	Inappropriate schedule of product administration	
1051596718	10515967	Fatigue	
1051596718	10515967	Nasal polyps	
1051596718	10515967	Musculoskeletal stiffness	
1052690058	10526900	Contusion	



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1052690058	10526900	Weight decreased	
1052690058	10526900	Off label use	
1052690058	10526900	Neck pain	
1052690058	10526900	Haemorrhage	
1052690058	10526900	Blood pressure systolic abnormal	
1052690058	10526900	Oropharyngeal pain	
1052690058	10526900	Osteoarthritis	
1052690058	10526900	Blood pressure diastolic abnormal	
1052690058	10526900	Body temperature decreased	
1052690058	10526900	Heart rate decreased	
1052690058	10526900	Blood pressure increased	
1052690058	10526900	Rheumatoid arthritis	
1052690058	10526900	Localised infection	
1052690058	10526900	Hypotension	
1052690058	10526900	Influenza	
1052690058	10526900	Arthralgia	
1052690058	10526900	Nasopharyngitis	
1052690058	10526900	Weight increased	
1052690058	10526900	Infusion related reaction	
1052690058	10526900	Oxygen saturation decreased	
1052690058	10526900	Blood pressure systolic increased	
1052690058	10526900	Hernia	
1052690058	10526900	Prostatic mass	
1052690058	10526900	Prostate cancer	
1054038738	10540387	Blood urine present	
1054038738	10540387	Anuria	
1054038738	10540387	Cardiac failure congestive	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1054038738	10540387	Cardiomegaly	
1054038738	10540387	Heart rate increased	
1054038738	10540387	Blood growth hormone increased	
1054038738	10540387	Blood pressure increased	
1054038738	10540387	Muscle spasms	
1054038738	10540387	Basal cell carcinoma	
1054038738	10540387	Injection site haemorrhage	
1054038738	10540387	COVID-19	
1054038738	10540387	Cystitis	
1054038738	10540387	Injection site mass	
1054038738	10540387	Atrial fibrillation	
1054038738	10540387	Seasonal affective disorder	
1054038738	10540387	Palpitations	
1054038738	10540387	Dysuria	
1054038738	10540387	Insulin-like growth factor increased	
1054038738	10540387	Headache	
1054038738	10540387	Heart rate irregular	
1054038738	10540387	Cardiac failure acute	
1054038738	10540387	Pain	
1054038738	10540387	Constipation	
1054038738	10540387	Device occlusion	
1054038738	10540387	Musculoskeletal stiffness	
1054038738	10540387	Micturition urgency	
1054038738	10540387	Ventricular extrasystoles	
1054038738	10540387	Prostatomegaly	
1054038738	10540387	Tendon rupture	
1054038738	10540387	Muscle tightness	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
105481232	10548123	Maternal exposure during pregnancy	
105481232	10548123	Stillbirth	
105524185	10552418	Weight increased	
105741013	10574101	Phaeohyphomycosis	
105741013	10574101	Abiotrophia defectiva endocarditis	
105741013	10574101	Fungal disease carrier	
105741013	10574101	Product use in unapproved indication	
105741013	10574101	Pneumonia bacterial	
105741013	10574101	Alternaria infection	
1058928657	10589286	Urinary tract infection	
1058928657	10589286	Pyrexia	
1058928657	10589286	Rash	
1058928657	10589286	Body temperature increased	
1058928657	10589286	Choking	
1058928657	10589286	Pruritus	
1058928657	10589286	Skin plaque	
1058928657	10589286	Body temperature decreased	
1058928657	10589286	Weight decreased	
1058928657	10589286	Productive cough	
1058928657	10589286	Osteoporosis	
1058928657	10589286	Pneumonia	
1058928657	10589286	Radius fracture	
1058928657	10589286	Respiratory tract infection	
1058928657	10589286	Tinnitus	
1058928657	10589286	Abdominal pain	
1058928657	10589286	Heart rate increased	
1058928657	10589286	Swelling face	

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Reaction Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1058928657	10589286	Upper limb fracture	
1058928657	10589286	Temperature intolerance	
1058928657	10589286	Anxiety	
1058928657	10589286	Oedema peripheral	
1058928657	10589286	Ulna fracture	
1058928657	10589286	Feeling abnormal	
1058928657	10589286	Lower respiratory tract infection bacterial	
1058928657	10589286	Injection site pain	
1058928657	10589286	Hypoaesthesia	
1058928657	10589286	Bronchitis	
1058928657	10589286	Cellulitis	
1058928657	10589286	Influenza	
1058928657	10589286	Face oedema	
1058928657	10589286	Arthralgia	
1058928657	10589286	Vomiting	
1058928657	10589286	Cough	
1058928657	10589286	Wrong technique in product usage process	
1058928657	10589286	Sleep disorder	
1058928657	10589286	Osteoarthritis	
1058928657	10589286	Vaccination site cellulitis	
1058928657	10589286	Off label use	
1058928657	10589286	Peripheral swelling	
1058928657	10589286	Diverticulitis	
1058928657	10589286	Throat irritation	
1058928657	10589286	Dyspnoea	
1058928657	10589286	Fatigue	
1058928657	10589286	Myalgia	

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Reaction Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1058928657	10589286	Pneumovirus test positive	
1058928657	10589286	Skin discolouration	
1058928657	10589286	Sputum discoloured	
1058928657	10589286	Haemoptysis	
1058928657	10589286	Body temperature fluctuation	
1058928657	10589286	Blood pressure systolic increased	
1058928657	10589286	Bronchial obstruction	
1058928657	10589286	Pneumonia	
1058928657	10589286	Limb mass	
1058928657	10589286	Asthenia	
1058928657	10589286	Swelling	
1058928657	10589286	Viral infection	
1058928657	10589286	Pain	
1058928657	10589286	Erythema	
1058928657	10589286	Pain in extremity	
1058928657	10589286	Secretion discharge	
105947013	10594701	Tachycardia	
105947013	10594701	Hypotonia	
105947013	10594701	Serotonin syndrome	
105947013	10594701	Blood prolactin increased	
105947013	10594701	Muscle rigidity	
105947013	10594701	Unresponsive to stimuli	
105947013	10594701	Suicidal behaviour	
105947013	10594701	Respiratory depression	
105947013	10594701	Hyperthermia	
105947013	10594701	Hypoxia	
105947013	10594701	Somnolence	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
105947013	10594701	Hyperhidrosis	
105947013	10594701	Overdose	
105947013	10594701	Miosis	
105947013	10594701	Clonus	
105947013	10594701	Status epilepticus	
105947013	10594701	Autonomic nervous system imbalance	
105947013	10594701	Mydriasis	
1060157312	10601573	Infrequent bowel movements	
1060157312	10601573	Single functional kidney	
1060157312	10601573	Blood urine present	
1060157312	10601573	Pneumonia	
1060157312	10601573	Infection	
1060157312	10601573	Urinary tract infection	
1060157312	10601573	Abdominal pain	
1060157312	10601573	Spinal pain	
1060157312	10601573	Lip erythema	
1060157312	10601573	Contusion	
1060157312	10601573	Rash	
1060157312	10601573	Death	
1060157312	10601573	Constipation	
1060157312	10601573	Skin atrophy	
1060157312	10601573	Platelet count decreased	
1060157312	10601573	Haemoglobin decreased	
1060157312	10601573	Renal pain	
1060157312	10601573	Cystitis	
1060157312	10601573	Hypotension	
1060157312	10601573	Nephrolithiasis	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1060157312	10601573	Oral discomfort	
106091663	10609166	Seizure	
106091663	10609166	Metabolic encephalopathy	
106091663	10609166	Stupor	
106091663	10609166	Somnolence	
106091663	10609166	Partial seizures	
106091663	10609166	Acute hepatic failure	
106091663	10609166	Disease progression	
106091663	10609166	Death	
106091663	10609166	Hepatic encephalopathy	
106091663	10609166	Partial seizures with secondary generalisation	
106091663	10609166	Hepatic failure	
106091663	10609166	Drug intolerance	
106091663	10609166	Drug ineffective	
106091663	10609166	Anticonvulsant drug level below therapeutic	
106091663	10609166	Mental status changes	
106091663	10609166	Ammonia increased	
106336646	10633664	Hyperprolactinaemia	
106336646	10633664	Galactorrhoea	
106336646	10633664	Emotional disorder	
106336646	10633664	Gynaecomastia	
106336646	10633664	Obesity	
106352232	10635223	Hepatic failure	
106352232	10635223	Partial seizures	
106352232	10635223	Metabolic encephalopathy	
106520463	10652046	Burning mouth syndrome	
1069198853	10691988	Myalgia	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1069198853	10691988	Chest discomfort	
1069198853	10691988	Oedema peripheral	
1069198853	10691988	Cataract	
1069198853	10691988	Cough	
1069198853	10691988	Myocardial infarction	
1069198853	10691988	Productive cough	
1069198853	10691988	Back pain	
1069198853	10691988	Dyspnoea	
1069198853	10691988	Blood pressure increased	
1069198853	10691988	Pneumonia	
1069198853	10691988	Influenza like illness	
1069198853	10691988	Influenza	
1069198853	10691988	Ear injury	
1069198853	10691988	Contusion	
1069198853	10691988	Nerve compression	
1069198853	10691988	Injection site swelling	
1069198853	10691988	Intervertebral disc protrusion	
1069198853	10691988	Nasal congestion	
1069198853	10691988	Infection	
1069198853	10691988	Nasopharyngitis	
1069198853	10691988	Pulmonary function test decreased	
1069198853	10691988	Asthma	
1069198853	10691988	Headache	
1069198853	10691988	Chills	
1069198853	10691988	Pyrexia	
1069198853	10691988	Weight decreased	
1069198853	10691988	Hypoaesthesia	



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1069198853	10691988	Rhinorrhoea	
1070483325	10704833	Off label use	
1070483325	10704833	Somnolence	
1070483325	10704833	Underdose	
1070483325	10704833	Pneumonia aspiration	
1070483325	10704833	Gastrooesophageal reflux disease	
1070483325	10704833	Coma	
1070483325	10704833	Incorrect route of product administration	
107314353	10731435	Feeling cold	
107314353	10731435	Drug interaction	
107314353	10731435	Hypotension	
107314353	10731435	Accidental overdose	
107314353	10731435	Depressed level of consciousness	
107314353	10731435	Sinus bradycardia	
107314353	10731435	Fatigue	
107314353	10731435	Hyperhidrosis	
107316442	10731644	Food interaction	
107316442	10731644	Insomnia	
107316442	10731644	Sleep apnoea syndrome	
107316442	10731644	Drug ineffective	
1074008517	10740085	Drug ineffective	
1074008517	10740085	Heart rate increased	
1074008517	10740085	Musculoskeletal stiffness	
1074008517	10740085	Infusion related reaction	
1074008517	10740085	Tooth abscess	
1074008517	10740085	Blood pressure increased	
1074008517	10740085	Atrial fibrillation	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1074008517	10740085	Emphysema	
1074008517	10740085	Dyspnoea	
1074008517	10740085	Smoke sensitivity	
1074008517	10740085	Hypersensitivity	
1074008517	10740085	Paraesthesia	
1074008517	10740085	Diverticulitis	
1074008517	10740085	Weight decreased	
1074008517	10740085	Cardiac failure congestive	
1074008517	10740085	Fungal infection	
107408544	10740854	Ear discomfort	
107408544	10740854	Nasopharyngitis	
107408544	10740854	Product prescribing error	
1074197911	10741979	Speech disorder	
1074197911	10741979	Body height decreased	
1074197911	10741979	Off label use	
1074197911	10741979	Off label use	
1074197911	10741979	Pain in extremity	
1074197911	10741979	Tendon rupture	
1074197911	10741979	Drug hypersensitivity	
107584123	10758412	Galactorrhoea	
107584123	10758412	Abnormal weight gain	
107584123	10758412	Gynaecomastia	
107584123	10758412	Hyperprolactinaemia	
1075880717	10758807	Feeling abnormal	
1075880717	10758807	Pain	
1075880717	10758807	Nasopharyngitis	
1075880717	10758807	Nausea	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1075880717	10758807	Feeling jittery	
1075880717	10758807	Dizziness	
1075880717	10758807	Vomiting	
1075880717	10758807	Menopause	
1075880717	10758807	Pyrexia	
1075880717	10758807	Arthralgia	
1075880717	10758807	Headache	
1075880717	10758807	Therapeutic response unexpected	
1075880717	10758807	Condition aggravated	
1075880717	10758807	Palpitations	
1075880717	10758807	Feeling abnormal	
1075880717	10758807	Withdrawal syndrome	
1075880717	10758807	Babesiosis	
1075880717	10758807	Body height decreased	
1075880717	10758807	Asthenia	
1075880717	10758807	Malaise	
1075880717	10758807	Back pain	
1075880717	10758807	Anxiety	
1075880717	10758807	Nervousness	
1075880717	10758807	Fall	
1075880717	10758807	Fall	
1075880717	10758807	Dizziness	
1075880717	10758807	Hormone level abnormal	
1078729218	10787292	Sneezing	
1078729218	10787292	Malaise	
1078729218	10787292	Abdominal pain upper	
1078729218	10787292	Pollakiuria	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1078729218	10787292	Forced expiratory volume decreased	
1078729218	10787292	Asthma	
1078729218	10787292	Blood pressure increased	
1078729218	10787292	Bronchial hyperreactivity	
1078729218	10787292	Respiratory rate increased	
1078729218	10787292	Vital capacity decreased	
1078729218	10787292	Rhinorrhoea	
1078729218	10787292	Cough	
1078729218	10787292	Lung disorder	
1078729218	10787292	Influenza like illness	
1078729218	10787292	Total lung capacity decreased	
1078729218	10787292	Weight decreased	
1078729218	10787292	Middle insomnia	
1078729218	10787292	Headache	
1078729218	10787292	Productive cough	
1078729218	10787292	Wheezing	
1078729218	10787292	Nasopharyngitis	
1078729218	10787292	Obstructive airways disorder	
1078729218	10787292	Dyspnoea	
1078729218	10787292	Heart rate increased	
1080136616	10801366	Lung disorder	
1080136616	10801366	COVID-19	
1080136616	10801366	Drug dependence	
1080136616	10801366	Depression	
1080136616	10801366	Decreased activity	
1080136616	10801366	Oral fungal infection	
1080136616	10801366	Pain	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Reaction Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
1080136616	10801366	Diplopia	
1080136616	10801366	Ill-defined disorder	
1080136616	10801366	Arthritis	
1080136616	10801366	Viral infection	
1080136616	10801366	Bone disorder	
1080136616	10801366	Vomiting	
1080136616	10801366	Pyrexia	
1080136616	10801366	Off label use	
1080136616	10801366	Uterine leiomyoma	
1080136616	10801366	Hand deformity	
1080136616	10801366	Bronchitis	
1080136616	10801366	Ear infection	
1080136616	10801366	Arthralgia	
1080136616	10801366	Menopause	
1080136616	10801366	Fatigue	
1080136616	10801366	Diarrhoea	
1080136616	10801366	Anxiety	
1080136616	10801366	Thymoma	
1080136616	10801366	Nausea	
1080136616	10801366	Inflammation	
1080136616	10801366	Myasthenia gravis	
1080136616	10801366	Drug intolerance	
108390175	10839017	Hypertensive heart disease	
108390175	10839017	Hypokalaemia	
108390175	10839017	Confusional state	
108390175	10839017	Dysarthria	
108390175	10839017	Blood urine present	

ADVERSE EVENT REPORTING SYSTEM (AERS)  
Reaction Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Preferred term to describe the event</i>	<i>Drug Recur Action data.</i>
108390175	10839017	Myocardial ischaemia	
108390175	10839017	Gait disturbance	
108390175	10839017	Multifocal motor neuropathy	
108390175	10839017	Fatigue	

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
100144838	10014483	Other Serious (Important Medical Event)
1001678124	10016781	Other Serious (Important Medical Event)
1002130539	10021305	Hospitalization - Initial or Prolonged
1002130539	10021305	Other Serious (Important Medical Event)
100293662	10029366	Other Serious (Important Medical Event)
100356167	10035616	Life-Threatening
100356167	10035616	Hospitalization - Initial or Prolonged
100356167	10035616	Death
1006401878	10064018	Other Serious (Important Medical Event)
1006401878	10064018	Hospitalization - Initial or Prolonged
1007468610	10074686	Other Serious (Important Medical Event)
1007468610	10074686	Hospitalization - Initial or Prolonged
100764782	10076478	Other Serious (Important Medical Event)
1008408132	10084081	Hospitalization - Initial or Prolonged
1008408132	10084081	Other Serious (Important Medical Event)
100941024	10094102	Other Serious (Important Medical Event)
1009418019	10094180	Hospitalization - Initial or Prolonged
1009418019	10094180	Life-Threatening
1009418019	10094180	Other Serious (Important Medical Event)
1014222251	10142222	Hospitalization - Initial or Prolonged
1014222251	10142222	Other Serious (Important Medical Event)
101451672	10145167	Other Serious (Important Medical Event)
1015212331	10152123	Hospitalization - Initial or Prolonged
1015212331	10152123	Other Serious (Important Medical Event)
101621574	10162157	Death
101621574	10162157	Hospitalization - Initial or Prolonged
1016611037	10166110	Hospitalization - Initial or Prolonged

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1016611037	10166110	Other Serious (Important Medical Event)
101676303	10167630	Life-Threatening
101676303	10167630	Disability
101676303	10167630	Other Serious (Important Medical Event)
101676313	10167631	Disability
101676313	10167631	Life-Threatening
101678657	10167865	Death
101678657	10167865	Other Serious (Important Medical Event)
1017130214	10171302	Other Serious (Important Medical Event)
1017572232	10175722	Other Serious (Important Medical Event)
101780773	10178077	Other Serious (Important Medical Event)
101916392	10191639	Hospitalization - Initial or Prolonged
101916392	10191639	Life-Threatening
101916392	10191639	Other Serious (Important Medical Event)
1020642923	10206429	Other Serious (Important Medical Event)
102371704	10237170	Life-Threatening
102371704	10237170	Hospitalization - Initial or Prolonged
102371704	10237170	Other Serious (Important Medical Event)
1027487983	10274879	Hospitalization - Initial or Prolonged
1027487983	10274879	Other Serious (Important Medical Event)
1028518546	10285185	Hospitalization - Initial or Prolonged
1028518546	10285185	Other Serious (Important Medical Event)
1030948614	10309486	Other Serious (Important Medical Event)
103443973	10344397	Other Serious (Important Medical Event)
1035913611	10359136	Hospitalization - Initial or Prolonged
1035913611	10359136	Other Serious (Important Medical Event)
103687216	10368721	Death



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
103687216	10368721	Hospitalization - Initial or Prolonged
103749689	10374968	Death
103749689	10374968	Hospitalization - Initial or Prolonged
103892335	10389233	Hospitalization - Initial or Prolonged
103985405	10398540	Other Serious (Important Medical Event)
104003092	10400309	Hospitalization - Initial or Prolonged
1040513313	10405133	Other Serious (Important Medical Event)
1041491125	10414911	Other Serious (Important Medical Event)
104232195	10423219	Other Serious (Important Medical Event)
104490482	10449048	Death
104490482	10449048	Other Serious (Important Medical Event)
104580772	10458077	Death
104580883	10458088	Death
104580883	10458088	Other Serious (Important Medical Event)
104665748	10466574	Other Serious (Important Medical Event)
104825157	10482515	Other Serious (Important Medical Event)
105144244	10514424	Other Serious (Important Medical Event)
1051596718	10515967	Hospitalization - Initial or Prolonged
1051596718	10515967	Other Serious (Important Medical Event)
1052690058	10526900	Other Serious (Important Medical Event)
1054038738	10540387	Hospitalization - Initial or Prolonged
1054038738	10540387	Other Serious (Important Medical Event)
105481232	10548123	Other Serious (Important Medical Event)
105741013	10574101	Other Serious (Important Medical Event)
1058928657	10589286	Hospitalization - Initial or Prolonged
1058928657	10589286	Other Serious (Important Medical Event)
105947013	10594701	Hospitalization - Initial or Prolonged

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
105947013	10594701	Life-Threatening
105947013	10594701	Other Serious (Important Medical Event)
1060157312	10601573	Hospitalization - Initial or Prolonged
1060157312	10601573	Death
1060157312	10601573	Other Serious (Important Medical Event)
106091663	10609166	Hospitalization - Initial or Prolonged
106091663	10609166	Death
106091663	10609166	Other Serious (Important Medical Event)
106336646	10633664	Other Serious (Important Medical Event)
106352232	10635223	Death
106352232	10635223	Other Serious (Important Medical Event)
1069198853	10691988	Hospitalization - Initial or Prolonged
1069198853	10691988	Other Serious (Important Medical Event)
1070483325	10704833	Hospitalization - Initial or Prolonged
1070483325	10704833	Other Serious (Important Medical Event)
107314353	10731435	Hospitalization - Initial or Prolonged
107314353	10731435	Other Serious (Important Medical Event)
107316442	10731644	Other Serious (Important Medical Event)
1074008517	10740085	Other Serious (Important Medical Event)
1074197911	10741979	Hospitalization - Initial or Prolonged
1074197911	10741979	Other Serious (Important Medical Event)
1075880717	10758807	Hospitalization - Initial or Prolonged
1078729218	10787292	Other Serious (Important Medical Event)
1080136616	10801366	Hospitalization - Initial or Prolonged
1080136616	10801366	Other Serious (Important Medical Event)
108390175	10839017	Death
108390175	10839017	Hospitalization - Initial or Prolonged

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
108390175	10839017	Other Serious (Important Medical Event)
108824172	10882417	Death
109031962	10903196	Hospitalization - Initial or Prolonged
109031962	10903196	Other Serious (Important Medical Event)
109108923	10910892	Hospitalization - Initial or Prolonged
109108923	10910892	Other Serious (Important Medical Event)
109174139	10917413	Hospitalization - Initial or Prolonged
109174139	10917413	Other Serious (Important Medical Event)
1092018038	10920180	Other Serious (Important Medical Event)
109651512	10965151	Death
109651512	10965151	Other Serious (Important Medical Event)
109680288	10968028	Hospitalization - Initial or Prolonged
109680288	10968028	Other Serious (Important Medical Event)
1097587654	10975876	Hospitalization - Initial or Prolonged
1097587654	10975876	Other Serious (Important Medical Event)
1098206364	10982063	Other Serious (Important Medical Event)
109893399	10989339	Other Serious (Important Medical Event)
1099047564	10990475	Other Serious (Important Medical Event)
109922307	10992230	Death
109922307	10992230	Hospitalization - Initial or Prolonged
109922307	10992230	Other Serious (Important Medical Event)
109948122	10994812	Other Serious (Important Medical Event)
109971003	10997100	Other Serious (Important Medical Event)
1102019552	11020195	Other Serious (Important Medical Event)
1102109863	11021098	Other Serious (Important Medical Event)
1102109863	11021098	Hospitalization - Initial or Prolonged
110215902	11021590	Hospitalization - Initial or Prolonged

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
110215902	11021590	Death
1102411313	11024113	Other Serious (Important Medical Event)
110462235	11046223	Hospitalization - Initial or Prolonged
110462235	11046223	Other Serious (Important Medical Event)
110462235	11046223	Death
110471852	11047185	Other Serious (Important Medical Event)
110471852	11047185	Hospitalization - Initial or Prolonged
110577006	11057700	Other Serious (Important Medical Event)
110734563	11073456	Hospitalization - Initial or Prolonged
110755913	11075591	Hospitalization - Initial or Prolonged
110755913	11075591	Death
110755913	11075591	Other Serious (Important Medical Event)
1107567522	11075675	Other Serious (Important Medical Event)
110781863	11078186	Other Serious (Important Medical Event)
1109083723	11090837	Hospitalization - Initial or Prolonged
1109083723	11090837	Other Serious (Important Medical Event)
110972475	11097247	Other Serious (Important Medical Event)
110995353	11099535	Death
110995353	11099535	Other Serious (Important Medical Event)
111012256	11101225	Other Serious (Important Medical Event)
111044465	11104446	Other Serious (Important Medical Event)
1112193211	11121932	Other Serious (Important Medical Event)
111425004	11142500	Hospitalization - Initial or Prolonged
111425004	11142500	Other Serious (Important Medical Event)
111430143	11143014	Hospitalization - Initial or Prolonged
111500224	11150022	Other Serious (Important Medical Event)
111513767	11151376	Hospitalization - Initial or Prolonged

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
111665733	11166573	Other Serious (Important Medical Event)
1117182022	11171820	Hospitalization - Initial or Prolonged
1117182022	11171820	Life-Threatening
1117182022	11171820	Other Serious (Important Medical Event)
111731695	11173169	Hospitalization - Initial or Prolonged
111731695	11173169	Other Serious (Important Medical Event)
111755239	11175523	Disability
111755239	11175523	Hospitalization - Initial or Prolonged
111772814	11177281	Hospitalization - Initial or Prolonged
111772814	11177281	Life-Threatening
111772814	11177281	Other Serious (Important Medical Event)
111787964	11178796	Death
111787964	11178796	Other Serious (Important Medical Event)
1118598419	11185984	Hospitalization - Initial or Prolonged
1118598419	11185984	Other Serious (Important Medical Event)
111984347	11198434	Other Serious (Important Medical Event)
1119850317	11198503	Hospitalization - Initial or Prolonged
1119850317	11198503	Other Serious (Important Medical Event)
112024568	11202456	Other Serious (Important Medical Event)
1121274917	11212749	Hospitalization - Initial or Prolonged
1121274917	11212749	Other Serious (Important Medical Event)
1121749411	11217494	Hospitalization - Initial or Prolonged
112237713	11223771	Other Serious (Important Medical Event)
112281423	11228142	Death
112281423	11228142	Hospitalization - Initial or Prolonged
112305158	11230515	Other Serious (Important Medical Event)
112362434	11236243	Other Serious (Important Medical Event)

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
112534824	11253482	Other Serious (Important Medical Event)
1126655518	11266555	Hospitalization - Initial or Prolonged
1126655518	11266555	Other Serious (Important Medical Event)
112687622	11268762	Hospitalization - Initial or Prolonged
112877752	11287775	Hospitalization - Initial or Prolonged
112904962	11290496	Hospitalization - Initial or Prolonged
1129109810	11291098	Disability
1129109810	11291098	Other Serious (Important Medical Event)
113024092	11302409	Hospitalization - Initial or Prolonged
113066405	11306640	Congenital Anomaly
113066405	11306640	Disability
113066405	11306640	Hospitalization - Initial or Prolonged
113066405	11306640	Other Serious (Important Medical Event)
1131105412	11311054	Life-Threatening
1131105412	11311054	Other Serious (Important Medical Event)
1131105412	11311054	Hospitalization - Initial or Prolonged
113146645	11314664	Hospitalization - Initial or Prolonged
113146645	11314664	Disability
113146645	11314664	Other Serious (Important Medical Event)
113155356	11315535	Other Serious (Important Medical Event)
113155356	11315535	Hospitalization - Initial or Prolonged
113257456	11325745	Other Serious (Important Medical Event)
1134491610	11344916	Other Serious (Important Medical Event)
1134491610	11344916	Hospitalization - Initial or Prolonged
113600164	11360016	Other Serious (Important Medical Event)
113625366	11362536	Hospitalization - Initial or Prolonged
113625366	11362536	Other Serious (Important Medical Event)

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
113625446	11362544	Hospitalization - Initial or Prolonged
113625446	11362544	Life-Threatening
113625446	11362544	Other Serious (Important Medical Event)
113662138	11366213	Disability
113662138	11366213	Hospitalization - Initial or Prolonged
113662138	11366213	Life-Threatening
113685715	11368571	Hospitalization - Initial or Prolonged
113755943	11375594	Hospitalization - Initial or Prolonged
1138286731	11382867	Congenital Anomaly
1138286731	11382867	Other Serious (Important Medical Event)
1138286731	11382867	Disability
1138286731	11382867	Hospitalization - Initial or Prolonged
113895298	11389529	Hospitalization - Initial or Prolonged
113895298	11389529	Other Serious (Important Medical Event)
1140884841	11408848	Other Serious (Important Medical Event)
114216053	11421605	Hospitalization - Initial or Prolonged
114216053	11421605	Other Serious (Important Medical Event)
1142723210	11427232	Hospitalization - Initial or Prolonged
1142723210	11427232	Other Serious (Important Medical Event)
114378733	11437873	Other Serious (Important Medical Event)
1144435333	11444353	Hospitalization - Initial or Prolonged
1144435333	11444353	Other Serious (Important Medical Event)
1144476723	11444767	Congenital Anomaly
1144476723	11444767	Death
1144476723	11444767	Disability
1144476723	11444767	Hospitalization - Initial or Prolonged
1144476723	11444767	Life-Threatening

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1144476723	11444767	Other Serious (Important Medical Event)
114473694	11447369	Hospitalization - Initial or Prolonged
1145016915	11450169	Other Serious (Important Medical Event)
1145717522	11457175	Congenital Anomaly
1145717522	11457175	Disability
1145717522	11457175	Hospitalization - Initial or Prolonged
1145717522	11457175	Other Serious (Important Medical Event)
114731322	11473132	Other Serious (Important Medical Event)
114734765	11473476	Other Serious (Important Medical Event)
1147514547	11475145	Other Serious (Important Medical Event)
114756606	11475660	Other Serious (Important Medical Event)
114798209	11479820	Other Serious (Important Medical Event)
1148683512	11486835	Disability
1148683512	11486835	Other Serious (Important Medical Event)
1149087937	11490879	Disability
1149087937	11490879	Hospitalization - Initial or Prolonged
1149087937	11490879	Life-Threatening
1149087937	11490879	Other Serious (Important Medical Event)
114958534	11495853	Other Serious (Important Medical Event)
115140276	11514027	Other Serious (Important Medical Event)
1151574948	11515749	Disability
1151574948	11515749	Hospitalization - Initial or Prolonged
1151574948	11515749	Life-Threatening
1151574948	11515749	Other Serious (Important Medical Event)
115173833	11517383	Other Serious (Important Medical Event)
1151945678	11519456	Congenital Anomaly
1151945678	11519456	Death



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1151945678	11519456	Other Serious (Important Medical Event)
1151945678	11519456	Life-Threatening
1151945678	11519456	Hospitalization - Initial or Prolonged
1151945678	11519456	Disability
115203716	11520371	Other Serious (Important Medical Event)
115203716	11520371	Hospitalization - Initial or Prolonged
1156227656	11562276	Hospitalization - Initial or Prolonged
1156227656	11562276	Other Serious (Important Medical Event)
115668012	11566801	Hospitalization - Initial or Prolonged
115668012	11566801	Other Serious (Important Medical Event)
115732526	11573252	Other Serious (Important Medical Event)
115732526	11573252	Hospitalization - Initial or Prolonged
1157787013	11577870	Other Serious (Important Medical Event)
115800019	11580001	Other Serious (Important Medical Event)
1158070941	11580709	Disability
1158070941	11580709	Death
1158070941	11580709	Congenital Anomaly
1158070941	11580709	Hospitalization - Initial or Prolonged
1158070941	11580709	Other Serious (Important Medical Event)
1158070941	11580709	Life-Threatening
115863238	11586323	Other Serious (Important Medical Event)
115900453	11590045	Hospitalization - Initial or Prolonged
115907586	11590758	Other Serious (Important Medical Event)
115925813	11592581	Hospitalization - Initial or Prolonged
115925813	11592581	Death
115925813	11592581	Life-Threatening
1161812071	11618120	Other Serious (Important Medical Event)

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1161812071	11618120	Hospitalization - Initial or Prolonged
116289952	11628995	Other Serious (Important Medical Event)
116313907	11631390	Other Serious (Important Medical Event)
1163175032	11631750	Hospitalization - Initial or Prolonged
1163175032	11631750	Other Serious (Important Medical Event)
116502727	11650272	Other Serious (Important Medical Event)
116530282	11653028	Other Serious (Important Medical Event)
116530282	11653028	Hospitalization - Initial or Prolonged
116533853	11653385	Other Serious (Important Medical Event)
116545458	11654545	Other Serious (Important Medical Event)
116545458	11654545	Hospitalization - Initial or Prolonged
1166352379	11663523	Other Serious (Important Medical Event)
116787914	11678791	Other Serious (Important Medical Event)
1168672145	11686721	Other Serious (Important Medical Event)
1168789257	11687892	Other Serious (Important Medical Event)
1168789257	11687892	Hospitalization - Initial or Prolonged
1169217617	11692176	Other Serious (Important Medical Event)
116951916	11695191	Hospitalization - Initial or Prolonged
116951916	11695191	Other Serious (Important Medical Event)
1169665434	11696654	Other Serious (Important Medical Event)
1169665434	11696654	Hospitalization - Initial or Prolonged
117037909	11703790	Disability
117037909	11703790	Hospitalization - Initial or Prolonged
117037909	11703790	Other Serious (Important Medical Event)
117194573	11719457	Other Serious (Important Medical Event)
1174511318	11745113	Hospitalization - Initial or Prolonged
1174511318	11745113	Other Serious (Important Medical Event)

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
117720064	11772006	Other Serious (Important Medical Event)
117760955	11776095	Other Serious (Important Medical Event)
117761484	11776148	Other Serious (Important Medical Event)
1178230313	11782303	Hospitalization - Initial or Prolonged
1178453618	11784536	Other Serious (Important Medical Event)
117876845	11787684	Other Serious (Important Medical Event)
1178812814	11788128	Hospitalization - Initial or Prolonged
1178812814	11788128	Other Serious (Important Medical Event)
1179178614	11791786	Other Serious (Important Medical Event)
118134552	11813455	Hospitalization - Initial or Prolonged
118134552	11813455	Other Serious (Important Medical Event)
118168512	11816851	Other Serious (Important Medical Event)
118171395	11817139	Other Serious (Important Medical Event)
118197754	11819775	Other Serious (Important Medical Event)
118278119	11827811	Other Serious (Important Medical Event)
118278119	11827811	Hospitalization - Initial or Prolonged
118406256	11840625	Hospitalization - Initial or Prolonged
118406256	11840625	Other Serious (Important Medical Event)
118406345	11840634	Other Serious (Important Medical Event)
118406345	11840634	Hospitalization - Initial or Prolonged
118490297	11849029	Other Serious (Important Medical Event)
1185945712	11859457	Other Serious (Important Medical Event)
1185945712	11859457	Hospitalization - Initial or Prolonged
118666423	11866642	Hospitalization - Initial or Prolonged
118666423	11866642	Other Serious (Important Medical Event)
118688722	11868872	Other Serious (Important Medical Event)
118688732	11868873	Other Serious (Important Medical Event)

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
118689052	11868905	Other Serious (Important Medical Event)
118689122	11868912	Other Serious (Important Medical Event)
118689132	11868913	Other Serious (Important Medical Event)
118689152	11868915	Other Serious (Important Medical Event)
118689222	11868922	Death
118689222	11868922	Other Serious (Important Medical Event)
118689722	11868972	Other Serious (Important Medical Event)
118689842	11868984	Other Serious (Important Medical Event)
118689852	11868985	Other Serious (Important Medical Event)
118689862	11868986	Other Serious (Important Medical Event)
118689872	11868987	Other Serious (Important Medical Event)
118689952	11868995	Other Serious (Important Medical Event)
118712772	11871277	Other Serious (Important Medical Event)
118713032	11871303	Death
118745404	11874540	Other Serious (Important Medical Event)
118745404	11874540	Hospitalization - Initial or Prolonged
118806382	11880638	Other Serious (Important Medical Event)
1189796319	11897963	Hospitalization - Initial or Prolonged
1189796319	11897963	Other Serious (Important Medical Event)
119104223	11910422	Hospitalization - Initial or Prolonged
119219533	11921953	Hospitalization - Initial or Prolonged
119219533	11921953	Other Serious (Important Medical Event)
119270783	11927078	Other Serious (Important Medical Event)
1192728610	11927286	Hospitalization - Initial or Prolonged
1192728610	11927286	Other Serious (Important Medical Event)
119326774	11932677	Hospitalization - Initial or Prolonged
1193375735	11933757	Hospitalization - Initial or Prolonged

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1193375735	11933757	Other Serious (Important Medical Event)
119338255	11933825	Hospitalization - Initial or Prolonged
119338255	11933825	Other Serious (Important Medical Event)
1193535523	11935355	Hospitalization - Initial or Prolonged
1193535523	11935355	Other Serious (Important Medical Event)
1193793115	11937931	Hospitalization - Initial or Prolonged
1193793115	11937931	Other Serious (Important Medical Event)
119478563	11947856	Death
119478563	11947856	Other Serious (Important Medical Event)
1196876534	11968765	Other Serious (Important Medical Event)
119875983	11987598	Other Serious (Important Medical Event)
120093639	12009363	Hospitalization - Initial or Prolonged
120093639	12009363	Other Serious (Important Medical Event)
1204027949	12040279	Disability
1204027949	12040279	Hospitalization - Initial or Prolonged
1204027949	12040279	Other Serious (Important Medical Event)
120668283	12066828	Other Serious (Important Medical Event)
120740156	12074015	Hospitalization - Initial or Prolonged
120751903	12075190	Hospitalization - Initial or Prolonged
120751903	12075190	Other Serious (Important Medical Event)
120779963	12077996	Life-Threatening
1207853043	12078530	Hospitalization - Initial or Prolonged
1207853043	12078530	Other Serious (Important Medical Event)
120813973	12081397	Hospitalization - Initial or Prolonged
1208222832	12082228	Hospitalization - Initial or Prolonged
1208222832	12082228	Other Serious (Important Medical Event)
1209904323	12099043	Hospitalization - Initial or Prolonged

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1209904323	12099043	Other Serious (Important Medical Event)
121031125	12103112	Death
121031125	12103112	Hospitalization - Initial or Prolonged
121031125	12103112	Other Serious (Important Medical Event)
1210599713	12105997	Hospitalization - Initial or Prolonged
1210599713	12105997	Other Serious (Important Medical Event)
121083429	12108342	Hospitalization - Initial or Prolonged
121090126	12109012	Other Serious (Important Medical Event)
1211671714	12116717	Death
1211671714	12116717	Hospitalization - Initial or Prolonged
1211671714	12116717	Other Serious (Important Medical Event)
121178303	12117830	Other Serious (Important Medical Event)
1212230540	12122305	Hospitalization - Initial or Prolonged
1212230540	12122305	Other Serious (Important Medical Event)
121225423	12122542	Other Serious (Important Medical Event)
1213390067	12133900	Hospitalization - Initial or Prolonged
1213390067	12133900	Other Serious (Important Medical Event)
121344112	12134411	Hospitalization - Initial or Prolonged
121344172	12134417	Hospitalization - Initial or Prolonged
121344383	12134438	Hospitalization - Initial or Prolonged
121345362	12134536	Hospitalization - Initial or Prolonged
121345362	12134536	Other Serious (Important Medical Event)
121345672	12134567	Hospitalization - Initial or Prolonged
121349972	12134997	Hospitalization - Initial or Prolonged
121349972	12134997	Other Serious (Important Medical Event)
121350152	12135015	Hospitalization - Initial or Prolonged
121350152	12135015	Other Serious (Important Medical Event)

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
121350502	12135050	Hospitalization - Initial or Prolonged
121350502	12135050	Other Serious (Important Medical Event)
121351362	12135136	Other Serious (Important Medical Event)
121351362	12135136	Hospitalization - Initial or Prolonged
121351453	12135145	Hospitalization - Initial or Prolonged
121351453	12135145	Other Serious (Important Medical Event)
121351482	12135148	Hospitalization - Initial or Prolonged
121351482	12135148	Other Serious (Important Medical Event)
121351512	12135151	Hospitalization - Initial or Prolonged
121351512	12135151	Other Serious (Important Medical Event)
1213893320	12138933	Other Serious (Important Medical Event)
121389514	12138951	Other Serious (Important Medical Event)
1213946925	12139469	Other Serious (Important Medical Event)
121400216	12140021	Life-Threatening
121400216	12140021	Hospitalization - Initial or Prolonged
121400216	12140021	Other Serious (Important Medical Event)
121614898	12161489	Hospitalization - Initial or Prolonged
121684513	12168451	Hospitalization - Initial or Prolonged
121684513	12168451	Other Serious (Important Medical Event)
121851406	12185140	Other Serious (Important Medical Event)
1218588315	12185883	Hospitalization - Initial or Prolonged
1218588315	12185883	Death
1218588315	12185883	Life-Threatening
1218588315	12185883	Other Serious (Important Medical Event)
1219006311	12190063	Other Serious (Important Medical Event)
1219366031	12193660	Other Serious (Important Medical Event)
121944728	12194472	Hospitalization - Initial or Prolonged

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
121944728	12194472	Life-Threatening
121944728	12194472	Other Serious (Important Medical Event)
122095957	12209595	Other Serious (Important Medical Event)
1220965353	12209653	Other Serious (Important Medical Event)
122104123	12210412	Life-Threatening
122104123	12210412	Other Serious (Important Medical Event)
122200518	12220051	Other Serious (Important Medical Event)
122200518	12220051	Hospitalization - Initial or Prolonged
1223166310	12231663	Other Serious (Important Medical Event)
1223166310	12231663	Hospitalization - Initial or Prolonged
1224068929	12240689	Other Serious (Important Medical Event)
1224068929	12240689	Hospitalization - Initial or Prolonged
122443472	12244347	Other Serious (Important Medical Event)
1224849317	12248493	Other Serious (Important Medical Event)
1224849317	12248493	Hospitalization - Initial or Prolonged
122512633	12251263	Other Serious (Important Medical Event)
122512633	12251263	Hospitalization - Initial or Prolonged
122550212	12255021	Other Serious (Important Medical Event)
122656474	12265647	Hospitalization - Initial or Prolonged
122657802	12265780	Other Serious (Important Medical Event)
122657802	12265780	Hospitalization - Initial or Prolonged
1226963211	12269632	Other Serious (Important Medical Event)
122815454	12281545	Other Serious (Important Medical Event)
122844006	12284400	Hospitalization - Initial or Prolonged
122844006	12284400	Other Serious (Important Medical Event)
1229068117	12290681	Other Serious (Important Medical Event)
1229378940	12293789	Hospitalization - Initial or Prolonged



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1229378940	12293789	Other Serious (Important Medical Event)
122975224	12297522	Hospitalization - Initial or Prolonged
122975224	12297522	Other Serious (Important Medical Event)
1230227453	12302274	Other Serious (Important Medical Event)
1230227453	12302274	Hospitalization - Initial or Prolonged
1230456626	12304566	Hospitalization - Initial or Prolonged
1230456626	12304566	Other Serious (Important Medical Event)
1230619217	12306192	Hospitalization - Initial or Prolonged
1230619217	12306192	Other Serious (Important Medical Event)
123066303	12306630	Life-Threatening
123066314	12306631	Other Serious (Important Medical Event)
123066314	12306631	Death
123090303	12309030	Death
123090423	12309042	Death
123097115	12309711	Hospitalization - Initial or Prolonged
123098207	12309820	Other Serious (Important Medical Event)
123098207	12309820	Disability
123098207	12309820	Death
123098207	12309820	Congenital Anomaly
123119083	12311908	Death
123119133	12311913	Death
123119193	12311919	Death
123119243	12311924	Life-Threatening
123119253	12311925	Death
123119263	12311926	Life-Threatening
123119286	12311928	Death
123119353	12311935	Death

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
123119363	12311936	Life-Threatening
123119443	12311944	Death
123120013	12312001	Death
123121313	12312131	Death
123333823	12333382	Other Serious (Important Medical Event)
123430863	12343086	Other Serious (Important Medical Event)
123430863	12343086	Hospitalization - Initial or Prolonged
123430863	12343086	Life-Threatening
1234722916	12347229	Other Serious (Important Medical Event)
1234722916	12347229	Hospitalization - Initial or Prolonged
123507647	12350764	Other Serious (Important Medical Event)
123507647	12350764	Hospitalization - Initial or Prolonged
123507647	12350764	Life-Threatening
1235162812	12351628	Other Serious (Important Medical Event)
1235162812	12351628	Disability
1235162812	12351628	Death
1235162812	12351628	Hospitalization - Initial or Prolonged
123563352	12356335	Other Serious (Important Medical Event)
1235836630	12358366	Other Serious (Important Medical Event)
123602163	12360216	Other Serious (Important Medical Event)
123602163	12360216	Hospitalization - Initial or Prolonged
123673573	12367357	Other Serious (Important Medical Event)
123712795	12371279	Hospitalization - Initial or Prolonged
123712795	12371279	Other Serious (Important Medical Event)
1237277237	12372772	Other Serious (Important Medical Event)
1237277237	12372772	Death
123828053	12382805	Hospitalization - Initial or Prolonged

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
123828053	12382805	Other Serious (Important Medical Event)
123865169	12386516	Other Serious (Important Medical Event)
1238769515	12387695	Other Serious (Important Medical Event)
123883414	12388341	Hospitalization - Initial or Prolonged
1239199829	12391998	Other Serious (Important Medical Event)
1239199829	12391998	Hospitalization - Initial or Prolonged
123928902	12392890	Other Serious (Important Medical Event)
124058976	12405897	Hospitalization - Initial or Prolonged
124058976	12405897	Other Serious (Important Medical Event)
1241345017	12413450	Life-Threatening
1241345017	12413450	Hospitalization - Initial or Prolonged
1241345017	12413450	Disability
1241345017	12413450	Other Serious (Important Medical Event)
1241683811	12416838	Hospitalization - Initial or Prolonged
1241683811	12416838	Life-Threatening
1241683811	12416838	Other Serious (Important Medical Event)
1241759015	12417590	Hospitalization - Initial or Prolonged
1241759015	12417590	Other Serious (Important Medical Event)
124193252	12419325	Other Serious (Important Medical Event)
1242381216	12423812	Hospitalization - Initial or Prolonged
1242381216	12423812	Other Serious (Important Medical Event)
1242661017	12426610	Other Serious (Important Medical Event)
124267893	12426789	Other Serious (Important Medical Event)
1243188715	12431887	Other Serious (Important Medical Event)
1244105814	12441058	Other Serious (Important Medical Event)
1244109913	12441099	Hospitalization - Initial or Prolonged
1244109913	12441099	Other Serious (Important Medical Event)

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
124519574	12451957	Other Serious (Important Medical Event)
124557465	12455746	Hospitalization - Initial or Prolonged
124557465	12455746	Life-Threatening
124557465	12455746	Other Serious (Important Medical Event)
124576196	12457619	Hospitalization - Initial or Prolonged
124576196	12457619	Other Serious (Important Medical Event)
124647052	12464705	Other Serious (Important Medical Event)
124656152	12465615	Hospitalization - Initial or Prolonged
124656152	12465615	Other Serious (Important Medical Event)
124658184	12465818	Hospitalization - Initial or Prolonged
124658184	12465818	Life-Threatening
124658184	12465818	Other Serious (Important Medical Event)
1246649231	12466492	Hospitalization - Initial or Prolonged
1246649231	12466492	Other Serious (Important Medical Event)
124697266	12469726	Other Serious (Important Medical Event)
124729263	12472926	Other Serious (Important Medical Event)
1248414317	12484143	Other Serious (Important Medical Event)
1248745116	12487451	Other Serious (Important Medical Event)
1248777719	12487777	Other Serious (Important Medical Event)
124879704	12487970	Hospitalization - Initial or Prolonged
124879704	12487970	Other Serious (Important Medical Event)
125035915	12503591	Hospitalization - Initial or Prolonged
1251723528	12517235	Other Serious (Important Medical Event)
1251723528	12517235	Hospitalization - Initial or Prolonged
1251759434	12517594	Hospitalization - Initial or Prolonged
1251759434	12517594	Other Serious (Important Medical Event)
125236397	12523639	Hospitalization - Initial or Prolonged

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
125236397	12523639	Other Serious (Important Medical Event)
1252758731	12527587	Hospitalization - Initial or Prolonged
1252758731	12527587	Other Serious (Important Medical Event)
125285222	12528522	Hospitalization - Initial or Prolonged
125285222	12528522	Other Serious (Important Medical Event)
125316252	12531625	Other Serious (Important Medical Event)
1253212410	12532124	Other Serious (Important Medical Event)
1253212410	12532124	Hospitalization - Initial or Prolonged
1253507817	12535078	Other Serious (Important Medical Event)
125419252	12541925	Other Serious (Important Medical Event)
1254806012	12548060	Other Serious (Important Medical Event)
125511353	12551135	Other Serious (Important Medical Event)
125511353	12551135	Hospitalization - Initial or Prolonged
125511353	12551135	Life-Threatening
125520368	12552036	Other Serious (Important Medical Event)
125520368	12552036	Hospitalization - Initial or Prolonged
125529493	12552949	Hospitalization - Initial or Prolonged
125529493	12552949	Other Serious (Important Medical Event)
125579484	12557948	Other Serious (Important Medical Event)
125595734	12559573	Other Serious (Important Medical Event)
125609252	12560925	Other Serious (Important Medical Event)
125619276	12561927	Other Serious (Important Medical Event)
1256504624	12565046	Other Serious (Important Medical Event)
1258205211	12582052	Other Serious (Important Medical Event)
1258205211	12582052	Hospitalization - Initial or Prolonged
1258253825	12582538	Other Serious (Important Medical Event)
1258700623	12587006	Life-Threatening

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1258700623	12587006	Other Serious (Important Medical Event)
1258700623	12587006	Hospitalization - Initial or Prolonged
1259605217	12596052	Other Serious (Important Medical Event)
125972513	12597251	Hospitalization - Initial or Prolonged
125972513	12597251	Other Serious (Important Medical Event)
126018092	12601809	Hospitalization - Initial or Prolonged
126018092	12601809	Other Serious (Important Medical Event)
126027722	12602772	Death
126052728	12605272	Hospitalization - Initial or Prolonged
126052728	12605272	Other Serious (Important Medical Event)
126083683	12608368	Other Serious (Important Medical Event)
126083763	12608376	Other Serious (Important Medical Event)
126102746	12610274	Other Serious (Important Medical Event)
1261220638	12612206	Other Serious (Important Medical Event)
1261220638	12612206	Disability
126144642	12614464	Hospitalization - Initial or Prolonged
126144642	12614464	Other Serious (Important Medical Event)
1261461519	12614615	Hospitalization - Initial or Prolonged
1261461519	12614615	Other Serious (Important Medical Event)
126146323	12614632	Other Serious (Important Medical Event)
1262188810	12621888	Hospitalization - Initial or Prolonged
1262194015	12621940	Hospitalization - Initial or Prolonged
1262194015	12621940	Other Serious (Important Medical Event)
1262399912	12623999	Hospitalization - Initial or Prolonged
126300813	12630081	Death
126300813	12630081	Other Serious (Important Medical Event)
126446453	12644645	Other Serious (Important Medical Event)

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1264583518	12645835	Hospitalization - Initial or Prolonged
1264583518	12645835	Other Serious (Important Medical Event)
1264862010	12648620	Other Serious (Important Medical Event)
1264877314	12648773	Hospitalization - Initial or Prolonged
1264877314	12648773	Other Serious (Important Medical Event)
126510864	12651086	Other Serious (Important Medical Event)
1265259319	12652593	Hospitalization - Initial or Prolonged
1265259319	12652593	Other Serious (Important Medical Event)
126525949	12652594	Hospitalization - Initial or Prolonged
126525949	12652594	Other Serious (Important Medical Event)
126566772	12656677	Death
126566772	12656677	Other Serious (Important Medical Event)
1265982714	12659827	Hospitalization - Initial or Prolonged
126599422	12659942	Other Serious (Important Medical Event)
126629514	12662951	Hospitalization - Initial or Prolonged
126629514	12662951	Other Serious (Important Medical Event)
126636233	12663623	Death
126636233	12663623	Other Serious (Important Medical Event)
126661713	12666171	Other Serious (Important Medical Event)
126666384	12666638	Death
126666384	12666638	Other Serious (Important Medical Event)
1266682834	12666828	Hospitalization - Initial or Prolonged
1266682834	12666828	Life-Threatening
1266682834	12666828	Other Serious (Important Medical Event)
126694216	12669421	Other Serious (Important Medical Event)
1267143810	12671438	Other Serious (Important Medical Event)
1267308830	12673088	Hospitalization - Initial or Prolonged

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1267308830	12673088	Other Serious (Important Medical Event)
1267604333	12676043	Disability
1267604333	12676043	Hospitalization - Initial or Prolonged
1267604333	12676043	Life-Threatening
1267604333	12676043	Other Serious (Important Medical Event)
126784766	12678476	Other Serious (Important Medical Event)
1267970510	12679705	Other Serious (Important Medical Event)
1268469220	12684692	Other Serious (Important Medical Event)
1268469220	12684692	Hospitalization - Initial or Prolonged
126849622	12684962	Life-Threatening
126865539	12686553	Hospitalization - Initial or Prolonged
126865539	12686553	Other Serious (Important Medical Event)
126908303	12690830	Hospitalization - Initial or Prolonged
126908303	12690830	Other Serious (Important Medical Event)
126915713	12691571	Other Serious (Important Medical Event)
126946204	12694620	Hospitalization - Initial or Prolonged
126946204	12694620	Other Serious (Important Medical Event)
1269688715	12696887	Congenital Anomaly
1269688715	12696887	Disability
1269688715	12696887	Hospitalization - Initial or Prolonged
1269688715	12696887	Other Serious (Important Medical Event)
1270466920	12704669	Hospitalization - Initial or Prolonged
1270466920	12704669	Other Serious (Important Medical Event)
127133207	12713320	Hospitalization - Initial or Prolonged
127133207	12713320	Other Serious (Important Medical Event)
1271450712	12714507	Hospitalization - Initial or Prolonged
1271617516	12716175	Other Serious (Important Medical Event)



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1271619614	12716196	Hospitalization - Initial or Prolonged
1271619614	12716196	Other Serious (Important Medical Event)
1272747538	12727475	Hospitalization - Initial or Prolonged
1272747538	12727475	Other Serious (Important Medical Event)
127335812	12733581	Death
1273672134	12736721	Death
1273672134	12736721	Hospitalization - Initial or Prolonged
1273672134	12736721	Other Serious (Important Medical Event)
127442575	12744257	Hospitalization - Initial or Prolonged
127442575	12744257	Other Serious (Important Medical Event)
127476922	12747692	Other Serious (Important Medical Event)
1276662113	12766621	Other Serious (Important Medical Event)
1276746115	12767461	Other Serious (Important Medical Event)
127688913	12768891	Other Serious (Important Medical Event)
127739882	12773988	Hospitalization - Initial or Prolonged
127739882	12773988	Other Serious (Important Medical Event)
127769588	12776958	Other Serious (Important Medical Event)
127795064	12779506	Death
127795064	12779506	Hospitalization - Initial or Prolonged
127795064	12779506	Other Serious (Important Medical Event)
1278946016	12789460	Hospitalization - Initial or Prolonged
1278946016	12789460	Other Serious (Important Medical Event)
1279005821	12790058	Other Serious (Important Medical Event)
127908472	12790847	Other Serious (Important Medical Event)
127919063	12791906	Hospitalization - Initial or Prolonged
127919063	12791906	Other Serious (Important Medical Event)
127923264	12792326	Other Serious (Important Medical Event)

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
127925774	12792577	Other Serious (Important Medical Event)
127928484	12792848	Other Serious (Important Medical Event)
127970915	12797091	Other Serious (Important Medical Event)
128111456	12811145	Other Serious (Important Medical Event)
128125275	12812527	Hospitalization - Initial or Prolonged
128125275	12812527	Disability
1281285321	12812853	Hospitalization - Initial or Prolonged
1281285321	12812853	Disability
1281285321	12812853	Other Serious (Important Medical Event)
1282456425	12824564	Other Serious (Important Medical Event)
1282456425	12824564	Disability
128337604	12833760	Other Serious (Important Medical Event)
1283816224	12838162	Other Serious (Important Medical Event)
1283816224	12838162	Hospitalization - Initial or Prolonged
1284001415	12840014	Other Serious (Important Medical Event)
1284111422	12841114	Hospitalization - Initial or Prolonged
1284111422	12841114	Other Serious (Important Medical Event)
128418645	12841864	Hospitalization - Initial or Prolonged
128418645	12841864	Other Serious (Important Medical Event)
128428173	12842817	Death
128428173	12842817	Other Serious (Important Medical Event)
128452458	12845245	Other Serious (Important Medical Event)
128452458	12845245	Hospitalization - Initial or Prolonged
128455702	12845570	Other Serious (Important Medical Event)
128533274	12853327	Other Serious (Important Medical Event)
1285374010	12853740	Other Serious (Important Medical Event)
1285374010	12853740	Hospitalization - Initial or Prolonged

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
128607137	12860713	Death
128607137	12860713	Hospitalization - Initial or Prolonged
128713873	12871387	Other Serious (Important Medical Event)
128759653	12875965	Other Serious (Important Medical Event)
128796683	12879668	Death
128796683	12879668	Hospitalization - Initial or Prolonged
128813852	12881385	Other Serious (Important Medical Event)
128815644	12881564	Other Serious (Important Medical Event)
128830863	12883086	Hospitalization - Initial or Prolonged
128835772	12883577	Other Serious (Important Medical Event)
1288783427	12887834	Other Serious (Important Medical Event)
1288783427	12887834	Hospitalization - Initial or Prolonged
128896804	12889680	Hospitalization - Initial or Prolonged
128906342	12890634	Other Serious (Important Medical Event)
129175148	12917514	Other Serious (Important Medical Event)
1292916520	12929165	Hospitalization - Initial or Prolonged
1292916520	12929165	Other Serious (Important Medical Event)
129309562	12930956	Other Serious (Important Medical Event)
129381218	12938121	Death
129381218	12938121	Other Serious (Important Medical Event)
1294339813	12943398	Hospitalization - Initial or Prolonged
1294339813	12943398	Other Serious (Important Medical Event)
1294445310	12944453	Other Serious (Important Medical Event)
1294587413	12945874	Hospitalization - Initial or Prolonged
1294587413	12945874	Disability
1294587413	12945874	Other Serious (Important Medical Event)
1294608711	12946087	Other Serious (Important Medical Event)

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
129482007	12948200	Other Serious (Important Medical Event)
129534697	12953469	Hospitalization - Initial or Prolonged
129534697	12953469	Other Serious (Important Medical Event)
1295393127	12953931	Disability
1295393127	12953931	Life-Threatening
1295393127	12953931	Other Serious (Important Medical Event)
1295753119	12957531	Death
1295753119	12957531	Hospitalization - Initial or Prolonged
1295753119	12957531	Other Serious (Important Medical Event)
1295809811	12958098	Hospitalization - Initial or Prolonged
1295809811	12958098	Other Serious (Important Medical Event)
129640184	12964018	Other Serious (Important Medical Event)
129661094	12966109	Other Serious (Important Medical Event)
129710933	12971093	Other Serious (Important Medical Event)
129756816	12975681	Hospitalization - Initial or Prolonged
129756816	12975681	Other Serious (Important Medical Event)
129758429	12975842	Hospitalization - Initial or Prolonged
129797152	12979715	Hospitalization - Initial or Prolonged
129797152	12979715	Other Serious (Important Medical Event)
1298165819	12981658	Other Serious (Important Medical Event)
1298245917	12982459	Disability
1298245917	12982459	Hospitalization - Initial or Prolonged
1298245917	12982459	Other Serious (Important Medical Event)
129832442	12983244	Death
129832442	12983244	Other Serious (Important Medical Event)
129832442	12983244	Hospitalization - Initial or Prolonged
129879489	12987948	Hospitalization - Initial or Prolonged

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
129879489	12987948	Other Serious (Important Medical Event)
129887515	12988751	Other Serious (Important Medical Event)
129895932	12989593	Hospitalization - Initial or Prolonged
129913302	12991330	Hospitalization - Initial or Prolonged
129913302	12991330	Other Serious (Important Medical Event)
129929712	12992971	Other Serious (Important Medical Event)
1299455329	12994553	Other Serious (Important Medical Event)
129969329	12996932	Hospitalization - Initial or Prolonged
129969329	12996932	Other Serious (Important Medical Event)
1300378736	13003787	Hospitalization - Initial or Prolonged
130099107	13009910	Other Serious (Important Medical Event)
130099107	13009910	Hospitalization - Initial or Prolonged
1301226125	13012261	Other Serious (Important Medical Event)
1301373012	13013730	Other Serious (Important Medical Event)
130167094	13016709	Other Serious (Important Medical Event)
130167094	13016709	Congenital Anomaly
1302401118	13024011	Other Serious (Important Medical Event)
1302401118	13024011	Hospitalization - Initial or Prolonged
130260364	13026036	Other Serious (Important Medical Event)
130297032	13029703	Other Serious (Important Medical Event)
130314855	13031485	Hospitalization - Initial or Prolonged
130314855	13031485	Other Serious (Important Medical Event)
130375084	13037508	Other Serious (Important Medical Event)
1305805713	13058057	Disability
1305805713	13058057	Other Serious (Important Medical Event)
1306707611	13067076	Hospitalization - Initial or Prolonged
1306707611	13067076	Other Serious (Important Medical Event)

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1306917111	13069171	Other Serious (Important Medical Event)
130714024	13071402	Other Serious (Important Medical Event)
130719762	13071976	Other Serious (Important Medical Event)
1307598415	13075984	Hospitalization - Initial or Prolonged
1307598415	13075984	Other Serious (Important Medical Event)
130765083	13076508	Hospitalization - Initial or Prolonged
130896044	13089604	Other Serious (Important Medical Event)
130896044	13089604	Hospitalization - Initial or Prolonged
130913686	13091368	Hospitalization - Initial or Prolonged
130951602	13095160	Other Serious (Important Medical Event)
1309831715	13098317	Disability
1310972321	13109723	Disability
131179953	13117995	Hospitalization - Initial or Prolonged
131181364	13118136	Other Serious (Important Medical Event)
131181465	13118146	Other Serious (Important Medical Event)
1312448414	13124484	Hospitalization - Initial or Prolonged
131300352	13130035	Hospitalization - Initial or Prolonged
131300352	13130035	Life-Threatening
1313174010	13131740	Other Serious (Important Medical Event)
131346387	13134638	Other Serious (Important Medical Event)
1314326413	13143264	Hospitalization - Initial or Prolonged
1314326413	13143264	Other Serious (Important Medical Event)
131474342	13147434	Other Serious (Important Medical Event)
1315318823	13153188	Hospitalization - Initial or Prolonged
1315318823	13153188	Other Serious (Important Medical Event)
131584896	13158489	Hospitalization - Initial or Prolonged
131614126	13161412	Life-Threatening

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
131717783	13171778	Other Serious (Important Medical Event)
131720564	13172056	Death
131720564	13172056	Hospitalization - Initial or Prolonged
131720564	13172056	Other Serious (Important Medical Event)
131884112	13188411	Other Serious (Important Medical Event)
131948255	13194825	Other Serious (Important Medical Event)
132256512	13225651	Other Serious (Important Medical Event)
1322723239	13227232	Hospitalization - Initial or Prolonged
1322723239	13227232	Life-Threatening
1322723239	13227232	Other Serious (Important Medical Event)
132292854	13229285	Hospitalization - Initial or Prolonged
1323008512	13230085	Hospitalization - Initial or Prolonged
1323008512	13230085	Other Serious (Important Medical Event)
132340655	13234065	Hospitalization - Initial or Prolonged
132446642	13244664	Other Serious (Important Medical Event)
132535658	13253565	Other Serious (Important Medical Event)
132535658	13253565	Hospitalization - Initial or Prolonged
132573907	13257390	Other Serious (Important Medical Event)
132573907	13257390	Hospitalization - Initial or Prolonged
132573907	13257390	Life-Threatening
1326573916	13265739	Other Serious (Important Medical Event)
132667138	13266713	Hospitalization - Initial or Prolonged
132667138	13266713	Congenital Anomaly
132667138	13266713	Other Serious (Important Medical Event)
1326925316	13269253	Hospitalization - Initial or Prolonged
1326925316	13269253	Other Serious (Important Medical Event)
1327001616	13270016	Other Serious (Important Medical Event)

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
132718234	13271823	Death
132718234	13271823	Other Serious (Important Medical Event)
1327789813	13277898	Hospitalization - Initial or Prolonged
1327789813	13277898	Other Serious (Important Medical Event)
132807613	13280761	Life-Threatening
132807613	13280761	Other Serious (Important Medical Event)
132818014	13281801	Other Serious (Important Medical Event)
132846696	13284669	Other Serious (Important Medical Event)
1328785317	13287853	Other Serious (Important Medical Event)
1329621913	13296219	Hospitalization - Initial or Prolonged
1329621913	13296219	Death
1329621913	13296219	Other Serious (Important Medical Event)
133030383	13303038	Other Serious (Important Medical Event)
133030383	13303038	Disability
1330367811	13303678	Hospitalization - Initial or Prolonged
1330367811	13303678	Other Serious (Important Medical Event)
1330513013	13305130	Other Serious (Important Medical Event)
133076635	13307663	Other Serious (Important Medical Event)
133108513	13310851	Other Serious (Important Medical Event)
133116253	13311625	Other Serious (Important Medical Event)
1331956117	13319561	Other Serious (Important Medical Event)
1331956117	13319561	Hospitalization - Initial or Prolonged
1333644913	13336449	Other Serious (Important Medical Event)
1333644913	13336449	Hospitalization - Initial or Prolonged
133365235	13336523	Hospitalization - Initial or Prolonged
133365235	13336523	Other Serious (Important Medical Event)
133429876	13342987	Hospitalization - Initial or Prolonged



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
133473682	13347368	Hospitalization - Initial or Prolonged
1335105016	13351050	Hospitalization - Initial or Prolonged
133523655	13352365	Death
133523655	13352365	Hospitalization - Initial or Prolonged
133523655	13352365	Life-Threatening
133523655	13352365	Other Serious (Important Medical Event)
133523846	13352384	Hospitalization - Initial or Prolonged
133523846	13352384	Other Serious (Important Medical Event)
1335529225	13355292	Hospitalization - Initial or Prolonged
1335529225	13355292	Other Serious (Important Medical Event)
133583395	13358339	Other Serious (Important Medical Event)
133599388	13359938	Life-Threatening
133599388	13359938	Other Serious (Important Medical Event)
1336515012	13365150	Other Serious (Important Medical Event)
1336515012	13365150	Hospitalization - Initial or Prolonged
133701598	13370159	Other Serious (Important Medical Event)
133748923	13374892	Other Serious (Important Medical Event)
133748923	13374892	Death
133761803	13376180	Other Serious (Important Medical Event)
133761803	13376180	Hospitalization - Initial or Prolonged
133761803	13376180	Life-Threatening
133829345	13382934	Other Serious (Important Medical Event)
133931897	13393189	Other Serious (Important Medical Event)
133931897	13393189	Hospitalization - Initial or Prolonged
133959212	13395921	Hospitalization - Initial or Prolonged
1339710411	13397104	Hospitalization - Initial or Prolonged
1339710411	13397104	Other Serious (Important Medical Event)

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Outcome Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
134010312	13401031	Hospitalization - Initial or Prolonged
134010312	13401031	Other Serious (Important Medical Event)
134018982	13401898	Other Serious (Important Medical Event)
134019173	13401917	Hospitalization - Initial or Prolonged
134019173	13401917	Other Serious (Important Medical Event)
134033914	13403391	Other Serious (Important Medical Event)
134040983	13404098	Hospitalization - Initial or Prolonged
134040983	13404098	Life-Threatening
134040983	13404098	Other Serious (Important Medical Event)
134065693	13406569	Death
134065693	13406569	Other Serious (Important Medical Event)
134066473	13406647	Disability
134066473	13406647	Other Serious (Important Medical Event)
134066473	13406647	Hospitalization - Initial or Prolonged
134083414	13408341	Other Serious (Important Medical Event)
134085342	13408534	Other Serious (Important Medical Event)
134085953	13408595	Other Serious (Important Medical Event)
134088083	13408808	Other Serious (Important Medical Event)
134088094	13408809	Other Serious (Important Medical Event)
134090483	13409048	Other Serious (Important Medical Event)
134091734	13409173	Other Serious (Important Medical Event)
134092954	13409295	Other Serious (Important Medical Event)
134092974	13409297	Other Serious (Important Medical Event)
134094214	13409421	Other Serious (Important Medical Event)
134095674	13409567	Other Serious (Important Medical Event)
1340999011	13409990	Other Serious (Important Medical Event)
134105123	13410512	Disability

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
134105123	13410512	Other Serious (Important Medical Event)
134107453	13410745	Other Serious (Important Medical Event)
134108014	13410801	Other Serious (Important Medical Event)
134108573	13410857	Other Serious (Important Medical Event)
134109483	13410948	Other Serious (Important Medical Event)
134110902	13411090	Other Serious (Important Medical Event)
134112744	13411274	Other Serious (Important Medical Event)
134112744	13411274	Hospitalization - Initial or Prolonged
134114023	13411402	Other Serious (Important Medical Event)
134115182	13411518	Other Serious (Important Medical Event)
134121044	13412104	Other Serious (Important Medical Event)
134121334	13412133	Hospitalization - Initial or Prolonged
134121494	13412149	Other Serious (Important Medical Event)
134128773	13412877	Other Serious (Important Medical Event)
134130353	13413035	Other Serious (Important Medical Event)
134137264	13413726	Other Serious (Important Medical Event)
134141165	13414116	Life-Threatening
134141165	13414116	Other Serious (Important Medical Event)
134141165	13414116	Hospitalization - Initial or Prolonged
134145813	13414581	Other Serious (Important Medical Event)
134190294	13419029	Other Serious (Important Medical Event)
134194003	13419400	Other Serious (Important Medical Event)
1341979423	13419794	Other Serious (Important Medical Event)
1341979423	13419794	Hospitalization - Initial or Prolonged
134281817	13428181	Other Serious (Important Medical Event)
1342967213	13429672	Other Serious (Important Medical Event)

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Outcome Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for a patient outcome.</i>
1342967213	13429672	Hospitalization - Initial or Prolonged
134333438	13433343	Hospitalization - Initial or Prolonged

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230149591	23014959	Consumer
230150561	23015056	Health Professional
230150731	23015073	Health Professional
230150811	23015081	Health Professional
230150931	23015093	Health Professional
230151421	23015142	Health Professional
230151441	23015144	Health Professional
230151461	23015146	Health Professional
230151481	23015148	Health Professional
230151491	23015149	Health Professional
230151501	23015150	Health Professional
230151511	23015151	Health Professional
230151701	23015170	Health Professional
230151751	23015175	Health Professional
230151771	23015177	Health Professional
230151831	23015183	Health Professional
230151901	23015190	Consumer
230152091	23015209	Health Professional
230152101	23015210	Health Professional
230152111	23015211	Health Professional
230152121	23015212	Health Professional
230152221	23015222	Health Professional
230152451	23015245	Health Professional
230152851	23015285	Health Professional
230152861	23015286	Health Professional
230152881	23015288	Health Professional
230152891	23015289	Health Professional
230152921	23015292	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230152931	23015293	Health Professional
230153341	23015334	Health Professional
230153391	23015339	Health Professional
230153411	23015341	Health Professional
230153431	23015343	Health Professional
230153471	23015347	Health Professional
230153491	23015349	Health Professional
230153521	23015352	Health Professional
230153591	23015359	Health Professional
230153821	23015382	Health Professional
230154961	23015496	Health Professional
230155621	23015562	Health Professional
230155661	23015566	Health Professional
230155771	23015577	Health Professional
230155811	23015581	Consumer
230155831	23015583	Health Professional
230155841	23015584	Health Professional
230155931	23015593	Health Professional
230155991	23015599	Health Professional
230156001	23015600	Health Professional
230156261	23015626	Health Professional
230157861	23015786	Health Professional
230157931	23015793	Health Professional
230157951	23015795	Health Professional
230158481	23015848	Consumer
230158591	23015859	Consumer
230158601	23015860	Consumer
230158781	23015878	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230158801	23015880	Health Professional
230159641	23015964	Consumer
230159651	23015965	Consumer
230159661	23015966	Consumer
230159681	23015968	Consumer
230159691	23015969	Consumer
230159701	23015970	Consumer
230159711	23015971	Consumer
230159811	23015981	Consumer
230159821	23015982	Consumer
230159871	23015987	Consumer
230160001	23016000	Consumer
230160011	23016001	Consumer
230160061	23016006	Consumer
230160211	23016021	Consumer
230160221	23016022	Consumer
230160231	23016023	Consumer
230197401	23019740	Consumer
230197411	23019741	Consumer
230197431	23019743	Health Professional
230197441	23019744	Consumer
230198071	23019807	Consumer
230198091	23019809	Consumer
230198111	23019811	Consumer
230198121	23019812	Consumer
230198131	23019813	Consumer
230198141	23019814	Consumer
230198781	23019878	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230198811	23019881	Consumer
230198821	23019882	Consumer
230199141	23019914	Consumer
230199181	23019918	Health Professional
230199191	23019919	Health Professional
230199201	23019920	Health Professional
230199601	23019960	Consumer
230199611	23019961	Consumer
230199631	23019963	Consumer
230199651	23019965	Health Professional
230199731	23019973	Consumer
230199741	23019974	Health Professional
230199751	23019975	Health Professional
230200111	23020011	Consumer
230200491	23020049	Health Professional
230200501	23020050	Consumer
230200741	23020074	Health Professional
230200751	23020075	Health Professional
230200761	23020076	Health Professional
230200781	23020078	Health Professional
230200791	23020079	Health Professional
230200811	23020081	Health Professional
230200821	23020082	Health Professional
230200831	23020083	Health Professional
230200841	23020084	Consumer
230201081	23020108	Consumer
230201101	23020110	Health Professional
230201191	23020119	Health Professional



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230201211	23020121	Health Professional
230201461	23020146	Health Professional
230201471	23020147	Health Professional
230201481	23020148	Health Professional
230201971	23020197	Health Professional
230201981	23020198	Consumer
230201991	23020199	Health Professional
230202011	23020201	Consumer
230202021	23020202	Health Professional
230202031	23020203	Health Professional
230202041	23020204	Health Professional
230202361	23020236	Health Professional
230202561	23020256	Health Professional
230202601	23020260	Health Professional
230202661	23020266	Health Professional
230202671	23020267	Health Professional
230202691	23020269	Health Professional
230202701	23020270	Health Professional
230202711	23020271	Health Professional
230202721	23020272	Health Professional
230202741	23020274	Health Professional
230202751	23020275	Health Professional
230202761	23020276	Health Professional
230202771	23020277	Consumer
230203241	23020324	Health Professional
230203251	23020325	Health Professional
230203261	23020326	Consumer
230203311	23020331	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230203331	23020333	Health Professional
230203441	23020344	Health Professional
230203461	23020346	Health Professional
230203511	23020351	Consumer
230203521	23020352	Health Professional
230203821	23020382	Consumer
230203841	23020384	Health Professional
230203851	23020385	Consumer
230203861	23020386	Consumer
230203871	23020387	Health Professional
230203881	23020388	Consumer
230204061	23020406	Consumer
230204861	23020486	Consumer
230204871	23020487	Consumer
230204961	23020496	Consumer
230204971	23020497	Health Professional
230205251	23020525	Consumer
230205261	23020526	Health Professional
230205291	23020529	Health Professional
230205301	23020530	Consumer
230205401	23020540	Health Professional
230205421	23020542	Consumer
230205721	23020572	Health Professional
230205891	23020589	Health Professional
230206921	23020692	Health Professional
230207111	23020711	Health Professional
230207441	23020744	Health Professional
230208151	23020815	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230208171	23020817	Health Professional
230208181	23020818	Health Professional
230208221	23020822	Health Professional
230208231	23020823	Health Professional
230209081	23020908	Health Professional
230209171	23020917	Health Professional
230209181	23020918	Health Professional
230209291	23020929	Health Professional
230209381	23020938	Health Professional
230210551	23021055	Health Professional
230210561	23021056	Consumer
230210741	23021074	Consumer
230211181	23021118	Health Professional
230211201	23021120	Health Professional
230211501	23021150	Health Professional
230211641	23021164	Health Professional
230211681	23021168	Health Professional
230212641	23021264	Health Professional
230212661	23021266	Health Professional
230213191	23021319	Health Professional
230213201	23021320	Health Professional
230213211	23021321	Health Professional
230213231	23021323	Health Professional
230213241	23021324	Consumer
230213291	23021329	Consumer
230213801	23021380	Health Professional
230213821	23021382	Health Professional
230213831	23021383	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230213841	23021384	Consumer
230213851	23021385	Consumer
230215161	23021516	Health Professional
230215581	23021558	Health Professional
230215591	23021559	Health Professional
230216671	23021667	Consumer
230216701	23021670	Consumer
230216721	23021672	Consumer
230216731	23021673	Health Professional
230216741	23021674	Health Professional
230216761	23021676	Health Professional
230216771	23021677	Consumer
230216781	23021678	Consumer
230216791	23021679	Health Professional
230216801	23021680	Consumer
230216811	23021681	Consumer
230217081	23021708	Consumer
230217141	23021714	Health Professional
230217181	23021718	Consumer
230217181	23021718	Foreign
230218001	23021800	Consumer
230218981	23021898	Health Professional
230220921	23022092	Health Professional
230221111	23022111	Health Professional
230221121	23022112	Health Professional
230221151	23022115	Health Professional
230221161	23022116	Health Professional
230221201	23022120	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230221221	23022122	Health Professional
230221231	23022123	Health Professional
230221611	23022161	Health Professional
230221621	23022162	Health Professional
230221631	23022163	Health Professional
230222141	23022214	Health Professional
230222151	23022215	Health Professional
230223471	23022347	Health Professional
230223521	23022352	Health Professional
230223541	23022354	Health Professional
230224461	23022446	Health Professional
230225671	23022567	Health Professional
230225681	23022568	Consumer
230225691	23022569	Health Professional
230227971	23022797	Health Professional
230228021	23022802	Health Professional
230228031	23022803	Consumer
230228651	23022865	Consumer
230228731	23022873	Consumer
230228741	23022874	Consumer
230228751	23022875	Consumer
230228761	23022876	Consumer
230228861	23022886	Consumer
230228881	23022888	Health Professional
230228891	23022889	Health Professional
230230021	23023002	Consumer
230230031	23023003	Consumer
230230111	23023011	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230233171	23023317	Health Professional
230233701	23023370	Health Professional
230233731	23023373	Health Professional
230233741	23023374	Health Professional
230233751	23023375	Health Professional
230233791	23023379	Health Professional
230234551	23023455	Health Professional
230266111	23026611	Health Professional
230266701	23026670	Health Professional
230266711	23026671	Health Professional
230267181	23026718	Health Professional
230267371	23026737	Health Professional
230267381	23026738	Health Professional
230267401	23026740	Health Professional
230267601	23026760	Health Professional
230267631	23026763	Health Professional
230267661	23026766	Health Professional
230268181	23026818	Health Professional
230268261	23026826	Consumer
230268391	23026839	Health Professional
230268691	23026869	Health Professional
230268701	23026870	Consumer
230268711	23026871	Health Professional
230268721	23026872	Consumer
230268741	23026874	Health Professional
230268751	23026875	Consumer
230268771	23026877	Health Professional
230268781	23026878	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230268801	23026880	Health Professional
230269091	23026909	Health Professional
230269131	23026913	Consumer
230269151	23026915	Health Professional
230269211	23026921	Health Professional
230269711	23026971	Consumer
230269741	23026974	Health Professional
230269751	23026975	Consumer
230270211	23027021	Health Professional
230270331	23027033	Health Professional
230270341	23027034	Health Professional
230270361	23027036	Consumer
230270971	23027097	Consumer
230270981	23027098	Consumer
230271001	23027100	Health Professional
230271021	23027102	Health Professional
230271031	23027103	Health Professional
230271041	23027104	Health Professional
230271051	23027105	Consumer
230271351	23027135	Consumer
230271361	23027136	Health Professional
230271391	23027139	Consumer
230271821	23027182	Consumer
230271921	23027192	Consumer
230272671	23027267	Consumer
230272681	23027268	Consumer
230272691	23027269	Health Professional
230272711	23027271	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230273111	23027311	Health Professional
230273121	23027312	Consumer
230273131	23027313	Health Professional
230273221	23027322	Health Professional
230273231	23027323	Health Professional
230273241	23027324	Consumer
230273251	23027325	Health Professional
230273331	23027333	Consumer
230273341	23027334	Health Professional
230275461	23027546	Health Professional
230275521	23027552	Consumer
230275531	23027553	Health Professional
230275541	23027554	Health Professional
230275551	23027555	Health Professional
230275971	23027597	Health Professional
230275991	23027599	Health Professional
230276451	23027645	Health Professional
230276561	23027656	Health Professional
230277301	23027730	Consumer
230277391	23027739	Health Professional
230277451	23027745	Health Professional
230277471	23027747	Health Professional
230277481	23027748	Health Professional
230277671	23027767	Consumer
230277691	23027769	Consumer
230278081	23027808	Health Professional
230278101	23027810	Consumer
230278111	23027811	Consumer



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230278201	23027820	Health Professional
230278211	23027821	Health Professional
230278221	23027822	Consumer
230278231	23027823	Consumer
230278971	23027897	Health Professional
230278991	23027899	Consumer
230279001	23027900	Consumer
230279051	23027905	Health Professional
230279061	23027906	Consumer
230279071	23027907	Consumer
230279081	23027908	Consumer
230279391	23027939	Consumer
230279401	23027940	Consumer
230279411	23027941	Health Professional
230279421	23027942	Health Professional
230279431	23027943	Consumer
230279441	23027944	Consumer
230279451	23027945	Consumer
230279461	23027946	Consumer
230279481	23027948	Consumer
230279491	23027949	Consumer
230279511	23027951	Consumer
230280121	23028012	Health Professional
230280141	23028014	Health Professional
230280161	23028016	Health Professional
230280171	23028017	Health Professional
230280381	23028038	Health Professional
230281151	23028115	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230281651	23028165	Health Professional
230281661	23028166	Health Professional
230281671	23028167	Consumer
230281771	23028177	Consumer
230281791	23028179	Consumer
230281821	23028182	Consumer
230282371	23028237	Health Professional
230282401	23028240	Health Professional
230282421	23028242	Consumer
230282471	23028247	Consumer
230282481	23028248	Consumer
230282511	23028251	Consumer
230282521	23028252	Consumer
230282531	23028253	Health Professional
230282541	23028254	Consumer
230282561	23028256	Health Professional
230282571	23028257	Consumer
230282591	23028259	Consumer
230282601	23028260	Consumer
230282621	23028262	Health Professional
230283291	23028329	Health Professional
230283331	23028333	Consumer
230283341	23028334	Consumer
230283351	23028335	Consumer
230283381	23028338	Health Professional
230283611	23028361	Consumer
230283641	23028364	Consumer
230283681	23028368	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230283771	23028377	Consumer
230283881	23028388	Health Professional
230284541	23028454	Health Professional
230284551	23028455	Health Professional
230284561	23028456	Consumer
230284571	23028457	Health Professional
230284591	23028459	Consumer
230284611	23028461	Health Professional
230284681	23028468	Health Professional
230284691	23028469	Health Professional
230284711	23028471	Health Professional
230284721	23028472	Health Professional
230284731	23028473	Health Professional
230284771	23028477	Health Professional
230285241	23028524	Health Professional
230285261	23028526	Health Professional
230285271	23028527	Health Professional
230285281	23028528	Health Professional
230285651	23028565	Health Professional
230285661	23028566	Health Professional
230286161	23028616	Health Professional
230286981	23028698	Health Professional
230286991	23028699	Health Professional
230287001	23028700	Health Professional
230287011	23028701	Health Professional
230287021	23028702	Health Professional
230289041	23028904	Health Professional
230289051	23028905	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230289451	23028945	Health Professional
230289471	23028947	Health Professional
230289481	23028948	Consumer
230289491	23028949	Health Professional
230289501	23028950	Health Professional
230289511	23028951	Health Professional
230289521	23028952	Health Professional
230289901	23028990	Health Professional
230289961	23028996	Health Professional
230289971	23028997	Health Professional
230290111	23029011	Consumer
230290231	23029023	Health Professional
230290241	23029024	Health Professional
230290251	23029025	Health Professional
230290281	23029028	Health Professional
230290911	23029091	Consumer
230290921	23029092	Health Professional
230290931	23029093	Consumer
230290961	23029096	Health Professional
230290971	23029097	Health Professional
230291371	23029137	Health Professional
230291621	23029162	Health Professional
230292491	23029249	Health Professional
230320321	23032032	Health Professional
230320331	23032033	Health Professional
230320351	23032035	Health Professional
230320651	23032065	Health Professional
230320691	23032069	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230320881	23032088	Health Professional
230320891	23032089	Health Professional
230321501	23032150	Health Professional
230321511	23032151	Health Professional
230321571	23032157	Health Professional
230321581	23032158	Health Professional
230322591	23032259	Health Professional
230322601	23032260	Health Professional
230323091	23032309	Consumer
230323131	23032313	Consumer
230323141	23032314	Consumer
230323161	23032316	Health Professional
230323721	23032372	Health Professional
230324311	23032431	Consumer
230324321	23032432	Health Professional
230324331	23032433	Health Professional
230324341	23032434	Health Professional
230324351	23032435	Health Professional
230324361	23032436	Health Professional
230324611	23032461	Health Professional
230324631	23032463	Health Professional
230324641	23032464	Health Professional
230324651	23032465	Health Professional
230324661	23032466	Health Professional
230324721	23032472	Health Professional
230324731	23032473	Health Professional
230324741	23032474	Health Professional
230324751	23032475	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230325151	23032515	Health Professional
230326301	23032630	Consumer
230327281	23032728	Health Professional
230327291	23032729	Health Professional
230327661	23032766	Health Professional
230327681	23032768	Health Professional
230327691	23032769	Health Professional
230327701	23032770	Health Professional
230327711	23032771	Health Professional
230327721	23032772	Health Professional
230327731	23032773	Health Professional
230327751	23032775	Health Professional
230327771	23032777	Health Professional
230328151	23032815	Health Professional
230330041	23033004	Health Professional
230330341	23033034	Health Professional
230330401	23033040	Health Professional
230330771	23033077	Health Professional
230330781	23033078	Consumer
230330821	23033082	Consumer
230331151	23033115	Health Professional
230331161	23033116	Health Professional
230331171	23033117	Consumer
230331181	23033118	Health Professional
230331191	23033119	Consumer
230331251	23033125	Consumer
230331271	23033127	Health Professional
230331311	23033131	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230331461	23033146	Consumer
230331691	23033169	Health Professional
230331721	23033172	Health Professional
230331751	23033175	Health Professional
230332511	23033251	Consumer
230333101	23033310	Health Professional
230333111	23033311	Consumer
230333121	23033312	Health Professional
230333131	23033313	Health Professional
230333471	23033347	Consumer
230333481	23033348	Health Professional
230333521	23033352	Consumer
230333531	23033353	Health Professional
230334131	23033413	Consumer
230334141	23033414	Consumer
230334151	23033415	Consumer
230334291	23033429	Health Professional
230334301	23033430	Consumer
230334811	23033481	Consumer
230334831	23033483	Consumer
230334841	23033484	Consumer
230335131	23033513	Health Professional
230335161	23033516	Consumer
230335171	23033517	Consumer
230335181	23033518	Consumer
230335191	23033519	Health Professional
230335201	23033520	Consumer
230335211	23033521	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230335221	23033522	Consumer
230335371	23033537	Consumer
230335391	23033539	Health Professional
230335401	23033540	Consumer
230335431	23033543	Health Professional
230335441	23033544	Health Professional
230335451	23033545	Consumer
230335461	23033546	Health Professional
230335911	23033591	Health Professional
230335931	23033593	Health Professional
230335941	23033594	Health Professional
230335951	23033595	Health Professional
230336271	23033627	Health Professional
230336281	23033628	Consumer
230336291	23033629	Consumer
230336301	23033630	Foreign
230336301	23033630	Consumer
230336311	23033631	Consumer
230336411	23033641	Health Professional
230336451	23033645	Health Professional
230336471	23033647	Consumer
230337211	23033721	Health Professional
230337461	23033746	Health Professional
230337491	23033749	Health Professional
230337891	23033789	Health Professional
230338211	23033821	Consumer
230338221	23033822	Health Professional
230338381	23033838	Health Professional



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230338421	23033842	Health Professional
230338721	23033872	Health Professional
230339191	23033919	Health Professional
230339771	23033977	Consumer
230339781	23033978	Health Professional
230339791	23033979	Health Professional
230339861	23033986	Consumer
230339881	23033988	Consumer
230339891	23033989	Health Professional
230339921	23033992	Consumer
230339931	23033993	Consumer
230339941	23033994	Consumer
230340521	23034052	Consumer
230340551	23034055	Consumer
230340581	23034058	Consumer
230340591	23034059	Consumer
230340601	23034060	Consumer
230340611	23034061	Health Professional
230340631	23034063	Consumer
230340981	23034098	Consumer
230341021	23034102	Health Professional
230341031	23034103	Consumer
230341041	23034104	Health Professional
230341081	23034108	Consumer
230341151	23034115	Health Professional
230341301	23034130	Consumer
230341321	23034132	Consumer
230341331	23034133	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230341341	23034134	Health Professional
230341351	23034135	Consumer
230341511	23034151	Health Professional
230341521	23034152	Health Professional
230341541	23034154	Consumer
230341731	23034173	Health Professional
230341741	23034174	Consumer
230341761	23034176	Consumer
230341771	23034177	Health Professional
230341791	23034179	Health Professional
230341801	23034180	Health Professional
230342101	23034210	Health Professional
230342111	23034211	Health Professional
230342291	23034229	Health Professional
230342311	23034231	Consumer
230342331	23034233	Health Professional
230342341	23034234	Health Professional
230342351	23034235	Health Professional
230342761	23034276	Health Professional
230342771	23034277	Consumer
230342801	23034280	Health Professional
230342881	23034288	Health Professional
230342891	23034289	Health Professional
230342921	23034292	Health Professional
230343431	23034343	Health Professional
230343441	23034344	Health Professional
230345131	23034513	Health Professional
230345141	23034514	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230345151	23034515	Consumer
230345161	23034516	Health Professional
230345181	23034518	Consumer
230345191	23034519	Health Professional
230345201	23034520	Health Professional
230345211	23034521	Consumer
230345231	23034523	Consumer
230345241	23034524	Health Professional
230345551	23034555	Consumer
230345561	23034556	Health Professional
230345571	23034557	Health Professional
230345581	23034558	Health Professional
230345631	23034563	Health Professional
230345701	23034570	Health Professional
230345721	23034572	Health Professional
230345751	23034575	Consumer
230345771	23034577	Health Professional
230345781	23034578	Health Professional
230345801	23034580	Health Professional
230345811	23034581	Consumer
230346081	23034608	Health Professional
230346091	23034609	Health Professional
230346301	23034630	Health Professional
230346321	23034632	Health Professional
230346371	23034637	Health Professional
230346381	23034638	Health Professional
230346871	23034687	Health Professional
230347261	23034726	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230347861	23034786	Consumer
230347971	23034797	Consumer
230372951	23037295	Health Professional
230372961	23037296	Health Professional
230372991	23037299	Consumer
230373491	23037349	Health Professional
230374001	23037400	Health Professional
230374011	23037401	Health Professional
230374021	23037402	Health Professional
230374031	23037403	Health Professional
230374391	23037439	Health Professional
230374821	23037482	Health Professional
230374831	23037483	Consumer
230374841	23037484	Health Professional
230374851	23037485	Health Professional
230374961	23037496	Health Professional
230375031	23037503	Health Professional
230375041	23037504	Consumer
230375061	23037506	Consumer
230375651	23037565	Consumer
230375731	23037573	Health Professional
230375811	23037581	Health Professional
230375861	23037586	Health Professional
230375871	23037587	Health Professional
230376261	23037626	Consumer
230376291	23037629	Consumer
230376821	23037682	Consumer
230376831	23037683	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230376861	23037686	Health Professional
230376881	23037688	Consumer
230376891	23037689	Consumer
230376901	23037690	Consumer
230377241	23037724	Health Professional
230377251	23037725	Health Professional
230377311	23037731	Consumer
230377321	23037732	Health Professional
230378171	23037817	Health Professional
230378181	23037818	Consumer
230378191	23037819	Health Professional
230378241	23037824	Consumer
230378251	23037825	Health Professional
230378261	23037826	Consumer
230378291	23037829	Consumer
230378331	23037833	Consumer
230378371	23037837	Health Professional
230379101	23037910	Health Professional
230379111	23037911	Consumer
230379391	23037939	Consumer
230379401	23037940	Consumer
230379411	23037941	Consumer
230379421	23037942	Health Professional
230379431	23037943	Health Professional
230379441	23037944	Health Professional
230379451	23037945	Consumer
230379461	23037946	Consumer
230379881	23037988	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230379901	23037990	Consumer
230379951	23037995	Health Professional
230379961	23037996	Consumer
230379971	23037997	Consumer
230380791	23038079	Consumer
230380891	23038089	Consumer
230381011	23038101	Consumer
230381631	23038163	Health Professional
230382081	23038208	Consumer
230382121	23038212	Consumer
230382131	23038213	Health Professional
230382681	23038268	Health Professional
230382691	23038269	Consumer
230382741	23038274	Health Professional
230382771	23038277	Consumer
230382801	23038280	Health Professional
230382821	23038282	Health Professional
230383031	23038303	Health Professional
230383041	23038304	Health Professional
230383051	23038305	Consumer
230383061	23038306	Health Professional
230383131	23038313	Health Professional
230383151	23038315	Health Professional
230383711	23038371	Health Professional
230383741	23038374	Health Professional
230383751	23038375	Consumer
230384011	23038401	Consumer
230384021	23038402	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230384031	23038403	Health Professional
230384041	23038404	Health Professional
230384051	23038405	Health Professional
230384261	23038426	Health Professional
230384301	23038430	Health Professional
230384321	23038432	Health Professional
230384341	23038434	Health Professional
230385151	23038515	Health Professional
230385311	23038531	Health Professional
230385851	23038585	Health Professional
230385861	23038586	Health Professional
230385921	23038592	Health Professional
230385931	23038593	Health Professional
230386301	23038630	Health Professional
230386311	23038631	Health Professional
230386321	23038632	Health Professional
230390331	23039033	Health Professional
230390341	23039034	Consumer
230390421	23039042	Health Professional
230390431	23039043	Health Professional
230391191	23039119	Health Professional
230391201	23039120	Consumer
230391481	23039148	Health Professional
230391491	23039149	Health Professional
230391501	23039150	Consumer
230391511	23039151	Consumer
230391861	23039186	Consumer
230391881	23039188	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230391891	23039189	Consumer
230392371	23039237	Health Professional
230392381	23039238	Consumer
230392391	23039239	Health Professional
230392401	23039240	Health Professional
230392411	23039241	Consumer
230392421	23039242	Consumer
230392431	23039243	Consumer
230392441	23039244	Consumer
230392461	23039246	Health Professional
230392471	23039247	Health Professional
230392481	23039248	Health Professional
230393551	23039355	Health Professional
230393571	23039357	Health Professional
230393731	23039373	Health Professional
230394991	23039499	Health Professional
230396691	23039669	Health Professional
230397591	23039759	Health Professional
230397641	23039764	Health Professional
230397691	23039769	Health Professional
230397701	23039770	Health Professional
230397711	23039771	Consumer
230397751	23039775	Health Professional
230397761	23039776	Consumer
230398271	23039827	Health Professional
230398331	23039833	Health Professional
230398341	23039834	Health Professional
230398351	23039835	Health Professional



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230398371	23039837	Health Professional
230398381	23039838	Health Professional
230398391	23039839	Health Professional
230398951	23039895	Health Professional
230398961	23039896	Health Professional
230398971	23039897	Health Professional
230399061	23039906	Health Professional
230399841	23039984	Health Professional
230401091	23040109	Health Professional
230401101	23040110	Health Professional
230401521	23040152	Consumer
230401541	23040154	Consumer
230401551	23040155	Consumer
230401561	23040156	Health Professional
230401601	23040160	Health Professional
230401611	23040161	Consumer
230401621	23040162	Health Professional
230401751	23040175	Consumer
230402331	23040233	Consumer
230402981	23040298	Health Professional
230403111	23040311	Health Professional
230404001	23040400	Consumer
230404051	23040405	Consumer
230404061	23040406	Health Professional
230404071	23040407	Health Professional
230404121	23040412	Health Professional
230404131	23040413	Health Professional
230404381	23040438	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230404421	23040442	Consumer
230404431	23040443	Health Professional
230404471	23040447	Health Professional
230404531	23040453	Health Professional
230404541	23040454	Health Professional
230404761	23040476	Consumer
230404791	23040479	Consumer
230404811	23040481	Consumer
230404821	23040482	Consumer
230488491	23048849	Health Professional
230488521	23048852	Consumer
230489301	23048930	Consumer
230490011	23049001	Health Professional
230490021	23049002	Health Professional
230490031	23049003	Health Professional
230490131	23049013	Health Professional
230490141	23049014	Consumer
230490151	23049015	Health Professional
230490181	23049018	Health Professional
230490191	23049019	Health Professional
230490201	23049020	Health Professional
230490801	23049080	Health Professional
230490841	23049084	Health Professional
230491351	23049135	Health Professional
230491381	23049138	Health Professional
230492071	23049207	Consumer
230492141	23049214	Health Professional
230492151	23049215	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230492161	23049216	Consumer
230492171	23049217	Health Professional
230492181	23049218	Consumer
230492211	23049221	Health Professional
230492261	23049226	Health Professional
230492281	23049228	Health Professional
230492301	23049230	Health Professional
230493181	23049318	Consumer
230493391	23049339	Health Professional
230493411	23049341	Health Professional
230493421	23049342	Health Professional
230493431	23049343	Health Professional
230493461	23049346	Health Professional
230493471	23049347	Health Professional
230493481	23049348	Health Professional
230493521	23049352	Health Professional
230493531	23049353	Health Professional
230493541	23049354	Health Professional
230494091	23049409	Health Professional
230494101	23049410	Health Professional
230494111	23049411	Health Professional
230494121	23049412	Health Professional
230494131	23049413	Health Professional
230494141	23049414	Health Professional
230494151	23049415	Health Professional
230494191	23049419	Health Professional
230494221	23049422	Health Professional
230494451	23049445	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230494471	23049447	Health Professional
230494491	23049449	Health Professional
230494551	23049455	Health Professional
230494561	23049456	Health Professional
230494571	23049457	Consumer
230494581	23049458	Consumer
230494611	23049461	Health Professional
230494641	23049464	Consumer
230494901	23049490	Consumer
230494911	23049491	Health Professional
230494961	23049496	Health Professional
230494971	23049497	Consumer
230495301	23049530	Health Professional
230495311	23049531	Health Professional
230495331	23049533	Consumer
230495341	23049534	Health Professional
230495361	23049536	Health Professional
230495431	23049543	Health Professional
230495441	23049544	Health Professional
230495451	23049545	Health Professional
230495461	23049546	Health Professional
230495481	23049548	Consumer
230495501	23049550	Consumer
230496161	23049616	Consumer
230496751	23049675	Consumer
230496761	23049676	Health Professional
230496771	23049677	Health Professional
230496841	23049684	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230496851	23049685	Health Professional
230496881	23049688	Health Professional
230496931	23049693	Health Professional
230496941	23049694	Health Professional
230496961	23049696	Health Professional
230497301	23049730	Consumer
230497331	23049733	Health Professional
230497361	23049736	Consumer
230497371	23049737	Consumer
230497381	23049738	Consumer
230497391	23049739	Health Professional
230497401	23049740	Health Professional
230497751	23049775	Health Professional
230497791	23049779	Consumer
230497801	23049780	Health Professional
230497811	23049781	Health Professional
230497891	23049789	Consumer
230497901	23049790	Consumer
230497921	23049792	Health Professional
230498111	23049811	Consumer
230498121	23049812	Consumer
230498131	23049813	Health Professional
230498141	23049814	Consumer
230498601	23049860	Health Professional
230498611	23049861	Consumer
230498621	23049862	Health Professional
230498631	23049863	Foreign
230498631	23049863	Consumer

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230498651	23049865	Consumer
230498661	23049866	Consumer
230498681	23049868	Health Professional
230498721	23049872	Consumer
230498731	23049873	Consumer
230498781	23049878	Consumer
230498791	23049879	Consumer
230498841	23049884	Consumer
230499421	23049942	Consumer
230499471	23049947	Consumer
230499501	23049950	Consumer
230499511	23049951	Health Professional
230499531	23049953	Health Professional
230499541	23049954	Consumer
230499551	23049955	Health Professional
230499581	23049958	Consumer
230499661	23049966	Consumer
230499681	23049968	Consumer
230499691	23049969	Consumer
230500131	23050013	Health Professional
230500161	23050016	Health Professional
230500861	23050086	Health Professional
230500871	23050087	Health Professional
230500881	23050088	Health Professional
230500891	23050089	Health Professional
230501341	23050134	Health Professional
230501491	23050149	Health Professional
230501781	23050178	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230502371	23050237	Health Professional
230502431	23050243	Consumer
230502701	23050270	Consumer
230502721	23050272	Consumer
230502801	23050280	Consumer
230502811	23050281	Consumer
230503011	23050301	Consumer
230503041	23050304	Health Professional
230503121	23050312	Health Professional
230503141	23050314	Health Professional
230503461	23050346	Consumer
230503491	23050349	Health Professional
230503501	23050350	Health Professional
230503531	23050353	Health Professional
230504781	23050478	Consumer
230504791	23050479	Consumer
230504811	23050481	Health Professional
230504821	23050482	Consumer
230504831	23050483	Health Professional
230504841	23050484	Foreign
230504841	23050484	Consumer
230504851	23050485	Consumer
230504861	23050486	Health Professional
230504871	23050487	Consumer
230504881	23050488	Health Professional
230504901	23050490	Health Professional
230504911	23050491	Health Professional
230505551	23050555	Health Professional

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Report Source Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Code for the source of the report.</i>
230505561	23050556	Health Professional
230505571	23050557	Health Professional
230505601	23050560	Health Professional
230505731	23050573	Health Professional
230505741	23050574	Health Professional
230505751	23050575	Health Professional
230505991	23050599	Consumer
230506001	23050600	Consumer
230506011	23050601	Consumer
230506031	23050603	Health Professional
230506541	23050654	Health Professional
230506591	23050659	Health Professional
230506601	23050660	Health Professional
230506611	23050661	Health Professional
230506621	23050662	Health Professional
230506661	23050666	Health Professional
230506741	23050674	Consumer
230506771	23050677	Consumer
230506791	23050679	Health Professional
230507081	23050708	Health Professional



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1001678124	10016781	1	201201	201204	.		4
1001678124	10016781	2	20120327	20120327	.		1
1001678124	10016781	4	20120327	20120327	.		1
1001678124	10016781	10	2012	2012	.		1
1001678124	10016781	11	20121005	20121005	.		1
1001678124	10016781	12	2012	2012	.		1
1001678124	10016781	14	20200121	20200121	.		1
1002130539	10021305	1	20131219	20131219	1	Days	1
1002130539	10021305	4	20140114	20140114	.		1
1002130539	10021305	5	20191119	20191119	.		1
100356167	10035616	1	2013	20140321	444	Days	444
100356167	10035616	2	20140321	20140321	.		1
100356167	10035616	3	20140321	20140321	.		1
100356167	10035616	4	20140321	20140321	.		1
100356167	10035616	5	20140321	20140321	.		1
100356167	10035616	6	20140321	20140321	.		1
100356167	10035616	7	20140321	20140321	.		1
100356167	10035616	8	20140321	20140321	.		1
1006401878	10064018	1	2006	20110520	5	Years	5
1006401878	10064018	2	20110628	20120412	290	Days	290
1006401878	10064018	3	20120510	20120703	55	Days	55
1006401878	10064018	4	20160312	20160312	.		1
1006401878	10064018	5	2006	2006	.		1
1006401878	10064018	6	20120827	20121022	57	Days	57
1006401878	10064018	7	20121119	20130225	99	Days	99
1006401878	10064018	8	20130325	20130325	1	Days	1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

Unique number for identifying a FAERS re	Number for identifying a FAERS case.	Drug sequence number for identifying a d	Date the therapy was started (or re-star	A date therapy was stopped for this drug	Numeric value of the duration (length) o	Units for therapy duration.	Derived duration.
1006401878	10064018	9	20130422	20160414	3	Years	3
1006401878	10064018	10	20160512	20180515	734	Days	734
1006401878	10064018	11	20120730	20120730	1	Days	1
1006401878	10064018	12	20180412	20200611	792	Days	792
1006401878	10064018	13	20200709	20210805	393	Days	393
1006401878	10064018	14	20210902	20211125	85	Days	85
1006401878	10064018	15	20211223	20220901	253	Days	253
1006401878	10064018	16	20221027	20221124	29	Days	29
1006401878	10064018	17	20221222	20221222	1	Days	1
1006401878	10064018	18	20230119	20230119	.		1
1006401878	10064018	20	20140609	20140609	.		1
1007468610	10074686	1	20070608	20070608	.		1
1007468610	10074686	2	20090414	20090414	.		1
1007468610	10074686	3	20130115	20130115	.		1
1008408132	10084081	1	20130429	20130429	.		1
1008408132	10084081	2	20131211	20131211	.		1
1008408132	10084081	3	20140319	20140319	.		1
1008408132	10084081	4	20160519	20160519	.		1
1009418019	10094180	1	20110112	20110112	.		1
1009418019	10094180	2	20110602	20110602	.		1
1009418019	10094180	3	20110630	20110630	.		1
1009418019	10094180	4	20150305	20150305	.		1
1009418019	10094180	5	20180307	20180307	.		1
1009418019	10094180	6	20130418	20130502	15	Days	15
1009418019	10094180	8	20220322	20220322	.		1
1009418019	10094180	14	20141013	20141013	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1014222251	10142222	1	20130815	20150513	637	Days	637
1014222251	10142222	2	20150611	20150611	.		1
1014222251	10142222	3	20150708	20161116	498	Days	498
1014222251	10142222	4	20161213	20161213	1	Days	1
1014222251	10142222	5	20170926	20171220	86	Days	86
1014222251	10142222	6	20171024	20171024	1	Days	1
1014222251	10142222	7	20221216	20221216	.		1
1014222251	10142222	8	20171220	20171220	.		1
101451672	10145167	1	2002	2002	.		1
1015212331	10152123	1	20131203	20131203	.		1
1015212331	10152123	2	20141104	20141104	.		1
1015212331	10152123	3	20150310	20150310	.		1
1015212331	10152123	4	20160128	20160128	.		1
1015212331	10152123	5	20170103	20170103	.		1
1015212331	10152123	6	20170131	20170131	.		1
1015212331	10152123	7	20180502	20180502	.		1
1015212331	10152123	8	20180724	20180724	.		1
1015212331	10152123	9	20180919	20180919	.		1
1015212331	10152123	10	20181211	20181211	.		1
1015212331	10152123	11	20190306	20190306	.		1
1015212331	10152123	12	20190529	20190529	.		1
1015212331	10152123	13	20200304	20200304	.		1
1015212331	10152123	14	20150130	20150130	.		1
1015212331	10152123	16	20210308	20210308	.		1
1015212331	10152123	17	20221018	20221018	.		1
1015212331	10152123	18	20230316	20230316	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
101621574	10162157	1	20140319	20140319	1	Days	1
101621574	10162157	2	20140319	20140319	1	Days	1
101621574	10162157	3	20140319	20140319	1	Days	1
101621574	10162157	4	20140319	20140319	1	Days	1
101621574	10162157	5	20140319	20140319	1	Days	1
101621574	10162157	6	20140211	20140211	.		1
101621574	10162157	7	20131105	20131105	.		1
1016611037	10166110	1	20140430	20140430	.		1
1016611037	10166110	2	20140813	20140813	.		1
1016611037	10166110	3	20160414	20160414	.		1
1016611037	10166110	5	20170201	20170201	.		1
1016611037	10166110	6	20171013	20171013	.		1
1016611037	10166110	7	20171208	20171208	.		1
1016611037	10166110	8	20180329	20180329	.		1
1016611037	10166110	9	20180607	20180607	.		1
1016611037	10166110	10	20181121	20181121	.		1
1016611037	10166110	11	20190313	20190313	.		1
1016611037	10166110	12	20190412	20190412	.		1
1016611037	10166110	14	20220309	20220309	.		1
1016611037	10166110	17	201504	201504	.		1
1016611037	10166110	18	201607	201607	.		1
1016611037	10166110	25	20210601	20210601	.		1
101678657	10167865	1	20140303	20140331	29	Days	29
101678657	10167865	2	2012	20140505	.		20138494
101678657	10167865	3	20140410	20140410	1	Days	1
101678657	10167865	4	20140412	20140419	7	Days	7

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
101678657	10167865	5	20140419	20140426	7	Days	7
101678657	10167865	6	20140426	20140429	3	Days	3
101678657	10167865	7	20140429	20140430	1	Days	1
101678657	10167865	8	20140411	20140411	.		1
101678657	10167865	9	20140417	20140418	1	Days	1
101678657	10167865	10	20140418	20140423	5	Days	5
101678657	10167865	11	20140501	20140503	2	Days	2
101678657	10167865	12	20140410	20140411	1	Days	1
101678657	10167865	13	20140418	20140422	4	Days	4
101678657	10167865	14	20140430	20140501	1	Days	1
101678657	10167865	15	20140404	20140505	31	Days	31
1017572232	10175722	1	20120827	20120827	.		1
1017572232	10175722	2	20120924	20120924	.		1
1017572232	10175722	3	20131024	20131024	.		1
1017572232	10175722	4	20131121	20131121	.		1
1017572232	10175722	5	20140424	20140424	.		1
1017572232	10175722	6	20140619	20140619	.		1
1017572232	10175722	7	20141001	20161215	807	Days	807
1017572232	10175722	8	20120827	20120827	.		1
1017572232	10175722	9	20141001	20220511	8	Years	8
1017572232	10175722	11	20230322	20230322	.		1
101780773	10178077	1	20130627	20141119	511	Days	511
101780773	10178077	2	20141203	202311	8	Years	8
101916392	10191639	1	2011	201202	6	Months	6
101916392	10191639	2	201202	201202	.		1
101916392	10191639	3	2008	2011	3	Years	3

# **ADVERSE EVENT REPORTING SYSTEM (AERS)** **Therapy Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
101916392	10191639	4	201202	2012	.		199189
101916392	10191639	5	2011	201202	6	Months	6
101916392	10191639	6	2008	2011	3	Years	3
101916392	10191639	7	2012	2012	.		1
101916392	10191639	8	201202	2012	5	Days	5
101916392	10191639	9	201202	2012	.		199189
1020642923	10206429	1	20110526	20110526	.		1
1020642923	10206429	2	20120209	20120209	.		1
1020642923	10206429	3	20131106	20131106	.		1
1020642923	10206429	4	20131204	20131204	.		1
1020642923	10206429	5	20131231	20131231	.		1
1020642923	10206429	6	20140226	20140226	.		1
1020642923	10206429	7	20140617	20140617	.		1
1020642923	10206429	8	20140812	20140812	.		1
1020642923	10206429	9	20141104	20141104	.		1
1020642923	10206429	10	20150317	20150317	.		1
1020642923	10206429	11	20151027	20151027	.		1
1020642923	10206429	12	20160927	20160927	.		1
1020642923	10206429	13	20161025	20161025	.		1
1020642923	10206429	14	20161122	20161122	.		1
1020642923	10206429	15	20161220	20161220	.		1
1020642923	10206429	16	20170314	20170314	.		1
1020642923	10206429	17	20170804	20170804	.		1
1020642923	10206429	18	20181109	20181109	.		1
1020642923	10206429	19	20200131	20200131	.		1
1020642923	10206429	20	20150130	20150130	.		1

# **ADVERSE EVENT REPORTING SYSTEM (AERS)** **Therapy Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1020642923	10206429	25	1984	1984	.		1
1020642923	10206429	26	2015	2016	1	Years	1
1020642923	10206429	28	1995	1995	.		1
1020642923	10206429	29	201412	201412	.		1
1020642923	10206429	30	201412	201412	.		1
102371704	10237170	1	201307	201308	2	Months	2
102371704	10237170	2	201401	201401	.		1
102371704	10237170	3	201307	201307	1	Days	1
102371704	10237170	4	201306	201306	.		1
102371704	10237170	5	201307	201307	.		1
102371704	10237170	6	201309	201309	2	Hours	2
1027487983	10274879	1	20110302	20200817	9	Years	9
1027487983	10274879	2	20141118	20141118	.		1
1027487983	10274879	3	2005	2011	6	Years	6
1027487983	10274879	4	20200914	2020	.		20198893
1027487983	10274879	5	20201019	20201019	.		1
1028518546	10285185	1	20121121	20170321	4	Years	4
1028518546	10285185	2	20140219	20140219	.		1
1028518546	10285185	3	20150923	20150923	.		1
1028518546	10285185	4	20161004	20161004	.		1
1028518546	10285185	5	20171214	20171214	.		1
1028518546	10285185	6	20171121	20171121	.		1
1028518546	10285185	10	20180628	20180628	.		1
1028518546	10285185	11	20180628	20180628	.		1
1028518546	10285185	12	20180628	20180628	.		1
1028518546	10285185	14	20161121	20161121	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1028518546	10285185	15	20171121	20171121	.		1
1028518546	10285185	16	20171121	20171121	.		1
103443973	10344397	1	201406	201406	.		1
103443973	10344397	2	20140612	20140612	.		1
103443973	10344397	3	20140530	20140530	.		1
103443973	10344397	4	20140530	20140530	.		1
1035913611	10359136	1	20070518	201304	5	Years	5
1035913611	10359136	2	201304	201304	1	Days	1
1035913611	10359136	3	20160913	20160913	.		1
103687216	10368721	1	20140325	20140421	28	Days	28
103687216	10368721	2	20140422	20140505	14	Days	14
103687216	10368721	3	20140415	20140415	.		1
103749689	10374968	1	20140714	20140714	1	Days	1
103749689	10374968	2	20140630	20140630	1	Days	1
103749689	10374968	3	20140611	20140611	1	Days	1
103749689	10374968	4	20140611	20140611	1	Days	1
103749689	10374968	5	20140714	20140714	1	Days	1
103749689	10374968	6	20140714	20140714	1	Days	1
103749689	10374968	7	20140714	20140714	1	Days	1
103749689	10374968	8	20140611	20140611	1	Days	1
103749689	10374968	9	20140714	20140714	1	Days	1
103749689	10374968	10	20140611	20140611	1	Days	1
103749689	10374968	11	20140611	20140721	984	Hours	984
103749689	10374968	12	20140611	20140721	984	Hours	984
103749689	10374968	13	20140619	20140619	1	Days	1
103749689	10374968	14	20140611	20140721	984	Hours	984



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
103749689	10374968	15	20140714	20140721	8	Days	8
103749689	10374968	16	20140611	20140721	984	Hours	984
103749689	10374968	17	20140721	20140724	4	Days	4
103749689	10374968	18	20140714	20140721	8	Days	8
103749689	10374968	19	20140725	20140726	2	Days	2
103749689	10374968	20	20140725	20140726	2	Days	2
103749689	10374968	21	20140725	20140726	2	Days	2
103749689	10374968	22	20140725	20140726	2	Days	2
103749689	10374968	23	20140725	20140726	2	Days	2
103749689	10374968	24	20140721	20140726	6	Days	6
103892335	10389233	1	200707	200707	.		1
103892335	10389233	2	200707	200707	.		1
103892335	10389233	3	200707	200707	.		1
103892335	10389233	4	200707	200707	.		1
103892335	10389233	5	200707	200707	.		1
103928076	10392807	1	2007	.	3	Days	3
103928076	10392807	2	20100407	20100410	3	Days	3
103928076	10392807	3	.	.	3	Days	3
103985405	10398540	1	20140430	20140430	.		1
103985405	10398540	2	20231101	20231101	.		1
104003092	10400309	2	2008	20110814	31536	Hours	31536
104003092	10400309	3	1993	20110814	6789	Days	6789
104003092	10400309	4	20110818	20110818	.		1
104003092	10400309	5	20110818	20110818	.		1
104003092	10400309	6	1993	1993	.		1
104003092	10400309	7	201004	20110818	.		19909815

# **ADVERSE EVENT REPORTING SYSTEM (AERS)** **Therapy Listings**

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104003092	10400309	8	2004	20110818	.		20108815
1040513313	10405133	1	20130409	20130409	.		1
1040513313	10405133	2	20110815	20130115	520	Days	520
1040513313	10405133	3	20140905	20141226	113	Days	113
1040513313	10405133	4	20150629	20151030	124	Days	124
1040513313	10405133	5	20160531	20160531	.		1
1041491125	10414911	1	20110518	20111104	171	Days	171
1041491125	10414911	2	20110518	20110518	.		1
1041491125	10414911	3	20111206	20111206	.		1
104232195	10423219	1	1998	2012	.		15
104232195	10423219	2	2008	2010	.		3
104232203	10423220	1	2008	2009	.		2
104232203	10423220	2	2009	2009	.		1
104266473	10426647	1	200808	201408	.		601
104266473	10426647	5	2014	2014	.		1
104635823	10463582	1	20020830	2003	.		20018826
104665748	10466574	1	20030110	20051004	6	Years	6
104665748	10466574	2	20091221	20130320	6	Years	6
104665748	10466574	3	.	.	6	Years	6
104665748	10466574	4	20091221	20130320	3	Years	3
104665748	10466574	5	2013	.	3	Years	3
104825157	10482515	1	1999	1999	.		1
105144244	10514424	1	20130219	20130219	.		1
1051596718	10515967	1	20120924	20120924	.		1
1051596718	10515967	2	20120924	20120924	.		1
1051596718	10515967	3	20150729	20150729	.		1

# **ADVERSE EVENT REPORTING SYSTEM (AERS)** **Therapy Listings**

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1052690058	10526900	1	20140110	20140110	.		1
1052690058	10526900	11	201910	201910	.		1
1054038738	10540387	1	20110416	20110416	.		1
1054038738	10540387	5	20150112	20150112	.		1
1054038738	10540387	6	201104	201808	.		705
1054038738	10540387	8	20231018	20231018	.		1
1054038738	10540387	9	20110317	20110317	1	Days	1
1058928657	10589286	1	20140401	20140401	.		1
1058928657	10589286	2	20141208	20141208	.		1
1058928657	10589286	3	20150217	20150217	.		1
1058928657	10589286	4	20150317	20150317	.		1
1058928657	10589286	5	20160315	20160315	.		1
1058928657	10589286	6	20160426	20160426	.		1
1058928657	10589286	7	20160510	20160510	.		1
1058928657	10589286	8	20160524	20160524	.		1
1058928657	10589286	9	20161025	20161025	.		1
1058928657	10589286	10	20161108	20161108	.		1
1058928657	10589286	11	20161122	20161122	.		1
1058928657	10589286	12	20161220	20161220	.		1
1058928657	10589286	13	20170214	20170214	.		1
1058928657	10589286	14	20170321	20170321	.		1
1058928657	10589286	15	20170516	20170516	.		1
1058928657	10589286	16	20170613	20170613	.		1
1058928657	10589286	17	20170626	20170626	.		1
1058928657	10589286	18	20170711	20170711	.		1
1058928657	10589286	19	20170721	20170721	.		1

# **ADVERSE EVENT REPORTING SYSTEM (AERS)** **Therapy Listings**

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1058928657	10589286	20	201707	201707	.		1
1058928657	10589286	21	20170815	20170815	1	Days	1
1058928657	10589286	22	20180417	20180417	.		1
1058928657	10589286	23	20181204	20181204	.		1
1058928657	10589286	24	20190115	20190115	.		1
1058928657	10589286	25	20190228	20190228	.		1
1058928657	10589286	26	20190423	20190423	.		1
1058928657	10589286	27	20190521	20190521	.		1
1058928657	10589286	28	20190604	20190604	.		1
1058928657	10589286	29	20190618	20190618	.		1
1058928657	10589286	30	20190730	20190730	.		1
1058928657	10589286	31	20191029	20191029	.		1
1058928657	10589286	32	20200303	20200303	.		1
1058928657	10589286	33	20200317	20200317	.		1
1058928657	10589286	34	20200331	20200331	.		1
1058928657	10589286	37	20171023	20171023	.		1
1058928657	10589286	38	20150130	20150130	.		1
1058928657	10589286	43	20221004	20221004	.		1
1058928657	10589286	45	20190503	20190503	.		1
1060157312	10601573	1	20130518	20130518	.		1
106336646	10633664	1	.	.	6	Years	6
106336646	10633664	2	20010215	20020122	6	Years	6
106336646	10633664	3	20020212	20070702	6	Years	6
1069198853	10691988	1	20120918	20120918	.		1
1069198853	10691988	2	201307	201307	.		1
1069198853	10691988	3	20140305	20140305	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1069198853	10691988	4	20140820	20140820	.		1
1069198853	10691988	5	20141029	20141029	.		1
1069198853	10691988	6	20150204	20150204	.		1
1069198853	10691988	7	20151028	20151028	.		1
1069198853	10691988	8	20151222	20151222	.		1
1069198853	10691988	9	20160105	20160105	.		1
1069198853	10691988	10	20160119	20160119	.		1
1069198853	10691988	11	20160202	20160202	.		1
1069198853	10691988	12	20160216	20160216	.		1
1069198853	10691988	13	20160301	20160301	.		1
1069198853	10691988	14	20160315	20160315	.		1
1069198853	10691988	15	20160329	20160329	.		1
1069198853	10691988	16	20160412	20160412	.		1
1069198853	10691988	17	20160426	20160426	.		1
1069198853	10691988	18	20160510	20160510	.		1
1069198853	10691988	19	20160525	20160525	.		1
1069198853	10691988	20	20160607	20160607	.		1
1069198853	10691988	21	20160622	20160622	.		1
1069198853	10691988	22	20160706	20160706	.		1
1069198853	10691988	23	20160720	20160720	.		1
1069198853	10691988	24	20160803	20160803	.		1
1069198853	10691988	25	20160816	20160816	.		1
1069198853	10691988	26	20160830	20160830	.		1
1069198853	10691988	27	20160913	20160913	.		1
1069198853	10691988	28	20160927	20160927	.		1
1069198853	10691988	29	20161011	20161011	.		1

# **ADVERSE EVENT REPORTING SYSTEM (AERS)** **Therapy Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1069198853	10691988	30	20161025	20161025	.		1
1069198853	10691988	31	20161108	20161108	.		1
1069198853	10691988	32	20161124	20161124	.		1
1069198853	10691988	33	20161206	20161206	.		1
1069198853	10691988	35	20161222	20161222	.		1
1069198853	10691988	36	20170103	20170103	.		1
1069198853	10691988	37	20170215	20170215	.		1
1069198853	10691988	38	20170228	20170228	.		1
1069198853	10691988	39	20170316	20170316	.		1
1069198853	10691988	40	20170328	20170328	.		1
1069198853	10691988	41	20170411	20170411	.		1
1069198853	10691988	42	20170425	20170425	.		1
1069198853	10691988	43	20170608	20170608	.		1
1069198853	10691988	44	201706	201706	.		1
1069198853	10691988	45	20170621	20170621	.		1
1069198853	10691988	46	20170704	20170704	.		1
1069198853	10691988	47	20170718	20170718	.		1
1069198853	10691988	48	20170802	20170802	.		1
1069198853	10691988	49	20170816	20170816	.		1
1069198853	10691988	50	20170830	20170830	.		1
1069198853	10691988	51	20170913	20170913	.		1
1069198853	10691988	53	20181023	20181023	.		1
1069198853	10691988	54	.	.	10	Days	10
1070483325	10704833	49	.	.	3	Days	3
1070483325	10704833	74	.	.	3	Days	3
1070483325	10704833	75	.	.	3	Days	3

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1070483325	10704833	79	.	.	3	Days	3
107316442	10731644	1	201403	201403	.		1
1074008517	10740085	1	20131125	20131125	.		1
1074008517	10740085	2	20150130	20150130	.		1
1074008517	10740085	3	20160623	20160623	.		1
1074008517	10740085	4	20170710	20170710	.		1
1074008517	10740085	5	20210213	20210213	.		1
1074008517	10740085	9	20131125	20131125	.		1
1074008517	10740085	10	20170710	20170710	.		1
1074008517	10740085	11	20131125	20131125	.		1
1074008517	10740085	12	20170710	20170710	.		1
1074008517	10740085	24	20131125	20131125	.		1
1074008517	10740085	25	20131125	20131125	.		1
107408544	10740854	1	2014	2014	.		1
1074197911	10741979	1	2011	2011	.		1
1074197911	10741979	6	202011	202011	.		1
1074197911	10741979	7	202011	202011	.		1
107584123	10758412	1	201201	201307	.		107
1075880717	10758807	1	2012	20150106	.		20148095
1075880717	10758807	2	201502	201502	.		1
1075880717	10758807	3	20150505	20150505	.		1
1075880717	10758807	6	2011	2011	.		1
1075880717	10758807	8	2007	2007	.		1
1078729218	10787292	1	20130327	20190926	6	Years	6
1078729218	10787292	2	20170711	20170711	.		1
1078729218	10787292	3	20170912	20170912	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1078729218	10787292	4	20171114	20171114	.		1
1078729218	10787292	5	20180718	20180718	.		1
1078729218	10787292	6	20181129	20190926	302	Days	302
1078729218	10787292	7	20200805	20200805	.		1
1080136616	10801366	1	20140813	201408	.		19939404
1080136616	10801366	2	20150522	20150522	.		1
1080136616	10801366	8	20211009	20211009	1	Days	1
1080136616	10801366	9	2022	2022	1	Days	1
1080136616	10801366	10	20150522	20150522	.		1
1080136616	10801366	11	20150522	20150522	.		1
1080136616	10801366	12	20150522	20150522	.		1
108390175	10839017	1	20140922	20140922	.		1
108390175	10839017	2	2002	2014	.		13
108390175	10839017	3	2014	2014	.		1
108390175	10839017	4	2002	20141126	.		20139125
108390175	10839017	5	201505	201505	.		1
109108923	10910892	1	201402	201402	.		1
109108923	10910892	2	201402	201402	.		1
109108923	10910892	3	201402	201402	.		1
109108923	10910892	16	20150323	20150323	.		1
109108923	10910892	17	20230301	20230301	.		1
1092018038	10920180	1	20140525	20140525	.		1
1092018038	10920180	6	2014	2014	.		1
1092018038	10920180	7	20150305	20150305	.		1
1092018038	10920180	8	20150625	20150625	.		1
1092018038	10920180	9	20151015	20151015	.		1



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1092018038	10920180	10	20151210	20151210	.		1
1092018038	10920180	11	20160204	20160204	.		1
1092018038	10920180	12	20160328	20160328	.		1
1092018038	10920180	13	20160519	20160519	.		1
1092018038	10920180	14	20160714	20160714	.		1
1092018038	10920180	15	20160908	20160908	.		1
1092018038	10920180	17	20161103	20161103	.		1
1092018038	10920180	18	20161229	20161229	.		1
1092018038	10920180	19	20170223	20170223	.		1
1092018038	10920180	20	20170420	20170420	.		1
1092018038	10920180	21	20170810	20170810	.		1
1092018038	10920180	22	20171006	20171006	.		1
1092018038	10920180	23	20171130	20171130	.		1
1092018038	10920180	24	20180125	20180125	.		1
1092018038	10920180	25	20180320	20180320	.		1
1092018038	10920180	26	20180320	20180320	.		1
1092018038	10920180	27	20180517	20180517	.		1
1092018038	10920180	28	20180712	20180712	.		1
1092018038	10920180	29	20180906	20180906	.		1
1092018038	10920180	30	20181101	20181101	.		1
1092018038	10920180	31	20181227	20181227	.		1
1092018038	10920180	32	20190221	20190221	.		1
1092018038	10920180	33	20190613	20190613	.		1
1092018038	10920180	34	20190808	20190808	.		1
1092018038	10920180	35	20191003	20191003	.		1
1092018038	10920180	36	20200318	20200318	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1092018038	10920180	37	20200513	20200513	.		1
109448672	10944867	1	2011	2013	.		3
109680288	10968028	1	201207	2012	.		199194
109680288	10968028	2	201210	201210	.		1
109680288	10968028	5	20150120	20150120	.		1
1097587654	10975876	1	20130219	20130219	.		1
1097587654	10975876	2	20130219	20130219	.		1
1097587654	10975876	4	20141028	20141028	.		1
1097587654	10975876	6	20181218	20181218	.		1
1097587654	10975876	7	20190212	20190212	.		1
1097587654	10975876	8	20191119	20191119	.		1
1097587654	10975876	10	20191119	20191119	.		1
1097587654	10975876	11	20130219	20130219	.		1
1098206364	10982063	1	201201	201502	3	Years	3
1098206364	10982063	2	20141218	20141218	.		1
1098206364	10982063	3	20160104	2020	4	Years	4
1098206364	10982063	4	20200513	20200513	.		1
1098206364	10982063	5	20200604	20210729	421	Days	421
1098206364	10982063	6	20210819	20210819	.		1
1098206364	10982063	8	201310	201310	.		1
1098206364	10982063	9	20140227	20141127	274	Days	274
1098206364	10982063	10	20141218	20150402	106	Days	106
1098206364	10982063	11	20160317	20160317	.		1
1098206364	10982063	12	20140202	20141127	299	Days	299
1098206364	10982063	13	20160115	20160115	1	Days	1
1098206364	10982063	14	20160206	20160206	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1098206364	10982063	15	20160203	20160203	.		1
1098206364	10982063	17	201201	2013	1	Years	1
1098206364	10982063	18	20140220	20140220	.		1
1098206364	10982063	19	20140220	20140220	.		1
1098206364	10982063	20	20140320	20140813	147	Days	147
1098206364	10982063	22	201607	201607	.		1
1098206364	10982063	23	201201	2013	1	Years	1
1099047564	10990475	1	20150312	20150312	1	Days	1
1099047564	10990475	2	20150506	20150506	1	Days	1
1099047564	10990475	3	20150603	20150603	1	Days	1
1099047564	10990475	4	20150630	20150630	1	Days	1
1099047564	10990475	5	20150729	20160128	184	Days	184
1099047564	10990475	6	20160226	20220509	6	Years	6
1099047564	10990475	7	20160201	20180820	932	Days	932
1099047564	10990475	8	20150706	2016	1	Years	1
1099047564	10990475	9	201506	2015	.		199490
1099047564	10990475	10	20210203	20210203	.		1
1099047564	10990475	11	20220606	20221026	143	Days	143
1099047564	10990475	12	20221123	20221221	29	Days	29
1099047564	10990475	13	20230112	20230202	22	Days	22
1099047564	10990475	14	20230328	20230328	.		1
1099047564	10990475	15	20190415	20200203	295	Days	295
1099047564	10990475	16	201501	201501	.		1
1099047564	10990475	18	201402	201402	.		1
1099047564	10990475	22	20151103	20151103	.		1
1099047564	10990475	23	20160120	20160120	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
109916134	10991613	1	2013	2013	.		1
109922307	10992230	1	.	.	12	Days	12
109922307	10992230	4	.	.	29	Days	29
109922307	10992230	10	.	.	15	Days	15
109922307	10992230	12	.	.	15	Days	15
109948122	10994812	1	20100706	20100706	.		1
109948122	10994812	2	2009	2009	.		1
109971003	10997100	1	20131211	20140121	42	Days	42
109971003	10997100	2	20140122	20140304	41	Days	41
109971003	10997100	3	20140305	20140311	7	Days	7
109971003	10997100	4	20140312	20140410	30	Days	30
109971003	10997100	5	20140514	20140605	23	Days	23
109971003	10997100	6	20140619	20141103	138	Days	138
109971003	10997100	7	20141103	20141118	16	Days	16
109971003	10997100	8	20130906	20160304	911	Days	911
109971003	10997100	11	20130613	20130613	.		1
109971003	10997100	13	20131211	20160628	931	Days	931
109971003	10997100	14	20131211	20140312	92	Days	92
109971003	10997100	15	20140312	20160628	840	Days	840
109971003	10997100	16	20131108	20160128	812	Days	812
109971003	10997100	19	20130613	20140205	238	Days	238
109971003	10997100	22	20140226	20140226	.		1
109971003	10997100	24	20130613	20140205	238	Days	238
109971003	10997100	25	20131013	20161012	3	Years	3
1102019552	11020195	1	20111028	20120316	141	Days	141
1102019552	11020195	2	20120413	20120413	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1102019552	11020195	3	20130412	20130412	.		1
1102019552	11020195	4	20130606	20130606	.		1
1102019552	11020195	5	20130704	20130704	.		1
1102019552	11020195	6	20130606	20130606	.		1
1102019552	11020195	7	20200130	20200130	.		1
1102019552	11020195	8	20221013	20221013	.		1
1102019552	11020195	9	2022	2022	.		1
1102019552	11020195	10	20130822	20130822	.		1
1102109863	11021098	1	20141110	20141110	.		1
1102109863	11021098	2	20141126	20141126	.		1
1102109863	11021098	3	20141208	20141208	.		1
1102109863	11021098	4	20141222	20141222	.		1
1102109863	11021098	5	20150105	20150105	.		1
1102109863	11021098	6	20150119	20150119	.		1
1102109863	11021098	7	20150316	20150316	.		1
1102109863	11021098	8	20150330	20150330	.		1
1102109863	11021098	9	20150413	20150413	.		1
1102109863	11021098	10	20150513	20150513	.		1
1102109863	11021098	11	20150525	20150525	.		1
1102109863	11021098	12	20150608	20150608	.		1
1102109863	11021098	13	20151014	20151014	.		1
1102109863	11021098	14	20151026	20151026	.		1
1102109863	11021098	15	20151208	20151208	.		1
1102109863	11021098	16	20151221	20151221	.		1
1102109863	11021098	17	20160118	20160118	.		1
1102109863	11021098	18	20160201	20160201	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1102109863	11021098	19	20160229	20160229	.		1
1102109863	11021098	20	20160314	20160314	.		1
1102109863	11021098	21	20160329	20160329	.		1
1102109863	11021098	22	20160411	20160411	.		1
1102109863	11021098	23	20160425	20160425	.		1
1102109863	11021098	24	20160509	20160509	.		1
1102109863	11021098	25	20160524	20160524	.		1
1102109863	11021098	26	20160620	20160620	.		1
1102109863	11021098	27	20160704	20160704	.		1
1102109863	11021098	28	20160718	20160718	.		1
1102109863	11021098	29	20160802	20160802	.		1
1102109863	11021098	30	20160815	20160815	.		1
1102109863	11021098	31	20160829	20160829	.		1
1102109863	11021098	32	20160912	20160912	.		1
1102109863	11021098	33	20161205	20161205	.		1
1102109863	11021098	34	20161219	20161219	.		1
1102109863	11021098	35	20170116	20170116	.		1
1102109863	11021098	36	20170508	20170508	.		1
1102109863	11021098	37	20170523	20170523	.		1
1102109863	11021098	38	20170703	20170703	.		1
1102109863	11021098	39	20170911	20170911	.		1
1102109863	11021098	40	20170925	20170925	.		1
1102109863	11021098	41	20171010	20171010	.		1
1102109863	11021098	42	20171023	20171023	.		1
1102109863	11021098	43	20171106	20171106	.		1
1102109863	11021098	44	20180115	20180115	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1102109863	11021098	45	20180409	20180409	.		1
1102109863	11021098	46	20181009	20181009	.		1
1102109863	11021098	47	20181022	20181022	.		1
1102109863	11021098	48	20181119	20181119	.		1
1102109863	11021098	49	20180312	20180312	.		1
1102109863	11021098	50	20180604	20180604	.		1
1102109863	11021098	51	20190225	20190225	.		1
1102109863	11021098	52	20190325	20190325	.		1
1102109863	11021098	53	20190704	20190704	.		1
1102109863	11021098	54	20191007	20191007	.		1
1102109863	11021098	55	20191104	20191104	.		1
1102109863	11021098	56	20191202	20191202	.		1
1102109863	11021098	57	20191118	20191118	.		1
1102109863	11021098	58	20191230	20191230	.		1
1102109863	11021098	59	20200113	20200113	.		1
1102109863	11021098	60	20200113	20200113	.		1
1102109863	11021098	62	20230308	20230308	.		1
1102109863	11021098	65	20150105	20150105	.		1
1102109863	11021098	67	20150616	20150616	.		1
1102109863	11021098	68	20151014	20151014	.		1
1102109863	11021098	71	20170129	20170129	.		1
1102109863	11021098	72	20170925	20170925	.		1
1102109863	11021098	77	20170129	20170129	.		1
1102109863	11021098	78	20170925	20170925	.		1
110215902	11021590	1	.	.	29	Days	29
110215902	11021590	3	.	.	15	Days	15

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## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
110215902	11021590	5	.	.	15	Days	15
110215902	11021590	6	.	.	12	Days	12
1102411313	11024113	1	20140516	20140516	1	Days	1
1102411313	11024113	2	20140526	20140526	.		1
1102411313	11024113	4	20140526	20140526	.		1
110471852	11047185	1	20000201	20000201	.		1
110471852	11047185	2	2020	2020	.		1
110577006	11057700	1	20141017	20141017	.		1
110577006	11057700	2	20160627	20160627	.		1
110577006	11057700	3	20150504	20150504	.		1
110577006	11057700	5	20150608	20150608	.		1
110734563	11073456	1	20130709	20130709	.		1
110734563	11073456	2	20130709	20130709	.		1
110734563	11073456	3	202309	202309	.		1
110734563	11073456	4	202309	202309	.		1
110734563	11073456	5	202309	202309	.		1
110755913	11075591	1	2015	2015	.		1
1107567522	11075675	1	20110316	20110316	.		1
1107567522	11075675	2	20110414	20110414	.		1
1107567522	11075675	3	20231114	20231114	.		1
110781863	11078186	1	1996	2004	.		9
1109083723	11090837	27	.	.	3	Days	3
1109083723	11090837	81	.	.	3	Days	3
1109083723	11090837	99	.	.	3	Days	3
1109083723	11090837	240	.	.	3	Days	3
111012256	11101225	1	202308	202308	.		1



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
111012256	11101225	2	20141106	20150511	187	Days	187
111012256	11101225	3	20141106	20150511	187	Days	187
111012256	11101225	4	20141106	20150511	187	Days	187
111012256	11101225	5	201409	201409	.		1
111012256	11101225	6	201409	201409	.		1
111012256	11101225	7	201409	201409	.		1
111012256	11101225	9	2015	2015	.		1
111012256	11101225	16	2015	2015	.		1
111012256	11101225	18	2015	2015	.		1
111043705	11104370	2	200509	200509	.		1
111044465	11104446	2	200809	200812	.		4
111044465	11104446	3	2008	2010	.		3
111044465	11104446	5	2010	2013	.		4
111092522	11109252	2	2011	2011	.		1
111186103	11118610	2	2004	2004	.		1
111191394	11119139	1	200608	200608	.		1
111191394	11119139	2	200609	200611	.		3
111191394	11119139	3	201109	201202	.		94
1112193211	11121932	1	20130423	20130710	79	Days	79
1112193211	11121932	2	20130711	20130814	35	Days	35
1112193211	11121932	3	20130925	20131125	62	Days	62
1112193211	11121932	4	20131126	20140115	51	Days	51
1112193211	11121932	5	20140116	20140225	41	Days	41
1112193211	11121932	6	20140226	20140612	107	Days	107
1112193211	11121932	7	20140613	20140901	75	Days	75
1112193211	11121932	8	20140914	20141116	64	Days	64

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1112193211	11121932	9	20141117	20150304	108	Days	108
1112193211	11121932	10	20150305	20150313	9	Days	9
1112193211	11121932	11	20150330	20150405	7	Days	7
1112193211	11121932	12	20150406	20150506	31	Days	31
1112193211	11121932	13	20150507	20150803	89	Days	89
1112193211	11121932	14	20150804	20150816	13	Days	13
1112193211	11121932	15	20140902	20170720	1053	Days	1053
1112193211	11121932	16	20150604	20150714	41	Days	41
1112193211	11121932	17	20150831	20150831	.		1
1112193211	11121932	18	20121210	20121210	.		1
1112193211	11121932	19	20130423	20130827	127	Days	127
1112193211	11121932	20	20130823	20130827	127	Days	127
1112193211	11121932	25	20090225	20170720	3068	Days	3068
1112193211	11121932	27	2009	20170720	.		20168712
1112193211	11121932	39	20090225	20090225	.		1
1112193211	11121932	42	2009	20170720	.		20168712
1112193211	11121932	43	20090806	20171128	3037	Days	3037
1112193211	11121932	44	20151020	2017	.		20149002
1112193211	11121932	45	20151130	20151130	.		1
111403192	11140319	2	2006	2009	.		4
111408893	11140889	1	200410	200608	.		199
111425004	11142500	1	200701	200701	.		1
111425004	11142500	3	2011	2011	.		1
111425004	11142500	9	20230401	20230401	.		1
111500224	11150022	1	201211	2012	.		199198
111500224	11150022	3	201504	201504	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
111500224	11150022	5	20130301	20130301	.		1
111500224	11150022	7	20140829	20140829	.		1
111500224	11150022	8	20120901	20120901	.		1
111500224	11150022	9	20120501	20120501	.		1
111500224	11150022	11	20110601	20110601	.		1
111500224	11150022	12	20091001	20091001	.		1
111500224	11150022	13	20021001	20021001	.		1
111500224	11150022	14	20011001	20011001	.		1
111500224	11150022	15	20150522	20150522	.		1
111500224	11150022	16	20150622	20150622	.		1
111513767	11151376	1	20101203	20101203	.		1
111513767	11151376	2	20101203	20101203	.		1
111513767	11151376	3	201307	201307	.		1
111513767	11151376	4	201307	201307	.		1
111513767	11151376	5	2010	2014	.		5
111513767	11151376	7	20170914	20170914	.		1
111513767	11151376	8	20190928	20190929	2	Days	2
111513767	11151376	9	20201204	20201204	.		1
111513767	11151376	10	20201204	20201204	.		1
111513767	11151376	11	20201204	20210112	40	Days	40
111513767	11151376	12	20201204	20201204	.		1
111513767	11151376	13	20201204	20210112	40	Days	40
111665733	11166573	1	2004	2010	.		7
1117182022	11171820	1	20140201	20140201	.		1
1117182022	11171820	2	20150409	20150409	.		1
1117182022	11171820	3	201610	201610	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
111731695	11173169	1	201301	201301	.		1
111731695	11173169	3	2013	2013	.		1
111731695	11173169	4	20110101	20110101	.		1
111731695	11173169	6	20110101	20110101	.		1
111731695	11173169	7	20151027	20151027	.		1
111731695	11173169	8	20151113	20151113	.		1
111755239	11175523	1	20131009	20131009	.		1
111755239	11175523	2	20141016	20150201	108	Days	108
111755239	11175523	3	20150215	20150508	82	Days	82
111755239	11175523	4	20150515	20150722	68	Days	68
111755239	11175523	5	20150731	20170303	.		19573
111755239	11175523	6	20131011	20141015	.		10005
111755239	11175523	7	20121210	20150505	201	Days	201
111755239	11175523	8	20160321	20170405	.		10085
111755239	11175523	9	20170406	20190521	.		20116
111755239	11175523	10	20150121	20150123	2	Days	2
111755239	11175523	11	20121210	20121210	.		1
111772814	11177281	1	.	.	21	Days	21
111787964	11178796	1	200804	201501	.		698
1118598419	11185984	1	20150501	20150501	.		1
1118598419	11185984	2	20170316	20170316	.		1
111984347	11198434	1	20120514	20120514	.		1
111984347	11198434	2	20131220	20131220	.		1
111984347	11198434	3	20140331	20140331	.		1
111984347	11198434	4	20150303	20150303	.		1
111984347	11198434	5	20160510	20160510	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
111984347	11198434	6	20170307	20170307	.		1
111984347	11198434	7	20170418	20170418	.		1
111984347	11198434	8	20170502	20170502	.		1
111984347	11198434	9	20190416	20190416	.		1
111984347	11198434	10	20200124	20200124	.		1
1119850317	11198503	1	201201	201201	.		1
1119850317	11198503	2	201204	201204	.		1
1119850317	11198503	4	20140314	20140717	126	Days	126
1119850317	11198503	7	20150528	20150528	.		1
1119850317	11198503	41	2007	2007	.		1
112024568	11202456	2	20080827	20080827	.		1
112024568	11202456	3	20150604	20150604	.		1
112024568	11202456	4	20160628	20160628	.		1
112024568	11202456	5	20160727	20160727	.		1
112024568	11202456	6	20160922	20160922	.		1
112024568	11202456	7	20161020	20161020	.		1
112024568	11202456	8	20171018	20171018	.		1
112024568	11202456	9	20180920	20180920	.		1
112024568	11202456	10	20181115	20181115	.		1
1121274917	11212749	1	20140920	20141110	52	Days	52
1121274917	11212749	2	20141111	20150520	191	Days	191
1121274917	11212749	3	20150525	20150611	18	Days	18
1121274917	11212749	4	20150623	20150731	39	Days	39
1121274917	11212749	5	20151019	20151023	5	Days	5
1121274917	11212749	6	20160411	20160411	.		1
1121274917	11212749	8	19960705	19960705	.		1

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Therapy Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1121274917	11212749	9	20131118	20131118	.		1
1121274917	11212749	10	20141111	20141111	.		1
1121274917	11212749	11	20140703	20140703	.		1
1121274917	11212749	13	20141011	20141011	.		1
1121274917	11212749	15	20121223	20121223	.		1
1121274917	11212749	19	20140208	20140208	.		1
1121274917	11212749	23	20140208	20140208	.		1
1121749411	11217494	1	20140717	20140717	.		1
112237713	11223771	1	20120601	20120601	.		1
112305158	11230515	1	20110601	20110601	.		1
112305158	11230515	2	20140612	20140612	.		1
112305158	11230515	3	20150129	20150129	.		1
112305158	11230515	4	20150618	20150618	.		1
112305158	11230515	5	20160310	20160310	.		1
112305158	11230515	6	20160602	20160602	.		1
112305158	11230515	7	20160616	20160616	.		1
112305158	11230515	8	20161215	20161215	.		1
112305158	11230515	9	20161229	20161229	.		1
112305158	11230515	10	20190917	20190917	.		1
112362434	11236243	1	201105	2011	.		199093
112362434	11236243	2	201504	201504	.		1
112362434	11236243	3	201504	201504	.		1
112362434	11236243	4	2015	2015	.		1
112362434	11236243	5	2015	2015	.		1
112362434	11236243	7	20150415	20150415	.		1
112362434	11236243	8	20150324	20150324	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
112362434	11236243	9	20150324	20150324	.		1
112362434	11236243	10	20150310	20150310	.		1
112362434	11236243	11	20150303	20150303	.		1
112362434	11236243	12	20150224	20150224	.		1
112362434	11236243	33	20150201	20150201	.		1
112362434	11236243	34	20160131	20160131	.		1
112534824	11253482	1	20150518	20170531	745	Days	745
1126655518	11266555	1	20100902	20100902	.		1
112687622	11268762	1	20130322	20150630	830	Days	830
112687622	11268762	2	20130322	20150630	830	Days	830
112687622	11268762	3	20130322	20150630	830	Days	830
112845682	11284568	1	20141114	20141114	.		1
112845693	11284569	1	20141203	20141203	.		1
112877752	11287775	1	20130322	20150630	19944	Hours	19944
112877752	11287775	2	20130322	20150630	19944	Hours	19944
112877752	11287775	3	20130322	20150630	19944	Hours	19944
112904962	11290496	1	20130322	20150630	830	Days	830
112904962	11290496	2	20130322	20150630	830	Days	830
112904962	11290496	3	20130322	20150630	830	Days	830
1129109810	11291098	1	201406	201406	.		1
1129109810	11291098	2	20141217	20170718	945	Days	945
1129109810	11291098	4	2014	2014	.		1
113024092	11302409	1	20130322	20150630	830	Days	830
113024092	11302409	2	20130322	20150630	830	Days	830
113024092	11302409	3	20130322	20150630	830	Days	830
1131105412	11311054	1	20140827	20140827	.		1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
1131105412	11311054	2	20160505	20160505	.		1
1131105412	11311054	3	20171215	20171215	.		1
1131105412	11311054	4	20140827	20210120	6	Years	6
1131105412	11311054	5	20210120	20210120	.		1
113146645	11314664	1	20100706	20100706	.		1
113146645	11314664	2	2009	2009	.		1
113155356	11315535	1	20140422	20140625	65	Days	65
113155356	11315535	2	20140626	20150619	359	Days	359
113155356	11315535	3	20150717	20170601	686	Days	686
113155356	11315535	4	20170601	20170601	.		1
113155356	11315535	5	1990	1990	.		1
113155356	11315535	6	2008	2008	.		1
113155356	11315535	7	20120510	20120510	.		1
113155356	11315535	8	20130807	20130807	.		1
113155356	11315535	9	2012	2012	.		1
113155356	11315535	10	2010	2010	.		1
113222892	11322289	2	2015	2015	.		1
113222892	11322289	3	2023	2023	.		1
113257456	11325745	1	20140423	20150310	322	Days	322
113257456	11325745	2	20140724	20140724	.		1
113257456	11325745	3	20150404	20150404	.		1
113257456	11325745	4	20150610	20150610	.		1
1134491610	11344916	1	20150506	20150710	65	Days	65
1134491610	11344916	2	20130720	20130720	.		1
1134491610	11344916	3	201306	20150702	.		19949397
1134491610	11344916	4	2006	2006	.		1



# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

Unique number for identifying a FAERS re	Number for identifying a FAERS case.	Drug sequence number for identifying a d	Date the therapy was started (or re-star	A date therapy was stopped for this drug	Numeric value of the duration (length) o	Units for therapy duration.	Derived duration.
1134491610	11344916	5	20141113	20150730	259	Days	259
1134491610	11344916	6	20150424	20150424	.		1
1134491610	11344916	7	2010	2010	.		1
1134491610	11344916	8	201410	201410	.		1
1134491610	11344916	9	201410	201410	.		1
1134491610	11344916	10	20150702	20150702	.		1
1134491610	11344916	11	201306	201306	.		1
1134491610	11344916	12	20150617	20150617	.		1
1134491610	11344916	13	20150715	20150721	6	Days	6
1134491610	11344916	14	20150711	20150717	6	Days	6
1134491610	11344916	15	20150718	20150720	2	Days	2
1134491610	11344916	16	20150720	20150720	.		1
1134491610	11344916	17	20150720	20150720	.		1
1134491610	11344916	18	20150421	20150630	70	Days	70
1134491610	11344916	19	20120421	20150730	.		30310
1134491610	11344916	20	20140710	20140710	.		1
1134491610	11344916	21	20150716	20150716	.		1
1134491610	11344916	22	20150717	20150717	.		1
113600164	11360016	1	20140805	20140827	23	Days	23
113600164	11360016	2	20140828	20140915	19	Days	19
113600164	11360016	3	20140916	20141027	42	Days	42
113600164	11360016	4	20141028	20150626	242	Days	242
113600164	11360016	5	20150714	20150714	.		1
113625366	11362536	1	2008	2008	.		1
113625366	11362536	48	.	.	1	Weeks	1
113625366	11362536	49	.	.	2	Weeks	2

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
113625366	11362536	50	.	.	30	Years	30
113625366	11362536	104	.	.	2	Weeks	2
113625366	11362536	111	2008	2008	.		1
113625366	11362536	112	2008	2008	.		1
113625366	11362536	121	2008	2008	.		1
113625366	11362536	122	.	.	1	Months	1
113625446	11362544	9	.	.	1	Weeks	1
113625446	11362544	10	.	.	2	Weeks	2
113659802	11365980	3	20150722	20150802	12	Days	12
113662138	11366213	1	20080328	20080328	.		1
113662138	11366213	2	20071105	2011	.		20069093
113662138	11366213	3	2011	2012	.		2
113662138	11366213	4	2012	2012	.		1
113662138	11366213	5	200911	200911	.		1
113662138	11366213	6	20140205	20140205	.		1
113662138	11366213	7	20150107	20150107	.		1
113662138	11366213	8	2014	2014	.		1
113662138	11366213	9	201505	20150510	.		19949006
113685715	11368571	4	2005	2005	.		1
113685715	11368571	31	2008	2008	.		1
113755943	11375594	1	2008	2008	.		1
113755943	11375594	4	2008	2008	1	Days	1
113755943	11375594	5	2008	2008	1	Days	1
113755943	11375594	6	2008	2008	1	Days	1
113755943	11375594	7	.	.	1	Days	1
113755943	11375594	8	2008	2008	1	Days	1

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Therapy Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Date the therapy was started (or re-star</i>	<i>A date therapy was stopped for this drug</i>	<i>Numeric value of the duration (length) o</i>	<i>Units for therapy duration.</i>	<i>Derived duration.</i>
113755943	11375594	9	2008	2008	1	Days	1
113755943	11375594	10	.	.	1	Days	1
113755943	11375594	11	2008	2008	1	Days	1
113755943	11375594	12	2008	2008	1	Days	1
113755943	11375594	13	2008	2008	1	Days	1
113755943	11375594	14	2008	2008	1	Days	1
113755943	11375594	15	.	.	1	Days	1
113755943	11375594	17	2008	2008	1	Days	1
1138286731	11382867	16	20150820	20150820	.		1
113868659	11386865	2	201506	201506	.		1
113868659	11386865	3	201505	201505	.		1
113868659	11386865	4	2016	2016	.		1
113895298	11389529	2	.	.	1	Days	1
113895298	11389529	5	.	.	1	Days	1
113895298	11389529	6	.	.	1	Days	1
113895298	11389529	7	.	.	1	Days	1
113895298	11389529	9	.	.	1	Days	1
113895298	11389529	11	.	.	1	Days	1
113895298	11389529	12	.	.	1	Days	1
113895298	11389529	16	.	.	1	Days	1
113895298	11389529	18	.	.	1	Days	1
1140884841	11408848	1	20150527	20180207	988	Days	988
1140884841	11408848	2	20160315	20160315	.		1
1140884841	11408848	3	20150501	20150501	.		1
1140884841	11408848	4	20170830	20180207	162	Days	162
1140884841	11408848	5	20180727	2023	5	Years	5

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1140884841	11408848	6	2023	2023	.		1
1142723210	11427232	1	20061010	20061010	.		1
1142723210	11427232	2	20160212	20160212	.		1
1142723210	11427232	3	20161202	20161202	.		1
1142723210	11427232	6	2021	2021	.		1
1142723210	11427232	7	20061010	20061010	.		1
1144435333	11444353	1	20141001	20141001	.		1
1144435333	11444353	2	20160420	20160420	.		1
1144435333	11444353	3	20160518	20160518	.		1
1144435333	11444353	4	20161102	20161102	.		1
1144435333	11444353	5	20161201	20161201	.		1
1144435333	11444353	6	20171129	20171129	.		1
1144435333	11444353	7	20180907	20180907	.		1
1144435333	11444353	8	20170614	20170614	.		1
1144435333	11444353	9	20181228	20181228	.		1
1144435333	11444353	10	20190418	20190418	.		1
1144435333	11444353	11	20190515	20190515	.		1
1144435333	11444353	12	20190612	20190612	.		1
1144435333	11444353	13	20191128	20191128	.		1
1144435333	11444353	14	20150130	20150130	.		1
1144476723	11444767	5	.	.	5	Months	5
1144476723	11444767	25	.	.	5	Months	5
1144476723	11444767	41	.	.	4	Months	4
1144476723	11444767	110	.	.	2	Years	2
1144476723	11444767	121	.	.	6	Months	6
1144476723	11444767	127	.	.	2	Years	2

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1144476723	11444767	141	.	.	9	Months	9
1144476723	11444767	146	.	.	9	Months	9
1144476723	11444767	167	.	.	4	Months	4
1144476723	11444767	175	.	.	4	Months	4
1144476723	11444767	180	.	.	4	Months	4
1144476723	11444767	288	.	.	4	Months	4
1145016915	11450169	1	20150805	20150805	.		1
114731322	11473132	1	20100111	20100322	70	Days	70
114731322	11473132	2	20100323	2010	.		20098312
114731322	11473132	3	20100212	20100322	39	Days	39
114731322	11473132	4	20101115	20101214	29	Days	29
114731322	11473132	5	201202	20120920	212	Days	212
114731322	11473132	6	20140519	20140519	.		1
114734765	11473476	1	201502	201502	.		1
114734765	11473476	2	201502	2015	.		199486
114734765	11473476	3	2015	2015	.		1
114734765	11473476	5	20150206	20150206	.		1
114734765	11473476	6	20150206	20150217	12	Days	12
114734765	11473476	7	20150206	20150217	12	Days	12
114734765	11473476	8	20150206	20150206	.		1
114734765	11473476	9	20150206	20150206	.		1
114734765	11473476	10	20150206	20150206	.		1
114734765	11473476	11	20150206	20150217	12	Days	12
114734765	11473476	12	20150206	20150206	.		1
114734765	11473476	13	20150206	20150206	.		1
114734765	11473476	14	20150206	20150303	26	Days	26

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114734765	11473476	15	20150206	20150206	.		1
114734765	11473476	16	20150206	20150206	.		1
114734765	11473476	18	20150206	20150206	.		1
114734765	11473476	19	20160105	20160105	.		1
114734765	11473476	20	20160129	20160129	.		1
114734765	11473476	21	20160120	20160120	.		1
114734765	11473476	22	20160120	20160120	.		1
114734765	11473476	23	20160120	20160120	.		1
114734765	11473476	24	20160120	20160120	.		1
114734765	11473476	25	20170801	20170801	.		1
114734765	11473476	26	20171201	20171201	.		1
114734765	11473476	27	20180605	20180605	.		1
114734765	11473476	28	20220114	20220114	.		1
114734765	11473476	29	20220114	20220114	.		1
114734765	11473476	30	20220201	20220201	.		1
114734765	11473476	31	20230613	20230613	.		1
114734765	11473476	32	20230710	20230710	.		1
114749292	11474929	1	20100718	20100718	.		1
114749292	11474929	2	20110222	20110222	.		1
114749292	11474929	3	20110311	20110311	.		1
114749292	11474929	4	20110606	20110606	.		1
114749292	11474929	5	20110812	20110812	.		1
114749292	11474929	6	20130104	20130104	.		1
114749292	11474929	7	20130318	20130318	.		1
114749292	11474929	8	201510	201510	.		1
1147514547	11475145	1	20130312	20130702	113 Days		113

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1147514547	11475145	2	20130730	20150723	724	Days	724
1147514547	11475145	3	20150528	20150528	.		1
1147514547	11475145	4	20150625	20150625	.		1
1147514547	11475145	5	20150903	20150903	.		1
1147514547	11475145	6	2015	2015	.		1
1147514547	11475145	7	20120807	20120821	15	Days	15
1147514547	11475145	8	20120807	20120821	15	Days	15
1147514547	11475145	9	20130312	20130702	113	Days	113
1147514547	11475145	10	20130730	20150723	724	Days	724
1147514547	11475145	11	20150903	20150903	.		1
1147514547	11475145	19	20120821	20120821	1	Days	1
1147514547	11475145	20	20120821	20120821	1	Days	1

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
100144838	10014483	1	HIV infection
100144838	10014483	2	Product used for unknown indication
100144838	10014483	4	Product used for unknown indication
100144838	10014483	7	HIV infection
100144838	10014483	8	Product used for unknown indication
100144838	10014483	9	HIV infection
100144838	10014483	10	Product used for unknown indication
100144838	10014483	11	HIV infection
100144838	10014483	12	Product used for unknown indication
100144838	10014483	13	Product used for unknown indication
100144838	10014483	16	Product used for unknown indication
100144838	10014483	18	Product used for unknown indication
100144838	10014483	21	Product used for unknown indication
100144838	10014483	23	Product used for unknown indication
100144838	10014483	27	Product used for unknown indication
100144838	10014483	29	Product used for unknown indication
100144838	10014483	30	Product used for unknown indication
100144838	10014483	33	Product used for unknown indication
100144838	10014483	34	Product used for unknown indication
100144838	10014483	35	Product used for unknown indication
100144838	10014483	36	Product used for unknown indication
100144838	10014483	37	Product used for unknown indication
100144838	10014483	38	Product used for unknown indication
100144838	10014483	39	Product used for unknown indication
100144838	10014483	40	Product used for unknown indication
100144838	10014483	41	Product used for unknown indication
100144838	10014483	42	Product used for unknown indication



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### Indication Listings

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100144838	10014483	43	Product used for unknown indication
1001678124	10016781	1	Neuroendocrine tumour
1001678124	10016781	4	Neuroendocrine tumour
1001678124	10016781	10	Neuroendocrine tumour
1001678124	10016781	11	Neuroendocrine tumour
1001678124	10016781	13	Product used for unknown indication
1001678124	10016781	14	Product used for unknown indication
1001678124	10016781	15	Product used for unknown indication
1001678124	10016781	16	Product used for unknown indication
1001678124	10016781	17	Product used for unknown indication
1001678124	10016781	18	Product used for unknown indication
1001678124	10016781	19	Product used for unknown indication
1001678124	10016781	20	Product used for unknown indication
1001678124	10016781	21	Product used for unknown indication
1002130539	10021305	1	Neuroendocrine tumour
1002130539	10021305	4	Neuroendocrine tumour
1002130539	10021305	7	Product used for unknown indication
100293662	10029366	1	Immunosuppressant drug therapy
100293662	10029366	2	Renal transplant
100293662	10029366	3	Immunosuppressant drug therapy
100293662	10029366	4	Renal transplant
100293662	10029366	5	Renal transplant
100293662	10029366	6	Immunosuppressant drug therapy
100293662	10029366	7	Immunosuppressant drug therapy
100293662	10029366	8	Renal transplant
100356167	10035616	1	Atrial fibrillation
100356167	10035616	2	Hypertension

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100356167	10035616	3	Hypertension
100356167	10035616	4	Atrial fibrillation
100356167	10035616	5	Hypertension
100356167	10035616	6	Product used for unknown indication
100356167	10035616	7	Viral hepatitis carrier
100356167	10035616	8	Viral hepatitis carrier
1006401878	10064018	1	Rheumatoid arthritis
1006401878	10064018	19	Product used for unknown indication
1006401878	10064018	20	Arthralgia
1006401878	10064018	21	Product used for unknown indication
1006401878	10064018	22	Product used for unknown indication
1006401878	10064018	23	Product used for unknown indication
1006401878	10064018	24	Product used for unknown indication
1006401878	10064018	25	Product used for unknown indication
1006401878	10064018	26	Product used for unknown indication
1006401878	10064018	27	Product used for unknown indication
1006401878	10064018	28	Product used for unknown indication
1006401878	10064018	29	Product used for unknown indication
1006401878	10064018	30	Product used for unknown indication
1006401878	10064018	31	Product used for unknown indication
1007468610	10074686	1	Asthma
1007468610	10074686	5	Product used for unknown indication
1007468610	10074686	6	Product used for unknown indication
1007468610	10074686	7	Product used for unknown indication
1007468610	10074686	8	Product used for unknown indication
100764782	10076478	1	Epilepsy
1008408132	10084081	1	Small intestine carcinoma

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1008408132	10084081	5	Product used for unknown indication
1008408132	10084081	6	Product used for unknown indication
1008408132	10084081	7	Product used for unknown indication
100941024	10094102	1	Epilepsy
1009418019	10094180	1	Juvenile idiopathic arthritis
1009418019	10094180	2	Rheumatoid arthritis
1009418019	10094180	6	Juvenile idiopathic arthritis
1009418019	10094180	7	Product used for unknown indication
1009418019	10094180	8	Rheumatoid arthritis
1014222251	10142222	1	Rheumatoid arthritis
1014222251	10142222	20	Product used for unknown indication
101451672	10145167	1	Psoriatic arthropathy
1015212331	10152123	1	Asthma
1015212331	10152123	19	Product used for unknown indication
1015212331	10152123	20	Product used for unknown indication
1015212331	10152123	23	Product used for unknown indication
1015212331	10152123	24	Product used for unknown indication
1015212331	10152123	27	Product used for unknown indication
1015212331	10152123	28	Product used for unknown indication
1015212331	10152123	29	Product used for unknown indication
1015212331	10152123	30	Chronic spontaneous urticaria
101621574	10162157	1	Colorectal cancer metastatic
101621574	10162157	2	Colorectal cancer metastatic
101621574	10162157	4	Colorectal cancer metastatic
101621574	10162157	5	Colorectal cancer metastatic
101621574	10162157	6	Therapeutic procedure
1016611037	10166110	1	Asthma

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1016611037	10166110	15	Product used for unknown indication
1016611037	10166110	19	Product used for unknown indication
1016611037	10166110	20	Product used for unknown indication
1016611037	10166110	21	Nasopharyngitis
1016611037	10166110	22	Illness
1016611037	10166110	23	Product used for unknown indication
1016611037	10166110	24	Product used for unknown indication
1016611037	10166110	25	Infected cyst
1016611037	10166110	26	Product used for unknown indication
101676303	10167630	1	HIV infection
101676303	10167630	2	Product used for unknown indication
101676303	10167630	3	Product used for unknown indication
101676303	10167630	4	Product used for unknown indication
101676303	10167630	5	Product used for unknown indication
101676303	10167630	6	Product used for unknown indication
101676303	10167630	7	Product used for unknown indication
101676313	10167631	1	HIV infection
101676313	10167631	2	Antiretroviral therapy
101676313	10167631	3	Tuberculosis
101676313	10167631	4	Tuberculosis
101676313	10167631	5	Tuberculosis
101676313	10167631	6	Tuberculosis
101676313	10167631	7	Antiretroviral therapy
101678657	10167865	1	Systemic lupus erythematosus
101678657	10167865	2	Systemic lupus erythematosus
101678657	10167865	3	Autoimmune neutropenia
101678657	10167865	8	Infection

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101678657	10167865	9	Clostridium difficile infection
101678657	10167865	12	Infection
101678657	10167865	13	Clostridium difficile infection
101678657	10167865	15	Infection
1017572232	10175722	1	Rheumatoid arthritis
101780773	10178077	1	Rheumatoid arthritis
101780773	10178077	2	Rheumatoid arthritis
101780773	10178077	3	Product used for unknown indication
101780773	10178077	4	Product used for unknown indication
101780773	10178077	5	Product used for unknown indication
101780773	10178077	6	Product used for unknown indication
101780773	10178077	7	Product used for unknown indication
101916392	10191639	1	Bipolar disorder
101916392	10191639	2	Bipolar disorder
101916392	10191639	3	Bipolar disorder
101916392	10191639	4	Bipolar disorder
101916392	10191639	5	Bipolar disorder
101916392	10191639	6	Bipolar disorder
101916392	10191639	7	Bipolar disorder
101916392	10191639	8	Agitation
101916392	10191639	9	Product used for unknown indication
1020642923	10206429	1	Asthma
1020642923	10206429	23	Product used for unknown indication
1020642923	10206429	24	Product used for unknown indication
1020642923	10206429	25	Product used for unknown indication
1020642923	10206429	27	Product used for unknown indication
1020642923	10206429	28	Asthma

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102371704	10237170	1	Epilepsy
102371704	10237170	2	Angina pectoris
102371704	10237170	3	Epilepsy
102371704	10237170	4	Epilepsy
102371704	10237170	5	Epilepsy
102371704	10237170	6	Upper respiratory tract infection
1027487983	10274879	1	Rheumatoid arthritis
1027487983	10274879	6	Product used for unknown indication
1027487983	10274879	7	Product used for unknown indication
1027487983	10274879	8	Product used for unknown indication
1027487983	10274879	9	Product used for unknown indication
1027487983	10274879	10	Product used for unknown indication
1028518546	10285185	1	Rheumatoid arthritis
1028518546	10285185	6	Rheumatoid arthritis
1028518546	10285185	10	Premedication
1028518546	10285185	11	Premedication
1028518546	10285185	12	Premedication
1028518546	10285185	14	Premedication
1028518546	10285185	15	Premedication
1028518546	10285185	16	Premedication
1030948614	10309486	1	Product used for unknown indication
1030948614	10309486	6	Product used for unknown indication
1030948614	10309486	8	Product used for unknown indication
103443973	10344397	1	Breast cancer
1035913611	10359136	1	Asthma
1035913611	10359136	4	Product used for unknown indication
1035913611	10359136	5	Pneumonia

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1035913611	10359136	6	Product used for unknown indication
1035913611	10359136	7	Product used for unknown indication
1035913611	10359136	8	Product used for unknown indication
1035913611	10359136	9	Product used for unknown indication
1035913611	10359136	10	Product used for unknown indication
1035913611	10359136	11	Product used for unknown indication
1035913611	10359136	12	Product used for unknown indication
1035913611	10359136	13	Product used for unknown indication
103687216	10368721	1	Non-small cell lung cancer
103687216	10368721	3	Dehydration
103749689	10374968	1	Colorectal cancer metastatic
103749689	10374968	3	Colorectal cancer metastatic
103749689	10374968	7	Colorectal cancer metastatic
103749689	10374968	9	Colorectal cancer metastatic
103749689	10374968	11	Prophylaxis
103749689	10374968	12	Prophylaxis
103749689	10374968	24	Prophylaxis
103892335	10389233	1	Non-Hodgkin's lymphoma
103892335	10389233	2	Non-Hodgkin's lymphoma
103892335	10389233	3	Non-Hodgkin's lymphoma
103892335	10389233	4	Non-Hodgkin's lymphoma
103892335	10389233	5	Non-Hodgkin's lymphoma
103892335	10389233	6	Prophylaxis
103892335	10389233	7	Prophylaxis
103892335	10389233	8	Prophylaxis
103892335	10389233	9	Prophylaxis
103928076	10392807	1	Attention deficit hyperactivity disorder

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103928375	10392837	1	Attention deficit hyperactivity disorder
103928375	10392837	3	Product used for unknown indication
103928375	10392837	4	Attention deficit hyperactivity disorder
103928375	10392837	5	Product used for unknown indication
103985405	10398540	1	Relapsing-remitting multiple sclerosis
104003092	10400309	1	Cardiac failure chronic
104003092	10400309	2	Product used for unknown indication
104003092	10400309	3	Myocardial ischaemia
104003092	10400309	4	Product used for unknown indication
104003092	10400309	5	Product used for unknown indication
104003092	10400309	6	Product used for unknown indication
104003092	10400309	7	Product used for unknown indication
104003092	10400309	8	Product used for unknown indication
1040513313	10405133	1	Asthma
1040513313	10405133	2	Asthma
1040513313	10405133	6	Product used for unknown indication
1040513313	10405133	7	Product used for unknown indication
1040513313	10405133	8	Product used for unknown indication
1040513313	10405133	9	Product used for unknown indication
1040513313	10405133	10	Product used for unknown indication
1040513313	10405133	11	Product used for unknown indication
1041491125	10414911	1	Carcinoid tumour
1041491125	10414911	5	Product used for unknown indication
1041491125	10414911	6	Product used for unknown indication
1041491125	10414911	7	Product used for unknown indication
1041491125	10414911	8	Product used for unknown indication
1041491125	10414911	9	Product used for unknown indication



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Indication Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS re case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1041491125	10414911	10	Product used for unknown indication
104232052	10423205	1	Product used for unknown indication
104232052	10423205	2	Product used for unknown indication
104232195	10423219	1	Product used for unknown indication
104232195	10423219	2	Product used for unknown indication
104232195	10423219	3	Product used for unknown indication
104232195	10423219	7	Product used for unknown indication
104232203	10423220	1	Product used for unknown indication
104232203	10423220	2	Product used for unknown indication
104266473	10426647	1	Tourette's disorder
104266473	10426647	2	Schizophrenia
104266473	10426647	3	Bipolar disorder
104266473	10426647	4	Psychotic disorder
104266473	10426647	5	Bipolar disorder
104266473	10426647	6	Tourette's disorder
104266473	10426647	7	Product used for unknown indication
104266473	10426647	8	Product used for unknown indication
104490482	10449048	1	Product used for unknown indication
104490482	10449048	2	Product used for unknown indication
104490482	10449048	3	Product used for unknown indication
104490482	10449048	4	Product used for unknown indication
104490482	10449048	5	Product used for unknown indication
104580772	10458077	1	Product used for unknown indication
104580772	10458077	2	Product used for unknown indication
104580772	10458077	3	Product used for unknown indication
104580772	10458077	4	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
104580883	10458088	1	Product used for unknown indication
104580883	10458088	2	Product used for unknown indication
104580883	10458088	3	Product used for unknown indication
104580883	10458088	4	Product used for unknown indication
104580883	10458088	5	Product used for unknown indication
104580883	10458088	6	Product used for unknown indication
104635823	10463582	1	Aggression
104635823	10463582	2	Product used for unknown indication
104665748	10466574	1	Bipolar II disorder
104665748	10466574	2	Bipolar disorder
104665748	10466574	3	Psychotic disorder
104665748	10466574	4	Bipolar II disorder
104665748	10466574	5	Psychotic disorder
104825157	10482515	1	Blood cholesterol abnormal
104825157	10482515	3	Hypertension
104825157	10482515	4	Product used for unknown indication
105144244	10514424	1	Psoriasis
1051596718	10515967	1	Gastroenteropancreatic neuroendocrine tumour disease
1052690058	10526900	1	Rheumatoid arthritis
1052690058	10526900	11	Localised infection
1054038738	10540387	1	Acromegaly
1054038738	10540387	9	Acromegaly
1054038738	10540387	12	Product used for unknown indication
1054038738	10540387	13	Product used for unknown indication
1054038738	10540387	14	Anticoagulant therapy
1054038738	10540387	15	Product used for unknown indication

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Indication Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
105481232	10548123	1	Epilepsy
105524185	10552418	1	Product used for unknown indication
105524185	10552418	2	Product used for unknown indication
105524185	10552418	3	Product used for unknown indication
105524185	10552418	4	Product used for unknown indication
105741013	10574101	1	Immunosuppression
105741013	10574101	2	Heart and lung transplant
105741013	10574101	3	Immunosuppression
105741013	10574101	4	Heart and lung transplant
105741013	10574101	5	Immunosuppression
105741013	10574101	6	Heart and lung transplant
1058928657	10589286	1	Asthma
1058928657	10589286	2	Psoriasis
1058928657	10589286	45	Product used for unknown indication
1058928657	10589286	46	Product used for unknown indication
1058928657	10589286	47	Product used for unknown indication
1058928657	10589286	48	Product used for unknown indication
1058928657	10589286	49	Product used for unknown indication
1058928657	10589286	50	Productive cough
1058928657	10589286	51	Product used for unknown indication
105947013	10594701	1	Back pain
105947013	10594701	2	Back pain
105947013	10594701	3	Back pain
1060157312	10601573	1	Myelofibrosis
1060157312	10601573	5	Product used for unknown indication
1060157312	10601573	6	Product used for unknown indication

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Indication Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
106091663	10609166	1	Partial seizures
106091663	10609166	2	Partial seizures with secondary generalisation
106091663	10609166	3	Partial seizures
106091663	10609166	6	Partial seizures
106091663	10609166	7	Partial seizures
106091663	10609166	8	Partial seizures
106336646	10633664	1	Attention deficit hyperactivity disorder
106336646	10633664	2	Disturbance in social behaviour
106336646	10633664	4	Product used for unknown indication
106352232	10635223	1	Partial seizures
106352232	10635223	3	Seizure
106352232	10635223	4	Seizure
106352232	10635223	5	Seizure
1069198853	10691988	1	Asthma
1069198853	10691988	54	Product used for unknown indication
1069198853	10691988	55	Product used for unknown indication
1069198853	10691988	56	Product used for unknown indication
1069198853	10691988	57	Product used for unknown indication
1069198853	10691988	58	Product used for unknown indication
1069198853	10691988	59	Product used for unknown indication
1069198853	10691988	60	Product used for unknown indication
1069198853	10691988	61	Diabetes mellitus
1070483325	10704833	1	Product used for unknown indication
1070483325	10704833	2	Product used for unknown indication
1070483325	10704833	10	Product used for unknown indication
1070483325	10704833	11	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1070483325	10704833	12	Product used for unknown indication
1070483325	10704833	13	Product used for unknown indication
1070483325	10704833	14	Product used for unknown indication
1070483325	10704833	17	Product used for unknown indication
1070483325	10704833	18	Product used for unknown indication
1070483325	10704833	20	Product used for unknown indication
1070483325	10704833	21	Product used for unknown indication
1070483325	10704833	22	Product used for unknown indication
1070483325	10704833	24	Product used for unknown indication
1070483325	10704833	25	Product used for unknown indication
1070483325	10704833	26	Product used for unknown indication
1070483325	10704833	27	Product used for unknown indication
1070483325	10704833	28	Product used for unknown indication
1070483325	10704833	29	Product used for unknown indication
1070483325	10704833	30	Product used for unknown indication
1070483325	10704833	32	Product used for unknown indication
1070483325	10704833	33	Product used for unknown indication
1070483325	10704833	34	Product used for unknown indication
1070483325	10704833	36	Product used for unknown indication
1070483325	10704833	37	Product used for unknown indication
1070483325	10704833	39	Product used for unknown indication
1070483325	10704833	40	Product used for unknown indication
1070483325	10704833	46	Product used for unknown indication
1070483325	10704833	49	Product used for unknown indication
1070483325	10704833	50	Product used for unknown indication
1070483325	10704833	51	Product used for unknown indication
1070483325	10704833	52	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1070483325	10704833	53	Pain
1070483325	10704833	54	Product used for unknown indication
1070483325	10704833	55	Product used for unknown indication
1070483325	10704833	56	Product used for unknown indication
1070483325	10704833	57	Product used for unknown indication
1070483325	10704833	58	Product used for unknown indication
1070483325	10704833	59	Product used for unknown indication
1070483325	10704833	60	Product used for unknown indication
1070483325	10704833	61	Product used for unknown indication
1070483325	10704833	67	Product used for unknown indication
1070483325	10704833	68	Product used for unknown indication
1070483325	10704833	71	Product used for unknown indication
1070483325	10704833	72	Product used for unknown indication
1070483325	10704833	73	Product used for unknown indication
1070483325	10704833	74	Product used for unknown indication
1070483325	10704833	75	Pain
1070483325	10704833	76	Product used for unknown indication
1070483325	10704833	85	Product used for unknown indication
1070483325	10704833	87	Product used for unknown indication
1070483325	10704833	88	Product used for unknown indication
1070483325	10704833	89	Product used for unknown indication
1070483325	10704833	90	Product used for unknown indication
1070483325	10704833	91	Product used for unknown indication
1070483325	10704833	93	Product used for unknown indication
1070483325	10704833	95	Product used for unknown indication
1070483325	10704833	96	Product used for unknown indication
1070483325	10704833	97	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1070483325	10704833	98	Product used for unknown indication
1070483325	10704833	99	Product used for unknown indication
1070483325	10704833	100	Product used for unknown indication
1070483325	10704833	101	Product used for unknown indication
1070483325	10704833	102	Product used for unknown indication
1070483325	10704833	103	Product used for unknown indication
1070483325	10704833	104	Product used for unknown indication
1070483325	10704833	105	Product used for unknown indication
1070483325	10704833	106	Product used for unknown indication
1070483325	10704833	107	Product used for unknown indication
1070483325	10704833	108	Product used for unknown indication
1070483325	10704833	109	Product used for unknown indication
1070483325	10704833	110	Product used for unknown indication
1070483325	10704833	111	Product used for unknown indication
1070483325	10704833	112	Product used for unknown indication
1070483325	10704833	113	Product used for unknown indication
1070483325	10704833	122	Product used for unknown indication
1070483325	10704833	123	Product used for unknown indication
1070483325	10704833	124	Product used for unknown indication
1070483325	10704833	125	Product used for unknown indication
1070483325	10704833	126	Product used for unknown indication
1070483325	10704833	127	Product used for unknown indication
1070483325	10704833	129	Product used for unknown indication
1070483325	10704833	130	Product used for unknown indication
1070483325	10704833	131	Product used for unknown indication
1070483325	10704833	132	Product used for unknown indication
1070483325	10704833	133	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1070483325	10704833	134	Product used for unknown indication
1070483325	10704833	136	Product used for unknown indication
1070483325	10704833	137	Product used for unknown indication
1070483325	10704833	138	Product used for unknown indication
1070483325	10704833	139	Product used for unknown indication
1070483325	10704833	141	Product used for unknown indication
1070483325	10704833	142	Product used for unknown indication
1070483325	10704833	143	Product used for unknown indication
1070483325	10704833	144	Product used for unknown indication
1070483325	10704833	145	Product used for unknown indication
1070483325	10704833	146	Product used for unknown indication
1070483325	10704833	147	Product used for unknown indication
1070483325	10704833	148	Product used for unknown indication
1070483325	10704833	149	Product used for unknown indication
1070483325	10704833	156	Product used for unknown indication
1070483325	10704833	157	Product used for unknown indication
1070483325	10704833	158	Product used for unknown indication
1070483325	10704833	159	Product used for unknown indication
1070483325	10704833	160	Product used for unknown indication
1070483325	10704833	161	Product used for unknown indication
1070483325	10704833	162	Product used for unknown indication
1070483325	10704833	163	Product used for unknown indication
1070483325	10704833	164	Product used for unknown indication
1070483325	10704833	165	Product used for unknown indication
1070483325	10704833	166	Product used for unknown indication
1070483325	10704833	167	Product used for unknown indication
1070483325	10704833	168	Product used for unknown indication



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1070483325	10704833	169	Product used for unknown indication
1070483325	10704833	170	Product used for unknown indication
1070483325	10704833	171	Product used for unknown indication
1070483325	10704833	172	Product used for unknown indication
1070483325	10704833	173	Product used for unknown indication
1070483325	10704833	174	Product used for unknown indication
1070483325	10704833	176	Product used for unknown indication
1070483325	10704833	177	Product used for unknown indication
1070483325	10704833	178	Product used for unknown indication
1070483325	10704833	179	Product used for unknown indication
1070483325	10704833	180	Product used for unknown indication
1070483325	10704833	181	Product used for unknown indication
1070483325	10704833	182	Product used for unknown indication
1070483325	10704833	183	Product used for unknown indication
1070483325	10704833	184	Product used for unknown indication
1070483325	10704833	185	Product used for unknown indication
1070483325	10704833	186	Product used for unknown indication
1070483325	10704833	187	Product used for unknown indication
1070483325	10704833	188	Product used for unknown indication
1070483325	10704833	189	Product used for unknown indication
1070483325	10704833	190	Product used for unknown indication
1070483325	10704833	191	Product used for unknown indication
1070483325	10704833	192	Product used for unknown indication
1070483325	10704833	194	Product used for unknown indication
1070483325	10704833	195	Product used for unknown indication
1070483325	10704833	196	Product used for unknown indication
1070483325	10704833	197	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1070483325	10704833	198	Product used for unknown indication
1070483325	10704833	199	Product used for unknown indication
1070483325	10704833	200	Product used for unknown indication
1070483325	10704833	201	Product used for unknown indication
1070483325	10704833	202	Product used for unknown indication
1070483325	10704833	203	Product used for unknown indication
1070483325	10704833	204	Product used for unknown indication
1070483325	10704833	206	Product used for unknown indication
1070483325	10704833	207	Product used for unknown indication
1070483325	10704833	211	Product used for unknown indication
1070483325	10704833	212	Product used for unknown indication
1070483325	10704833	213	Product used for unknown indication
1070483325	10704833	214	Product used for unknown indication
1070483325	10704833	215	Product used for unknown indication
1070483325	10704833	218	Product used for unknown indication
1070483325	10704833	219	Product used for unknown indication
1070483325	10704833	220	Product used for unknown indication
1070483325	10704833	221	Product used for unknown indication
1070483325	10704833	225	Product used for unknown indication
1070483325	10704833	226	Product used for unknown indication
1070483325	10704833	227	Product used for unknown indication
1070483325	10704833	228	Product used for unknown indication
1070483325	10704833	229	Product used for unknown indication
1070483325	10704833	230	Product used for unknown indication
1070483325	10704833	231	Product used for unknown indication
1070483325	10704833	232	Product used for unknown indication
1070483325	10704833	233	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1070483325	10704833	234	Product used for unknown indication
1070483325	10704833	235	Product used for unknown indication
1070483325	10704833	236	Product used for unknown indication
1070483325	10704833	237	Product used for unknown indication
1070483325	10704833	238	Product used for unknown indication
1070483325	10704833	240	Product used for unknown indication
1070483325	10704833	241	Product used for unknown indication
1070483325	10704833	242	Pain
1070483325	10704833	243	Product used for unknown indication
1070483325	10704833	244	Product used for unknown indication
1070483325	10704833	245	Product used for unknown indication
1070483325	10704833	246	Product used for unknown indication
1070483325	10704833	247	Product used for unknown indication
1070483325	10704833	248	Product used for unknown indication
1070483325	10704833	253	Product used for unknown indication
1070483325	10704833	254	Product used for unknown indication
1070483325	10704833	255	Product used for unknown indication
1070483325	10704833	256	Product used for unknown indication
1070483325	10704833	263	Product used for unknown indication
1070483325	10704833	264	Product used for unknown indication
1070483325	10704833	265	Product used for unknown indication
1070483325	10704833	266	Product used for unknown indication
1070483325	10704833	267	Product used for unknown indication
1070483325	10704833	268	Product used for unknown indication
1070483325	10704833	269	Product used for unknown indication
1070483325	10704833	270	Product used for unknown indication
1070483325	10704833	271	Product used for unknown indication

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Indication Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
107314353	10731435	1	Attention deficit hyperactivity disorder
107314353	10731435	3	Attention deficit hyperactivity disorder
107314353	10731435	5	Attention deficit hyperactivity disorder
107316442	10731644	1	Onychomycosis
107316442	10731644	2	Product used for unknown indication
1074008517	10740085	1	Rheumatoid arthritis
1074008517	10740085	6	Product used for unknown indication
1074008517	10740085	7	Product used for unknown indication
1074008517	10740085	8	Fluid imbalance
1074008517	10740085	9	Premedication
1074008517	10740085	11	Premedication
1074008517	10740085	22	Tachycardia
1074008517	10740085	23	Product used for unknown indication
1074008517	10740085	24	Premedication
1074008517	10740085	25	Premedication
1074008517	10740085	26	Product used for unknown indication
107408544	10740854	1	Rheumatoid arthritis
1074197911	10741979	1	Rheumatoid arthritis
107584123	10758412	1	Bipolar disorder
107584123	10758412	2	Seizure
107584123	10758412	3	Product used for unknown indication
1075880717	10758807	1	Hormone replacement therapy
1075880717	10758807	2	Osteoporosis
1075880717	10758807	3	Bone disorder
1075880717	10758807	4	Bone density abnormal
1075880717	10758807	6	Arthritis
1075880717	10758807	7	Back pain

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Indication Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1075880717	10758807	8	Panic attack
1078729218	10787292	1	Asthma
1078729218	10787292	2	Asthma
1080136616	10801366	1	Polymyositis
1080136616	10801366	2	Dermatomyositis
1080136616	10801366	3	Product used for unknown indication
1080136616	10801366	4	Product used for unknown indication
1080136616	10801366	5	Product used for unknown indication
1080136616	10801366	6	Product used for unknown indication
1080136616	10801366	7	Product used for unknown indication
1080136616	10801366	8	Product used for unknown indication
1080136616	10801366	9	Contrast media allergy
1080136616	10801366	10	Premedication
1080136616	10801366	11	Premedication
1080136616	10801366	12	Premedication
108390175	10839017	1	Hypertension
108390175	10839017	2	Hypertension
108390175	10839017	4	Hypertension
108390175	10839017	5	Influenza like illness
108390175	10839017	6	Dyspnoea
108390175	10839017	7	Catarrh
108824172	10882417	1	Testis cancer
108824172	10882417	2	Testis cancer
108824172	10882417	3	Testis cancer
1088288812	10882888	1	Rheumatoid arthritis
1088288812	10882888	4	Hypertension
1088288812	10882888	5	Diabetes mellitus

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1088288812	10882888	6	Diabetes mellitus
1088288812	10882888	7	Blood cholesterol abnormal
109031962	10903196	1	Agitation
109031962	10903196	3	Product used for unknown indication
109031962	10903196	4	Product used for unknown indication
109031962	10903196	5	Delirium
109031962	10903196	7	Product used for unknown indication
109031962	10903196	8	Product used for unknown indication
109108923	10910892	1	Narcolepsy
109108923	10910892	4	Diabetes mellitus
109108923	10910892	5	Hypertension
109108923	10910892	6	Restless legs syndrome
109108923	10910892	7	Narcolepsy
109108923	10910892	8	Vitamin D deficiency
109108923	10910892	9	Anaemia
109108923	10910892	10	Neuropathy peripheral
109108923	10910892	11	Intervertebral disc protrusion
109108923	10910892	12	Spinal cord compression
109108923	10910892	13	Hypertension
109108923	10910892	14	Product used for unknown indication
109108923	10910892	15	Product used for unknown indication
109108923	10910892	16	Product used for unknown indication
109108923	10910892	17	Product used for unknown indication
109174139	10917413	1	Depression
109174139	10917413	2	Product used for unknown indication
109174139	10917413	4	Depression
109174139	10917413	5	Depression

# ADVERSE EVENT REPORTING SYSTEM (AERS)

## Indication Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
109174139	10917413	6	Depression
109174139	10917413	7	Depression
109174139	10917413	8	Depression
109174139	10917413	10	Depression
109174139	10917413	11	Depression
109174139	10917413	12	Depression
109174139	10917413	13	Depression
109174139	10917413	14	Depression
109174139	10917413	15	Depression
109174139	10917413	16	Depression
109174139	10917413	17	Depression
109174139	10917413	18	Depression
109174139	10917413	19	Depression
109174139	10917413	20	Depression
109174139	10917413	21	Depression
109174139	10917413	22	Depression
109174139	10917413	23	Depression
1092018038	10920180	1	Muckle-Wells syndrome
109448672	10944867	1	Aggression
109448672	10944867	2	Product used for unknown indication
109651512	10965151	1	Central nervous system lymphoma
109651512	10965151	2	Central nervous system lymphoma
109651512	10965151	3	Central nervous system lymphoma
109651512	10965151	4	Central nervous system lymphoma
109680288	10968028	1	Cataplexy
109680288	10968028	2	Narcolepsy

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Indication Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
109680288	10968028	3	Somnolence
109680288	10968028	4	Product used for unknown indication
109680288	10968028	5	Product used for unknown indication
109680288	10968028	6	Product used for unknown indication
1097587654	10975876	1	Neuroendocrine tumour
1097587654	10975876	12	Product used for unknown indication
1098206364	10982063	1	HER2 positive breast cancer
1098206364	10982063	8	Product used for unknown indication
1098206364	10982063	9	Breast cancer metastatic
1098206364	10982063	13	Breast cancer metastatic
1098206364	10982063	16	Product used for unknown indication
1098206364	10982063	17	Product used for unknown indication
1098206364	10982063	18	Pain
1098206364	10982063	21	Premedication
1098206364	10982063	22	Breast cancer
1098206364	10982063	24	Flushing
109893399	10989339	1	Rheumatoid arthritis
1099047564	10990475	1	Rheumatoid arthritis
1099047564	10990475	15	Product used for unknown indication
109916134	10991613	1	Smoking cessation therapy
109916134	10991613	5	Blood pressure abnormal
109916134	10991613	9	Anxiety
109922307	10992230	1	Pyrexia
109922307	10992230	2	Stem cell transplant
109922307	10992230	3	Prophylaxis against graft versus host disease
109922307	10992230	4	Proteus test positive



## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Indication Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
109922307	10992230	5	Allogenic stem cell transplantation
109922307	10992230	6	Prophylaxis against graft versus host disease
109922307	10992230	7	Allogenic stem cell transplantation
109922307	10992230	8	Prophylaxis against graft versus host disease
109922307	10992230	9	Pyrexia
109922307	10992230	10	Pyrexia
109922307	10992230	11	Allogenic stem cell transplantation
109922307	10992230	12	Pyrexia
109948122	10994812	1	Mucopolysaccharidosis VI
109948122	10994812	3	Product used for unknown indication
109948122	10994812	4	Product used for unknown indication
109948122	10994812	5	Product used for unknown indication
109948122	10994812	6	Product used for unknown indication
109971003	10997100	1	Type IIa hyperlipidaemia
109971003	10997100	8	Carotid artery disease
109971003	10997100	10	Osteoporosis prophylaxis
109971003	10997100	11	Supplementation therapy
109971003	10997100	12	Insomnia
109971003	10997100	13	Supplementation therapy
109971003	10997100	14	Supplementation therapy
109971003	10997100	16	Chest pain
109971003	10997100	17	Product used for unknown indication
109971003	10997100	18	Product used for unknown indication
109971003	10997100	19	Mental disorder
109971003	10997100	20	Product used for unknown indication
109971003	10997100	21	Product used for unknown indication

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Indication Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
109971003	10997100	22	Nausea
109971003	10997100	23	Vomiting
109971003	10997100	24	Depression
109971003	10997100	25	Vitamin D deficiency
1102019552	11020195	1	Rheumatoid arthritis
1102019552	11020195	10	Hypertension
1102019552	11020195	11	Diabetes mellitus
1102019552	11020195	12	Diabetes mellitus
1102019552	11020195	17	Product used for unknown indication
1102109863	11021098	1	Asthma
1102109863	11021098	63	Product used for unknown indication
1102109863	11021098	64	Dyspnoea exertional
1102109863	11021098	65	Dyspnoea
1102109863	11021098	66	Asthma
1102109863	11021098	74	Product used for unknown indication
1102109863	11021098	75	Asthma
1102109863	11021098	80	Product used for unknown indication
1102109863	11021098	81	Product used for unknown indication
1102109863	11021098	83	Product used for unknown indication
1102109863	11021098	84	Product used for unknown indication
1102109863	11021098	85	Product used for unknown indication
110215902	11021590	1	Proteus test positive
110215902	11021590	2	Culture stool positive
110215902	11021590	3	Pyrexia
110215902	11021590	4	Proteus test positive
110215902	11021590	5	Pyrexia

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Indication Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
110215902	11021590	6	Pyrexia
110215902	11021590	7	Bone marrow conditioning regimen
110215902	11021590	8	Chemotherapy
110215902	11021590	9	Chronic myeloid leukaemia
110215902	11021590	10	Chemotherapy
110215902	11021590	11	Chronic myeloid leukaemia
110215902	11021590	12	Chemotherapy
110215902	11021590	13	Chronic myeloid leukaemia
110215902	11021590	14	Bone marrow conditioning regimen
110215902	11021590	15	Bone marrow conditioning regimen
110215902	11021590	16	Allogenic stem cell transplantation
110215902	11021590	17	Prophylaxis against graft versus host disease
110215902	11021590	18	Allogenic stem cell transplantation
110215902	11021590	19	Prophylaxis against graft versus host disease
110215902	11021590	20	Prophylaxis against graft versus host disease
110215902	11021590	21	Stem cell transplant
110215902	11021590	22	Pyrexia
1102411313	11024113	1	Neuroendocrine carcinoma
1102411313	11024113	4	Neuroendocrine carcinoma
1102411313	11024113	5	Product used for unknown indication
1102411313	11024113	6	Product used for unknown indication
1102411313	11024113	7	Product used for unknown indication
1102411313	11024113	8	Product used for unknown indication
1102411313	11024113	9	Product used for unknown indication
110462235	11046223	1	Pyrexia
110462235	11046223	2	Proteus test positive

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
110462235	11046223	3	Culture stool positive
110462235	11046223	4	Pyrexia
110462235	11046223	5	Chronic myeloid leukaemia
110462235	11046223	6	Chemotherapy
110462235	11046223	7	Pyrexia
110462235	11046223	8	Proteus test positive
110462235	11046223	9	Prophylaxis
110462235	11046223	10	Aspergillus test positive
110462235	11046223	11	Stem cell transplant
110462235	11046223	12	Prophylaxis against graft versus host disease
110462235	11046223	13	Chronic myeloid leukaemia
110462235	11046223	14	Chemotherapy
110462235	11046223	15	Chronic myeloid leukaemia
110462235	11046223	16	Prophylaxis against graft versus host disease
110462235	11046223	17	Allogenic stem cell transplantation
110462235	11046223	18	Bone marrow conditioning regimen
110462235	11046223	19	Chronic myeloid leukaemia
110462235	11046223	20	Pyrexia
110462235	11046223	21	Product used for unknown indication
110462235	11046223	22	Prophylaxis
110462235	11046223	23	Stem cell transplant
110462235	11046223	24	Allogenic stem cell transplantation
110462235	11046223	25	Product used for unknown indication
110462235	11046223	26	Aspergillus test positive
110462235	11046223	27	Allogenic stem cell transplantation
110462235	11046223	28	Bone marrow conditioning regimen

## ADVERSE EVENT REPORTING SYSTEM (AERS)

### Indication Listings

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
110471852	11047185	1	Psoriatic arthropathy
110577006	11057700	1	Multiple sclerosis
110577006	11057700	3	Product used for unknown indication
110577006	11057700	4	Product used for unknown indication
110577006	11057700	5	Product used for unknown indication
110577006	11057700	6	Product used for unknown indication
110577006	11057700	7	Product used for unknown indication
110577006	11057700	8	Product used for unknown indication
110734563	11073456	1	Hereditary angioedema
110734563	11073456	2	Hereditary angioedema
110734563	11073456	3	Immune system disorder
110734563	11073456	4	Immune system disorder
110734563	11073456	5	Immune system disorder
110755913	11075591	1	Malignant melanoma
1107567522	11075675	1	Acromegaly
1107567522	11075675	2	Gastroenteropancreatic neuroendocrine tumour disease
1107567522	11075675	4	Cardiac disorder
1107567522	11075675	5	Cardiac disorder
1107567522	11075675	6	Product used for unknown indication
1107567522	11075675	7	Product used for unknown indication
1107567522	11075675	8	Hypertension
110781863	11078186	1	Attention deficit hyperactivity disorder
110781863	11078186	2	Obsessive-compulsive disorder
110781863	11078186	3	Product used for unknown indication
1109083723	11090837	1	Product used for unknown indication
1109083723	11090837	2	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1109083723	11090837	3	Product used for unknown indication
1109083723	11090837	4	Product used for unknown indication
1109083723	11090837	5	Product used for unknown indication
1109083723	11090837	6	Product used for unknown indication
1109083723	11090837	7	Product used for unknown indication
1109083723	11090837	8	Product used for unknown indication
1109083723	11090837	9	Product used for unknown indication
1109083723	11090837	10	Product used for unknown indication
1109083723	11090837	11	Product used for unknown indication
1109083723	11090837	12	Product used for unknown indication
1109083723	11090837	13	Product used for unknown indication
1109083723	11090837	14	Product used for unknown indication
1109083723	11090837	15	Product used for unknown indication
1109083723	11090837	16	Product used for unknown indication
1109083723	11090837	17	Product used for unknown indication
1109083723	11090837	18	Product used for unknown indication
1109083723	11090837	19	Product used for unknown indication
1109083723	11090837	20	Product used for unknown indication
1109083723	11090837	21	Product used for unknown indication
1109083723	11090837	22	Product used for unknown indication
1109083723	11090837	23	Product used for unknown indication
1109083723	11090837	24	Product used for unknown indication
1109083723	11090837	25	Product used for unknown indication
1109083723	11090837	26	Product used for unknown indication
1109083723	11090837	27	Product used for unknown indication
1109083723	11090837	28	Pain
1109083723	11090837	29	Pain

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1109083723	11090837	30	Pain
1109083723	11090837	31	Product used for unknown indication
1109083723	11090837	32	Product used for unknown indication
1109083723	11090837	33	Product used for unknown indication
1109083723	11090837	34	Product used for unknown indication
1109083723	11090837	35	Product used for unknown indication
1109083723	11090837	36	Product used for unknown indication
1109083723	11090837	37	Product used for unknown indication
1109083723	11090837	38	Product used for unknown indication
1109083723	11090837	39	Product used for unknown indication
1109083723	11090837	40	Product used for unknown indication
1109083723	11090837	41	Product used for unknown indication
1109083723	11090837	42	Product used for unknown indication
1109083723	11090837	43	Product used for unknown indication
1109083723	11090837	44	Product used for unknown indication
1109083723	11090837	45	Product used for unknown indication
1109083723	11090837	46	Product used for unknown indication
1109083723	11090837	47	Product used for unknown indication
1109083723	11090837	48	Product used for unknown indication
1109083723	11090837	49	Product used for unknown indication
1109083723	11090837	50	Product used for unknown indication
1109083723	11090837	51	Product used for unknown indication
1109083723	11090837	52	Product used for unknown indication
1109083723	11090837	53	Product used for unknown indication
1109083723	11090837	54	Product used for unknown indication
1109083723	11090837	55	Product used for unknown indication
1109083723	11090837	56	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1109083723	11090837	57	Product used for unknown indication
1109083723	11090837	58	Product used for unknown indication
1109083723	11090837	59	Product used for unknown indication
1109083723	11090837	60	Product used for unknown indication
1109083723	11090837	61	Product used for unknown indication
1109083723	11090837	63	Product used for unknown indication
1109083723	11090837	64	Product used for unknown indication
1109083723	11090837	75	Product used for unknown indication
1109083723	11090837	76	Pain
1109083723	11090837	77	Product used for unknown indication
1109083723	11090837	78	Product used for unknown indication
1109083723	11090837	79	Product used for unknown indication
1109083723	11090837	80	Product used for unknown indication
1109083723	11090837	81	Product used for unknown indication
1109083723	11090837	82	Product used for unknown indication
1109083723	11090837	83	Product used for unknown indication
1109083723	11090837	84	Product used for unknown indication
1109083723	11090837	85	Product used for unknown indication
1109083723	11090837	86	Product used for unknown indication
1109083723	11090837	87	Product used for unknown indication
1109083723	11090837	88	Product used for unknown indication
1109083723	11090837	89	Product used for unknown indication
1109083723	11090837	90	Product used for unknown indication
1109083723	11090837	91	Product used for unknown indication
1109083723	11090837	92	Product used for unknown indication
1109083723	11090837	93	Product used for unknown indication
1109083723	11090837	95	Product used for unknown indication



**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1109083723	11090837	96	Pain
1109083723	11090837	97	Product used for unknown indication
1109083723	11090837	98	Product used for unknown indication
1109083723	11090837	99	Product used for unknown indication
1109083723	11090837	100	Product used for unknown indication
1109083723	11090837	101	Product used for unknown indication
1109083723	11090837	102	Product used for unknown indication
1109083723	11090837	103	Product used for unknown indication
1109083723	11090837	104	Product used for unknown indication
1109083723	11090837	105	Product used for unknown indication
1109083723	11090837	106	Product used for unknown indication
1109083723	11090837	107	Product used for unknown indication
1109083723	11090837	108	Product used for unknown indication
1109083723	11090837	109	Product used for unknown indication
1109083723	11090837	110	Product used for unknown indication
1109083723	11090837	111	Product used for unknown indication
1109083723	11090837	112	Product used for unknown indication
1109083723	11090837	113	Product used for unknown indication
1109083723	11090837	114	Product used for unknown indication
1109083723	11090837	115	Product used for unknown indication
1109083723	11090837	116	Product used for unknown indication
1109083723	11090837	117	Product used for unknown indication
1109083723	11090837	118	Product used for unknown indication
1109083723	11090837	119	Product used for unknown indication
1109083723	11090837	120	Product used for unknown indication
1109083723	11090837	121	Product used for unknown indication
1109083723	11090837	122	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1109083723	11090837	123	Product used for unknown indication
1109083723	11090837	124	Product used for unknown indication
1109083723	11090837	125	Product used for unknown indication
1109083723	11090837	126	Product used for unknown indication
1109083723	11090837	127	Product used for unknown indication
1109083723	11090837	128	Product used for unknown indication
1109083723	11090837	129	Product used for unknown indication
1109083723	11090837	130	Product used for unknown indication
1109083723	11090837	131	Product used for unknown indication
1109083723	11090837	132	Product used for unknown indication
1109083723	11090837	133	Product used for unknown indication
1109083723	11090837	134	Product used for unknown indication
1109083723	11090837	135	Product used for unknown indication
1109083723	11090837	138	Product used for unknown indication
1109083723	11090837	140	Product used for unknown indication
1109083723	11090837	141	Product used for unknown indication
1109083723	11090837	142	Product used for unknown indication
1109083723	11090837	143	Product used for unknown indication
1109083723	11090837	146	Product used for unknown indication
1109083723	11090837	147	Product used for unknown indication
1109083723	11090837	151	Product used for unknown indication
1109083723	11090837	155	Product used for unknown indication
1109083723	11090837	156	Product used for unknown indication
1109083723	11090837	157	Product used for unknown indication
1109083723	11090837	158	Product used for unknown indication
1109083723	11090837	159	Product used for unknown indication
1109083723	11090837	160	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1109083723	11090837	161	Product used for unknown indication
1109083723	11090837	164	Product used for unknown indication
1109083723	11090837	165	Product used for unknown indication
1109083723	11090837	166	Product used for unknown indication
1109083723	11090837	167	Product used for unknown indication
1109083723	11090837	168	Product used for unknown indication
1109083723	11090837	169	Product used for unknown indication
1109083723	11090837	170	Product used for unknown indication
1109083723	11090837	171	Product used for unknown indication
1109083723	11090837	172	Product used for unknown indication
1109083723	11090837	173	Product used for unknown indication
1109083723	11090837	174	Product used for unknown indication
1109083723	11090837	175	Product used for unknown indication
1109083723	11090837	176	Product used for unknown indication
1109083723	11090837	177	Product used for unknown indication
1109083723	11090837	179	Product used for unknown indication
1109083723	11090837	191	Product used for unknown indication
1109083723	11090837	200	Product used for unknown indication
1109083723	11090837	201	Product used for unknown indication
1109083723	11090837	202	Product used for unknown indication
1109083723	11090837	204	Product used for unknown indication
1109083723	11090837	205	Product used for unknown indication
1109083723	11090837	206	Product used for unknown indication
1109083723	11090837	207	Product used for unknown indication
1109083723	11090837	213	Product used for unknown indication
1109083723	11090837	214	Product used for unknown indication
1109083723	11090837	215	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1109083723	11090837	216	Product used for unknown indication
1109083723	11090837	217	Product used for unknown indication
1109083723	11090837	218	Product used for unknown indication
1109083723	11090837	219	Product used for unknown indication
1109083723	11090837	220	Pain
1109083723	11090837	221	Product used for unknown indication
1109083723	11090837	222	Product used for unknown indication
1109083723	11090837	223	Product used for unknown indication
1109083723	11090837	224	Product used for unknown indication
1109083723	11090837	225	Product used for unknown indication
1109083723	11090837	226	Product used for unknown indication
1109083723	11090837	227	Product used for unknown indication
1109083723	11090837	228	Product used for unknown indication
1109083723	11090837	229	Product used for unknown indication
1109083723	11090837	230	Product used for unknown indication
1109083723	11090837	231	Product used for unknown indication
1109083723	11090837	232	Product used for unknown indication
1109083723	11090837	233	Product used for unknown indication
1109083723	11090837	234	Product used for unknown indication
1109083723	11090837	235	Product used for unknown indication
1109083723	11090837	236	Product used for unknown indication
1109083723	11090837	237	Product used for unknown indication
1109083723	11090837	238	Product used for unknown indication
1109083723	11090837	239	Pain
1109083723	11090837	240	Product used for unknown indication
1109083723	11090837	241	Product used for unknown indication
1109083723	11090837	242	Product used for unknown indication

**ADVERSE EVENT REPORTING SYSTEM (AERS)**  
**Indication Listings**

<i>Unique number for identifying a FAERS re</i>	<i>Number for identifying a FAERS case.</i>	<i>Drug sequence number for identifying a d</i>	<i>Preferred Term-level medical terminology</i>
1109083723	11090837	243	Product used for unknown indication
1109083723	11090837	244	Product used for unknown indication
1109083723	11090837	245	Product used for unknown indication
1109083723	11090837	246	Product used for unknown indication
1109083723	11090837	247	Product used for unknown indication
1109083723	11090837	248	Product used for unknown indication
1109083723	11090837	249	Product used for unknown indication
1109083723	11090837	250	Product used for unknown indication
1109083723	11090837	251	Product used for unknown indication
1109083723	11090837	252	Product used for unknown indication
1109083723	11090837	253	Product used for unknown indication
1109083723	11090837	254	Product used for unknown indication

***Summary Tables***

The Summary Tables section presents aggregated safety data to support pharmacovigilance signal detection and risk evaluation. These tables include analyses of adverse events by System Organ Class (SOC) and Preferred Term (PT), drug-event frequencies, patient outcomes (e.g., death, hospitalization), and demographic trends (e.g., gender, age groups).

The data are summarized to provide a high-level overview of potential safety concerns and reporting patterns across the database.

### Demographic Summary Table

#### Derived Age Group

		Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
D_AGE (YEARS)	N	27299	52972	112E3	39042	232E3
	MEAN	13.60	39.52	63.93	81.73	55.41
	MEDIAN	14.00	40.00	64.00	80.00	60.00
	GM	13.60	39.52	63.93	81.73	55.41
	MIN	0.00	26.00	51.00	76.00	0.00
	MAX	25.00	50.00	75.00	700.0	700.0
	RANGE	0-25	26-50	51-75	76-700	0-700
	STD	7.47	7.10	6.91	6.30	21.54
D_WT (KILOGRAMS)	N	6377	12059	28574	9408	56418
	MEAN	45.89	78.97	80.03	70.76	74.40
	MEDIAN	45.60	74.80	73.01	69.00	70.31
	GM	45.89	78.97	80.03	70.76	74.40
	MIN	0.12	0.00	0.00	3.00	0.00
	MAX	291.6	390.0	87075	220.0	87075
	RANGE	0.117-291.6	0-390	0-87075	3-220	0-87075
	STD	30.28	25.28	515.2	18.84	367.2
GNDR_COD (GENDER)	M	13148 (48.2)	18824 (35.5)	45791 (40.8)	17412 (44.6)	95175 (.)
	F	13156 (48.2)	33152 (62.6)	64255 (57.3)	20645 (52.9)	131208 (.)
	U	14 (0.1)	29 (0.1)	54 (0.0)	19 (0.0)	116 (.)
OCCP_COD (OCCUPATION)	HP	7140 (26.2)	13985 (26.4)	24866 (22.2)	7240 (18.5)	53231 (.)
	MD	9987 (36.6)	16735 (31.6)	32657 (29.1)	10399 (26.6)	69778 (.)
	PH	1022 (3.7)	2667 (5.0)	6826 (6.1)	3420 (8.8)	13935 (.)
	LW	362 (1.3)	593 (1.1)	610 (0.5)	48 (0.1)	1613 (.)
	CN	8505 (31.2)	17801 (33.6)	44223 (39.4)	17083 (43.8)	87612 (.)
REPT_COD (REPORT)	EXP	15003 (55.0)	33251 (62.8)	66923 (59.6)	24270 (62.2)	139447 (.)
	PER	8716 (31.9)	16262 (30.7)	37631 (33.5)	12475 (32.0)	75084 (.)
	DIR	788 (2.9)	2690 (5.1)	6006 (5.4)	1858 (4.8)	11342 (.)

Demographic Summary Table  
Derived Age Group

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
5DAY	7 (0.0)	48 (0.1)	137 (0.1)	23 (0.1)	215 (.)
30DAY	2785 (10.2)	721 (1.4)	1502 (1.3)	416 (1.1)	5424 (.)



Drug Summary Table  
Derived Age Group

		Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
DECHAL	Y	8300 ( 9.2%)	20084 ( 22.2%)	46171 ( 51.0%)	15954 ( 17.6%)	90509
	N	1242 ( 7.6%)	3822 ( 23.3%)	8747 ( 53.4%)	2558 ( 15.6%)	16369
	U	35635 ( 8.2%)	134900 ( 31.2%)	189151 ( 43.7%)	72861 ( 16.8%)	432547
	D	13910 ( 10.4%)	38574 ( 28.8%)	57000 ( 42.6%)	24469 ( 18.3%)	133953
RECHAL	Y	230 ( 9.7%)	548 ( 23.2%)	1259 ( 53.3%)	324 ( 13.7%)	2361
	N	355 ( 6.4%)	1611 ( 29.0%)	2797 ( 50.4%)	785 ( 14.1%)	5548
	U	12934 ( 15.3%)	23145 ( 27.3%)	36700 ( 43.3%)	11914 ( 14.1%)	84693
	D	405 ( 6.7%)	1569 ( 25.8%)	3309 ( 54.4%)	804 ( 13.2%)	6087
ROLE_COD	PS	27306 ( 11.8%)	52981 ( 22.9%)	112170 ( 48.5%)	39039 ( 16.9%)	231496
	SS	44835 ( 9.3%)	157234 ( 32.6%)	206943 ( 43.0%)	72795 ( 15.1%)	481807
	C	32182 ( 6.7%)	104405 ( 21.8%)	256845 ( 53.7%)	84829 ( 17.7%)	478261
	I	749 ( 8.1%)	2071 ( 22.3%)	2945 ( 31.7%)	3525 ( 37.9%)	9290
ROUTE	Un	27750 ( 7.9%)	101318 ( 28.7%)	165245 ( 46.7%)	59181 ( 16.7%)	353494
	Or	14456 ( 6.6%)	52120 ( 23.7%)	107486 ( 48.8%)	46137 ( 21.0%)	220199
	Su	12398 ( 11.8%)	35091 ( 33.3%)	46580 ( 44.3%)	11174 ( 10.6%)	105243
	In	11442 ( 12.4%)	26790 ( 29.1%)	42843 ( 46.6%)	10843 ( 11.8%)	91918
	In	1312 ( 6.8%)	3994 ( 20.8%)	11289 ( 58.9%)	2575 ( 13.4%)	19170
	Ot	1091 ( 8.6%)	3744 ( 29.3%)	5932 ( 46.5%)	1993 ( 15.6%)	12760
	In	923 ( 12.4%)	2106 ( 28.2%)	3664 ( 49.1%)	776 ( 10.4%)	7469
	To	381 ( 7.7%)	1928 ( 38.9%)	1836 ( 37.0%)	812 ( 16.4%)	4957
	Re	290 ( 6.7%)	648 ( 15.0%)	2051 ( 47.5%)	1332 ( 30.8%)	4321
	Tr	2359 ( 84.3%)	394 ( 14.1%)	39 ( 1.4%)	8 ( 0.3%)	2800
	Op	74 ( 3.9%)	426 ( 22.6%)	929 ( 49.3%)	454 ( 24.1%)	1883
	In	124 ( 6.6%)	524 ( 28.1%)	965 ( 51.7%)	255 ( 13.7%)	1868
	In	2 ( 0.1%)	1403 ( 86.0%)	222 ( 13.6%)	5 ( 0.3%)	1632
	In	393 ( 27.6%)	485 ( 34.1%)	481 ( 33.8%)	63 ( 4.4%)	1422
	In	328 ( 23.6%)	1019 ( 73.4%)	41 ( 3.0%)	0 ( 0.0%)	1388

**Drug Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Na	142 ( 11.4%)	267 ( 21.5%)	680 ( 54.7%)	155 ( 12.5%)	1244
Tr	106 ( 8.5%)	213 ( 17.1%)	600 ( 48.3%)	324 ( 26.1%)	1243
Re	78 ( 7.1%)	338 ( 30.7%)	163 ( 14.8%)	521 ( 47.4%)	1100
In	60 ( 6.7%)	204 ( 22.7%)	467 ( 51.9%)	169 ( 18.8%)	900
Cu	25 ( 2.9%)	637 ( 74.6%)	151 ( 17.7%)	41 ( 4.8%)	854
In	7 ( 0.9%)	657 ( 85.5%)	83 ( 10.8%)	21 ( 2.7%)	768
En	6 ( 0.9%)	549 ( 78.1%)	136 ( 19.3%)	12 ( 1.7%)	703
Va	13 ( 2.1%)	173 ( 28.5%)	321 ( 53.0%)	99 ( 16.3%)	606
Su	43 ( 9.6%)	165 ( 36.7%)	199 ( 44.3%)	42 ( 9.4%)	449
In	23 ( 5.8%)	144 ( 36.3%)	209 ( 52.6%)	21 ( 5.3%)	397
Pa	34 ( 8.7%)	93 ( 23.8%)	211 ( 54.0%)	53 ( 13.6%)	391
Bu	9 ( 2.3%)	278 ( 72.2%)	70 ( 18.2%)	28 ( 7.3%)	385
In	15 ( 4.0%)	39 ( 10.4%)	205 ( 54.7%)	116 ( 30.9%)	375
Ep	19 ( 8.4%)	151 ( 66.8%)	54 ( 23.9%)	2 ( 0.9%)	226
In	5 ( 2.7%)	137 ( 73.3%)	36 ( 19.3%)	9 ( 4.8%)	187
In	3 ( 1.9%)	31 ( 19.6%)	29 ( 18.4%)	95 ( 60.1%)	158
Ur	2 ( 1.3%)	122 ( 81.9%)	24 ( 16.1%)	1 ( 0.7%)	149
Su	10 ( 8.3%)	89 ( 74.2%)	16 ( 13.3%)	5 ( 4.2%)	120
De	20 ( 22.2%)	36 ( 40.0%)	30 ( 33.3%)	4 ( 4.4%)	90
In	11 ( 14.9%)	20 ( 27.0%)	41 ( 55.4%)	2 ( 2.7%)	74
Pe	0 ( 0.0%)	56 ( 87.5%)	8 ( 12.5%)	0 ( 0.0%)	64
Tr	56 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	56
In	2 ( 3.8%)	25 ( 48.1%)	25 ( 48.1%)	0 ( 0.0%)	52
In	16 ( 35.6%)	16 ( 35.6%)	13 ( 28.9%)	0 ( 0.0%)	45
Or	1 ( 2.3%)	17 ( 38.6%)	22 ( 50.0%)	4 ( 9.1%)	44
Au	3 ( 7.0%)	12 ( 27.9%)	21 ( 48.8%)	7 ( 16.3%)	43
In	2 ( 5.9%)	2 ( 5.9%)	30 ( 88.2%)	0 ( 0.0%)	34

Drug Summary Table  
Derived Age Group

		Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
	In	0 ( 0.0%)	12 ( 63.2%)	7 ( 36.8%)	0 ( 0.0%)	19
	In	2 ( 11.1%)	15 ( 83.3%)	1 ( 5.6%)	0 ( 0.0%)	18
	In	3 ( 18.8%)	5 ( 31.3%)	5 ( 31.3%)	3 ( 18.8%)	16
	In	0 ( 0.0%)	4 ( 28.6%)	9 ( 64.3%)	1 ( 7.1%)	14
	In	1 ( 7.7%)	10 ( 76.9%)	2 ( 15.4%)	0 ( 0.0%)	13
	En	0 ( 0.0%)	1 ( 7.7%)	7 ( 53.8%)	5 ( 38.5%)	13
	Oc	1 ( 7.7%)	8 ( 61.5%)	4 ( 30.8%)	0 ( 0.0%)	13
	In	0 ( 0.0%)	6 ( 50.0%)	4 ( 33.3%)	2 ( 16.7%)	12
	He	0 ( 0.0%)	3 ( 25.0%)	8 ( 66.7%)	1 ( 8.3%)	12
	In	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8
	In	1 ( 12.5%)	1 ( 12.5%)	4 ( 50.0%)	2 ( 25.0%)	8
	In	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
	lo	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
	En	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	0 ( 0.0%)	5
	Pe	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
	Re	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
	In	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
	In	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
	In	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
	Ex	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
	In	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
VAL_VBM	Va	104021 ( 8.8%)	313888 ( 26.4%)	571404 ( 48.1%)	197759 ( 16.7%)	1187072
	Ve	1051 ( 7.6%)	2803 ( 20.3%)	7499 ( 54.4%)	2429 ( 17.6%)	13782

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Off label use	2900 ( 14.6%)	4796 ( 24.2%)	9115 ( 46.0%)	2997 ( 15.1%)	19808
Fatigue	636 ( 5.0%)	3536 ( 27.8%)	6694 ( 52.6%)	1863 ( 14.6%)	12729
Drug ineffective	1612 ( 12.7%)	3822 ( 30.2%)	5924 ( 46.8%)	1312 ( 10.4%)	12670
Diarrhoea	1297 ( 12.1%)	2137 ( 20.0%)	5527 ( 51.7%)	1732 ( 16.2%)	10693
Death	234 ( 2.3%)	894 ( 8.9%)	4796 ( 47.9%)	4090 ( 40.8%)	10014
Nausea	722 ( 7.5%)	2768 ( 28.6%)	5059 ( 52.3%)	1118 ( 11.6%)	9667
COVID-19	475 ( 5.4%)	2348 ( 26.9%)	4830 ( 55.3%)	1083 ( 12.4%)	8736
Pain	504 ( 6.1%)	2577 ( 31.0%)	4375 ( 52.6%)	863 ( 10.4%)	8319
Headache	678 ( 8.3%)	2865 ( 35.1%)	3975 ( 48.7%)	641 ( 7.9%)	8159
Product dose omission issue	914 ( 11.5%)	2149 ( 27.1%)	3814 ( 48.1%)	1050 ( 13.2%)	7927
Dyspnoea	461 ( 6.3%)	1779 ( 24.3%)	3867 ( 52.8%)	1219 ( 16.6%)	7326
Arthralgia	385 ( 5.3%)	2178 ( 30.0%)	4029 ( 55.5%)	663 ( 9.1%)	7255
Pruritus	987 ( 14.3%)	1983 ( 28.8%)	3161 ( 45.9%)	750 ( 10.9%)	6881
Rash	826 ( 13.0%)	1685 ( 26.6%)	3071 ( 48.5%)	753 ( 11.9%)	6335
Vomiting	1030 ( 16.3%)	1754 ( 27.8%)	2832 ( 44.9%)	687 ( 10.9%)	6303
Pyrexia	1093 ( 17.6%)	1700 ( 27.4%)	2847 ( 45.9%)	569 ( 9.2%)	6209
Drug dose omission by device	1435 ( 23.4%)	543 ( 8.8%)	3056 ( 49.8%)	1107 ( 18.0%)	6141
Malaise	334 ( 5.5%)	1572 ( 25.9%)	3229 ( 53.2%)	939 ( 15.5%)	6074
Dizziness	387 ( 6.5%)	1676 ( 28.2%)	2878 ( 48.5%)	992 ( 16.7%)	5933
Asthenia	255 ( 4.6%)	1305 ( 23.5%)	2877 ( 51.8%)	1119 ( 20.1%)	5556
Pneumonia	369 ( 7.0%)	1005 ( 19.0%)	2915 ( 55.2%)	995 ( 18.8%)	5284
Inappropriate schedule of product administration	728 ( 14.2%)	1340 ( 26.1%)	2483 ( 48.4%)	584 ( 11.4%)	5135
Fall	259 ( 5.2%)	674 ( 13.5%)	2487 ( 49.9%)	1562 ( 31.4%)	4982
Cough	498 ( 10.1%)	1134 ( 23.0%)	2665 ( 54.0%)	639 ( 12.9%)	4936
Condition aggravated	582 ( 12.3%)	1417 ( 29.9%)	2202 ( 46.5%)	535 ( 11.3%)	4736
Injection site pain	757 ( 17.4%)	1188 ( 27.3%)	1960 ( 45.0%)	449 ( 10.3%)	4354
Nasopharyngitis	433 ( 10.1%)	1450 ( 33.8%)	2026 ( 47.3%)	376 ( 8.8%)	4285

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Product use in unapproved indication	621 ( 14.6%)	1341 ( 31.5%)	1802 ( 42.3%)	494 ( 11.6%)	4258
Weight decreased	351 ( 8.3%)	955 ( 22.5%)	2252 ( 53.0%)	688 ( 16.2%)	4246
Pain in extremity	229 ( 5.5%)	1124 ( 26.8%)	2329 ( 55.6%)	506 ( 12.1%)	4188
Decreased appetite	347 ( 8.9%)	747 ( 19.2%)	2006 ( 51.5%)	797 ( 20.5%)	3897
Device difficult to use	218 ( 5.9%)	351 ( 9.4%)	2146 ( 57.8%)	1000 ( 26.9%)	3715
Illness	314 ( 8.6%)	862 ( 23.7%)	1947 ( 53.4%)	521 ( 14.3%)	3644
Abdominal pain	459 ( 12.8%)	1127 ( 31.4%)	1649 ( 46.0%)	350 ( 9.8%)	3585
Neutropenia	285 ( 8.0%)	928 ( 26.0%)	1792 ( 50.2%)	568 ( 15.9%)	3573
Anxiety	367 ( 10.7%)	1330 ( 38.9%)	1449 ( 42.4%)	274 ( 8.0%)	3420
Constipation	199 ( 5.9%)	596 ( 17.6%)	1861 ( 55.0%)	730 ( 21.6%)	3386
Back pain	137 ( 4.1%)	872 ( 25.8%)	1925 ( 57.1%)	440 ( 13.0%)	3374
Urinary tract infection	142 ( 4.2%)	641 ( 19.2%)	1787 ( 53.4%)	777 ( 23.2%)	3347
Hypertension	137 ( 4.2%)	892 ( 27.3%)	1679 ( 51.3%)	563 ( 17.2%)	3271
Insomnia	235 ( 7.4%)	1086 ( 34.3%)	1487 ( 47.0%)	358 ( 11.3%)	3166
Gait disturbance	144 ( 4.7%)	753 ( 24.8%)	1599 ( 52.7%)	540 ( 17.8%)	3036
Incorrect dose administered	574 ( 19.0%)	824 ( 27.3%)	1293 ( 42.9%)	324 ( 10.7%)	3015
Weight increased	411 ( 14.1%)	1085 ( 37.1%)	1227 ( 42.0%)	201 ( 6.9%)	2924
Acute kidney injury	256 ( 8.8%)	510 ( 17.5%)	1464 ( 50.4%)	677 ( 23.3%)	2907
Anaemia	159 ( 5.6%)	500 ( 17.8%)	1539 ( 54.7%)	618 ( 21.9%)	2816
Abdominal pain upper	260 ( 9.4%)	841 ( 30.3%)	1364 ( 49.1%)	312 ( 11.2%)	2777
Wrong technique in product usage process	220 ( 7.9%)	448 ( 16.1%)	1519 ( 54.7%)	589 ( 21.2%)	2776
Drug hypersensitivity	125 ( 4.5%)	736 ( 26.6%)	1502 ( 54.2%)	409 ( 14.8%)	2772
Peripheral swelling	105 ( 3.8%)	672 ( 24.5%)	1449 ( 52.8%)	520 ( 18.9%)	2746
Hypotension	238 ( 8.8%)	607 ( 22.5%)	1304 ( 48.3%)	553 ( 20.5%)	2702
Erythema	359 ( 13.7%)	760 ( 29.0%)	1239 ( 47.3%)	260 ( 9.9%)	2618
Somnolence	393 ( 15.1%)	725 ( 27.9%)	1046 ( 40.3%)	432 ( 16.6%)	2596
Accidental exposure to product	238 ( 9.2%)	598 ( 23.1%)	1396 ( 54.0%)	353 ( 13.7%)	2585

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blood pressure increased	94 ( 3.6%)	533 ( 20.6%)	1614 ( 62.5%)	342 ( 13.2%)	2583
Infection	218 ( 8.6%)	699 ( 27.4%)	1288 ( 50.5%)	343 ( 13.5%)	2548
Abdominal discomfort	192 ( 7.6%)	755 ( 29.8%)	1261 ( 49.7%)	329 ( 13.0%)	2537
Dry skin	614 ( 25.7%)	646 ( 27.0%)	920 ( 38.5%)	209 ( 8.7%)	2389
White blood cell count decreased	72 ( 3.0%)	390 ( 16.3%)	1514 ( 63.4%)	412 ( 17.3%)	2388
Feeling abnormal	143 ( 6.1%)	652 ( 27.6%)	1249 ( 52.9%)	317 ( 13.4%)	2361
Toxicity to various agents	535 ( 22.7%)	746 ( 31.7%)	863 ( 36.6%)	211 ( 9.0%)	2355
Alopecia	126 ( 5.4%)	699 ( 29.7%)	1228 ( 52.2%)	298 ( 12.7%)	2351
Joint swelling	106 ( 4.6%)	694 ( 29.9%)	1289 ( 55.5%)	234 ( 10.1%)	2323
Product use issue	367 ( 15.9%)	657 ( 28.5%)	998 ( 43.2%)	286 ( 12.4%)	2308
Muscle spasms	116 ( 5.0%)	665 ( 28.9%)	1219 ( 53.0%)	301 ( 13.1%)	2301
Hospitalisation	218 ( 9.6%)	469 ( 20.8%)	1093 ( 48.4%)	480 ( 21.2%)	2260
Therapy interrupted	92 ( 4.1%)	503 ( 22.5%)	1225 ( 54.8%)	417 ( 18.6%)	2237
Myalgia	137 ( 6.1%)	658 ( 29.5%)	1201 ( 53.8%)	237 ( 10.6%)	2233
Influenza	261 ( 11.7%)	712 ( 31.9%)	1079 ( 48.3%)	180 ( 8.1%)	2232
Hypoaesthesia	130 ( 5.8%)	872 ( 39.2%)	1047 ( 47.1%)	175 ( 7.9%)	2224
Urticaria	283 ( 12.8%)	885 ( 39.9%)	888 ( 40.1%)	160 ( 7.2%)	2216
Hypersensitivity	174 ( 7.9%)	819 ( 37.2%)	1026 ( 46.6%)	182 ( 8.3%)	2201
Depression	207 ( 9.7%)	843 ( 39.5%)	923 ( 43.3%)	161 ( 7.5%)	2134
Asthma	190 ( 9.0%)	627 ( 29.7%)	1107 ( 52.4%)	189 ( 8.9%)	2113
Disease recurrence	103 ( 4.9%)	550 ( 26.0%)	1281 ( 60.6%)	179 ( 8.5%)	2113
Platelet count decreased	116 ( 5.5%)	305 ( 14.5%)	1267 ( 60.4%)	411 ( 19.6%)	2099
Chest pain	145 ( 6.9%)	648 ( 31.0%)	1082 ( 51.8%)	212 ( 10.2%)	2087
Sinusitis	126 ( 6.1%)	703 ( 34.2%)	1082 ( 52.7%)	143 ( 7.0%)	2054
Memory impairment	67 ( 3.4%)	501 ( 25.1%)	1063 ( 53.3%)	363 ( 18.2%)	1994
Confusional state	91 ( 4.6%)	498 ( 25.1%)	895 ( 45.1%)	502 ( 25.3%)	1986
Drug interaction	235 ( 11.9%)	483 ( 24.5%)	898 ( 45.5%)	359 ( 18.2%)	1975

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Seizure	661 ( 34.0%)	537 ( 27.6%)	609 ( 31.3%)	137 ( 7.0%)	1944
Haemorrhage	577 ( 29.8%)	631 ( 32.6%)	539 ( 27.8%)	191 ( 9.9%)	1938
Disease progression	123 ( 6.5%)	458 ( 24.3%)	1069 ( 56.7%)	234 ( 12.4%)	1884
Paraesthesia	121 ( 6.4%)	770 ( 41.0%)	842 ( 44.9%)	144 ( 7.7%)	1877
Tremor	167 ( 9.0%)	482 ( 26.0%)	882 ( 47.5%)	326 ( 17.6%)	1857
Chills	150 ( 8.1%)	574 ( 31.0%)	941 ( 50.9%)	184 ( 10.0%)	1849
Oropharyngeal pain	184 ( 10.0%)	621 ( 33.9%)	888 ( 48.4%)	141 ( 7.7%)	1834
Thrombocytopenia	171 ( 9.5%)	343 ( 19.1%)	977 ( 54.5%)	303 ( 16.9%)	1794
Eczema	610 ( 34.8%)	509 ( 29.1%)	543 ( 31.0%)	90 ( 5.1%)	1752
General physical health deterioration	72 ( 4.1%)	505 ( 28.8%)	829 ( 47.3%)	345 ( 19.7%)	1751
Therapeutic product effect incomplete	158 ( 9.2%)	457 ( 26.6%)	913 ( 53.1%)	192 ( 11.2%)	1720
Muscular weakness	75 ( 4.4%)	543 ( 32.0%)	814 ( 48.0%)	265 ( 15.6%)	1697
Malignant neoplasm progression	33 ( 2.0%)	251 ( 14.9%)	1084 ( 64.3%)	317 ( 18.8%)	1685
Rheumatoid arthritis	32 ( 1.9%)	588 ( 35.2%)	911 ( 54.5%)	141 ( 8.4%)	1672
Gastrointestinal disorder	117 ( 7.0%)	537 ( 32.2%)	840 ( 50.4%)	172 ( 10.3%)	1666
Infusion related reaction	133 ( 8.3%)	763 ( 47.5%)	636 ( 39.6%)	74 ( 4.6%)	1606
Musculoskeletal stiffness	70 ( 4.4%)	574 ( 35.8%)	792 ( 49.4%)	167 ( 10.4%)	1603
Sepsis	135 ( 8.6%)	256 ( 16.3%)	857 ( 54.4%)	327 ( 20.8%)	1575
Haemoglobin decreased	83 ( 5.3%)	294 ( 18.8%)	878 ( 56.3%)	305 ( 19.6%)	1560
Visual impairment	79 ( 5.1%)	424 ( 27.3%)	744 ( 47.9%)	306 ( 19.7%)	1553
Hyperhidrosis	111 ( 7.2%)	521 ( 33.8%)	766 ( 49.7%)	144 ( 9.3%)	1542
Abdominal distension	111 ( 7.2%)	452 ( 29.4%)	764 ( 49.8%)	208 ( 13.6%)	1535
Dehydration	146 ( 9.5%)	256 ( 16.7%)	807 ( 52.6%)	325 ( 21.2%)	1534
Neuropathy peripheral	35 ( 2.3%)	212 ( 14.0%)	1006 ( 66.6%)	258 ( 17.1%)	1511
Loss of consciousness	170 ( 11.3%)	346 ( 23.0%)	717 ( 47.7%)	269 ( 17.9%)	1502
Drug intolerance	100 ( 6.7%)	547 ( 36.5%)	630 ( 42.0%)	222 ( 14.8%)	1499
Overdose	318 ( 21.5%)	517 ( 35.0%)	463 ( 31.4%)	178 ( 12.1%)	1476

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Vision blurred	116 ( 7.9%)	456 ( 31.0%)	731 ( 49.7%)	168 ( 11.4%)	1471
Psoriasis	64 ( 4.4%)	510 ( 35.0%)	778 ( 53.4%)	104 ( 7.1%)	1456
Hereditary angioedema	254 ( 17.4%)	823 ( 56.5%)	364 ( 25.0%)	15 ( 1.0%)	1456
Contusion	154 ( 10.6%)	411 ( 28.4%)	669 ( 46.2%)	215 ( 14.8%)	1449
Cerebrovascular accident	23 ( 1.6%)	137 ( 9.5%)	827 ( 57.3%)	456 ( 31.6%)	1443
Sleep disorder	239 ( 16.6%)	515 ( 35.7%)	551 ( 38.2%)	137 ( 9.5%)	1442
Chest discomfort	107 ( 7.5%)	417 ( 29.1%)	765 ( 53.3%)	146 ( 10.2%)	1435
Myelosuppression	136 ( 9.7%)	318 ( 22.7%)	802 ( 57.2%)	145 ( 10.3%)	1401
Device leakage	809 ( 57.8%)	132 ( 9.4%)	313 ( 22.4%)	146 ( 10.4%)	1400
Swelling	96 ( 6.9%)	538 ( 38.7%)	604 ( 43.4%)	153 ( 11.0%)	1391
Heart rate increased	142 ( 10.2%)	459 ( 33.1%)	650 ( 46.9%)	136 ( 9.8%)	1387
Blood glucose increased	56 ( 4.1%)	187 ( 13.6%)	867 ( 62.8%)	270 ( 19.6%)	1380
Renal impairment	56 ( 4.1%)	221 ( 16.1%)	753 ( 54.8%)	344 ( 25.0%)	1374
Maternal exposure during pregnancy	211 ( 15.5%)	1104 ( 81.0%)	47 ( 3.4%)	1 ( 0.1%)	1363
Crohn's disease	264 ( 19.4%)	550 ( 40.4%)	489 ( 36.0%)	57 ( 4.2%)	1360
Migraine	114 ( 8.4%)	712 ( 52.4%)	497 ( 36.6%)	35 ( 2.6%)	1358
Colitis ulcerative	202 ( 15.0%)	580 ( 43.0%)	495 ( 36.7%)	72 ( 5.3%)	1349
Intentional product use issue	73 ( 5.4%)	324 ( 24.0%)	680 ( 50.4%)	271 ( 20.1%)	1348
Febrile neutropenia	283 ( 21.1%)	220 ( 16.4%)	644 ( 48.0%)	194 ( 14.5%)	1341
Device issue	437 ( 32.7%)	305 ( 22.8%)	472 ( 35.3%)	123 ( 9.2%)	1337
Arthritis	64 ( 4.8%)	238 ( 17.8%)	832 ( 62.3%)	201 ( 15.1%)	1335
Rhinorrhoea	157 ( 11.9%)	344 ( 26.1%)	678 ( 51.4%)	140 ( 10.6%)	1319
Stress	115 ( 8.7%)	416 ( 31.6%)	661 ( 50.2%)	126 ( 9.6%)	1318
Atrial fibrillation	9 ( 0.7%)	57 ( 4.3%)	739 ( 56.3%)	508 ( 38.7%)	1313
Bronchitis	80 ( 6.1%)	314 ( 24.0%)	775 ( 59.1%)	142 ( 10.8%)	1311
Oedema peripheral	51 ( 3.9%)	290 ( 22.2%)	669 ( 51.3%)	295 ( 22.6%)	1305
Palpitations	67 ( 5.1%)	476 ( 36.5%)	623 ( 47.8%)	137 ( 10.5%)	1303



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Nasal congestion	170 ( 13.0%)	413 ( 31.7%)	636 ( 48.8%)	84 ( 6.4%)	1303
Discomfort	151 ( 11.6%)	537 ( 41.4%)	520 ( 40.1%)	89 ( 6.9%)	1297
Product dose omission in error	221 ( 17.3%)	331 ( 25.9%)	612 ( 47.8%)	115 ( 9.0%)	1279
Renal failure	85 ( 6.7%)	292 ( 22.9%)	668 ( 52.3%)	232 ( 18.2%)	1277
Hot flush	21 ( 1.7%)	240 ( 19.2%)	721 ( 57.8%)	265 ( 21.3%)	1247
Neoplasm progression	27 ( 2.2%)	167 ( 13.4%)	792 ( 63.8%)	256 ( 20.6%)	1242
Injection site erythema	215 ( 17.5%)	436 ( 35.4%)	518 ( 42.0%)	63 ( 5.1%)	1232
Balance disorder	51 ( 4.1%)	228 ( 18.5%)	631 ( 51.3%)	321 ( 26.1%)	1231
No adverse event	199 ( 16.2%)	410 ( 33.4%)	484 ( 39.4%)	136 ( 11.1%)	1229
Tachycardia	261 ( 21.3%)	435 ( 35.5%)	430 ( 35.1%)	99 ( 8.1%)	1225
Loss of personal independence in daily activities	75 ( 6.2%)	319 ( 26.3%)	664 ( 54.7%)	157 ( 12.9%)	1215
Haematochezia	160 ( 13.2%)	414 ( 34.1%)	519 ( 42.8%)	121 ( 10.0%)	1214
Skin exfoliation	244 ( 20.1%)	342 ( 28.2%)	522 ( 43.1%)	104 ( 8.6%)	1212
Syncope	155 ( 12.9%)	320 ( 26.5%)	494 ( 41.0%)	237 ( 19.7%)	1206
Mobility decreased	36 ( 3.0%)	379 ( 31.5%)	599 ( 49.8%)	190 ( 15.8%)	1204
Neutrophil count decreased	48 ( 4.1%)	191 ( 16.3%)	732 ( 62.5%)	200 ( 17.1%)	1171
Intentional product misuse	166 ( 14.2%)	340 ( 29.2%)	495 ( 42.5%)	164 ( 14.1%)	1165
Dermatitis atopic	364 ( 31.7%)	367 ( 31.9%)	379 ( 33.0%)	40 ( 3.5%)	1150
Dysphagia	93 ( 8.1%)	265 ( 23.1%)	566 ( 49.4%)	221 ( 19.3%)	1145
Dyspepsia	49 ( 4.3%)	354 ( 31.1%)	617 ( 54.2%)	118 ( 10.4%)	1138
Wheezing	59 ( 5.2%)	336 ( 29.7%)	589 ( 52.1%)	147 ( 13.0%)	1131
Treatment failure	238 ( 21.4%)	490 ( 44.0%)	330 ( 29.6%)	56 ( 5.0%)	1114
Injection site swelling	248 ( 22.5%)	374 ( 33.9%)	430 ( 38.9%)	52 ( 4.7%)	1104
Dry mouth	26 ( 2.4%)	396 ( 36.0%)	524 ( 47.6%)	155 ( 14.1%)	1101
Hepatic enzyme increased	94 ( 8.7%)	429 ( 39.6%)	482 ( 44.5%)	79 ( 7.3%)	1084
Oxygen saturation decreased	139 ( 12.9%)	188 ( 17.5%)	586 ( 54.4%)	164 ( 15.2%)	1077
Cardiac failure	42 ( 3.9%)	123 ( 11.5%)	537 ( 50.0%)	371 ( 34.6%)	1073

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Productive cough	72 ( 6.7%)	207 ( 19.3%)	630 ( 58.8%)	162 ( 15.1%)	1071
Injection site haemorrhage	98 ( 9.3%)	300 ( 28.5%)	541 ( 51.3%)	115 ( 10.9%)	1054
Hallucination	71 ( 6.7%)	118 ( 11.2%)	509 ( 48.3%)	355 ( 33.7%)	1053
Stomatitis	54 ( 5.2%)	316 ( 30.3%)	546 ( 52.3%)	127 ( 12.2%)	1043
Epistaxis	220 ( 21.2%)	172 ( 16.5%)	464 ( 44.6%)	184 ( 17.7%)	1040
Dry eye	144 ( 14.0%)	300 ( 29.2%)	500 ( 48.6%)	85 ( 8.3%)	1029
Blood pressure decreased	78 ( 7.6%)	204 ( 19.9%)	564 ( 54.9%)	181 ( 17.6%)	1027
Product preparation error	60 ( 5.9%)	168 ( 16.4%)	637 ( 62.1%)	160 ( 15.6%)	1025
Inflammation	103 ( 10.1%)	411 ( 40.3%)	455 ( 44.7%)	50 ( 4.9%)	1019
Device breakage	778 ( 76.3%)	127 ( 12.5%)	94 ( 9.2%)	20 ( 2.0%)	1019
Suicidal ideation	184 ( 18.1%)	466 ( 45.9%)	327 ( 32.2%)	38 ( 3.7%)	1015
Myocardial infarction	10 ( 1.0%)	146 ( 14.5%)	605 ( 60.2%)	244 ( 24.3%)	1005
Influenza like illness	67 ( 6.7%)	441 ( 44.0%)	441 ( 44.0%)	54 ( 5.4%)	1003
Blood creatinine increased	41 ( 4.1%)	206 ( 20.6%)	539 ( 54.0%)	212 ( 21.2%)	998
Intentional overdose	399 ( 40.0%)	337 ( 33.8%)	231 ( 23.1%)	31 ( 3.1%)	998
Pulmonary embolism	50 ( 5.1%)	194 ( 19.8%)	566 ( 57.6%)	172 ( 17.5%)	982
Gastrooesophageal reflux disease	78 ( 8.1%)	262 ( 27.1%)	494 ( 51.1%)	133 ( 13.8%)	967
Cardiac disorder	35 ( 3.6%)	114 ( 11.9%)	514 ( 53.4%)	299 ( 31.1%)	962
Product storage error	109 ( 11.3%)	185 ( 19.3%)	501 ( 52.1%)	166 ( 17.3%)	961
Herpes zoster	23 ( 2.4%)	224 ( 23.3%)	570 ( 59.3%)	144 ( 15.0%)	961
Injection site bruising	109 ( 11.4%)	305 ( 31.9%)	468 ( 48.9%)	75 ( 7.8%)	957
Device malfunction	284 ( 29.8%)	188 ( 19.7%)	389 ( 40.8%)	92 ( 9.7%)	953
Leukopenia	79 ( 8.3%)	277 ( 29.2%)	458 ( 48.2%)	136 ( 14.3%)	950
Drug abuse	225 ( 23.7%)	516 ( 54.3%)	173 ( 18.2%)	36 ( 3.8%)	950
Dysphonia	21 ( 2.2%)	204 ( 21.7%)	519 ( 55.1%)	198 ( 21.0%)	942
Arthropathy	35 ( 3.7%)	349 ( 37.0%)	451 ( 47.9%)	107 ( 11.4%)	942
Lower respiratory tract infection	31 ( 3.3%)	385 ( 41.2%)	408 ( 43.7%)	110 ( 11.8%)	934

### Reaction Summary Table Derived Age Group

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Thrombosis	46 ( 4.9%)	163 ( 17.5%)	513 ( 55.0%)	211 ( 22.6%)	933
Cardiac arrest	114 ( 12.3%)	266 ( 28.7%)	408 ( 44.0%)	139 ( 15.0%)	927
Wrong technique in device usage process	494 ( 53.3%)	104 ( 11.2%)	254 ( 27.4%)	74 ( 8.0%)	926
Device use error	257 ( 27.8%)	64 ( 6.9%)	397 ( 42.9%)	207 ( 22.4%)	925
Upper respiratory tract infection	89 ( 9.7%)	281 ( 30.6%)	459 ( 50.1%)	88 ( 9.6%)	917
Respiratory failure	134 ( 14.6%)	172 ( 18.8%)	471 ( 51.4%)	139 ( 15.2%)	916
Hypoacusis	13 ( 1.4%)	56 ( 6.1%)	388 ( 42.5%)	457 ( 50.0%)	914
Drug ineffective for unapproved indication	195 ( 21.3%)	286 ( 31.3%)	363 ( 39.7%)	70 ( 7.7%)	914
Anaphylactic reaction	147 ( 16.2%)	305 ( 33.5%)	367 ( 40.3%)	91 ( 10.0%)	910
Cytokine release syndrome	64 ( 7.0%)	152 ( 16.7%)	594 ( 65.3%)	99 ( 10.9%)	909
Interstitial lung disease	23 ( 2.5%)	90 ( 9.9%)	518 ( 57.0%)	277 ( 30.5%)	908
Psoriatic arthropathy	18 ( 2.0%)	445 ( 49.1%)	390 ( 43.0%)	53 ( 5.8%)	906
Diabetes mellitus	15 ( 1.7%)	149 ( 16.5%)	589 ( 65.3%)	149 ( 16.5%)	902
Pancytopenia	85 ( 9.4%)	152 ( 16.9%)	485 ( 53.8%)	180 ( 20.0%)	902
Pleural effusion	71 ( 7.9%)	162 ( 18.0%)	451 ( 50.1%)	216 ( 24.0%)	900
Cataract	18 ( 2.0%)	65 ( 7.3%)	630 ( 70.3%)	183 ( 20.4%)	896
Swelling face	98 ( 10.9%)	315 ( 35.2%)	407 ( 45.4%)	76 ( 8.5%)	896
Treatment noncompliance	167 ( 18.7%)	299 ( 33.4%)	292 ( 32.6%)	137 ( 15.3%)	895
Suicide attempt	307 ( 34.4%)	371 ( 41.6%)	191 ( 21.4%)	23 ( 2.6%)	892
Therapeutic response decreased	181 ( 20.5%)	268 ( 30.4%)	365 ( 41.3%)	69 ( 7.8%)	883
Neck pain	31 ( 3.5%)	295 ( 33.5%)	470 ( 53.4%)	84 ( 9.5%)	880
C-reactive protein increased	98 ( 11.2%)	305 ( 34.7%)	409 ( 46.6%)	66 ( 7.5%)	878
Oedema	63 ( 7.2%)	277 ( 31.8%)	398 ( 45.6%)	134 ( 15.4%)	872
Therapeutic product effect decreased	72 ( 8.3%)	383 ( 44.1%)	332 ( 38.2%)	81 ( 9.3%)	868
Rash pruritic	69 ( 8.0%)	218 ( 25.4%)	454 ( 52.9%)	118 ( 13.7%)	859
Bone pain	31 ( 3.6%)	242 ( 28.3%)	498 ( 58.3%)	83 ( 9.7%)	854
Adverse drug reaction	127 ( 15.1%)	251 ( 29.8%)	356 ( 42.3%)	108 ( 12.8%)	842

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Intentional dose omission	104 ( 12.4%)	257 ( 30.6%)	363 ( 43.2%)	116 ( 13.8%)	840
Hyponatraemia	28 ( 3.4%)	95 ( 11.4%)	404 ( 48.6%)	305 ( 36.7%)	832
Alanine aminotransferase increased	113 ( 13.6%)	226 ( 27.3%)	417 ( 50.3%)	73 ( 8.8%)	829
Flushing	68 ( 8.2%)	267 ( 32.4%)	414 ( 50.2%)	76 ( 9.2%)	825
Blister	47 ( 5.7%)	351 ( 42.5%)	339 ( 41.1%)	88 ( 10.7%)	825
Therapeutic response shortened	171 ( 20.8%)	298 ( 36.2%)	319 ( 38.7%)	36 ( 4.4%)	824
Feeling hot	65 ( 8.0%)	295 ( 36.3%)	378 ( 46.6%)	74 ( 9.1%)	812
Emotional distress	117 ( 14.5%)	319 ( 39.4%)	341 ( 42.2%)	32 ( 4.0%)	809
Hypokalaemia	75 ( 9.3%)	141 ( 17.5%)	426 ( 52.9%)	164 ( 20.3%)	806
Depressed mood	83 ( 10.3%)	225 ( 28.1%)	416 ( 51.9%)	78 ( 9.7%)	802
Adverse event	60 ( 7.5%)	158 ( 19.7%)	397 ( 49.5%)	187 ( 23.3%)	802
Septic shock	85 ( 10.7%)	122 ( 15.4%)	445 ( 56.0%)	142 ( 17.9%)	794
Hypothyroidism	28 ( 3.5%)	189 ( 23.8%)	470 ( 59.3%)	106 ( 13.4%)	793
Underdose	243 ( 30.7%)	181 ( 22.9%)	265 ( 33.5%)	102 ( 12.9%)	791
Chronic kidney disease	25 ( 3.2%)	230 ( 29.1%)	436 ( 55.2%)	99 ( 12.5%)	790
Lung disorder	28 ( 3.5%)	233 ( 29.5%)	422 ( 53.5%)	106 ( 13.4%)	789
Flatulence	82 ( 10.4%)	172 ( 21.8%)	432 ( 54.8%)	102 ( 12.9%)	788
Therapy non-responder	128 ( 16.5%)	299 ( 38.5%)	282 ( 36.3%)	68 ( 8.8%)	777
Burning sensation	44 ( 5.7%)	224 ( 29.2%)	423 ( 55.2%)	75 ( 9.8%)	766
Product prescribing error	171 ( 22.4%)	140 ( 18.3%)	300 ( 39.3%)	153 ( 20.0%)	764
Dysgeusia	30 ( 3.9%)	170 ( 22.3%)	442 ( 58.0%)	120 ( 15.7%)	762
Needle issue	144 ( 18.9%)	216 ( 28.4%)	333 ( 43.8%)	68 ( 8.9%)	761
Exposure via skin contact	161 ( 21.2%)	163 ( 21.4%)	357 ( 46.9%)	80 ( 10.5%)	761
Vertigo	44 ( 5.8%)	215 ( 28.3%)	404 ( 53.1%)	98 ( 12.9%)	761
Gait inability	40 ( 5.3%)	238 ( 31.3%)	371 ( 48.8%)	111 ( 14.6%)	760
Lactic acidosis	63 ( 8.3%)	131 ( 17.4%)	438 ( 58.0%)	123 ( 16.3%)	755
Cellulitis	61 ( 8.1%)	199 ( 26.4%)	404 ( 53.5%)	91 ( 12.1%)	755

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Therapy cessation	99 ( 13.1%)	165 ( 21.9%)	371 ( 49.2%)	119 ( 15.8%)	754
Osteoarthritis	3 ( 0.4%)	220 ( 29.6%)	422 ( 56.8%)	98 ( 13.2%)	743
Device mechanical issue	647 ( 87.3%)	28 ( 3.8%)	52 ( 7.0%)	14 ( 1.9%)	741
Hepatic function abnormal	49 ( 6.6%)	157 ( 21.3%)	412 ( 55.8%)	120 ( 16.3%)	738
Brain fog	41 ( 5.6%)	222 ( 30.2%)	388 ( 52.8%)	84 ( 11.4%)	735
Neoplasm malignant	9 ( 1.2%)	127 ( 17.3%)	450 ( 61.5%)	146 ( 19.9%)	732
Exposure during pregnancy	155 ( 21.2%)	546 ( 74.7%)	30 ( 4.1%)	0 ( 0.0%)	731
Blood cholesterol increased	16 ( 2.2%)	296 ( 40.6%)	363 ( 49.8%)	54 ( 7.4%)	729
Bradycardia	80 ( 11.0%)	144 ( 19.8%)	298 ( 40.9%)	206 ( 28.3%)	728
Frequent bowel movements	75 ( 10.3%)	260 ( 35.8%)	335 ( 46.1%)	56 ( 7.7%)	726
Osteoporosis	15 ( 2.1%)	214 ( 30.0%)	406 ( 56.9%)	79 ( 11.1%)	714
Agitation	164 ( 23.1%)	227 ( 32.0%)	240 ( 33.9%)	78 ( 11.0%)	709
Nephrolithiasis	25 ( 3.6%)	186 ( 26.4%)	433 ( 61.5%)	60 ( 8.5%)	704
Rash erythematous	126 ( 18.0%)	189 ( 27.0%)	334 ( 47.7%)	51 ( 7.3%)	700
Incorrect dose administered by device	181 ( 26.0%)	97 ( 13.9%)	313 ( 45.0%)	105 ( 15.1%)	696
Surgery	47 ( 6.8%)	235 ( 33.9%)	342 ( 49.3%)	70 ( 10.1%)	694
Aspartate aminotransferase increased	103 ( 14.9%)	166 ( 24.0%)	341 ( 49.2%)	83 ( 12.0%)	693
Speech disorder	41 ( 5.9%)	160 ( 23.1%)	364 ( 52.6%)	127 ( 18.4%)	692
Liver disorder	35 ( 5.1%)	234 ( 34.3%)	324 ( 47.4%)	90 ( 13.2%)	683
Viral infection	149 ( 21.8%)	195 ( 28.6%)	283 ( 41.4%)	56 ( 8.2%)	683
Multiple organ dysfunction syndrome	152 ( 22.4%)	124 ( 18.2%)	294 ( 43.2%)	110 ( 16.2%)	680
Amnesia	24 ( 3.6%)	244 ( 36.1%)	312 ( 46.2%)	95 ( 14.1%)	675
Injection site pruritus	104 ( 15.4%)	247 ( 36.6%)	286 ( 42.4%)	37 ( 5.5%)	674
Extra dose administered	79 ( 11.8%)	176 ( 26.3%)	339 ( 50.7%)	74 ( 11.1%)	668
Limb injury	103 ( 15.5%)	148 ( 22.3%)	316 ( 47.5%)	98 ( 14.7%)	665
Plasma cell myeloma	1 ( 0.2%)	55 ( 8.3%)	453 ( 68.3%)	154 ( 23.2%)	663
Dyspnoea exertional	14 ( 2.1%)	94 ( 14.2%)	386 ( 58.4%)	167 ( 25.3%)	661

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Eye pruritus	126 ( 19.1%)	157 ( 23.8%)	334 ( 50.7%)	42 ( 6.4%)	659
Ocular hyperaemia	143 ( 21.8%)	163 ( 24.8%)	298 ( 45.4%)	52 ( 7.9%)	656
Ear infection	159 ( 24.6%)	210 ( 32.5%)	255 ( 39.5%)	22 ( 3.4%)	646
Throat irritation	41 ( 6.4%)	272 ( 42.3%)	289 ( 44.9%)	41 ( 6.4%)	643
Completed suicide	82 ( 12.8%)	243 ( 37.9%)	273 ( 42.6%)	43 ( 6.7%)	641
Gastrointestinal haemorrhage	57 ( 8.9%)	91 ( 14.2%)	304 ( 47.4%)	189 ( 29.5%)	641
Angioedema	57 ( 9.0%)	219 ( 34.6%)	288 ( 45.5%)	69 ( 10.9%)	633
Lethargy	101 ( 16.0%)	177 ( 28.1%)	258 ( 41.0%)	94 ( 14.9%)	630
Respiratory tract infection	70 ( 11.1%)	134 ( 21.3%)	362 ( 57.5%)	64 ( 10.2%)	630
Hypoglycaemia	57 ( 9.1%)	138 ( 21.9%)	306 ( 48.6%)	128 ( 20.3%)	629
Colitis	50 ( 8.0%)	121 ( 19.4%)	383 ( 61.3%)	71 ( 11.4%)	625
Pulmonary oedema	34 ( 5.4%)	120 ( 19.2%)	331 ( 53.0%)	140 ( 22.4%)	625
Heart rate decreased	35 ( 5.7%)	109 ( 17.7%)	368 ( 59.7%)	104 ( 16.9%)	616
Contraindicated product administered	21 ( 3.4%)	294 ( 47.7%)	234 ( 38.0%)	67 ( 10.9%)	616
Drug-induced liver injury	66 ( 10.7%)	208 ( 33.9%)	272 ( 44.3%)	68 ( 11.1%)	614
Injection site mass	52 ( 8.5%)	140 ( 22.8%)	337 ( 55.0%)	84 ( 13.7%)	613
Ill-defined disorder	38 ( 6.2%)	249 ( 40.8%)	271 ( 44.4%)	53 ( 8.7%)	611
Cognitive disorder	51 ( 8.3%)	145 ( 23.7%)	265 ( 43.4%)	150 ( 24.5%)	611
Renal disorder	16 ( 2.6%)	95 ( 15.6%)	360 ( 59.1%)	138 ( 22.7%)	609
SARS-CoV-2 test positive	38 ( 6.3%)	239 ( 39.8%)	278 ( 46.3%)	46 ( 7.7%)	601
Product availability issue	145 ( 24.2%)	186 ( 31.0%)	227 ( 37.8%)	42 ( 7.0%)	600
Hypoxia	84 ( 14.0%)	137 ( 22.9%)	259 ( 43.3%)	118 ( 19.7%)	598
Red blood cell count decreased	15 ( 2.5%)	95 ( 15.9%)	358 ( 59.9%)	130 ( 21.7%)	598
Multiple sclerosis	26 ( 4.4%)	338 ( 56.6%)	224 ( 37.5%)	9 ( 1.5%)	597
Limb discomfort	27 ( 4.5%)	166 ( 27.9%)	327 ( 55.0%)	75 ( 12.6%)	595
Disturbance in attention	72 ( 12.1%)	192 ( 32.3%)	281 ( 47.3%)	49 ( 8.2%)	594
Blood pressure systolic increased	8 ( 1.4%)	80 ( 13.6%)	418 ( 71.2%)	81 ( 13.8%)	587

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Eye irritation	102 ( 17.4%)	168 ( 28.6%)	249 ( 42.4%)	68 ( 11.6%)	587
Rectal haemorrhage	57 ( 9.8%)	171 ( 29.3%)	276 ( 47.3%)	79 ( 13.6%)	583
Skin disorder	36 ( 6.2%)	133 ( 22.9%)	312 ( 53.6%)	101 ( 17.4%)	582
Fluid retention	17 ( 2.9%)	147 ( 25.3%)	305 ( 52.6%)	111 ( 19.1%)	580
Delirium	62 ( 10.8%)	145 ( 25.2%)	202 ( 35.1%)	167 ( 29.0%)	576
Road traffic accident	51 ( 8.9%)	273 ( 47.4%)	205 ( 35.6%)	47 ( 8.2%)	576
Taste disorder	9 ( 1.6%)	143 ( 25.0%)	309 ( 53.9%)	112 ( 19.5%)	573
Skin discolouration	92 ( 16.2%)	114 ( 20.0%)	275 ( 48.3%)	88 ( 15.5%)	569
Irritability	160 ( 28.1%)	188 ( 33.0%)	187 ( 32.9%)	34 ( 6.0%)	569
Eye pain	50 ( 8.8%)	156 ( 27.6%)	275 ( 48.7%)	84 ( 14.9%)	565
Systemic lupus erythematosus	21 ( 3.7%)	373 ( 66.0%)	161 ( 28.5%)	10 ( 1.8%)	565
Medication error	70 ( 12.4%)	240 ( 42.6%)	173 ( 30.7%)	81 ( 14.4%)	564
Electrocardiogram QT prolonged	107 ( 19.1%)	144 ( 25.7%)	224 ( 39.9%)	86 ( 15.3%)	561
Hepatic cytolysis	67 ( 11.9%)	134 ( 23.9%)	276 ( 49.2%)	84 ( 15.0%)	561
Intestinal obstruction	37 ( 6.7%)	125 ( 22.5%)	312 ( 56.1%)	82 ( 14.7%)	556
Depressed level of consciousness	91 ( 16.5%)	118 ( 21.3%)	224 ( 40.5%)	120 ( 21.7%)	553
Cystitis	23 ( 4.2%)	104 ( 19.0%)	313 ( 57.2%)	107 ( 19.6%)	547
Hyperkalaemia	24 ( 4.4%)	69 ( 12.6%)	292 ( 53.4%)	162 ( 29.6%)	547
Wound	33 ( 6.1%)	294 ( 53.9%)	178 ( 32.7%)	40 ( 7.3%)	545
Haemarthrosis	224 ( 41.2%)	218 ( 40.1%)	92 ( 16.9%)	10 ( 1.8%)	544
Multiple sclerosis relapse	34 ( 6.3%)	325 ( 59.9%)	182 ( 33.5%)	2 ( 0.4%)	543
Deep vein thrombosis	25 ( 4.6%)	122 ( 22.6%)	305 ( 56.6%)	87 ( 16.1%)	539
Fungal infection	35 ( 6.6%)	178 ( 33.4%)	267 ( 50.1%)	53 ( 9.9%)	533
Head injury	106 ( 20.0%)	65 ( 12.2%)	221 ( 41.6%)	139 ( 26.2%)	531
Injection site reaction	86 ( 16.3%)	204 ( 38.6%)	217 ( 41.0%)	22 ( 4.2%)	529
Skin lesion	41 ( 7.8%)	137 ( 26.0%)	281 ( 53.3%)	68 ( 12.9%)	527
Movement disorder	27 ( 5.1%)	151 ( 28.7%)	264 ( 50.1%)	85 ( 16.1%)	527

### Reaction Summary Table

#### Derived Age Group

	<i>Group1 (0-25)</i> (N=&AGEGRP1)	<i>Group2 (26-50)</i> (N=&AGEGRP2)	<i>Group3 (51-75)</i> (N=&AGEGRP3)	<i>Group4 (75+)</i> (N=&AGEGRP4)	<i>Total</i> (N=&AGEGRP5)
Skin fissures	132 ( 25.2%)	175 ( 33.4%)	189 ( 36.1%)	28 ( 5.3%)	524
Acne	103 ( 19.7%)	214 ( 41.0%)	179 ( 34.3%)	26 ( 5.0%)	522
Pollakiuria	25 ( 4.8%)	108 ( 20.7%)	289 ( 55.4%)	100 ( 19.2%)	522
Liver injury	49 ( 9.4%)	251 ( 48.2%)	183 ( 35.1%)	38 ( 7.3%)	521
Lacrimation increased	37 ( 7.1%)	103 ( 19.8%)	320 ( 61.4%)	61 ( 11.7%)	521
Rash macular	75 ( 14.5%)	119 ( 22.9%)	248 ( 47.8%)	77 ( 14.8%)	519
Metabolic acidosis	107 ( 20.6%)	103 ( 19.8%)	230 ( 44.3%)	79 ( 15.2%)	519
Injury	55 ( 10.6%)	273 ( 52.8%)	152 ( 29.4%)	37 ( 7.2%)	517
Device expulsion	135 ( 26.2%)	368 ( 71.3%)	12 ( 2.3%)	1 ( 0.2%)	516
Rhabdomyolysis	61 ( 11.8%)	147 ( 28.5%)	212 ( 41.2%)	95 ( 18.4%)	515
Lymphadenopathy	72 ( 14.0%)	144 ( 28.0%)	251 ( 48.7%)	48 ( 9.3%)	515
Epilepsy	115 ( 22.4%)	186 ( 36.2%)	150 ( 29.2%)	63 ( 12.3%)	514
Oral herpes	50 ( 9.8%)	194 ( 38.1%)	242 ( 47.5%)	23 ( 4.5%)	509
Product prescribing issue	77 ( 15.2%)	96 ( 19.0%)	243 ( 48.1%)	89 ( 17.6%)	505
Mental disorder	64 ( 12.7%)	205 ( 40.7%)	181 ( 35.9%)	54 ( 10.7%)	504
Coma	68 ( 13.5%)	157 ( 31.2%)	215 ( 42.7%)	64 ( 12.7%)	504
Pancreatitis	53 ( 10.6%)	159 ( 31.7%)	240 ( 47.8%)	50 ( 10.0%)	502
Chronic obstructive pulmonary disease	2 ( 0.4%)	36 ( 7.2%)	326 ( 65.1%)	137 ( 27.3%)	501
Impaired healing	14 ( 2.8%)	280 ( 56.1%)	172 ( 34.5%)	33 ( 6.6%)	499
Fibromyalgia	11 ( 2.2%)	277 ( 55.5%)	195 ( 39.1%)	16 ( 3.2%)	499
White blood cell count increased	50 ( 10.0%)	165 ( 33.1%)	232 ( 46.6%)	51 ( 10.2%)	498
Pneumonitis	19 ( 3.8%)	82 ( 16.5%)	318 ( 63.9%)	79 ( 15.9%)	498
Arrhythmia	29 ( 5.8%)	129 ( 26.0%)	245 ( 49.3%)	94 ( 18.9%)	497
Drug dependence	76 ( 15.5%)	242 ( 49.3%)	143 ( 29.1%)	30 ( 6.1%)	491
Nervousness	23 ( 4.7%)	100 ( 20.5%)	273 ( 55.9%)	92 ( 18.9%)	488
Full blood count abnormal	11 ( 2.3%)	56 ( 11.5%)	328 ( 67.2%)	93 ( 19.1%)	488
Dysarthria	47 ( 9.7%)	145 ( 30.0%)	222 ( 45.9%)	70 ( 14.5%)	484



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Drug reaction with eosinophilia and systemic symptoms	113 ( 23.4%)	127 ( 26.3%)	168 ( 34.9%)	74 ( 15.4%)	482
Product communication issue	41 ( 8.5%)	75 ( 15.6%)	277 ( 57.6%)	88 ( 18.3%)	481
Knee arthroplasty	3 ( 0.6%)	101 ( 21.0%)	327 ( 68.0%)	50 ( 10.4%)	481
Neuralgia	15 ( 3.1%)	177 ( 36.9%)	229 ( 47.7%)	59 ( 12.3%)	480
Bone density decreased	12 ( 2.5%)	221 ( 46.2%)	223 ( 46.7%)	22 ( 4.6%)	478
Device dislocation	96 ( 20.1%)	243 ( 50.9%)	94 ( 19.7%)	44 ( 9.2%)	477
Dyskinesia	101 ( 21.2%)	87 ( 18.3%)	210 ( 44.1%)	78 ( 16.4%)	476
Hyperglycaemia	55 ( 11.6%)	80 ( 16.9%)	244 ( 51.6%)	94 ( 19.9%)	473
Therapy partial responder	79 ( 16.7%)	123 ( 26.0%)	235 ( 49.7%)	36 ( 7.6%)	473
Dysuria	26 ( 5.5%)	120 ( 25.4%)	238 ( 50.4%)	88 ( 18.6%)	472
Type 2 diabetes mellitus	3 ( 0.6%)	265 ( 56.1%)	172 ( 36.4%)	32 ( 6.8%)	472
Eye swelling	74 ( 15.7%)	138 ( 29.3%)	216 ( 45.9%)	43 ( 9.1%)	471
Full blood count decreased	6 ( 1.3%)	42 ( 8.9%)	268 ( 56.9%)	155 ( 32.9%)	471
Anaphylactic shock	39 ( 8.3%)	139 ( 29.6%)	247 ( 52.6%)	45 ( 9.6%)	470
Conjunctivitis	110 ( 23.6%)	132 ( 28.3%)	183 ( 39.2%)	42 ( 9.0%)	467
Device information output issue	424 ( 92.0%)	15 ( 3.3%)	18 ( 3.9%)	4 ( 0.9%)	461
Night sweats	8 ( 1.8%)	221 ( 48.7%)	178 ( 39.2%)	47 ( 10.4%)	454
Joint injury	93 ( 20.5%)	91 ( 20.0%)	208 ( 45.8%)	62 ( 13.7%)	454
Device use issue	240 ( 53.0%)	57 ( 12.6%)	114 ( 25.2%)	42 ( 9.3%)	453
COVID-19 pneumonia	10 ( 2.2%)	108 ( 23.9%)	252 ( 55.8%)	82 ( 18.1%)	452
Foetal exposure during pregnancy	446 ( 99.1%)	4 ( 0.9%)	0 ( 0.0%)	0 ( 0.0%)	450
Aggression	141 ( 31.4%)	138 ( 30.7%)	97 ( 21.6%)	73 ( 16.3%)	449
Unevaluable event	25 ( 5.6%)	106 ( 23.8%)	224 ( 50.2%)	91 ( 20.4%)	446
Dysstasia	21 ( 4.7%)	113 ( 25.3%)	232 ( 52.0%)	80 ( 17.9%)	446
Bacterial infection	54 ( 12.1%)	95 ( 21.3%)	239 ( 53.7%)	57 ( 12.8%)	445
Urinary retention	46 ( 10.4%)	81 ( 18.2%)	186 ( 41.9%)	131 ( 29.5%)	444
Anhedonia	25 ( 5.7%)	215 ( 48.8%)	199 ( 45.1%)	2 ( 0.5%)	441

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Synovitis	22 ( 5.0%)	259 ( 59.0%)	142 ( 32.3%)	16 ( 3.6%)	439
Blindness	22 ( 5.0%)	101 ( 23.1%)	221 ( 50.5%)	94 ( 21.5%)	438
Syringe issue	46 ( 10.6%)	60 ( 13.9%)	202 ( 46.7%)	125 ( 28.9%)	433
Ascites	32 ( 7.4%)	99 ( 22.9%)	226 ( 52.3%)	75 ( 17.4%)	432
Diverticulitis	1 ( 0.2%)	67 ( 15.6%)	284 ( 66.0%)	78 ( 18.1%)	430
Tinnitus	17 ( 4.0%)	141 ( 32.9%)	231 ( 54.0%)	39 ( 9.1%)	428
Product administration interrupted	80 ( 18.7%)	183 ( 42.9%)	136 ( 31.9%)	28 ( 6.6%)	427
Altered state of consciousness	49 ( 11.5%)	115 ( 27.0%)	156 ( 36.6%)	106 ( 24.9%)	426
Therapeutic response unexpected	35 ( 8.2%)	82 ( 19.3%)	223 ( 52.5%)	85 ( 20.0%)	425
Pneumonia aspiration	35 ( 8.3%)	67 ( 15.8%)	171 ( 40.3%)	151 ( 35.6%)	424
Liver function test increased	21 ( 5.0%)	122 ( 28.8%)	211 ( 49.8%)	70 ( 16.5%)	424
Cardiac failure congestive	6 ( 1.4%)	50 ( 11.9%)	205 ( 48.7%)	160 ( 38.0%)	421
Hip fracture	1 ( 0.2%)	17 ( 4.0%)	212 ( 50.5%)	190 ( 45.2%)	420
Body temperature increased	90 ( 21.5%)	119 ( 28.5%)	159 ( 38.0%)	50 ( 12.0%)	418
Poor quality device used	349 ( 83.9%)	26 ( 6.3%)	30 ( 7.2%)	11 ( 2.6%)	416
Intercepted product preparation error	18 ( 4.3%)	22 ( 5.3%)	221 ( 53.3%)	154 ( 37.1%)	415
Sneezing	29 ( 7.0%)	91 ( 21.9%)	240 ( 57.8%)	55 ( 13.3%)	415
Eye disorder	23 ( 5.5%)	95 ( 22.9%)	210 ( 50.6%)	87 ( 21.0%)	415
Incorrect route of product administration	54 ( 13.0%)	131 ( 31.6%)	157 ( 37.8%)	73 ( 17.6%)	415
Cerebral haemorrhage	21 ( 5.1%)	52 ( 12.6%)	209 ( 50.5%)	132 ( 31.9%)	414
Lymphocyte count decreased	21 ( 5.1%)	121 ( 29.2%)	239 ( 57.7%)	33 ( 8.0%)	414
Urinary incontinence	25 ( 6.1%)	102 ( 24.7%)	208 ( 50.4%)	78 ( 18.9%)	413
Laboratory test abnormal	26 ( 6.3%)	67 ( 16.3%)	233 ( 56.6%)	86 ( 20.9%)	412
Restlessness	63 ( 15.4%)	137 ( 33.6%)	165 ( 40.4%)	43 ( 10.5%)	408
Respiratory disorder	62 ( 15.3%)	113 ( 27.8%)	185 ( 45.6%)	46 ( 11.3%)	406
Product dispensing error	49 ( 12.1%)	59 ( 14.6%)	215 ( 53.2%)	81 ( 20.0%)	404
Skin burning sensation	49 ( 12.1%)	137 ( 33.9%)	191 ( 47.3%)	27 ( 6.7%)	404

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Disorientation	25 ( 6.2%)	117 ( 29.1%)	181 ( 45.0%)	79 ( 19.7%)	402
Kidney infection	19 ( 4.7%)	119 ( 29.7%)	219 ( 54.6%)	44 ( 11.0%)	401
Localised infection	18 ( 4.5%)	68 ( 17.2%)	241 ( 60.9%)	69 ( 17.4%)	396
Irritable bowel syndrome	7 ( 1.8%)	267 ( 67.4%)	103 ( 26.0%)	19 ( 4.8%)	396
Hypersomnia	53 ( 13.4%)	115 ( 29.1%)	159 ( 40.3%)	68 ( 17.2%)	395
Musculoskeletal pain	2 ( 0.5%)	189 ( 48.0%)	177 ( 44.9%)	26 ( 6.6%)	394
Adrenal insufficiency	36 ( 9.1%)	101 ( 25.6%)	203 ( 51.5%)	54 ( 13.7%)	394
Gastritis	37 ( 9.4%)	114 ( 28.9%)	208 ( 52.8%)	35 ( 8.9%)	394
Middle insomnia	43 ( 10.9%)	132 ( 33.5%)	191 ( 48.5%)	28 ( 7.1%)	394
Crying	117 ( 29.9%)	124 ( 31.7%)	127 ( 32.5%)	23 ( 5.9%)	391
Cholelithiasis	18 ( 4.6%)	100 ( 25.6%)	223 ( 57.2%)	49 ( 12.6%)	390
Blood pressure fluctuation	5 ( 1.3%)	80 ( 20.5%)	251 ( 64.4%)	54 ( 13.8%)	390
Sciatica	4 ( 1.0%)	172 ( 44.2%)	171 ( 44.0%)	42 ( 10.8%)	389
Blood potassium decreased	18 ( 4.6%)	53 ( 13.6%)	262 ( 67.4%)	56 ( 14.4%)	389
Lip swelling	59 ( 15.4%)	101 ( 26.4%)	161 ( 42.0%)	62 ( 16.2%)	383
Sleep disorder due to a general medical condition	72 ( 18.8%)	73 ( 19.1%)	201 ( 52.6%)	36 ( 9.4%)	382
Product quality issue	57 ( 15.0%)	123 ( 32.3%)	150 ( 39.4%)	51 ( 13.4%)	381
Generalised tonic-clonic seizure	144 ( 37.9%)	120 ( 31.6%)	91 ( 23.9%)	25 ( 6.6%)	380
Product administration error	46 ( 12.1%)	82 ( 21.6%)	172 ( 45.3%)	80 ( 21.1%)	380
Accidental overdose	96 ( 25.3%)	78 ( 20.5%)	153 ( 40.3%)	53 ( 13.9%)	380
Glossodynia	5 ( 1.3%)	256 ( 67.5%)	100 ( 26.4%)	18 ( 4.7%)	379
Impaired quality of life	69 ( 18.4%)	129 ( 34.3%)	158 ( 42.0%)	20 ( 5.3%)	376
Panic attack	66 ( 17.6%)	172 ( 45.7%)	125 ( 33.2%)	13 ( 3.5%)	376
Procedural pain	50 ( 13.3%)	127 ( 33.9%)	171 ( 45.6%)	27 ( 7.2%)	375
Pericarditis	10 ( 2.7%)	265 ( 71.0%)	91 ( 24.4%)	7 ( 1.9%)	373
Blood pressure abnormal	11 ( 3.0%)	48 ( 12.9%)	223 ( 59.9%)	90 ( 24.2%)	372
Joint stiffness	16 ( 4.3%)	128 ( 34.4%)	196 ( 52.7%)	32 ( 8.6%)	372

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hypocalcaemia	24 ( 6.5%)	54 ( 14.6%)	202 ( 54.4%)	91 ( 24.5%)	371
Proteinuria	41 ( 11.1%)	93 ( 25.1%)	169 ( 45.7%)	67 ( 18.1%)	370
Poor quality sleep	27 ( 7.3%)	104 ( 28.2%)	183 ( 49.6%)	55 ( 14.9%)	369
Hypophagia	44 ( 11.9%)	59 ( 16.0%)	174 ( 47.2%)	92 ( 24.9%)	369
Emotional disorder	122 ( 33.1%)	99 ( 26.8%)	123 ( 33.3%)	25 ( 6.8%)	369
Hallucination, visual	39 ( 10.6%)	43 ( 11.7%)	159 ( 43.2%)	127 ( 34.5%)	368
Nightmare	31 ( 8.4%)	106 ( 28.8%)	179 ( 48.6%)	52 ( 14.1%)	368
Lower limb fracture	13 ( 3.6%)	141 ( 38.5%)	162 ( 44.3%)	50 ( 13.7%)	366
Palmar-plantar erythrodysaesthesia syndrome	8 ( 2.2%)	55 ( 15.1%)	260 ( 71.2%)	42 ( 11.5%)	365
Abdominal pain lower	51 ( 14.0%)	132 ( 36.2%)	152 ( 41.6%)	30 ( 8.2%)	365
Skin haemorrhage	86 ( 23.6%)	97 ( 26.6%)	142 ( 38.9%)	40 ( 11.0%)	365
Breast cancer	1 ( 0.3%)	102 ( 28.0%)	218 ( 59.9%)	43 ( 11.8%)	364
Shock	51 ( 14.0%)	88 ( 24.2%)	177 ( 48.6%)	48 ( 13.2%)	364
Hepatotoxicity	52 ( 14.4%)	76 ( 21.0%)	189 ( 52.2%)	45 ( 12.4%)	362
Feeling cold	9 ( 2.5%)	107 ( 29.6%)	208 ( 57.6%)	37 ( 10.2%)	361
Injection site rash	72 ( 19.9%)	118 ( 32.7%)	153 ( 42.4%)	18 ( 5.0%)	361
Blood glucose decreased	31 ( 8.6%)	59 ( 16.3%)	210 ( 58.2%)	61 ( 16.9%)	361
Rash maculo-papular	37 ( 10.2%)	72 ( 19.9%)	215 ( 59.6%)	37 ( 10.2%)	361
Mental status changes	71 ( 19.7%)	77 ( 21.4%)	151 ( 41.9%)	61 ( 16.9%)	360
Psychotic disorder	52 ( 14.4%)	147 ( 40.8%)	138 ( 38.3%)	23 ( 6.4%)	360
Ear pain	32 ( 8.9%)	136 ( 37.9%)	168 ( 46.8%)	23 ( 6.4%)	359
Device delivery system issue	189 ( 52.6%)	31 ( 8.6%)	105 ( 29.2%)	34 ( 9.5%)	359
Staphylococcal infection	44 ( 12.3%)	88 ( 24.6%)	171 ( 47.8%)	55 ( 15.4%)	358
Blood bilirubin increased	45 ( 12.6%)	70 ( 19.6%)	216 ( 60.5%)	26 ( 7.3%)	357
Throat tightness	44 ( 12.3%)	155 ( 43.4%)	136 ( 38.1%)	22 ( 6.2%)	357
Injection site urticaria	93 ( 26.1%)	137 ( 38.4%)	120 ( 33.6%)	7 ( 2.0%)	357
Diabetic ketoacidosis	34 ( 9.5%)	115 ( 32.2%)	174 ( 48.7%)	34 ( 9.5%)	357

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blood creatine phosphokinase increased	43 ( 12.1%)	78 ( 21.9%)	162 ( 45.5%)	73 ( 20.5%)	356
Cardio-respiratory arrest	36 ( 10.1%)	77 ( 21.6%)	177 ( 49.7%)	66 ( 18.5%)	356
Ankylosing spondylitis	14 ( 3.9%)	181 ( 50.8%)	144 ( 40.4%)	17 ( 4.8%)	356
Device defective	120 ( 33.8%)	70 ( 19.7%)	126 ( 35.5%)	39 ( 11.0%)	355
Seasonal allergy	25 ( 7.1%)	81 ( 22.9%)	207 ( 58.5%)	41 ( 11.6%)	354
Dementia	3 ( 0.8%)	7 ( 2.0%)	126 ( 35.6%)	218 ( 61.6%)	354
Unresponsive to stimuli	60 ( 17.0%)	65 ( 18.4%)	174 ( 49.3%)	54 ( 15.3%)	353
Drug eruption	29 ( 8.2%)	74 ( 21.0%)	195 ( 55.4%)	54 ( 15.3%)	352
Drug effective for unapproved indication	54 ( 15.3%)	80 ( 22.7%)	161 ( 45.7%)	57 ( 16.2%)	352
Mucosal inflammation	51 ( 14.6%)	70 ( 20.0%)	186 ( 53.1%)	43 ( 12.3%)	350
Cytopenia	38 ( 10.9%)	28 ( 8.0%)	202 ( 57.9%)	81 ( 23.2%)	349
Aphasia	23 ( 6.6%)	96 ( 27.5%)	174 ( 49.9%)	56 ( 16.0%)	349
Skin ulcer	10 ( 2.9%)	74 ( 21.2%)	211 ( 60.5%)	54 ( 15.5%)	349
Haemoptysis	25 ( 7.2%)	67 ( 19.3%)	174 ( 50.0%)	82 ( 23.6%)	348
Oral pain	32 ( 9.2%)	70 ( 20.2%)	195 ( 56.4%)	49 ( 14.2%)	346
Decreased immune responsiveness	13 ( 3.8%)	109 ( 31.6%)	202 ( 58.6%)	21 ( 6.1%)	345
Gastroenteritis viral	79 ( 23.0%)	86 ( 25.1%)	157 ( 45.8%)	21 ( 6.1%)	343
Obesity	52 ( 15.2%)	203 ( 59.2%)	80 ( 23.3%)	8 ( 2.3%)	343
Feeding disorder	36 ( 10.5%)	63 ( 18.4%)	182 ( 53.1%)	62 ( 18.1%)	343
Drug effect less than expected	47 ( 13.8%)	113 ( 33.1%)	139 ( 40.8%)	42 ( 12.3%)	341
Mouth ulceration	39 ( 11.4%)	93 ( 27.3%)	178 ( 52.2%)	31 ( 9.1%)	341
Pallor	89 ( 26.2%)	91 ( 26.8%)	119 ( 35.0%)	41 ( 12.1%)	340
Clostridium difficile infection	42 ( 12.4%)	76 ( 22.4%)	173 ( 50.9%)	49 ( 14.4%)	340
Hip arthroplasty	1 ( 0.3%)	106 ( 31.3%)	183 ( 54.0%)	49 ( 14.5%)	339
Encephalopathy	65 ( 19.2%)	59 ( 17.4%)	149 ( 44.0%)	66 ( 19.5%)	339
Device adhesion issue	3 ( 0.9%)	52 ( 15.3%)	233 ( 68.7%)	51 ( 15.0%)	339
Poor venous access	67 ( 19.8%)	102 ( 30.2%)	145 ( 42.9%)	24 ( 7.1%)	338

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Exposure to toxic agent	37 ( 10.9%)	107 ( 31.7%)	159 ( 47.0%)	35 ( 10.4%)	338
Haematoma	57 ( 17.0%)	79 ( 23.6%)	126 ( 37.6%)	73 ( 21.8%)	335
Insurance issue	51 ( 15.2%)	99 ( 29.6%)	164 ( 49.0%)	21 ( 6.3%)	335
Serotonin syndrome	89 ( 26.6%)	115 ( 34.3%)	104 ( 31.0%)	27 ( 8.1%)	335
Rib fracture	3 ( 0.9%)	50 ( 15.0%)	194 ( 58.1%)	87 ( 26.0%)	334
Hand deformity	1 ( 0.3%)	244 ( 73.3%)	79 ( 23.7%)	9 ( 2.7%)	333
Metastases to bone	2 ( 0.6%)	75 ( 22.5%)	216 ( 64.9%)	40 ( 12.0%)	333
Prescribed underdose	47 ( 14.2%)	135 ( 40.7%)	115 ( 34.6%)	35 ( 10.5%)	332
Osteopenia	11 ( 3.3%)	116 ( 34.9%)	190 ( 57.2%)	15 ( 4.5%)	332
Incorrect product administration duration	24 ( 7.3%)	62 ( 18.7%)	143 ( 43.2%)	102 ( 30.8%)	331
Haematuria	37 ( 11.2%)	47 ( 14.2%)	160 ( 48.3%)	87 ( 26.3%)	331
Transient ischaemic attack	3 ( 0.9%)	50 ( 15.1%)	167 ( 50.5%)	111 ( 33.5%)	331
Abortion spontaneous	59 ( 17.9%)	266 ( 80.9%)	4 ( 1.2%)	0 ( 0.0%)	329
Ageusia	7 ( 2.1%)	69 ( 21.1%)	185 ( 56.6%)	66 ( 20.2%)	327
Erectile dysfunction	36 ( 11.0%)	149 ( 45.7%)	121 ( 37.1%)	20 ( 6.1%)	326
Sedation	52 ( 16.0%)	91 ( 27.9%)	132 ( 40.5%)	51 ( 15.6%)	326
Osteonecrosis	21 ( 6.5%)	154 ( 47.4%)	139 ( 42.8%)	11 ( 3.4%)	325
Tooth disorder	18 ( 5.6%)	79 ( 24.4%)	181 ( 55.9%)	46 ( 14.2%)	324
Hepatic failure	32 ( 9.9%)	84 ( 26.1%)	164 ( 50.9%)	42 ( 13.0%)	322
Spinal operation	7 ( 2.2%)	39 ( 12.1%)	234 ( 72.9%)	41 ( 12.8%)	321
Immune effector cell-associated neurotoxicity syndrom	28 ( 8.8%)	62 ( 19.4%)	192 ( 60.2%)	37 ( 11.6%)	319
Presyncope	23 ( 7.2%)	78 ( 24.5%)	153 ( 48.1%)	64 ( 20.1%)	318
Respiratory distress	50 ( 15.7%)	62 ( 19.5%)	149 ( 46.9%)	57 ( 17.9%)	318
Blood test abnormal	18 ( 5.7%)	59 ( 18.6%)	174 ( 54.7%)	67 ( 21.1%)	318
Transaminases increased	51 ( 16.1%)	64 ( 20.2%)	143 ( 45.1%)	59 ( 18.6%)	317
Mood altered	90 ( 28.8%)	103 ( 32.9%)	88 ( 28.1%)	32 ( 10.2%)	313
Scratch	94 ( 30.0%)	69 ( 22.0%)	119 ( 38.0%)	31 ( 9.9%)	313

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Sinus disorder	11 ( 3.5%)	61 ( 19.6%)	186 ( 59.6%)	54 ( 17.3%)	312
Cardiogenic shock	41 ( 13.2%)	111 ( 35.7%)	102 ( 32.8%)	57 ( 18.3%)	311
Pulmonary fibrosis	3 ( 1.0%)	91 ( 29.3%)	157 ( 50.5%)	60 ( 19.3%)	311
Eating disorder	35 ( 11.3%)	72 ( 23.2%)	156 ( 50.3%)	47 ( 15.2%)	310
Neurotoxicity	62 ( 20.1%)	66 ( 21.4%)	146 ( 47.4%)	34 ( 11.0%)	308
Foot fracture	10 ( 3.2%)	92 ( 29.9%)	165 ( 53.6%)	41 ( 13.3%)	308
Intervertebral disc protrusion	7 ( 2.3%)	97 ( 31.6%)	183 ( 59.6%)	20 ( 6.5%)	307
Product complaint	20 ( 6.5%)	69 ( 22.5%)	167 ( 54.6%)	50 ( 16.3%)	306
Lymphopenia	42 ( 13.7%)	115 ( 37.6%)	132 ( 43.1%)	17 ( 5.6%)	306
Immunodeficiency	17 ( 5.6%)	103 ( 33.8%)	161 ( 52.8%)	24 ( 7.9%)	305
Hepatic steatosis	21 ( 6.9%)	106 ( 34.9%)	153 ( 50.3%)	24 ( 7.9%)	304
Agranulocytosis	19 ( 6.3%)	71 ( 23.4%)	167 ( 54.9%)	47 ( 15.5%)	304
Acute myocardial infarction	13 ( 4.3%)	69 ( 22.8%)	159 ( 52.5%)	62 ( 20.5%)	303
Cholestasis	20 ( 6.6%)	60 ( 19.9%)	147 ( 48.7%)	75 ( 24.8%)	302
Pericardial effusion	37 ( 12.3%)	69 ( 22.8%)	150 ( 49.7%)	46 ( 15.2%)	302
Device physical property issue	191 ( 63.5%)	32 ( 10.6%)	54 ( 17.9%)	24 ( 8.0%)	301
Hepatitis	30 ( 10.0%)	97 ( 32.3%)	142 ( 47.3%)	31 ( 10.3%)	300
Helicobacter infection	12 ( 4.0%)	228 ( 76.0%)	56 ( 18.7%)	4 ( 1.3%)	300
Pemphigus	2 ( 0.7%)	232 ( 77.6%)	60 ( 20.1%)	5 ( 1.7%)	299
Prescribed overdose	22 ( 7.4%)	168 ( 56.4%)	77 ( 25.8%)	31 ( 10.4%)	298
Product distribution issue	28 ( 9.4%)	76 ( 25.6%)	139 ( 46.8%)	54 ( 18.2%)	297
Infusion site pain	39 ( 13.1%)	75 ( 25.3%)	148 ( 49.8%)	35 ( 11.8%)	297
Tooth loss	21 ( 7.1%)	134 ( 45.1%)	126 ( 42.4%)	16 ( 5.4%)	297
Musculoskeletal discomfort	18 ( 6.1%)	72 ( 24.3%)	170 ( 57.4%)	36 ( 12.2%)	296
Acute respiratory distress syndrome	70 ( 23.7%)	64 ( 21.7%)	132 ( 44.7%)	29 ( 9.8%)	295
Device occlusion	60 ( 20.3%)	53 ( 18.0%)	147 ( 49.8%)	35 ( 11.9%)	295
Obstructive airways disorder	18 ( 6.1%)	62 ( 21.0%)	141 ( 47.8%)	74 ( 25.1%)	295

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Toothache	13 ( 4.4%)	105 ( 35.6%)	149 ( 50.5%)	28 ( 9.5%)	295
Eosinophilia	21 ( 7.1%)	64 ( 21.7%)	144 ( 48.8%)	66 ( 22.4%)	295
Skin laceration	46 ( 15.6%)	57 ( 19.4%)	136 ( 46.3%)	55 ( 18.7%)	294
Pancreatitis acute	43 ( 14.6%)	95 ( 32.3%)	130 ( 44.2%)	26 ( 8.8%)	294
Swollen tongue	11 ( 3.7%)	110 ( 37.4%)	134 ( 45.6%)	39 ( 13.3%)	294
Acute respiratory failure	23 ( 7.8%)	63 ( 21.4%)	151 ( 51.4%)	57 ( 19.4%)	294
Candida infection	36 ( 12.3%)	76 ( 25.9%)	141 ( 48.1%)	40 ( 13.7%)	293
Angina pectoris	11 ( 3.8%)	61 ( 20.9%)	162 ( 55.5%)	58 ( 19.9%)	292
Folliculitis	4 ( 1.4%)	243 ( 83.2%)	42 ( 14.4%)	3 ( 1.0%)	292
Hypomagnesaemia	6 ( 2.1%)	25 ( 8.6%)	159 ( 54.5%)	102 ( 34.9%)	292
Cerebral infarction	6 ( 2.1%)	31 ( 10.7%)	143 ( 49.3%)	110 ( 37.9%)	290
Drug resistance	42 ( 14.5%)	77 ( 26.6%)	136 ( 47.1%)	34 ( 11.8%)	289
Pulmonary mass	9 ( 3.1%)	50 ( 17.4%)	172 ( 59.7%)	57 ( 19.8%)	288
Bursitis	1 ( 0.3%)	196 ( 68.1%)	83 ( 28.8%)	8 ( 2.8%)	288
Thyroid disorder	7 ( 2.4%)	52 ( 18.1%)	195 ( 67.7%)	34 ( 11.8%)	288
Deafness	17 ( 5.9%)	37 ( 12.9%)	127 ( 44.3%)	106 ( 36.9%)	287
Faeces discoloured	31 ( 10.9%)	43 ( 15.1%)	145 ( 50.9%)	66 ( 23.2%)	285
Tooth infection	14 ( 4.9%)	85 ( 29.8%)	158 ( 55.4%)	28 ( 9.8%)	285
Musculoskeletal chest pain	10 ( 3.5%)	66 ( 23.2%)	178 ( 62.5%)	31 ( 10.9%)	285
Respiratory syncytial virus infection	94 ( 33.1%)	50 ( 17.6%)	111 ( 39.1%)	29 ( 10.2%)	284
Haemophagocytic lymphohistiocytosis	63 ( 22.3%)	84 ( 29.7%)	123 ( 43.5%)	13 ( 4.6%)	283
Joint range of motion decreased	8 ( 2.8%)	181 ( 64.0%)	70 ( 24.7%)	24 ( 8.5%)	283
Head discomfort	27 ( 9.6%)	82 ( 29.1%)	134 ( 47.5%)	39 ( 13.8%)	282
Lung neoplasm malignant	0 ( 0.0%)	16 ( 5.7%)	188 ( 66.9%)	77 ( 27.4%)	281
Pharyngeal swelling	21 ( 7.5%)	116 ( 41.4%)	117 ( 41.8%)	26 ( 9.3%)	280
Hyperthyroidism	14 ( 5.0%)	82 ( 29.3%)	158 ( 56.4%)	26 ( 9.3%)	280
Uveitis	38 ( 13.6%)	88 ( 31.5%)	122 ( 43.7%)	31 ( 11.1%)	279



### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Skin irritation	54 ( 19.4%)	83 ( 29.7%)	121 ( 43.4%)	21 ( 7.5%)	279
Body temperature decreased	24 ( 8.6%)	59 ( 21.2%)	172 ( 61.9%)	23 ( 8.3%)	278
Haemorrhoids	16 ( 5.8%)	65 ( 23.5%)	156 ( 56.3%)	40 ( 14.4%)	277
Pain in jaw	11 ( 4.0%)	78 ( 28.2%)	154 ( 55.6%)	34 ( 12.3%)	277
Drug level increased	46 ( 16.6%)	96 ( 34.7%)	115 ( 41.5%)	20 ( 7.2%)	277
Femur fracture	15 ( 5.4%)	22 ( 7.9%)	144 ( 52.0%)	96 ( 34.7%)	277
Spinal pain	10 ( 3.6%)	102 ( 36.8%)	151 ( 54.5%)	14 ( 5.1%)	277
Product use complaint	75 ( 27.2%)	44 ( 15.9%)	100 ( 36.2%)	57 ( 20.7%)	276
Pharyngitis streptococcal	93 ( 33.8%)	100 ( 36.4%)	71 ( 25.8%)	11 ( 4.0%)	275
Metastases to liver	0 ( 0.0%)	61 ( 22.3%)	187 ( 68.2%)	26 ( 9.5%)	274
Device failure	92 ( 33.7%)	62 ( 22.7%)	97 ( 35.5%)	22 ( 8.1%)	273
Sleep apnoea syndrome	22 ( 8.1%)	94 ( 34.4%)	149 ( 54.6%)	8 ( 2.9%)	273
Diplopia	16 ( 5.9%)	67 ( 24.5%)	154 ( 56.4%)	36 ( 13.2%)	273
Pain of skin	18 ( 6.6%)	74 ( 27.2%)	156 ( 57.4%)	24 ( 8.8%)	272
Respiratory tract congestion	20 ( 7.4%)	65 ( 24.1%)	153 ( 56.7%)	32 ( 11.9%)	270
Melaena	12 ( 4.5%)	36 ( 13.4%)	108 ( 40.1%)	113 ( 42.0%)	269
Gynaecomastia	180 ( 66.9%)	35 ( 13.0%)	36 ( 13.4%)	18 ( 6.7%)	269
Glomerular filtration rate decreased	6 ( 2.2%)	43 ( 16.1%)	165 ( 61.8%)	53 ( 19.9%)	267
Anger	50 ( 18.7%)	113 ( 42.3%)	85 ( 31.8%)	19 ( 7.1%)	267
Retching	57 ( 21.3%)	74 ( 27.7%)	109 ( 40.8%)	27 ( 10.1%)	267
Vascular device infection	71 ( 26.6%)	71 ( 26.6%)	114 ( 42.7%)	11 ( 4.1%)	267
Mental impairment	31 ( 11.7%)	81 ( 30.5%)	125 ( 47.0%)	29 ( 10.9%)	266
Aphonia	8 ( 3.0%)	63 ( 23.8%)	156 ( 58.9%)	38 ( 14.3%)	265
Pneumothorax	33 ( 12.5%)	45 ( 17.0%)	130 ( 49.1%)	57 ( 21.5%)	265
Blood alkaline phosphatase increased	14 ( 5.3%)	50 ( 18.9%)	162 ( 61.1%)	39 ( 14.7%)	265
Dermatitis	40 ( 15.2%)	75 ( 28.4%)	126 ( 47.7%)	23 ( 8.7%)	264
Duodenal ulcer perforation	1 ( 0.4%)	240 ( 90.9%)	20 ( 7.6%)	3 ( 1.1%)	264

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Choking	29 ( 11.0%)	46 ( 17.5%)	134 ( 51.0%)	54 ( 20.5%)	263
Tubulointerstitial nephritis	28 ( 10.7%)	47 ( 17.9%)	159 ( 60.7%)	28 ( 10.7%)	262
Leukocytosis	35 ( 13.4%)	59 ( 22.5%)	141 ( 53.8%)	27 ( 10.3%)	262
Nervous system disorder	29 ( 11.1%)	102 ( 39.1%)	105 ( 40.2%)	25 ( 9.6%)	261
Neutrophil count normal	26 ( 10.0%)	117 ( 45.0%)	112 ( 43.1%)	5 ( 1.9%)	260
Skin infection	36 ( 13.9%)	83 ( 32.0%)	118 ( 45.6%)	22 ( 8.5%)	259
Eye infection	19 ( 7.4%)	59 ( 22.9%)	149 ( 57.8%)	31 ( 12.0%)	258
Polyneuropathy	10 ( 3.9%)	44 ( 17.1%)	167 ( 64.7%)	37 ( 14.3%)	258
Jaundice	15 ( 5.8%)	55 ( 21.4%)	127 ( 49.4%)	60 ( 23.3%)	257
Abnormal behaviour	61 ( 23.9%)	83 ( 32.5%)	68 ( 26.7%)	43 ( 16.9%)	255
Faeces soft	42 ( 16.5%)	70 ( 27.6%)	112 ( 44.1%)	30 ( 11.8%)	254
Hernia	8 ( 3.2%)	53 ( 20.9%)	158 ( 62.5%)	34 ( 13.4%)	253
Laryngitis	7 ( 2.8%)	91 ( 36.0%)	137 ( 54.2%)	18 ( 7.1%)	253
Expired product administered	32 ( 12.7%)	37 ( 14.7%)	117 ( 46.4%)	66 ( 26.2%)	252
Product supply issue	32 ( 12.7%)	65 ( 25.8%)	125 ( 49.6%)	30 ( 11.9%)	252
Autoimmune disorder	15 ( 6.0%)	152 ( 60.6%)	74 ( 29.5%)	10 ( 4.0%)	251
Upper limb fracture	24 ( 9.6%)	24 ( 9.6%)	158 ( 62.9%)	45 ( 17.9%)	251
Therapeutic reaction time decreased	34 ( 13.5%)	109 ( 43.4%)	97 ( 38.6%)	11 ( 4.4%)	251
Prostate cancer	0 ( 0.0%)	6 ( 2.4%)	183 ( 73.2%)	61 ( 24.4%)	250
Hypertransaminaemia	46 ( 18.5%)	60 ( 24.1%)	111 ( 44.6%)	32 ( 12.9%)	249
Toxic epidermal necrolysis	15 ( 6.0%)	57 ( 22.9%)	134 ( 53.8%)	43 ( 17.3%)	249
Secretion discharge	42 ( 16.9%)	73 ( 29.3%)	112 ( 45.0%)	22 ( 8.8%)	249
Gamma-glutamyltransferase increased	29 ( 11.6%)	52 ( 20.9%)	138 ( 55.4%)	30 ( 12.0%)	249
Parkinson's disease	0 ( 0.0%)	9 ( 3.6%)	142 ( 57.0%)	98 ( 39.4%)	249
Hepatic cirrhosis	5 ( 2.0%)	77 ( 31.0%)	142 ( 57.3%)	24 ( 9.7%)	248
Tachypnoea	51 ( 20.6%)	67 ( 27.0%)	102 ( 41.1%)	28 ( 11.3%)	248
Spinal fracture	5 ( 2.0%)	27 ( 10.9%)	140 ( 56.5%)	76 ( 30.6%)	248

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Glycosylated haemoglobin increased	3 ( 1.2%)	38 ( 15.4%)	164 ( 66.7%)	41 ( 16.7%)	246
Ankle fracture	5 ( 2.0%)	72 ( 29.4%)	147 ( 60.0%)	21 ( 8.6%)	245
Haematocrit decreased	16 ( 6.6%)	58 ( 23.9%)	137 ( 56.4%)	32 ( 13.2%)	243
Pharyngitis	44 ( 18.2%)	80 ( 33.1%)	107 ( 44.2%)	11 ( 4.5%)	242
Ligament sprain	42 ( 17.4%)	53 ( 22.0%)	126 ( 52.3%)	20 ( 8.3%)	241
Anti-cyclic citrullinated peptide antibody positive	1 ( 0.4%)	206 ( 85.5%)	34 ( 14.1%)	0 ( 0.0%)	241
Myoclonus	37 ( 15.4%)	75 ( 31.3%)	98 ( 40.8%)	30 ( 12.5%)	240
Sinus congestion	15 ( 6.3%)	64 ( 26.7%)	140 ( 58.3%)	21 ( 8.8%)	240
Chromaturia	20 ( 8.3%)	55 ( 22.9%)	122 ( 50.8%)	43 ( 17.9%)	240
Multiple fractures	3 ( 1.3%)	107 ( 44.6%)	122 ( 50.8%)	8 ( 3.3%)	240
Gastroenteritis	57 ( 23.8%)	66 ( 27.5%)	95 ( 39.6%)	22 ( 9.2%)	240
Blood iron decreased	17 ( 7.1%)	61 ( 25.4%)	122 ( 50.8%)	40 ( 16.7%)	240
Temperature intolerance	11 ( 4.6%)	93 ( 38.9%)	122 ( 51.0%)	13 ( 5.4%)	239
Face oedema	35 ( 14.6%)	81 ( 33.9%)	108 ( 45.2%)	15 ( 6.3%)	239
Sputum discoloured	12 ( 5.0%)	32 ( 13.4%)	142 ( 59.7%)	52 ( 21.8%)	238
Gout	0 ( 0.0%)	36 ( 15.3%)	139 ( 58.9%)	61 ( 25.8%)	236
Nonspecific reaction	3 ( 1.3%)	12 ( 5.1%)	129 ( 54.7%)	92 ( 39.0%)	236
Immune system disorder	11 ( 4.7%)	47 ( 19.9%)	155 ( 65.7%)	23 ( 9.7%)	236
Muscle twitching	33 ( 14.0%)	87 ( 37.0%)	100 ( 42.6%)	15 ( 6.4%)	235
Increased appetite	43 ( 18.3%)	73 ( 31.1%)	102 ( 43.4%)	17 ( 7.2%)	235
Haematemesis	22 ( 9.4%)	62 ( 26.4%)	102 ( 43.4%)	49 ( 20.9%)	235
Thrombotic microangiopathy	50 ( 21.3%)	54 ( 23.0%)	112 ( 47.7%)	19 ( 8.1%)	235
Lip dry	30 ( 12.8%)	165 ( 70.2%)	28 ( 11.9%)	12 ( 5.1%)	235
Myocarditis	25 ( 10.7%)	72 ( 30.8%)	98 ( 41.9%)	39 ( 16.7%)	234
Withdrawal syndrome	34 ( 14.5%)	81 ( 34.6%)	107 ( 45.7%)	12 ( 5.1%)	234
Muscle spasticity	11 ( 4.7%)	113 ( 48.7%)	101 ( 43.5%)	7 ( 3.0%)	232
Sinus tachycardia	59 ( 25.4%)	67 ( 28.9%)	94 ( 40.5%)	12 ( 5.2%)	232

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Ventricular tachycardia	15 ( 6.5%)	94 ( 40.5%)	76 ( 32.8%)	47 ( 20.3%)	232
Grip strength decreased	3 ( 1.3%)	139 ( 59.9%)	82 ( 35.3%)	8 ( 3.4%)	232
Blood urine present	12 ( 5.2%)	60 ( 26.0%)	120 ( 51.9%)	39 ( 16.9%)	231
Nodule	10 ( 4.3%)	55 ( 23.8%)	145 ( 62.8%)	21 ( 9.1%)	231
Pneumocystis jirovecii pneumonia	30 ( 13.0%)	36 ( 15.6%)	137 ( 59.3%)	28 ( 12.1%)	231
Multiple allergies	16 ( 7.0%)	30 ( 13.1%)	155 ( 67.7%)	28 ( 12.2%)	229
Bone loss	1 ( 0.4%)	116 ( 50.9%)	107 ( 46.9%)	4 ( 1.8%)	228
Glaucoma	18 ( 7.9%)	39 ( 17.1%)	120 ( 52.6%)	51 ( 22.4%)	228
Platelet count increased	33 ( 14.5%)	51 ( 22.4%)	127 ( 55.7%)	17 ( 7.5%)	228
Paraesthesia oral	10 ( 4.4%)	72 ( 31.6%)	136 ( 59.6%)	10 ( 4.4%)	228
Coronavirus infection	6 ( 2.6%)	70 ( 30.8%)	106 ( 46.7%)	45 ( 19.8%)	227
Orthostatic hypotension	4 ( 1.8%)	24 ( 10.6%)	109 ( 48.2%)	89 ( 39.4%)	226
Ischaemic stroke	3 ( 1.3%)	24 ( 10.6%)	135 ( 59.7%)	64 ( 28.3%)	226
Cytomegalovirus infection	49 ( 21.7%)	46 ( 20.4%)	112 ( 49.6%)	19 ( 8.4%)	226
Muscle injury	6 ( 2.7%)	185 ( 82.2%)	24 ( 10.7%)	10 ( 4.4%)	225
Acute myeloid leukaemia	20 ( 8.9%)	39 ( 17.3%)	117 ( 52.0%)	49 ( 21.8%)	225
Back disorder	3 ( 1.3%)	30 ( 13.4%)	141 ( 62.9%)	50 ( 22.3%)	224
Bone disorder	4 ( 1.8%)	33 ( 14.7%)	150 ( 67.0%)	37 ( 16.5%)	224
Delusion	17 ( 7.6%)	52 ( 23.2%)	100 ( 44.6%)	55 ( 24.6%)	224
Circulatory collapse	35 ( 15.7%)	48 ( 21.5%)	96 ( 43.0%)	44 ( 19.7%)	223
Osteonecrosis of jaw	1 ( 0.5%)	17 ( 7.7%)	150 ( 67.6%)	54 ( 24.3%)	222
Eructation	20 ( 9.0%)	36 ( 16.3%)	138 ( 62.4%)	27 ( 12.2%)	221
Rheumatic fever	0 ( 0.0%)	197 ( 89.1%)	24 ( 10.9%)	0 ( 0.0%)	221
Stevens-Johnson syndrome	20 ( 9.0%)	65 ( 29.4%)	103 ( 46.6%)	33 ( 14.9%)	221
Skin cancer	0 ( 0.0%)	20 ( 9.0%)	135 ( 61.1%)	66 ( 29.9%)	221
Restless legs syndrome	8 ( 3.6%)	63 ( 28.6%)	123 ( 55.9%)	26 ( 11.8%)	220
Initial insomnia	39 ( 17.8%)	72 ( 32.9%)	93 ( 42.5%)	15 ( 6.8%)	219

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Sickle cell anaemia with crisis	83 ( 37.9%)	102 ( 46.6%)	34 ( 15.5%)	0 ( 0.0%)	219
Blood sodium decreased	9 ( 4.1%)	28 ( 12.8%)	132 ( 60.3%)	50 ( 22.8%)	219
Red blood cell sedimentation rate increased	23 ( 10.5%)	83 ( 37.9%)	100 ( 45.7%)	13 ( 5.9%)	219
Blood lactate dehydrogenase increased	43 ( 19.6%)	38 ( 17.4%)	113 ( 51.6%)	25 ( 11.4%)	219
Oropharyngeal discomfort	17 ( 7.8%)	64 ( 29.5%)	112 ( 51.6%)	24 ( 11.1%)	217
Pneumonia bacterial	15 ( 6.9%)	31 ( 14.3%)	118 ( 54.4%)	53 ( 24.4%)	217
Blood pressure diastolic decreased	8 ( 3.7%)	53 ( 24.4%)	125 ( 57.6%)	31 ( 14.3%)	217
Fear	24 ( 11.1%)	72 ( 33.3%)	98 ( 45.4%)	22 ( 10.2%)	216
Post procedural complication	17 ( 7.9%)	61 ( 28.2%)	108 ( 50.0%)	30 ( 13.9%)	216
Acute hepatic failure	60 ( 27.8%)	40 ( 18.5%)	98 ( 45.4%)	18 ( 8.3%)	216
Weight fluctuation	16 ( 7.4%)	47 ( 21.9%)	127 ( 59.1%)	25 ( 11.6%)	215
Hallucination, auditory	42 ( 19.5%)	61 ( 28.4%)	91 ( 42.3%)	21 ( 9.8%)	215
Symptom recurrence	19 ( 8.9%)	81 ( 37.9%)	102 ( 47.7%)	12 ( 5.6%)	214
Cold sweat	29 ( 13.6%)	58 ( 27.1%)	104 ( 48.6%)	23 ( 10.7%)	214
Basal cell carcinoma	0 ( 0.0%)	30 ( 14.0%)	144 ( 67.3%)	40 ( 18.7%)	214
Rash papular	23 ( 10.7%)	54 ( 25.2%)	110 ( 51.4%)	27 ( 12.6%)	214
Accident	28 ( 13.1%)	38 ( 17.8%)	108 ( 50.7%)	39 ( 18.3%)	213
Bacteraemia	22 ( 10.4%)	56 ( 26.4%)	107 ( 50.5%)	27 ( 12.7%)	212
Product administered at inappropriate site	30 ( 14.2%)	53 ( 25.1%)	95 ( 45.0%)	33 ( 15.6%)	211
Device related infection	46 ( 21.8%)	62 ( 29.4%)	87 ( 41.2%)	16 ( 7.6%)	211
Renal injury	10 ( 4.7%)	70 ( 33.2%)	116 ( 55.0%)	15 ( 7.1%)	211
Intercepted product administration error	6 ( 2.8%)	28 ( 13.3%)	137 ( 64.9%)	40 ( 19.0%)	211
Carpal tunnel syndrome	6 ( 2.9%)	44 ( 21.0%)	137 ( 65.2%)	23 ( 11.0%)	210
Anosmia	7 ( 3.3%)	81 ( 38.8%)	105 ( 50.2%)	16 ( 7.7%)	209
Oral candidiasis	11 ( 5.3%)	46 ( 22.0%)	118 ( 56.5%)	34 ( 16.3%)	209
Pulmonary toxicity	9 ( 4.3%)	21 ( 10.0%)	120 ( 57.4%)	59 ( 28.2%)	209
Nocturia	2 ( 1.0%)	46 ( 22.0%)	117 ( 56.0%)	44 ( 21.1%)	209

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Heart rate irregular	9 ( 4.3%)	41 ( 19.6%)	115 ( 55.0%)	44 ( 21.1%)	209
Hypercalcaemia	10 ( 4.8%)	33 ( 15.8%)	115 ( 55.0%)	51 ( 24.4%)	209
Disseminated intravascular coagulation	33 ( 15.9%)	42 ( 20.2%)	109 ( 52.4%)	24 ( 11.5%)	208
Premature delivery	44 ( 21.2%)	164 ( 78.8%)	0 ( 0.0%)	0 ( 0.0%)	208
C-reactive protein abnormal	7 ( 3.4%)	158 ( 76.0%)	41 ( 19.7%)	2 ( 1.0%)	208
Vasculitis	14 ( 6.7%)	53 ( 25.5%)	126 ( 60.6%)	15 ( 7.2%)	208
Drug withdrawal syndrome	25 ( 12.0%)	102 ( 49.0%)	61 ( 29.3%)	20 ( 9.6%)	208
Knee operation	3 ( 1.4%)	30 ( 14.5%)	145 ( 70.0%)	29 ( 14.0%)	207
Muscle tightness	11 ( 5.3%)	81 ( 39.1%)	95 ( 45.9%)	20 ( 9.7%)	207
Abscess	26 ( 12.6%)	66 ( 31.9%)	91 ( 44.0%)	24 ( 11.6%)	207
Rheumatoid factor positive	1 ( 0.5%)	160 ( 77.3%)	45 ( 21.7%)	1 ( 0.5%)	207
Sensitivity to weather change	13 ( 6.3%)	43 ( 20.9%)	128 ( 62.1%)	22 ( 10.7%)	206
Photophobia	23 ( 11.2%)	77 ( 37.4%)	92 ( 44.7%)	14 ( 6.8%)	206
Myasthenia gravis	10 ( 4.9%)	38 ( 18.5%)	82 ( 40.0%)	75 ( 36.6%)	205
Anal incontinence	10 ( 4.9%)	54 ( 26.3%)	112 ( 54.6%)	29 ( 14.1%)	205
Neutrophil count increased	13 ( 6.3%)	61 ( 29.8%)	116 ( 56.6%)	15 ( 7.3%)	205
Poisoning	35 ( 17.2%)	126 ( 61.8%)	34 ( 16.7%)	9 ( 4.4%)	204
Poisoning deliberate	59 ( 28.9%)	69 ( 33.8%)	61 ( 29.9%)	15 ( 7.4%)	204
Electrolyte imbalance	27 ( 13.3%)	47 ( 23.2%)	105 ( 51.7%)	24 ( 11.8%)	203
Immune-mediated enterocolitis	1 ( 0.5%)	27 ( 13.3%)	144 ( 70.9%)	31 ( 15.3%)	203
Tendonitis	7 ( 3.5%)	74 ( 36.6%)	111 ( 55.0%)	10 ( 5.0%)	202
Gastric ulcer	15 ( 7.4%)	38 ( 18.8%)	115 ( 56.9%)	34 ( 16.8%)	202
Fracture	9 ( 4.5%)	31 ( 15.3%)	94 ( 46.5%)	68 ( 33.7%)	202
Vaginal haemorrhage	30 ( 14.9%)	108 ( 53.7%)	54 ( 26.9%)	9 ( 4.5%)	201
Dermatitis allergic	31 ( 15.4%)	64 ( 31.8%)	95 ( 47.3%)	11 ( 5.5%)	201
Respiratory rate increased	35 ( 17.5%)	39 ( 19.5%)	102 ( 51.0%)	24 ( 12.0%)	200
Skin plaque	13 ( 6.5%)	68 ( 34.2%)	110 ( 55.3%)	8 ( 4.0%)	199

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Small intestinal obstruction	13 ( 6.6%)	62 ( 31.3%)	97 ( 49.0%)	26 ( 13.1%)	198
Muscle rigidity	22 ( 11.1%)	48 ( 24.2%)	99 ( 50.0%)	29 ( 14.6%)	198
Quality of life decreased	23 ( 11.7%)	77 ( 39.1%)	85 ( 43.1%)	12 ( 6.1%)	197
Complication associated with device	44 ( 22.3%)	76 ( 38.6%)	60 ( 30.5%)	17 ( 8.6%)	197
Cyst	15 ( 7.6%)	56 ( 28.4%)	113 ( 57.4%)	13 ( 6.6%)	197
Gastrointestinal infection	15 ( 7.7%)	72 ( 36.7%)	90 ( 45.9%)	19 ( 9.7%)	196
Product substitution issue	14 ( 7.1%)	63 ( 32.1%)	83 ( 42.3%)	36 ( 18.4%)	196
Hypervolaemia	12 ( 6.1%)	37 ( 18.9%)	110 ( 56.1%)	37 ( 18.9%)	196
Mood swings	41 ( 21.0%)	71 ( 36.4%)	66 ( 33.8%)	17 ( 8.7%)	195
Decreased activity	12 ( 6.2%)	52 ( 26.7%)	109 ( 55.9%)	22 ( 11.3%)	195
Hypokinesia	9 ( 4.6%)	68 ( 34.9%)	107 ( 54.9%)	11 ( 5.6%)	195
Gallbladder disorder	5 ( 2.6%)	46 ( 23.7%)	125 ( 64.4%)	18 ( 9.3%)	194
Tumour marker increased	1 ( 0.5%)	35 ( 18.0%)	130 ( 67.0%)	28 ( 14.4%)	194
Hemiparesis	14 ( 7.2%)	57 ( 29.4%)	98 ( 50.5%)	25 ( 12.9%)	194
Muscle atrophy	16 ( 8.2%)	46 ( 23.7%)	110 ( 56.7%)	22 ( 11.3%)	194
Liver function test abnormal	27 ( 14.0%)	34 ( 17.6%)	103 ( 53.4%)	29 ( 15.0%)	193
Injury associated with device	15 ( 7.8%)	42 ( 21.8%)	94 ( 48.7%)	42 ( 21.8%)	193
Wrist fracture	13 ( 6.7%)	23 ( 11.9%)	118 ( 61.1%)	39 ( 20.2%)	193
Brain oedema	26 ( 13.5%)	75 ( 38.9%)	83 ( 43.0%)	9 ( 4.7%)	193
Appendicitis	35 ( 18.2%)	60 ( 31.3%)	64 ( 33.3%)	33 ( 17.2%)	192
Pulmonary hypertension	25 ( 13.1%)	38 ( 19.9%)	85 ( 44.5%)	43 ( 22.5%)	191
Defaecation urgency	11 ( 5.8%)	51 ( 26.7%)	100 ( 52.4%)	29 ( 15.2%)	191
Cyanosis	39 ( 20.5%)	47 ( 24.7%)	88 ( 46.3%)	16 ( 8.4%)	190
Nephropathy toxic	29 ( 15.3%)	48 ( 25.3%)	85 ( 44.7%)	28 ( 14.7%)	190
Peritonitis	18 ( 9.5%)	40 ( 21.1%)	95 ( 50.0%)	37 ( 19.5%)	190
Progressive multifocal leukoencephalopathy	5 ( 2.6%)	67 ( 35.3%)	92 ( 48.4%)	26 ( 13.7%)	190
Back injury	3 ( 1.6%)	79 ( 41.8%)	79 ( 41.8%)	28 ( 14.8%)	189

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> (N=&AGEGRP1)	<i>Group2 (26-50)</i> (N=&AGEGRP2)	<i>Group3 (51-75)</i> (N=&AGEGRP3)	<i>Group4 (75+)</i> (N=&AGEGRP4)	<i>Total</i> (N=&AGEGRP5)
Foot deformity	10 ( 5.3%)	61 ( 32.3%)	104 ( 55.0%)	14 ( 7.4%)	189
Dermatitis contact	15 ( 8.0%)	69 ( 36.7%)	87 ( 46.3%)	17 ( 9.0%)	188
Wound infection	1 ( 0.5%)	108 ( 57.4%)	66 ( 35.1%)	13 ( 6.9%)	188
Tumour lysis syndrome	13 ( 6.9%)	33 ( 17.6%)	106 ( 56.4%)	36 ( 19.1%)	188
Blood potassium increased	10 ( 5.3%)	23 ( 12.2%)	108 ( 57.4%)	47 ( 25.0%)	188
Blood glucose abnormal	7 ( 3.7%)	36 ( 19.3%)	119 ( 63.6%)	25 ( 13.4%)	187
Clostridium difficile colitis	31 ( 16.6%)	36 ( 19.3%)	85 ( 45.5%)	35 ( 18.7%)	187
Coronary artery disease	1 ( 0.5%)	15 ( 8.1%)	119 ( 64.0%)	51 ( 27.4%)	186
Upper gastrointestinal haemorrhage	13 ( 7.0%)	31 ( 16.7%)	93 ( 50.0%)	49 ( 26.3%)	186
Mass	17 ( 9.2%)	33 ( 17.8%)	122 ( 65.9%)	13 ( 7.0%)	185
Blood triglycerides increased	18 ( 9.7%)	68 ( 36.8%)	89 ( 48.1%)	10 ( 5.4%)	185
Aspiration	27 ( 14.7%)	24 ( 13.0%)	64 ( 34.8%)	69 ( 37.5%)	184
Asphyxia	13 ( 7.1%)	97 ( 53.0%)	63 ( 34.4%)	10 ( 5.5%)	183
Pregnancy	19 ( 10.4%)	163 ( 89.1%)	1 ( 0.5%)	0 ( 0.0%)	183
Thirst	11 ( 6.0%)	63 ( 34.4%)	87 ( 47.5%)	22 ( 12.0%)	183
Apathy	19 ( 10.4%)	60 ( 32.8%)	75 ( 41.0%)	29 ( 15.8%)	183
Autism spectrum disorder	176 ( 96.2%)	6 ( 3.3%)	1 ( 0.5%)	0 ( 0.0%)	183
Peripheral coldness	21 ( 11.5%)	38 ( 20.9%)	94 ( 51.6%)	29 ( 15.9%)	182
Second primary malignancy	5 ( 2.7%)	23 ( 12.6%)	134 ( 73.6%)	20 ( 11.0%)	182
Sleep disorder due to general medical condition, inso	4 ( 2.2%)	141 ( 77.5%)	34 ( 18.7%)	3 ( 1.6%)	182
Injection site discharge	40 ( 22.1%)	57 ( 31.5%)	70 ( 38.7%)	14 ( 7.7%)	181
Metastases to lung	2 ( 1.1%)	34 ( 18.8%)	121 ( 66.9%)	24 ( 13.3%)	181
Immune-mediated hepatic disorder	1 ( 0.6%)	32 ( 17.7%)	124 ( 68.5%)	24 ( 13.3%)	181
Swollen joint count increased	0 ( 0.0%)	150 ( 82.9%)	29 ( 16.0%)	2 ( 1.1%)	181
Musculoskeletal disorder	6 ( 3.3%)	40 ( 22.1%)	107 ( 59.1%)	28 ( 15.5%)	181
Immunosuppression	15 ( 8.3%)	49 ( 27.1%)	91 ( 50.3%)	26 ( 14.4%)	181
Ileus	26 ( 14.4%)	44 ( 24.4%)	81 ( 45.0%)	29 ( 16.1%)	180



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Neutrophilia	16 ( 8.9%)	56 ( 31.1%)	100 ( 55.6%)	8 ( 4.4%)	180
Abnormal dreams	7 ( 3.9%)	52 ( 29.1%)	89 ( 49.7%)	31 ( 17.3%)	179
Extrapyramidal disorder	41 ( 22.9%)	52 ( 29.1%)	69 ( 38.5%)	17 ( 9.5%)	179
Impaired work ability	6 ( 3.4%)	85 ( 47.5%)	80 ( 44.7%)	8 ( 4.5%)	179
Tenderness	21 ( 11.7%)	60 ( 33.5%)	91 ( 50.8%)	7 ( 3.9%)	179
Heavy menstrual bleeding	33 ( 18.5%)	141 ( 79.2%)	4 ( 2.2%)	0 ( 0.0%)	178
Bronchopulmonary aspergillosis	19 ( 10.7%)	16 ( 9.0%)	123 ( 69.1%)	20 ( 11.2%)	178
Haemorrhage intracranial	26 ( 14.6%)	27 ( 15.2%)	64 ( 36.0%)	61 ( 34.3%)	178
Hyperbilirubinaemia	24 ( 13.5%)	47 ( 26.4%)	80 ( 44.9%)	27 ( 15.2%)	178
Joint dislocation	19 ( 10.7%)	59 ( 33.3%)	81 ( 45.8%)	18 ( 10.2%)	177
Bronchiectasis	3 ( 1.7%)	21 ( 11.9%)	101 ( 57.1%)	52 ( 29.4%)	177
Injection site warmth	24 ( 13.6%)	58 ( 32.8%)	87 ( 49.2%)	8 ( 4.5%)	177
End stage renal disease	7 ( 4.0%)	72 ( 40.7%)	78 ( 44.1%)	20 ( 11.3%)	177
Diabetes mellitus inadequate control	11 ( 6.2%)	30 ( 16.9%)	101 ( 57.1%)	35 ( 19.8%)	177
Ejection fraction decreased	10 ( 5.7%)	32 ( 18.2%)	110 ( 62.5%)	24 ( 13.6%)	176
Gingival bleeding	25 ( 14.2%)	53 ( 30.1%)	78 ( 44.3%)	20 ( 11.4%)	176
Skin swelling	30 ( 17.1%)	45 ( 25.7%)	87 ( 49.7%)	13 ( 7.4%)	175
Affective disorder	49 ( 28.0%)	56 ( 32.0%)	59 ( 33.7%)	11 ( 6.3%)	175
Akathisia	43 ( 24.6%)	88 ( 50.3%)	39 ( 22.3%)	5 ( 2.9%)	175
Photosensitivity reaction	28 ( 16.0%)	47 ( 26.9%)	77 ( 44.0%)	23 ( 13.1%)	175
Drug level decreased	53 ( 30.3%)	62 ( 35.4%)	53 ( 30.3%)	7 ( 4.0%)	175
Hypoaesthesia oral	17 ( 9.8%)	66 ( 37.9%)	81 ( 46.6%)	10 ( 5.7%)	174
Ulcer	7 ( 4.0%)	42 ( 24.1%)	86 ( 49.4%)	39 ( 22.4%)	174
Mydriasis	82 ( 47.1%)	49 ( 28.2%)	32 ( 18.4%)	11 ( 6.3%)	174
Hypoalbuminaemia	33 ( 19.0%)	37 ( 21.3%)	78 ( 44.8%)	26 ( 14.9%)	174
Frustration tolerance decreased	16 ( 9.2%)	35 ( 20.1%)	89 ( 51.1%)	34 ( 19.5%)	174
Metastases to central nervous system	3 ( 1.7%)	47 ( 27.0%)	112 ( 64.4%)	12 ( 6.9%)	174

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Prostatic specific antigen increased	0 ( 0.0%)	2 ( 1.2%)	113 ( 65.3%)	58 ( 33.5%)	173
Psychomotor hyperactivity	53 ( 30.6%)	53 ( 30.6%)	56 ( 32.4%)	11 ( 6.4%)	173
Venooclusive disease	57 ( 32.9%)	34 ( 19.7%)	81 ( 46.8%)	1 ( 0.6%)	173
Eosinophil count increased	22 ( 12.7%)	44 ( 25.4%)	86 ( 49.7%)	21 ( 12.1%)	173
Paralysis	8 ( 4.6%)	57 ( 32.9%)	91 ( 52.6%)	17 ( 9.8%)	173
Incorrect disposal of product	1 ( 0.6%)	15 ( 8.7%)	118 ( 68.6%)	38 ( 22.1%)	172
Liquid product physical issue	75 ( 43.6%)	38 ( 22.1%)	47 ( 27.3%)	12 ( 7.0%)	172
Schizophrenia	16 ( 9.3%)	66 ( 38.4%)	87 ( 50.6%)	3 ( 1.7%)	172
Haematotoxicity	18 ( 10.5%)	36 ( 21.1%)	99 ( 57.9%)	18 ( 10.5%)	171
Pulmonary congestion	9 ( 5.3%)	40 ( 23.4%)	101 ( 59.1%)	21 ( 12.3%)	171
Infusion site swelling	23 ( 13.5%)	42 ( 24.6%)	88 ( 51.5%)	18 ( 10.5%)	171
Respiratory depression	43 ( 25.3%)	54 ( 31.8%)	57 ( 33.5%)	16 ( 9.4%)	170
Generalised oedema	13 ( 7.6%)	53 ( 31.2%)	82 ( 48.2%)	22 ( 12.9%)	170
Poor quality product administered	51 ( 30.2%)	34 ( 20.1%)	64 ( 37.9%)	20 ( 11.8%)	169
Coagulopathy	33 ( 19.5%)	31 ( 18.3%)	76 ( 45.0%)	29 ( 17.2%)	169
Food allergy	24 ( 14.2%)	69 ( 40.8%)	67 ( 39.6%)	9 ( 5.3%)	169
Intentional self-injury	63 ( 37.7%)	78 ( 46.7%)	25 ( 15.0%)	1 ( 0.6%)	167
Blood calcium decreased	8 ( 4.8%)	26 ( 15.6%)	84 ( 50.3%)	49 ( 29.3%)	167
Nerve injury	3 ( 1.8%)	54 ( 32.5%)	88 ( 53.0%)	21 ( 12.7%)	166
Tuberculosis	5 ( 3.0%)	62 ( 37.3%)	87 ( 52.4%)	12 ( 7.2%)	166
Bradykinesia	14 ( 8.4%)	27 ( 16.3%)	89 ( 53.6%)	36 ( 21.7%)	166
Macular degeneration	3 ( 1.8%)	13 ( 7.8%)	89 ( 53.6%)	61 ( 36.7%)	166
Gastrointestinal pain	9 ( 5.5%)	37 ( 22.4%)	102 ( 61.8%)	17 ( 10.3%)	165
Gastrointestinal inflammation	27 ( 16.4%)	57 ( 34.5%)	74 ( 44.8%)	7 ( 4.2%)	165
Paranoia	25 ( 15.2%)	58 ( 35.2%)	66 ( 40.0%)	16 ( 9.7%)	165
Nail disorder	4 ( 2.4%)	56 ( 33.9%)	84 ( 50.9%)	21 ( 12.7%)	165
Live birth	14 ( 8.5%)	146 ( 88.5%)	5 ( 3.0%)	0 ( 0.0%)	165

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Vitamin D deficiency	10 ( 6.1%)	63 ( 38.4%)	79 ( 48.2%)	12 ( 7.3%)	164
Cholecystitis	9 ( 5.5%)	24 ( 14.6%)	98 ( 59.8%)	33 ( 20.1%)	164
Economic problem	8 ( 4.9%)	98 ( 59.8%)	57 ( 34.8%)	1 ( 0.6%)	164
Neoplasm	7 ( 4.3%)	31 ( 19.0%)	110 ( 67.5%)	15 ( 9.2%)	163
Mucous stools	18 ( 11.0%)	75 ( 46.0%)	59 ( 36.2%)	11 ( 6.7%)	163
Sopor	31 ( 19.0%)	38 ( 23.3%)	64 ( 39.3%)	30 ( 18.4%)	163
Hunger	15 ( 9.3%)	46 ( 28.4%)	91 ( 56.2%)	10 ( 6.2%)	162
Hypercholesterolaemia	3 ( 1.9%)	88 ( 54.7%)	46 ( 28.6%)	24 ( 14.9%)	161
Blood urea increased	11 ( 6.8%)	29 ( 18.0%)	98 ( 60.9%)	23 ( 14.3%)	161
Micturition urgency	10 ( 6.2%)	45 ( 28.0%)	78 ( 48.4%)	28 ( 17.4%)	161
Tooth abscess	10 ( 6.2%)	45 ( 28.0%)	92 ( 57.1%)	14 ( 8.7%)	161
Infusion site erythema	20 ( 12.4%)	42 ( 26.1%)	79 ( 49.1%)	20 ( 12.4%)	161
Miosis	18 ( 11.2%)	67 ( 41.6%)	54 ( 33.5%)	22 ( 13.7%)	161
Eye haemorrhage	14 ( 8.8%)	21 ( 13.1%)	105 ( 65.6%)	20 ( 12.5%)	160
Osteomyelitis	11 ( 6.9%)	35 ( 21.9%)	92 ( 57.5%)	22 ( 13.8%)	160
Lupus-like syndrome	40 ( 25.0%)	81 ( 50.6%)	36 ( 22.5%)	3 ( 1.9%)	160
Blood magnesium decreased	3 ( 1.9%)	21 ( 13.2%)	112 ( 70.4%)	23 ( 14.5%)	159
Accidental underdose	10 ( 6.3%)	56 ( 35.2%)	82 ( 51.6%)	11 ( 6.9%)	159
Injection site discomfort	28 ( 17.6%)	43 ( 27.0%)	78 ( 49.1%)	10 ( 6.3%)	159
Bowel movement irregularity	18 ( 11.3%)	32 ( 20.1%)	95 ( 59.7%)	14 ( 8.8%)	159
Peripheral venous disease	0 ( 0.0%)	125 ( 78.6%)	27 ( 17.0%)	7 ( 4.4%)	159
Circumstance or information capable of leading to med	31 ( 19.5%)	16 ( 10.1%)	76 ( 47.8%)	36 ( 22.6%)	159
Neuroleptic malignant syndrome	10 ( 6.3%)	58 ( 36.5%)	81 ( 50.9%)	10 ( 6.3%)	159
Eye inflammation	24 ( 15.1%)	49 ( 30.8%)	68 ( 42.8%)	18 ( 11.3%)	159
Lymphoma	6 ( 3.8%)	29 ( 18.4%)	94 ( 59.5%)	29 ( 18.4%)	158
Dizziness postural	3 ( 1.9%)	21 ( 13.3%)	96 ( 60.8%)	38 ( 24.1%)	158
Pulmonary thrombosis	1 ( 0.6%)	21 ( 13.3%)	103 ( 65.2%)	33 ( 20.9%)	158

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Rotator cuff syndrome	1 ( 0.6%)	28 ( 17.8%)	115 ( 73.2%)	13 ( 8.3%)	157
Facet joint syndrome	0 ( 0.0%)	144 ( 91.7%)	13 ( 8.3%)	0 ( 0.0%)	157
Abnormal faeces	28 ( 17.9%)	33 ( 21.2%)	73 ( 46.8%)	22 ( 14.1%)	156
Swelling of eyelid	19 ( 12.2%)	44 ( 28.2%)	78 ( 50.0%)	15 ( 9.6%)	156
Pelvic pain	27 ( 17.3%)	64 ( 41.0%)	53 ( 34.0%)	12 ( 7.7%)	156
Fear of injection	66 ( 42.3%)	34 ( 21.8%)	47 ( 30.1%)	9 ( 5.8%)	156
Unintentional medical device removal	9 ( 5.8%)	42 ( 26.9%)	90 ( 57.7%)	15 ( 9.6%)	156
Enteritis	39 ( 25.0%)	25 ( 16.0%)	71 ( 45.5%)	21 ( 13.5%)	156
Aphthous ulcer	15 ( 9.6%)	48 ( 30.8%)	86 ( 55.1%)	7 ( 4.5%)	156
Metastasis	2 ( 1.3%)	49 ( 31.6%)	84 ( 54.2%)	20 ( 12.9%)	155
Cardiovascular disorder	14 ( 9.0%)	62 ( 40.0%)	62 ( 40.0%)	17 ( 11.0%)	155
Salivary hypersecretion	32 ( 20.6%)	48 ( 31.0%)	54 ( 34.8%)	21 ( 13.5%)	155
Anal abscess	22 ( 14.2%)	65 ( 41.9%)	64 ( 41.3%)	4 ( 2.6%)	155
Dystonia	51 ( 32.9%)	42 ( 27.1%)	50 ( 32.3%)	12 ( 7.7%)	155
Sensory disturbance	9 ( 5.8%)	73 ( 47.4%)	54 ( 35.1%)	18 ( 11.7%)	154
Motor dysfunction	17 ( 11.0%)	25 ( 16.2%)	97 ( 63.0%)	15 ( 9.7%)	154
Bronchospasm	25 ( 16.2%)	29 ( 18.8%)	85 ( 55.2%)	15 ( 9.7%)	154
Renal tubular necrosis	4 ( 2.6%)	45 ( 29.4%)	77 ( 50.3%)	27 ( 17.6%)	153
Myelodysplastic syndrome	4 ( 2.6%)	19 ( 12.4%)	93 ( 60.8%)	37 ( 24.2%)	153
Facial paralysis	16 ( 10.5%)	38 ( 24.8%)	74 ( 48.4%)	25 ( 16.3%)	153
Escherichia infection	18 ( 11.8%)	25 ( 16.3%)	85 ( 55.6%)	25 ( 16.3%)	153
Bedridden	13 ( 8.5%)	29 ( 19.0%)	64 ( 41.8%)	47 ( 30.7%)	153
Product physical issue	25 ( 16.4%)	31 ( 20.4%)	77 ( 50.7%)	19 ( 12.5%)	152
Upper-airway cough syndrome	5 ( 3.3%)	37 ( 24.3%)	90 ( 59.2%)	20 ( 13.2%)	152
Spinal disorder	2 ( 1.3%)	40 ( 26.3%)	95 ( 62.5%)	15 ( 9.9%)	152
Petechiae	28 ( 18.4%)	23 ( 15.1%)	76 ( 50.0%)	25 ( 16.4%)	152
Visual acuity reduced	13 ( 8.6%)	39 ( 25.7%)	71 ( 46.7%)	29 ( 19.1%)	152

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Body height decreased	9 ( 6.0%)	14 ( 9.3%)	70 ( 46.4%)	58 ( 38.4%)	151
Scar	14 ( 9.3%)	44 ( 29.1%)	85 ( 56.3%)	8 ( 5.3%)	151
Device deployment issue	17 ( 11.3%)	53 ( 35.1%)	54 ( 35.8%)	27 ( 17.9%)	151
Pulmonary arterial hypertension	7 ( 4.6%)	35 ( 23.2%)	75 ( 49.7%)	34 ( 22.5%)	151
Periorbital swelling	25 ( 16.7%)	41 ( 27.3%)	68 ( 45.3%)	16 ( 10.7%)	150
Subarachnoid haemorrhage	5 ( 3.4%)	22 ( 14.8%)	78 ( 52.3%)	44 ( 29.5%)	149
Posterior reversible encephalopathy syndrome	54 ( 36.2%)	28 ( 18.8%)	61 ( 40.9%)	6 ( 4.0%)	149
Inappropriate antidiuretic hormone secretion	11 ( 7.4%)	12 ( 8.1%)	62 ( 41.6%)	64 ( 43.0%)	149
Mania	31 ( 20.8%)	64 ( 43.0%)	50 ( 33.6%)	4 ( 2.7%)	149
Scab	21 ( 14.2%)	26 ( 17.6%)	78 ( 52.7%)	23 ( 15.5%)	148
Incorrect drug administration rate	29 ( 19.6%)	32 ( 21.6%)	67 ( 45.3%)	20 ( 13.5%)	148
Ventricular fibrillation	8 ( 5.4%)	34 ( 23.0%)	64 ( 43.2%)	42 ( 28.4%)	148
Lung opacity	6 ( 4.1%)	13 ( 8.8%)	75 ( 51.0%)	53 ( 36.1%)	147
Diffuse large B-cell lymphoma	17 ( 11.6%)	27 ( 18.5%)	64 ( 43.8%)	38 ( 26.0%)	146
Colitis microscopic	0 ( 0.0%)	29 ( 19.9%)	82 ( 56.2%)	35 ( 24.0%)	146
Bone marrow failure	26 ( 17.9%)	28 ( 19.3%)	71 ( 49.0%)	20 ( 13.8%)	145
Disability	5 ( 3.5%)	62 ( 43.1%)	64 ( 44.4%)	13 ( 9.0%)	144
Malnutrition	13 ( 9.0%)	24 ( 16.7%)	85 ( 59.0%)	22 ( 15.3%)	144
Urosepsis	4 ( 2.8%)	14 ( 9.7%)	84 ( 58.3%)	42 ( 29.2%)	144
Post procedural infection	5 ( 3.5%)	28 ( 19.4%)	96 ( 66.7%)	15 ( 10.4%)	144
Non-small cell lung cancer	1 ( 0.7%)	19 ( 13.2%)	95 ( 66.0%)	29 ( 20.1%)	144
Cerebral disorder	11 ( 7.6%)	32 ( 22.2%)	79 ( 54.9%)	22 ( 15.3%)	144
On and off phenomenon	0 ( 0.0%)	9 ( 6.3%)	85 ( 59.0%)	50 ( 34.7%)	144
Lymphoedema	5 ( 3.5%)	24 ( 16.8%)	87 ( 60.8%)	27 ( 18.9%)	143
Spinal compression fracture	0 ( 0.0%)	16 ( 11.2%)	77 ( 53.8%)	50 ( 35.0%)	143
Hiatus hernia	3 ( 2.1%)	22 ( 15.4%)	96 ( 67.1%)	22 ( 15.4%)	143
Ear discomfort	6 ( 4.2%)	58 ( 40.6%)	64 ( 44.8%)	15 ( 10.5%)	143

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Aspergillus infection	15 ( 10.5%)	23 ( 16.1%)	96 ( 67.1%)	9 ( 6.3%)	143
Impaired gastric emptying	11 ( 7.7%)	44 ( 31.0%)	76 ( 53.5%)	11 ( 7.7%)	142
Skin reaction	8 ( 5.6%)	49 ( 34.5%)	66 ( 46.5%)	19 ( 13.4%)	142
Tooth extraction	9 ( 6.3%)	27 ( 19.0%)	84 ( 59.2%)	22 ( 15.5%)	142
Colon cancer	1 ( 0.7%)	16 ( 11.3%)	84 ( 59.2%)	41 ( 28.9%)	142
Pyelonephritis	8 ( 5.6%)	45 ( 31.7%)	69 ( 48.6%)	20 ( 14.1%)	142
Fistula	21 ( 14.8%)	52 ( 36.6%)	64 ( 45.1%)	5 ( 3.5%)	142
Inability to afford medication	11 ( 7.8%)	32 ( 22.7%)	68 ( 48.2%)	30 ( 21.3%)	141
Nerve compression	1 ( 0.7%)	33 ( 23.4%)	86 ( 61.0%)	21 ( 14.9%)	141
Immune thrombocytopenia	7 ( 5.0%)	34 ( 24.1%)	68 ( 48.2%)	32 ( 22.7%)	141
Tendon rupture	5 ( 3.5%)	26 ( 18.4%)	81 ( 57.4%)	29 ( 20.6%)	141
Mouth haemorrhage	45 ( 32.1%)	25 ( 17.9%)	52 ( 37.1%)	18 ( 12.9%)	140
Erythema multiforme	12 ( 8.6%)	22 ( 15.7%)	80 ( 57.1%)	26 ( 18.6%)	140
Tooth fracture	6 ( 4.3%)	30 ( 21.4%)	94 ( 67.1%)	10 ( 7.1%)	140
Hypothermia	22 ( 15.7%)	35 ( 25.0%)	58 ( 41.4%)	25 ( 17.9%)	140
Blood pressure diastolic increased	9 ( 6.5%)	60 ( 43.2%)	59 ( 42.4%)	11 ( 7.9%)	139
Muscle strain	15 ( 10.8%)	43 ( 30.9%)	68 ( 48.9%)	13 ( 9.4%)	139
Thinking abnormal	7 ( 5.0%)	39 ( 28.1%)	65 ( 46.8%)	28 ( 20.1%)	139
Product administered to patient of inappropriate age	117 ( 84.2%)	11 ( 7.9%)	10 ( 7.2%)	1 ( 0.7%)	139
Malignant melanoma	3 ( 2.2%)	21 ( 15.2%)	87 ( 63.0%)	27 ( 19.6%)	138
Arteriosclerosis coronary artery	3 ( 2.2%)	17 ( 12.3%)	86 ( 62.3%)	32 ( 23.2%)	138
Discouragement	13 ( 9.5%)	46 ( 33.6%)	66 ( 48.2%)	12 ( 8.8%)	137
Subdural haematoma	2 ( 1.5%)	9 ( 6.6%)	70 ( 51.1%)	56 ( 40.9%)	137
Pseudomonas infection	18 ( 13.1%)	41 ( 29.9%)	63 ( 46.0%)	15 ( 10.9%)	137
Respiratory arrest	32 ( 23.4%)	31 ( 22.6%)	63 ( 46.0%)	11 ( 8.0%)	137
Pancreatic carcinoma	0 ( 0.0%)	9 ( 6.6%)	94 ( 68.6%)	34 ( 24.8%)	137
Eye discharge	19 ( 13.9%)	34 ( 24.8%)	67 ( 48.9%)	17 ( 12.4%)	137

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Expired device used	86 ( 62.8%)	18 ( 13.1%)	29 ( 21.2%)	4 ( 2.9%)	137
Renal pain	7 ( 5.1%)	48 ( 35.0%)	73 ( 53.3%)	9 ( 6.6%)	137
Breast cancer metastatic	0 ( 0.0%)	42 ( 30.7%)	87 ( 63.5%)	8 ( 5.8%)	137
Rhinitis	20 ( 14.7%)	42 ( 30.9%)	65 ( 47.8%)	9 ( 6.6%)	136
Therapy change	14 ( 10.3%)	28 ( 20.6%)	63 ( 46.3%)	31 ( 22.8%)	136
Cutaneous vasculitis	21 ( 15.6%)	37 ( 27.4%)	55 ( 40.7%)	22 ( 16.3%)	135
Breath sounds abnormal	14 ( 10.4%)	10 ( 7.4%)	77 ( 57.0%)	34 ( 25.2%)	135
Pulmonary alveolar haemorrhage	6 ( 4.4%)	35 ( 25.9%)	72 ( 53.3%)	22 ( 16.3%)	135
Iron deficiency anaemia	5 ( 3.7%)	43 ( 31.9%)	57 ( 42.2%)	30 ( 22.2%)	135
Flank pain	5 ( 3.7%)	28 ( 20.7%)	88 ( 65.2%)	14 ( 10.4%)	135
Ocular discomfort	13 ( 9.6%)	48 ( 35.6%)	59 ( 43.7%)	15 ( 11.1%)	135
Blood thyroid stimulating hormone increased	3 ( 2.2%)	18 ( 13.3%)	73 ( 54.1%)	41 ( 30.4%)	135
Myositis	5 ( 3.7%)	21 ( 15.7%)	72 ( 53.7%)	36 ( 26.9%)	134
Atelectasis	23 ( 17.2%)	23 ( 17.2%)	58 ( 43.3%)	30 ( 22.4%)	134
Rales	5 ( 3.7%)	16 ( 11.9%)	65 ( 48.5%)	48 ( 35.8%)	134
Coeliac disease	11 ( 8.2%)	67 ( 50.0%)	54 ( 40.3%)	2 ( 1.5%)	134
Coordination abnormal	13 ( 9.8%)	70 ( 52.6%)	44 ( 33.1%)	6 ( 4.5%)	133
Arthropod bite	19 ( 14.3%)	33 ( 24.8%)	74 ( 55.6%)	7 ( 5.3%)	133
Pemphigoid	4 ( 3.0%)	3 ( 2.3%)	68 ( 51.5%)	57 ( 43.2%)	132
Toxic skin eruption	5 ( 3.8%)	26 ( 19.7%)	76 ( 57.6%)	25 ( 18.9%)	132
Brain injury	15 ( 11.4%)	62 ( 47.0%)	45 ( 34.1%)	10 ( 7.6%)	132
Metastases to lymph nodes	0 ( 0.0%)	29 ( 22.0%)	91 ( 68.9%)	12 ( 9.1%)	132
Device operational issue	18 ( 13.6%)	15 ( 11.4%)	80 ( 60.6%)	19 ( 14.4%)	132
Postoperative wound infection	7 ( 5.3%)	32 ( 24.4%)	83 ( 63.4%)	9 ( 6.9%)	131
Exostosis	1 ( 0.8%)	50 ( 38.2%)	64 ( 48.9%)	16 ( 12.2%)	131
Living in residential institution	6 ( 4.6%)	21 ( 16.2%)	86 ( 66.2%)	17 ( 13.1%)	130
Skin weeping	38 ( 29.2%)	48 ( 36.9%)	37 ( 28.5%)	7 ( 5.4%)	130

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Diarrhoea haemorrhagic	12 ( 9.2%)	51 ( 39.2%)	53 ( 40.8%)	14 ( 10.8%)	130
Inflammatory marker increased	18 ( 13.8%)	24 ( 18.5%)	66 ( 50.8%)	22 ( 16.9%)	130
Nephropathy	3 ( 2.3%)	34 ( 26.4%)	70 ( 54.3%)	22 ( 17.1%)	129
Cardiomyopathy	8 ( 6.2%)	37 ( 28.7%)	64 ( 49.6%)	20 ( 15.5%)	129
Concussion	7 ( 5.4%)	28 ( 21.7%)	73 ( 56.6%)	21 ( 16.3%)	129
Retinal detachment	3 ( 2.3%)	27 ( 21.1%)	75 ( 58.6%)	23 ( 18.0%)	128
Hypophosphataemia	4 ( 3.1%)	25 ( 19.5%)	51 ( 39.8%)	48 ( 37.5%)	128
Muscle haemorrhage	61 ( 47.7%)	44 ( 34.4%)	17 ( 13.3%)	6 ( 4.7%)	128
Injection site discolouration	19 ( 14.8%)	39 ( 30.5%)	65 ( 50.8%)	5 ( 3.9%)	128
Hidradenitis	23 ( 18.0%)	75 ( 58.6%)	29 ( 22.7%)	1 ( 0.8%)	128
Troponin increased	28 ( 21.9%)	24 ( 18.8%)	42 ( 32.8%)	34 ( 26.6%)	128
Bladder disorder	6 ( 4.7%)	29 ( 22.7%)	73 ( 57.0%)	20 ( 15.6%)	128
Rhinovirus infection	77 ( 60.2%)	11 ( 8.6%)	37 ( 28.9%)	3 ( 2.3%)	128
Drug use disorder	32 ( 25.0%)	62 ( 48.4%)	32 ( 25.0%)	2 ( 1.6%)	128
Application site pain	16 ( 12.6%)	40 ( 31.5%)	61 ( 48.0%)	10 ( 7.9%)	127
Polyp	4 ( 3.1%)	17 ( 13.4%)	94 ( 74.0%)	12 ( 9.4%)	127
Hypertensive crisis	5 ( 3.9%)	26 ( 20.5%)	81 ( 63.8%)	15 ( 11.8%)	127
Transplant rejection	16 ( 12.6%)	57 ( 44.9%)	54 ( 42.5%)	0 ( 0.0%)	127
Haemodynamic instability	22 ( 17.5%)	23 ( 18.3%)	71 ( 56.3%)	10 ( 7.9%)	126
Sluggishness	11 ( 8.7%)	33 ( 26.2%)	65 ( 51.6%)	17 ( 13.5%)	126
Ear pruritus	2 ( 1.6%)	44 ( 34.9%)	79 ( 62.7%)	1 ( 0.8%)	126
Feeling jittery	12 ( 9.5%)	43 ( 34.1%)	51 ( 40.5%)	20 ( 15.9%)	126
Shock haemorrhagic	6 ( 4.8%)	21 ( 16.7%)	56 ( 44.4%)	43 ( 34.1%)	126
Sensation of foreign body	10 ( 8.0%)	33 ( 26.4%)	66 ( 52.8%)	16 ( 12.8%)	125
Euglycaemic diabetic ketoacidosis	1 ( 0.8%)	31 ( 24.8%)	71 ( 56.8%)	22 ( 17.6%)	125
Organising pneumonia	13 ( 10.4%)	14 ( 11.2%)	67 ( 53.6%)	31 ( 24.8%)	125
Cholecystectomy	4 ( 3.2%)	40 ( 32.3%)	73 ( 58.9%)	7 ( 5.6%)	124



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hepatomegaly	30 ( 24.2%)	39 ( 31.5%)	50 ( 40.3%)	5 ( 4.0%)	124
Rebound effect	25 ( 20.2%)	34 ( 27.4%)	56 ( 45.2%)	9 ( 7.3%)	124
Complication of device insertion	41 ( 33.1%)	82 ( 66.1%)	1 ( 0.8%)	0 ( 0.0%)	124
Hypogammaglobulinaemia	23 ( 18.7%)	17 ( 13.8%)	81 ( 65.9%)	2 ( 1.6%)	123
Blindness unilateral	8 ( 6.5%)	22 ( 17.9%)	57 ( 46.3%)	36 ( 29.3%)	123
Vitreous floaters	3 ( 2.4%)	24 ( 19.5%)	73 ( 59.3%)	23 ( 18.7%)	123
Ataxia	17 ( 13.9%)	37 ( 30.3%)	56 ( 45.9%)	12 ( 9.8%)	122
Blood pressure diastolic abnormal	7 ( 5.7%)	43 ( 35.2%)	68 ( 55.7%)	4 ( 3.3%)	122
Thyroiditis	2 ( 1.6%)	36 ( 29.5%)	71 ( 58.2%)	13 ( 10.7%)	122
Hypertriglyceridaemia	28 ( 23.0%)	51 ( 41.8%)	40 ( 32.8%)	3 ( 2.5%)	122
Attention deficit hyperactivity disorder	84 ( 68.9%)	26 ( 21.3%)	11 ( 9.0%)	1 ( 0.8%)	122
Post procedural haemorrhage	22 ( 18.0%)	18 ( 14.8%)	56 ( 45.9%)	26 ( 21.3%)	122
Skin abrasion	17 ( 13.9%)	24 ( 19.7%)	57 ( 46.7%)	24 ( 19.7%)	122
Venoocclusive liver disease	29 ( 23.8%)	37 ( 30.3%)	55 ( 45.1%)	1 ( 0.8%)	122
Respiration abnormal	12 ( 9.9%)	26 ( 21.5%)	68 ( 56.2%)	15 ( 12.4%)	121
Gingival pain	2 ( 1.7%)	33 ( 27.3%)	76 ( 62.8%)	10 ( 8.3%)	121
Spinal stenosis	1 ( 0.8%)	14 ( 11.6%)	79 ( 65.3%)	27 ( 22.3%)	121
Blood pressure systolic abnormal	2 ( 1.7%)	26 ( 21.5%)	85 ( 70.2%)	8 ( 6.6%)	121
Magnetic resonance imaging head abnormal	104 ( 86.0%)	8 ( 6.6%)	9 ( 7.4%)	0 ( 0.0%)	121
Genital haemorrhage	31 ( 25.6%)	83 ( 68.6%)	7 ( 5.8%)	0 ( 0.0%)	121
Dry throat	7 ( 5.8%)	37 ( 30.6%)	64 ( 52.9%)	13 ( 10.7%)	121
Blepharospasm	9 ( 7.5%)	97 ( 80.8%)	10 ( 8.3%)	4 ( 3.3%)	120
Behaviour disorder	49 ( 40.8%)	30 ( 25.0%)	33 ( 27.5%)	8 ( 6.7%)	120
Cardiomegaly	9 ( 7.5%)	27 ( 22.5%)	57 ( 47.5%)	27 ( 22.5%)	120
Polyuria	21 ( 17.5%)	33 ( 27.5%)	48 ( 40.0%)	18 ( 15.0%)	120
Parkinsonism	4 ( 3.3%)	17 ( 14.2%)	81 ( 67.5%)	18 ( 15.0%)	120
Electric shock sensation	9 ( 7.6%)	60 ( 50.4%)	44 ( 37.0%)	6 ( 5.0%)	119

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hydronephrosis	9 ( 7.6%)	18 ( 15.1%)	57 ( 47.9%)	35 ( 29.4%)	119
Injection site irritation	27 ( 22.7%)	49 ( 41.2%)	42 ( 35.3%)	1 ( 0.8%)	119
Papule	18 ( 15.1%)	39 ( 32.8%)	51 ( 42.9%)	11 ( 9.2%)	119
Cytomegalovirus infection reactivation	23 ( 19.3%)	42 ( 35.3%)	53 ( 44.5%)	1 ( 0.8%)	119
Breast mass	3 ( 2.5%)	52 ( 43.7%)	60 ( 50.4%)	4 ( 3.4%)	119
Intestinal perforation	6 ( 5.1%)	18 ( 15.3%)	80 ( 67.8%)	14 ( 11.9%)	118
Hyperaesthesia	6 ( 5.1%)	42 ( 35.6%)	59 ( 50.0%)	11 ( 9.3%)	118
Oral discomfort	5 ( 4.2%)	20 ( 16.9%)	77 ( 65.3%)	16 ( 13.6%)	118
Breast cancer female	1 ( 0.8%)	32 ( 27.1%)	75 ( 63.6%)	10 ( 8.5%)	118
Product adhesion issue	14 ( 11.9%)	26 ( 22.0%)	63 ( 53.4%)	15 ( 12.7%)	118
Haematological infection	7 ( 5.9%)	22 ( 18.6%)	70 ( 59.3%)	19 ( 16.1%)	118
Vitamin D decreased	10 ( 8.5%)	36 ( 30.8%)	68 ( 58.1%)	3 ( 2.6%)	117
Cholangitis	2 ( 1.7%)	17 ( 14.5%)	57 ( 48.7%)	41 ( 35.0%)	117
Hospice care	2 ( 1.7%)	9 ( 7.7%)	56 ( 47.9%)	50 ( 42.7%)	117
Hyperthermia	17 ( 14.5%)	40 ( 34.2%)	54 ( 46.2%)	6 ( 5.1%)	117
Chronic sinusitis	11 ( 9.4%)	22 ( 18.8%)	79 ( 67.5%)	5 ( 4.3%)	117
Hysterectomy	4 ( 3.4%)	62 ( 53.0%)	50 ( 42.7%)	1 ( 0.9%)	117
Infusion site discharge	16 ( 13.7%)	21 ( 17.9%)	60 ( 51.3%)	20 ( 17.1%)	117
Oesophagitis	10 ( 8.5%)	21 ( 17.9%)	70 ( 59.8%)	16 ( 13.7%)	117
Ventricular extrasystoles	9 ( 7.7%)	33 ( 28.2%)	57 ( 48.7%)	18 ( 15.4%)	117
Product leakage	10 ( 8.6%)	51 ( 44.0%)	44 ( 37.9%)	11 ( 9.5%)	116
Pelvic fracture	0 ( 0.0%)	7 ( 6.0%)	54 ( 46.6%)	55 ( 47.4%)	116
Tardive dyskinesia	14 ( 12.1%)	28 ( 24.1%)	52 ( 44.8%)	22 ( 19.0%)	116
Deep vein thrombosis postoperative	0 ( 0.0%)	111 ( 95.7%)	3 ( 2.6%)	2 ( 1.7%)	116
Device power source issue	79 ( 68.7%)	9 ( 7.8%)	23 ( 20.0%)	4 ( 3.5%)	115
Nasal polyps	3 ( 2.6%)	28 ( 24.3%)	82 ( 71.3%)	2 ( 1.7%)	115
Emphysema	3 ( 2.6%)	16 ( 13.9%)	77 ( 67.0%)	19 ( 16.5%)	115

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Suspected COVID-19	13 ( 11.3%)	41 ( 35.7%)	52 ( 45.2%)	9 ( 7.8%)	115
Rhinitis allergic	7 ( 6.1%)	21 ( 18.3%)	82 ( 71.3%)	5 ( 4.3%)	115
Maternal exposure before pregnancy	27 ( 23.5%)	88 ( 76.5%)	0 ( 0.0%)	0 ( 0.0%)	115
Streptococcal infection	39 ( 33.9%)	44 ( 38.3%)	25 ( 21.7%)	7 ( 6.1%)	115
Appetite disorder	15 ( 13.0%)	22 ( 19.1%)	55 ( 47.8%)	23 ( 20.0%)	115
Dental caries	14 ( 12.2%)	40 ( 34.8%)	41 ( 35.7%)	20 ( 17.4%)	115
Inguinal hernia	12 ( 10.4%)	31 ( 27.0%)	52 ( 45.2%)	20 ( 17.4%)	115
Injection site induration	15 ( 13.0%)	43 ( 37.4%)	51 ( 44.3%)	6 ( 5.2%)	115
Autoimmune hepatitis	9 ( 7.8%)	25 ( 21.7%)	69 ( 60.0%)	12 ( 10.4%)	115
Incontinence	6 ( 5.3%)	31 ( 27.2%)	62 ( 54.4%)	15 ( 13.2%)	114
Encephalitis	15 ( 13.2%)	25 ( 21.9%)	65 ( 57.0%)	9 ( 7.9%)	114
Anal fistula	14 ( 12.3%)	61 ( 53.5%)	39 ( 34.2%)	0 ( 0.0%)	114
Skin mass	5 ( 4.4%)	29 ( 25.4%)	66 ( 57.9%)	14 ( 12.3%)	114
Mitral valve incompetence	22 ( 19.3%)	21 ( 18.4%)	46 ( 40.4%)	25 ( 21.9%)	114
Blood uric acid increased	6 ( 5.3%)	27 ( 23.7%)	48 ( 42.1%)	33 ( 28.9%)	114
Status epilepticus	35 ( 31.0%)	35 ( 31.0%)	31 ( 27.4%)	12 ( 10.6%)	113
Brain neoplasm	12 ( 10.6%)	37 ( 32.7%)	50 ( 44.2%)	14 ( 12.4%)	113
Hepatic encephalopathy	10 ( 8.9%)	14 ( 12.5%)	74 ( 66.1%)	14 ( 12.5%)	112
Product preparation issue	26 ( 23.2%)	36 ( 32.1%)	39 ( 34.8%)	11 ( 9.8%)	112
Product packaging quantity issue	8 ( 7.1%)	8 ( 7.1%)	63 ( 56.3%)	33 ( 29.5%)	112
Blood calcium increased	1 ( 0.9%)	10 ( 8.9%)	60 ( 53.6%)	41 ( 36.6%)	112
Sensitive skin	15 ( 13.5%)	44 ( 39.6%)	44 ( 39.6%)	8 ( 7.2%)	111
Myopathy	17 ( 15.3%)	19 ( 17.1%)	60 ( 54.1%)	15 ( 13.5%)	111
Cardiac operation	7 ( 6.3%)	5 ( 4.5%)	72 ( 64.9%)	27 ( 24.3%)	111
Enterocolitis	6 ( 5.4%)	20 ( 18.0%)	60 ( 54.1%)	25 ( 22.5%)	111
Tendon pain	3 ( 2.7%)	54 ( 48.6%)	40 ( 36.0%)	14 ( 12.6%)	111
Breast pain	8 ( 7.2%)	28 ( 25.2%)	61 ( 55.0%)	14 ( 12.6%)	111

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bone demineralisation	4 ( 3.6%)	49 ( 44.1%)	57 ( 51.4%)	1 ( 0.9%)	111
Dissociation	10 ( 9.0%)	61 ( 55.0%)	38 ( 34.2%)	2 ( 1.8%)	111
Klebsiella infection	13 ( 11.8%)	42 ( 38.2%)	50 ( 45.5%)	5 ( 4.5%)	110
Polyarthritis	14 ( 12.7%)	22 ( 20.0%)	59 ( 53.6%)	15 ( 13.6%)	110
Major depression	13 ( 11.8%)	65 ( 59.1%)	30 ( 27.3%)	2 ( 1.8%)	110
Amenorrhoea	20 ( 18.2%)	84 ( 76.4%)	6 ( 5.5%)	0 ( 0.0%)	110
Sinus bradycardia	6 ( 5.5%)	39 ( 35.5%)	45 ( 40.9%)	20 ( 18.2%)	110
Hip surgery	0 ( 0.0%)	17 ( 15.5%)	69 ( 62.7%)	24 ( 21.8%)	110
Eyelid ptosis	9 ( 8.3%)	33 ( 30.3%)	39 ( 35.8%)	28 ( 25.7%)	109
Internal haemorrhage	10 ( 9.2%)	16 ( 14.7%)	49 ( 45.0%)	34 ( 31.2%)	109
Hand fracture	6 ( 5.5%)	38 ( 34.9%)	52 ( 47.7%)	13 ( 11.9%)	109
Proctalgia	24 ( 22.0%)	34 ( 31.2%)	44 ( 40.4%)	7 ( 6.4%)	109
Blood cholesterol abnormal	1 ( 0.9%)	7 ( 6.4%)	93 ( 85.3%)	8 ( 7.3%)	109
White blood cell count abnormal	5 ( 4.6%)	12 ( 11.1%)	75 ( 69.4%)	16 ( 14.8%)	108
Large intestine polyp	4 ( 3.7%)	23 ( 21.3%)	66 ( 61.1%)	15 ( 13.9%)	108
Drug specific antibody present	33 ( 30.6%)	32 ( 29.6%)	42 ( 38.9%)	1 ( 0.9%)	108
Red cell distribution width increased	2 ( 1.9%)	32 ( 29.6%)	63 ( 58.3%)	11 ( 10.2%)	108
Arteriosclerosis	1 ( 0.9%)	15 ( 13.9%)	77 ( 71.3%)	15 ( 13.9%)	108
Ovarian cyst	15 ( 14.0%)	65 ( 60.7%)	27 ( 25.2%)	0 ( 0.0%)	107
Infusion site haemorrhage	16 ( 15.0%)	22 ( 20.6%)	53 ( 49.5%)	16 ( 15.0%)	107
Electrocardiogram QRS complex prolonged	26 ( 24.3%)	40 ( 37.4%)	40 ( 37.4%)	1 ( 0.9%)	107
Pathogen resistance	6 ( 5.6%)	40 ( 37.4%)	43 ( 40.2%)	18 ( 16.8%)	107
Concomitant disease aggravated	11 ( 10.3%)	22 ( 20.6%)	50 ( 46.7%)	24 ( 22.4%)	107
Leukaemia	2 ( 1.9%)	20 ( 18.7%)	65 ( 60.7%)	20 ( 18.7%)	107
Blood disorder	4 ( 3.7%)	10 ( 9.3%)	68 ( 63.6%)	25 ( 23.4%)	107
Foot operation	4 ( 3.7%)	15 ( 14.0%)	84 ( 78.5%)	4 ( 3.7%)	107
Immune reconstitution inflammatory syndrome	4 ( 3.7%)	65 ( 60.7%)	35 ( 32.7%)	3 ( 2.8%)	107

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Onychomycosis	1 ( 0.9%)	52 ( 48.6%)	49 ( 45.8%)	5 ( 4.7%)	107
Food poisoning	11 ( 10.3%)	39 ( 36.4%)	48 ( 44.9%)	9 ( 8.4%)	107
Pigmentation disorder	5 ( 4.7%)	32 ( 30.2%)	59 ( 55.7%)	10 ( 9.4%)	106
Hordeolum	17 ( 16.0%)	31 ( 29.2%)	51 ( 48.1%)	7 ( 6.6%)	106
Distributive shock	52 ( 49.1%)	16 ( 15.1%)	35 ( 33.0%)	3 ( 2.8%)	106
Bipolar disorder	7 ( 6.6%)	52 ( 49.1%)	42 ( 39.6%)	5 ( 4.7%)	106
Stoma site discharge	1 ( 0.9%)	3 ( 2.8%)	70 ( 66.0%)	32 ( 30.2%)	106
Left ventricular failure	2 ( 1.9%)	7 ( 6.6%)	60 ( 56.6%)	37 ( 34.9%)	106
Dialysis	2 ( 1.9%)	16 ( 15.1%)	62 ( 58.5%)	26 ( 24.5%)	106
Drooling	39 ( 36.8%)	28 ( 26.4%)	28 ( 26.4%)	11 ( 10.4%)	106
Furuncle	14 ( 13.2%)	27 ( 25.5%)	55 ( 51.9%)	10 ( 9.4%)	106
Intermenstrual bleeding	32 ( 30.2%)	58 ( 54.7%)	14 ( 13.2%)	2 ( 1.9%)	106
Infusion site pruritus	14 ( 13.3%)	23 ( 21.9%)	57 ( 54.3%)	11 ( 10.5%)	105
Menstruation irregular	17 ( 16.2%)	82 ( 78.1%)	6 ( 5.7%)	0 ( 0.0%)	105
Renal cyst	3 ( 2.9%)	31 ( 29.5%)	52 ( 49.5%)	19 ( 18.1%)	105
Adverse reaction	6 ( 5.7%)	42 ( 40.0%)	42 ( 40.0%)	15 ( 14.3%)	105
Splenomegaly	18 ( 17.1%)	30 ( 28.6%)	48 ( 45.7%)	9 ( 8.6%)	105
Dermatitis exfoliative generalised	11 ( 10.5%)	7 ( 6.7%)	53 ( 50.5%)	34 ( 32.4%)	105
Optic neuritis	8 ( 7.6%)	59 ( 56.2%)	35 ( 33.3%)	3 ( 2.9%)	105
Skeletal injury	5 ( 4.8%)	42 ( 40.0%)	57 ( 54.3%)	1 ( 1.0%)	105
Meniscus injury	2 ( 1.9%)	21 ( 20.0%)	77 ( 73.3%)	5 ( 4.8%)	105
Injection site vesicles	22 ( 21.0%)	41 ( 39.0%)	38 ( 36.2%)	4 ( 3.8%)	105
Toxic encephalopathy	26 ( 25.0%)	19 ( 18.3%)	41 ( 39.4%)	18 ( 17.3%)	104
Hiccups	0 ( 0.0%)	24 ( 23.1%)	56 ( 53.8%)	24 ( 23.1%)	104
Tension	4 ( 3.8%)	41 ( 39.4%)	45 ( 43.3%)	14 ( 13.5%)	104
Type 1 diabetes mellitus	7 ( 6.7%)	21 ( 20.2%)	56 ( 53.8%)	20 ( 19.2%)	104
Shoulder fracture	2 ( 1.9%)	12 ( 11.5%)	58 ( 55.8%)	32 ( 30.8%)	104

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Meningitis	12 ( 11.7%)	36 ( 35.0%)	46 ( 44.7%)	9 ( 8.7%)	103
Sensory loss	7 ( 6.8%)	45 ( 43.7%)	45 ( 43.7%)	6 ( 5.8%)	103
International normalised ratio increased	11 ( 10.7%)	9 ( 8.7%)	55 ( 53.4%)	28 ( 27.2%)	103
Immune-mediated hypothyroidism	1 ( 1.0%)	17 ( 16.5%)	67 ( 65.0%)	18 ( 17.5%)	103
Iron deficiency	11 ( 10.7%)	28 ( 27.2%)	34 ( 33.0%)	30 ( 29.1%)	103
Cardiac failure acute	7 ( 6.8%)	18 ( 17.5%)	48 ( 46.6%)	30 ( 29.1%)	103
Platelet count abnormal	10 ( 9.7%)	18 ( 17.5%)	61 ( 59.2%)	14 ( 13.6%)	103
Tendon disorder	4 ( 3.9%)	35 ( 34.3%)	54 ( 52.9%)	9 ( 8.8%)	102
Monocyte count increased	16 ( 15.7%)	36 ( 35.3%)	39 ( 38.2%)	11 ( 10.8%)	102
Cardiotoxicity	15 ( 14.7%)	39 ( 38.2%)	41 ( 40.2%)	7 ( 6.9%)	102
Refusal of treatment by patient	40 ( 39.2%)	16 ( 15.7%)	27 ( 26.5%)	19 ( 18.6%)	102
Dyslipidaemia	7 ( 6.9%)	36 ( 35.3%)	37 ( 36.3%)	22 ( 21.6%)	102
Finger deformity	3 ( 2.9%)	49 ( 48.0%)	32 ( 31.4%)	18 ( 17.6%)	102
Facial pain	7 ( 6.9%)	37 ( 36.3%)	49 ( 48.0%)	9 ( 8.8%)	102
Acidosis	26 ( 25.5%)	27 ( 26.5%)	35 ( 34.3%)	14 ( 13.7%)	102
Breast cancer stage III	0 ( 0.0%)	98 ( 96.1%)	4 ( 3.9%)	0 ( 0.0%)	102
Psychiatric symptom	6 ( 5.9%)	25 ( 24.5%)	50 ( 49.0%)	21 ( 20.6%)	102
Tonsillitis	30 ( 29.4%)	39 ( 38.2%)	32 ( 31.4%)	1 ( 1.0%)	102
Spinal osteoarthritis	1 ( 1.0%)	29 ( 28.7%)	57 ( 56.4%)	14 ( 13.9%)	101
Respiratory symptom	17 ( 16.8%)	20 ( 19.8%)	60 ( 59.4%)	4 ( 4.0%)	101
Central nervous system lesion	9 ( 8.9%)	37 ( 36.6%)	52 ( 51.5%)	3 ( 3.0%)	101
Complication of device removal	15 ( 15.0%)	77 ( 77.0%)	8 ( 8.0%)	0 ( 0.0%)	100
Dermatitis acneiform	20 ( 20.0%)	15 ( 15.0%)	50 ( 50.0%)	15 ( 15.0%)	100
Forced expiratory volume decreased	5 ( 5.0%)	30 ( 30.0%)	61 ( 61.0%)	4 ( 4.0%)	100
Squamous cell carcinoma of skin	1 ( 1.0%)	11 ( 11.1%)	65 ( 65.7%)	22 ( 22.2%)	99
Haemolytic anaemia	14 ( 14.1%)	8 ( 8.1%)	60 ( 60.6%)	17 ( 17.2%)	99
Hyperlipidaemia	4 ( 4.0%)	16 ( 16.2%)	71 ( 71.7%)	8 ( 8.1%)	99

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Walking aid user	2 ( 2.0%)	33 ( 33.3%)	43 ( 43.4%)	21 ( 21.2%)	99
Supraventricular tachycardia	3 ( 3.0%)	23 ( 23.2%)	59 ( 59.6%)	14 ( 14.1%)	99
Cytomegalovirus viraemia	20 ( 20.2%)	27 ( 27.3%)	48 ( 48.5%)	4 ( 4.0%)	99
Oral disorder	14 ( 14.1%)	19 ( 19.2%)	57 ( 57.6%)	9 ( 9.1%)	99
General physical condition abnormal	5 ( 5.1%)	33 ( 33.3%)	36 ( 36.4%)	25 ( 25.3%)	99
Eye movement disorder	23 ( 23.2%)	32 ( 32.3%)	29 ( 29.3%)	15 ( 15.2%)	99
Decubitus ulcer	9 ( 9.1%)	13 ( 13.1%)	53 ( 53.5%)	24 ( 24.2%)	99
Odynophagia	16 ( 16.2%)	34 ( 34.3%)	46 ( 46.5%)	3 ( 3.0%)	99
Embedded device	16 ( 16.3%)	54 ( 55.1%)	20 ( 20.4%)	8 ( 8.2%)	98
Maternal exposure during breast feeding	18 ( 18.4%)	80 ( 81.6%)	0 ( 0.0%)	0 ( 0.0%)	98
Hemiplegia	8 ( 8.2%)	22 ( 22.4%)	52 ( 53.1%)	16 ( 16.3%)	98
Hyperpyrexia	15 ( 15.3%)	34 ( 34.7%)	47 ( 48.0%)	2 ( 2.0%)	98
Increased tendency to bruise	4 ( 4.1%)	22 ( 22.4%)	58 ( 59.2%)	14 ( 14.3%)	98
Mean cell volume increased	7 ( 7.1%)	16 ( 16.3%)	58 ( 59.2%)	17 ( 17.3%)	98
Groin pain	5 ( 5.2%)	20 ( 20.6%)	60 ( 61.9%)	12 ( 12.4%)	97
Electrocardiogram abnormal	16 ( 16.5%)	15 ( 15.5%)	47 ( 48.5%)	19 ( 19.6%)	97
Hepatocellular injury	13 ( 13.5%)	22 ( 22.9%)	57 ( 59.4%)	4 ( 4.2%)	96
Blood immunoglobulin G decreased	10 ( 10.4%)	34 ( 35.4%)	47 ( 49.0%)	5 ( 5.2%)	96
Atrioventricular block	3 ( 3.1%)	4 ( 4.2%)	42 ( 43.8%)	47 ( 49.0%)	96
BRASH syndrome	0 ( 0.0%)	5 ( 5.2%)	37 ( 38.5%)	54 ( 56.3%)	96
Staphylococcal bacteraemia	7 ( 7.3%)	21 ( 21.9%)	45 ( 46.9%)	23 ( 24.0%)	96
Hepatocellular carcinoma	3 ( 3.1%)	13 ( 13.5%)	62 ( 64.6%)	18 ( 18.8%)	96
Exercise tolerance decreased	2 ( 2.1%)	34 ( 35.4%)	46 ( 47.9%)	14 ( 14.6%)	96
Blood albumin decreased	21 ( 22.1%)	13 ( 13.7%)	51 ( 53.7%)	10 ( 10.5%)	95
Blood pressure systolic decreased	8 ( 8.4%)	39 ( 41.1%)	41 ( 43.2%)	7 ( 7.4%)	95
Intracranial pressure increased	31 ( 32.6%)	47 ( 49.5%)	11 ( 11.6%)	6 ( 6.3%)	95
Low density lipoprotein increased	6 ( 6.3%)	27 ( 28.4%)	51 ( 53.7%)	11 ( 11.6%)	95

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Loss of libido	20 ( 21.1%)	60 ( 63.2%)	13 ( 13.7%)	2 ( 2.1%)	95
Meningitis aseptic	9 ( 9.5%)	45 ( 47.4%)	31 ( 32.6%)	10 ( 10.5%)	95
Neurodermatitis	8 ( 8.4%)	25 ( 26.3%)	60 ( 63.2%)	2 ( 2.1%)	95
Peripheral sensory neuropathy	11 ( 11.6%)	11 ( 11.6%)	60 ( 63.2%)	13 ( 13.7%)	95
Febrile bone marrow aplasia	9 ( 9.5%)	17 ( 17.9%)	64 ( 67.4%)	5 ( 5.3%)	95
Infusion site extravasation	15 ( 15.8%)	22 ( 23.2%)	47 ( 49.5%)	11 ( 11.6%)	95
Libido decreased	10 ( 10.6%)	47 ( 50.0%)	33 ( 35.1%)	4 ( 4.3%)	94
Limb operation	2 ( 2.1%)	17 ( 18.1%)	66 ( 70.2%)	9 ( 9.6%)	94
Obstruction	17 ( 18.1%)	15 ( 16.0%)	48 ( 51.1%)	14 ( 14.9%)	94
Embolism	12 ( 12.8%)	12 ( 12.8%)	56 ( 59.6%)	14 ( 14.9%)	94
Adjustment disorder with depressed mood	1 ( 1.1%)	87 ( 92.6%)	5 ( 5.3%)	1 ( 1.1%)	94
Herpes virus infection	8 ( 8.6%)	38 ( 40.9%)	38 ( 40.9%)	9 ( 9.7%)	93
Post-traumatic stress disorder	11 ( 11.8%)	41 ( 44.1%)	40 ( 43.0%)	1 ( 1.1%)	93
Vaginal discharge	11 ( 11.8%)	22 ( 23.7%)	56 ( 60.2%)	4 ( 4.3%)	93
Bladder cancer	0 ( 0.0%)	2 ( 2.2%)	65 ( 69.9%)	26 ( 28.0%)	93
Immune-mediated myositis	1 ( 1.1%)	18 ( 19.4%)	58 ( 62.4%)	16 ( 17.2%)	93
Blood lactic acid increased	11 ( 11.8%)	22 ( 23.7%)	54 ( 58.1%)	6 ( 6.5%)	93
Pneumonia fungal	9 ( 9.7%)	8 ( 8.6%)	71 ( 76.3%)	5 ( 5.4%)	93
Shoulder operation	1 ( 1.1%)	20 ( 21.5%)	65 ( 69.9%)	7 ( 7.5%)	93
Parosmia	5 ( 5.4%)	26 ( 28.3%)	56 ( 60.9%)	5 ( 5.4%)	92
Erysipelas	4 ( 4.3%)	23 ( 25.0%)	50 ( 54.3%)	15 ( 16.3%)	92
Throat clearing	3 ( 3.3%)	26 ( 28.3%)	51 ( 55.4%)	12 ( 13.0%)	92
Loss of therapeutic response	4 ( 4.3%)	39 ( 42.4%)	43 ( 46.7%)	6 ( 6.5%)	92
Intervertebral disc degeneration	3 ( 3.3%)	23 ( 25.0%)	58 ( 63.0%)	8 ( 8.7%)	92
Gastrointestinal motility disorder	9 ( 9.8%)	22 ( 23.9%)	47 ( 51.1%)	14 ( 15.2%)	92
Anti-neutrophil cytoplasmic antibody positive vasculi	1 ( 1.1%)	13 ( 14.1%)	50 ( 54.3%)	28 ( 30.4%)	92
Joint effusion	13 ( 14.3%)	19 ( 20.9%)	52 ( 57.1%)	7 ( 7.7%)	91



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Spondylitis	2 ( 2.2%)	42 ( 46.2%)	41 ( 45.1%)	6 ( 6.6%)	91
Dyschezia	7 ( 7.7%)	24 ( 26.4%)	47 ( 51.6%)	13 ( 14.3%)	91
Feeling of despair	16 ( 17.6%)	34 ( 37.4%)	35 ( 38.5%)	6 ( 6.6%)	91
Skin toxicity	14 ( 15.6%)	10 ( 11.1%)	55 ( 61.1%)	11 ( 12.2%)	90
Paronychia	9 ( 10.0%)	18 ( 20.0%)	50 ( 55.6%)	13 ( 14.4%)	90
Neutropenic sepsis	1 ( 1.1%)	28 ( 31.1%)	55 ( 61.1%)	6 ( 6.7%)	90
Oral mucosal blistering	7 ( 7.8%)	20 ( 22.2%)	48 ( 53.3%)	15 ( 16.7%)	90
Sjogren's syndrome	0 ( 0.0%)	25 ( 27.8%)	54 ( 60.0%)	11 ( 12.2%)	90
Anal fissure	10 ( 11.1%)	42 ( 46.7%)	34 ( 37.8%)	4 ( 4.4%)	90
Dementia Alzheimer's type	0 ( 0.0%)	2 ( 2.2%)	33 ( 36.7%)	55 ( 61.1%)	90
Intraocular pressure increased	14 ( 15.6%)	7 ( 7.8%)	46 ( 51.1%)	23 ( 25.6%)	90
Abnormal loss of weight	2 ( 2.2%)	14 ( 15.6%)	65 ( 72.2%)	9 ( 10.0%)	90
Ketoacidosis	3 ( 3.3%)	23 ( 25.6%)	49 ( 54.4%)	15 ( 16.7%)	90
Diabetes insipidus	18 ( 20.2%)	20 ( 22.5%)	48 ( 53.9%)	3 ( 3.4%)	89
Transfusion	8 ( 9.0%)	11 ( 12.4%)	38 ( 42.7%)	32 ( 36.0%)	89
Heart rate abnormal	4 ( 4.5%)	34 ( 38.2%)	39 ( 43.8%)	12 ( 13.5%)	89
Eyelid oedema	19 ( 21.3%)	26 ( 29.2%)	32 ( 36.0%)	12 ( 13.5%)	89
Torsade de pointes	15 ( 16.9%)	18 ( 20.2%)	47 ( 52.8%)	9 ( 10.1%)	89
Pustule	7 ( 7.9%)	24 ( 27.0%)	53 ( 59.6%)	5 ( 5.6%)	89
Post transplant lymphoproliferative disorder	37 ( 41.6%)	26 ( 29.2%)	24 ( 27.0%)	2 ( 2.2%)	89
Proctitis	1 ( 1.1%)	21 ( 23.6%)	65 ( 73.0%)	2 ( 2.2%)	89
Squamous cell carcinoma	1 ( 1.1%)	11 ( 12.4%)	57 ( 64.0%)	20 ( 22.5%)	89
Scoliosis	30 ( 33.7%)	7 ( 7.9%)	33 ( 37.1%)	19 ( 21.3%)	89
Eye operation	1 ( 1.1%)	5 ( 5.6%)	68 ( 76.4%)	15 ( 16.9%)	89
Foreign body in throat	1 ( 1.1%)	10 ( 11.2%)	49 ( 55.1%)	29 ( 32.6%)	89
Urine output decreased	22 ( 24.7%)	10 ( 11.2%)	40 ( 44.9%)	17 ( 19.1%)	89
Wrong product administered	15 ( 17.0%)	23 ( 26.1%)	35 ( 39.8%)	15 ( 17.0%)	88

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Skin atrophy	5 ( 5.7%)	20 ( 22.7%)	41 ( 46.6%)	22 ( 25.0%)	88
Metastases to spine	0 ( 0.0%)	16 ( 18.2%)	65 ( 73.9%)	7 ( 8.0%)	88
Haemoglobin abnormal	6 ( 6.8%)	18 ( 20.5%)	48 ( 54.5%)	16 ( 18.2%)	88
Nephrotic syndrome	17 ( 19.3%)	13 ( 14.8%)	38 ( 43.2%)	20 ( 22.7%)	88
Obstructive sleep apnoea syndrome	8 ( 9.1%)	19 ( 21.6%)	52 ( 59.1%)	9 ( 10.2%)	88
Bradyphrenia	12 ( 13.6%)	36 ( 40.9%)	28 ( 31.8%)	12 ( 13.6%)	88
Renal cancer	0 ( 0.0%)	18 ( 20.5%)	57 ( 64.8%)	13 ( 14.8%)	88
Colitis ischaemic	3 ( 3.4%)	12 ( 13.8%)	56 ( 64.4%)	16 ( 18.4%)	87
Duodenal ulcer	9 ( 10.3%)	6 ( 6.9%)	45 ( 51.7%)	27 ( 31.0%)	87
Urine abnormality	10 ( 11.5%)	13 ( 14.9%)	55 ( 63.2%)	9 ( 10.3%)	87
Hyperuricaemia	10 ( 11.5%)	14 ( 16.1%)	51 ( 58.6%)	12 ( 13.8%)	87
Depressive symptom	10 ( 11.5%)	24 ( 27.6%)	51 ( 58.6%)	2 ( 2.3%)	87
Product odour abnormal	27 ( 31.0%)	11 ( 12.6%)	44 ( 50.6%)	5 ( 5.7%)	87
Protein urine present	7 ( 8.0%)	25 ( 28.7%)	46 ( 52.9%)	9 ( 10.3%)	87
Infusion site bruising	13 ( 14.9%)	22 ( 25.3%)	41 ( 47.1%)	11 ( 12.6%)	87
Euphoric mood	5 ( 5.7%)	55 ( 63.2%)	24 ( 27.6%)	3 ( 3.4%)	87
Tooth injury	4 ( 4.7%)	34 ( 39.5%)	47 ( 54.7%)	1 ( 1.2%)	86
Synovial cyst	3 ( 3.5%)	28 ( 32.6%)	50 ( 58.1%)	5 ( 5.8%)	86
Sexual dysfunction	19 ( 22.1%)	52 ( 60.5%)	13 ( 15.1%)	2 ( 2.3%)	86
Hepatic enzyme abnormal	8 ( 9.3%)	28 ( 32.6%)	43 ( 50.0%)	7 ( 8.1%)	86
Cushing's syndrome	10 ( 11.6%)	55 ( 64.0%)	19 ( 22.1%)	2 ( 2.3%)	86
Post-acute COVID-19 syndrome	1 ( 1.2%)	18 ( 20.9%)	53 ( 61.6%)	14 ( 16.3%)	86
Lipase increased	3 ( 3.5%)	19 ( 22.1%)	54 ( 62.8%)	10 ( 11.6%)	86
Labelled drug-drug interaction medication error	4 ( 4.7%)	18 ( 20.9%)	44 ( 51.2%)	20 ( 23.3%)	86
Lichenoid keratosis	1 ( 1.2%)	12 ( 14.0%)	58 ( 67.4%)	15 ( 17.4%)	86
Acute generalised exanthematous pustulosis	11 ( 12.8%)	15 ( 17.4%)	47 ( 54.7%)	13 ( 15.1%)	86
Hypernatraemia	13 ( 15.1%)	19 ( 22.1%)	35 ( 40.7%)	19 ( 22.1%)	86

### Reaction Summary Table

#### Derived Age Group

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Prescription drug used without a prescription	12 ( 14.0%)	32 ( 37.2%)	33 ( 38.4%)	9 ( 10.5%)	86
Dermatitis bullous	4 ( 4.7%)	17 ( 19.8%)	40 ( 46.5%)	25 ( 29.1%)	86
Gingivitis	1 ( 1.2%)	28 ( 32.6%)	48 ( 55.8%)	9 ( 10.5%)	86
Arteriospasm coronary	4 ( 4.7%)	34 ( 40.0%)	44 ( 51.8%)	3 ( 3.5%)	85
Purpura	3 ( 3.5%)	14 ( 16.5%)	39 ( 45.9%)	29 ( 34.1%)	85
Atrial flutter	2 ( 2.4%)	9 ( 10.6%)	46 ( 54.1%)	28 ( 32.9%)	85
Catatonica	20 ( 23.5%)	40 ( 47.1%)	3 ( 3.5%)	22 ( 25.9%)	85
Dysgraphia	9 ( 10.6%)	10 ( 11.8%)	51 ( 60.0%)	15 ( 17.6%)	85
Cardiac dysfunction	14 ( 16.7%)	12 ( 14.3%)	38 ( 45.2%)	20 ( 23.8%)	84
Panic reaction	4 ( 4.8%)	23 ( 27.4%)	47 ( 56.0%)	10 ( 11.9%)	84
Tricuspid valve incompetence	24 ( 28.6%)	9 ( 10.7%)	36 ( 42.9%)	15 ( 17.9%)	84
Sudden death	2 ( 2.4%)	9 ( 10.7%)	39 ( 46.4%)	34 ( 40.5%)	84
Hypotonia	32 ( 38.1%)	20 ( 23.8%)	21 ( 25.0%)	11 ( 13.1%)	84
B-lymphocyte count decreased	5 ( 6.0%)	49 ( 59.0%)	28 ( 33.7%)	1 ( 1.2%)	83
Respiratory acidosis	13 ( 15.7%)	24 ( 28.9%)	27 ( 32.5%)	19 ( 22.9%)	83
Femoral neck fracture	0 ( 0.0%)	11 ( 13.3%)	32 ( 38.6%)	40 ( 48.2%)	83
Dislocation of vertebra	0 ( 0.0%)	72 ( 86.7%)	9 ( 10.8%)	2 ( 2.4%)	83
Peritonitis bacterial	9 ( 10.8%)	13 ( 15.7%)	46 ( 55.4%)	15 ( 18.1%)	83
Physical deconditioning	2 ( 2.4%)	18 ( 21.7%)	31 ( 37.3%)	32 ( 38.6%)	83
Impaired driving ability	5 ( 6.0%)	18 ( 21.7%)	49 ( 59.0%)	11 ( 13.3%)	83
Screaming	34 ( 41.0%)	20 ( 24.1%)	14 ( 16.9%)	15 ( 18.1%)	83
Freezing phenomenon	0 ( 0.0%)	2 ( 2.4%)	54 ( 65.9%)	26 ( 31.7%)	82
Vaginal infection	5 ( 6.1%)	41 ( 50.0%)	33 ( 40.2%)	3 ( 3.7%)	82
Hepatitis acute	9 ( 11.0%)	26 ( 31.7%)	35 ( 42.7%)	12 ( 14.6%)	82
Plasma cell myeloma recurrent	0 ( 0.0%)	4 ( 4.9%)	66 ( 80.5%)	12 ( 14.6%)	82
Macular oedema	3 ( 3.7%)	15 ( 18.3%)	53 ( 64.6%)	11 ( 13.4%)	82
Enterococcal infection	11 ( 13.4%)	23 ( 28.0%)	35 ( 42.7%)	13 ( 15.9%)	82

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Laryngeal oedema	10 ( 12.2%)	35 ( 42.7%)	32 ( 39.0%)	5 ( 6.1%)	82
Maculopathy	4 ( 4.9%)	28 ( 34.1%)	46 ( 56.1%)	4 ( 4.9%)	82
Varicose vein	0 ( 0.0%)	17 ( 21.0%)	53 ( 65.4%)	11 ( 13.6%)	81
Immune-mediated lung disease	2 ( 2.5%)	5 ( 6.2%)	59 ( 72.8%)	15 ( 18.5%)	81
Arthritis infective	0 ( 0.0%)	15 ( 18.5%)	53 ( 65.4%)	13 ( 16.0%)	81
Skin warm	10 ( 12.3%)	22 ( 27.2%)	46 ( 56.8%)	3 ( 3.7%)	81
Neoplasm recurrence	8 ( 9.9%)	8 ( 9.9%)	45 ( 55.6%)	20 ( 24.7%)	81
Ear disorder	4 ( 4.9%)	25 ( 30.9%)	42 ( 51.9%)	10 ( 12.3%)	81
Immune-mediated myocarditis	2 ( 2.5%)	7 ( 8.6%)	43 ( 53.1%)	29 ( 35.8%)	81
Endocarditis	4 ( 4.9%)	28 ( 34.6%)	41 ( 50.6%)	8 ( 9.9%)	81
Bronchiolitis	45 ( 55.6%)	10 ( 12.3%)	21 ( 25.9%)	5 ( 6.2%)	81
Partial seizures	35 ( 43.2%)	17 ( 21.0%)	25 ( 30.9%)	4 ( 4.9%)	81
Nasal discomfort	5 ( 6.3%)	25 ( 31.3%)	45 ( 56.3%)	5 ( 6.3%)	80
Secondary adrenocortical insufficiency	3 ( 3.8%)	16 ( 20.0%)	43 ( 53.8%)	18 ( 22.5%)	80
Onychoclasia	1 ( 1.3%)	14 ( 17.5%)	51 ( 63.8%)	14 ( 17.5%)	80
Sleep terror	15 ( 18.8%)	13 ( 16.3%)	45 ( 56.3%)	7 ( 8.8%)	80
Sunburn	7 ( 8.8%)	24 ( 30.0%)	41 ( 51.3%)	8 ( 10.0%)	80
Oliguria	16 ( 20.0%)	14 ( 17.5%)	33 ( 41.3%)	17 ( 21.3%)	80
Peroneal nerve palsy	6 ( 7.5%)	28 ( 35.0%)	44 ( 55.0%)	2 ( 2.5%)	80
Haemolysis	10 ( 12.5%)	15 ( 18.8%)	41 ( 51.3%)	14 ( 17.5%)	80
Glucose tolerance impaired	10 ( 12.5%)	19 ( 23.8%)	45 ( 56.3%)	6 ( 7.5%)	80
Eosinophil count decreased	4 ( 5.0%)	31 ( 38.8%)	43 ( 53.8%)	2 ( 2.5%)	80
Cardiac tamponade	5 ( 6.3%)	28 ( 35.0%)	37 ( 46.3%)	10 ( 12.5%)	80
Multiple-drug resistance	26 ( 32.5%)	30 ( 37.5%)	20 ( 25.0%)	4 ( 5.0%)	80
Large intestine perforation	7 ( 8.8%)	8 ( 10.0%)	53 ( 66.3%)	12 ( 15.0%)	80
Lumbar vertebral fracture	1 ( 1.3%)	8 ( 10.0%)	48 ( 60.0%)	23 ( 28.8%)	80
Premature baby	68 ( 85.0%)	12 ( 15.0%)	0 ( 0.0%)	0 ( 0.0%)	80

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Myocardial ischaemia	7 ( 8.9%)	12 ( 15.2%)	44 ( 55.7%)	16 ( 20.3%)	79
Faeces hard	6 ( 7.6%)	10 ( 12.7%)	44 ( 55.7%)	19 ( 24.1%)	79
Personality change	25 ( 31.6%)	30 ( 38.0%)	17 ( 21.5%)	7 ( 8.9%)	79
Mouth swelling	1 ( 1.3%)	22 ( 27.8%)	47 ( 59.5%)	9 ( 11.4%)	79
Sedation complication	12 ( 15.2%)	21 ( 26.6%)	12 ( 15.2%)	34 ( 43.0%)	79
Anuria	14 ( 17.7%)	10 ( 12.7%)	44 ( 55.7%)	11 ( 13.9%)	79
Lung infiltration	16 ( 20.3%)	18 ( 22.8%)	36 ( 45.6%)	9 ( 11.4%)	79
Inflammatory bowel disease	19 ( 24.1%)	19 ( 24.1%)	37 ( 46.8%)	4 ( 5.1%)	79
Tibia fracture	7 ( 8.9%)	16 ( 20.3%)	48 ( 60.8%)	8 ( 10.1%)	79
Caesarean section	20 ( 25.3%)	59 ( 74.7%)	0 ( 0.0%)	0 ( 0.0%)	79
Serum ferritin increased	13 ( 16.5%)	9 ( 11.4%)	45 ( 57.0%)	12 ( 15.2%)	79
Raynaud's phenomenon	8 ( 10.1%)	22 ( 27.8%)	33 ( 41.8%)	16 ( 20.3%)	79
Product taste abnormal	9 ( 11.4%)	11 ( 13.9%)	44 ( 55.7%)	15 ( 19.0%)	79
Onychomadesis	0 ( 0.0%)	38 ( 48.1%)	34 ( 43.0%)	7 ( 8.9%)	79
Cholecystitis acute	1 ( 1.3%)	19 ( 24.4%)	39 ( 50.0%)	19 ( 24.4%)	78
Melanocytic naevus	3 ( 3.8%)	21 ( 26.9%)	47 ( 60.3%)	7 ( 9.0%)	78
Hyperprolactinaemia	23 ( 29.5%)	43 ( 55.1%)	11 ( 14.1%)	1 ( 1.3%)	78
Intestinal haemorrhage	4 ( 5.1%)	18 ( 23.1%)	38 ( 48.7%)	18 ( 23.1%)	78
Diverticulum	0 ( 0.0%)	8 ( 10.3%)	51 ( 65.4%)	19 ( 24.4%)	78
Cystitis noninfective	8 ( 10.4%)	40 ( 51.9%)	27 ( 35.1%)	2 ( 2.6%)	77
Hair growth abnormal	5 ( 6.5%)	23 ( 29.9%)	35 ( 45.5%)	14 ( 18.2%)	77
Hyperammonaemia	29 ( 37.7%)	20 ( 26.0%)	19 ( 24.7%)	9 ( 11.7%)	77
Bone erosion	3 ( 3.9%)	43 ( 55.8%)	29 ( 37.7%)	2 ( 2.6%)	77
Atrioventricular block complete	5 ( 6.5%)	9 ( 11.7%)	29 ( 37.7%)	34 ( 44.2%)	77
Stress cardiomyopathy	7 ( 9.1%)	6 ( 7.8%)	52 ( 67.5%)	12 ( 15.6%)	77
Contrast media allergy	4 ( 5.2%)	22 ( 28.6%)	43 ( 55.8%)	8 ( 10.4%)	77
Application site erythema	16 ( 21.1%)	24 ( 31.6%)	30 ( 39.5%)	6 ( 7.9%)	76

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pre-eclampsia	12 ( 15.8%)	64 ( 84.2%)	0 ( 0.0%)	0 ( 0.0%)	76
Vein disorder	2 ( 2.6%)	17 ( 22.4%)	42 ( 55.3%)	15 ( 19.7%)	76
Hepatic cancer	0 ( 0.0%)	10 ( 13.2%)	53 ( 69.7%)	13 ( 17.1%)	76
Cheilitis	16 ( 21.1%)	22 ( 28.9%)	29 ( 38.2%)	9 ( 11.8%)	76
Sleep deficit	5 ( 6.6%)	23 ( 30.3%)	44 ( 57.9%)	4 ( 5.3%)	76
Immune-mediated hepatitis	0 ( 0.0%)	12 ( 15.8%)	46 ( 60.5%)	18 ( 23.7%)	76
Iridocyclitis	14 ( 18.4%)	13 ( 17.1%)	37 ( 48.7%)	12 ( 15.8%)	76
Cardiac failure chronic	0 ( 0.0%)	2 ( 2.6%)	17 ( 22.4%)	57 ( 75.0%)	76
Unintended pregnancy	40 ( 52.6%)	36 ( 47.4%)	0 ( 0.0%)	0 ( 0.0%)	76
Pleurisy	1 ( 1.3%)	23 ( 30.3%)	43 ( 56.6%)	9 ( 11.8%)	76
Acute coronary syndrome	1 ( 1.3%)	15 ( 19.7%)	41 ( 53.9%)	19 ( 25.0%)	76
Gastric haemorrhage	3 ( 4.0%)	14 ( 18.7%)	37 ( 49.3%)	21 ( 28.0%)	75
Renal function test abnormal	1 ( 1.3%)	6 ( 8.0%)	37 ( 49.3%)	31 ( 41.3%)	75
Overweight	11 ( 14.7%)	15 ( 20.0%)	32 ( 42.7%)	17 ( 22.7%)	75
Eosinophilic granulomatosis with polyangiitis	3 ( 4.0%)	10 ( 13.3%)	58 ( 77.3%)	4 ( 5.3%)	75
Injection site inflammation	18 ( 24.0%)	23 ( 30.7%)	32 ( 42.7%)	2 ( 2.7%)	75
Blood glucose fluctuation	4 ( 5.3%)	10 ( 13.3%)	44 ( 58.7%)	17 ( 22.7%)	75
Epstein-Barr virus infection	35 ( 46.7%)	9 ( 12.0%)	25 ( 33.3%)	6 ( 8.0%)	75
Substance abuse	18 ( 24.0%)	54 ( 72.0%)	3 ( 4.0%)	0 ( 0.0%)	75
Ileus paralytic	5 ( 6.7%)	14 ( 18.7%)	47 ( 62.7%)	9 ( 12.0%)	75
Product label issue	7 ( 9.3%)	14 ( 18.7%)	36 ( 48.0%)	18 ( 24.0%)	75
Device safety feature issue	4 ( 5.3%)	11 ( 14.7%)	43 ( 57.3%)	17 ( 22.7%)	75
Brain natriuretic peptide increased	7 ( 9.3%)	12 ( 16.0%)	32 ( 42.7%)	24 ( 32.0%)	75
Performance status decreased	6 ( 8.0%)	18 ( 24.0%)	35 ( 46.7%)	16 ( 21.3%)	75
Cardiac murmur	17 ( 23.0%)	5 ( 6.8%)	33 ( 44.6%)	19 ( 25.7%)	74
Urine odour abnormal	5 ( 6.8%)	18 ( 24.3%)	39 ( 52.7%)	12 ( 16.2%)	74
Therapeutic product effect delayed	3 ( 4.1%)	25 ( 33.8%)	35 ( 47.3%)	11 ( 14.9%)	74

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Demyelination	13 ( 17.6%)	34 ( 45.9%)	20 ( 27.0%)	7 ( 9.5%)	74
Graft versus host disease	17 ( 23.0%)	17 ( 23.0%)	40 ( 54.1%)	0 ( 0.0%)	74
Hyperkeratosis	3 ( 4.1%)	10 ( 13.5%)	49 ( 66.2%)	12 ( 16.2%)	74
Injection site injury	5 ( 6.8%)	31 ( 41.9%)	36 ( 48.6%)	2 ( 2.7%)	74
Idiopathic pulmonary fibrosis	0 ( 0.0%)	1 ( 1.4%)	47 ( 63.5%)	26 ( 35.1%)	74
Blepharitis	13 ( 17.6%)	20 ( 27.0%)	34 ( 45.9%)	7 ( 9.5%)	74
Endophthalmitis	0 ( 0.0%)	8 ( 10.8%)	42 ( 56.8%)	24 ( 32.4%)	74
Type IV hypersensitivity reaction	7 ( 9.6%)	20 ( 27.4%)	39 ( 53.4%)	7 ( 9.6%)	73
Ligament rupture	7 ( 9.6%)	26 ( 35.6%)	36 ( 49.3%)	4 ( 5.5%)	73
Spontaneous haemorrhage	19 ( 26.0%)	38 ( 52.1%)	15 ( 20.5%)	1 ( 1.4%)	73
Food intolerance	5 ( 6.8%)	31 ( 42.5%)	26 ( 35.6%)	11 ( 15.1%)	73
Haemoglobin increased	9 ( 12.3%)	12 ( 16.4%)	48 ( 65.8%)	4 ( 5.5%)	73
Hepatic lesion	3 ( 4.1%)	19 ( 26.0%)	45 ( 61.6%)	6 ( 8.2%)	73
Mixed liver injury	0 ( 0.0%)	9 ( 12.3%)	48 ( 65.8%)	16 ( 21.9%)	73
Incorrect dosage administered	9 ( 12.3%)	11 ( 15.1%)	36 ( 49.3%)	17 ( 23.3%)	73
Lymphocyte count increased	16 ( 21.9%)	22 ( 30.1%)	26 ( 35.6%)	9 ( 12.3%)	73
Tongue disorder	4 ( 5.5%)	6 ( 8.2%)	53 ( 72.6%)	10 ( 13.7%)	73
Neurological symptom	2 ( 2.7%)	12 ( 16.4%)	50 ( 68.5%)	9 ( 12.3%)	73
Dysmenorrhoea	22 ( 30.1%)	47 ( 64.4%)	3 ( 4.1%)	1 ( 1.4%)	73
Rosacea	2 ( 2.8%)	29 ( 40.3%)	38 ( 52.8%)	3 ( 4.2%)	72
Device infusion issue	11 ( 15.3%)	13 ( 18.1%)	39 ( 54.2%)	9 ( 12.5%)	72
Listless	6 ( 8.3%)	35 ( 48.6%)	22 ( 30.6%)	9 ( 12.5%)	72
Gastric infection	11 ( 15.3%)	24 ( 33.3%)	30 ( 41.7%)	7 ( 9.7%)	72
Abdominal hernia	5 ( 6.9%)	16 ( 22.2%)	40 ( 55.6%)	11 ( 15.3%)	72
Herpes simplex	12 ( 16.7%)	16 ( 22.2%)	37 ( 51.4%)	7 ( 9.7%)	72
Product container issue	5 ( 6.9%)	14 ( 19.4%)	40 ( 55.6%)	13 ( 18.1%)	72
Obsessive-compulsive disorder	28 ( 38.9%)	27 ( 37.5%)	13 ( 18.1%)	4 ( 5.6%)	72

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Lack of injection site rotation	18 ( 25.0%)	14 ( 19.4%)	30 ( 41.7%)	10 ( 13.9%)	72
Pathological fracture	2 ( 2.8%)	12 ( 16.9%)	40 ( 56.3%)	17 ( 23.9%)	71
Liver abscess	5 ( 7.0%)	7 ( 9.9%)	52 ( 73.2%)	7 ( 9.9%)	71
Benign prostatic hyperplasia	0 ( 0.0%)	1 ( 1.4%)	39 ( 54.9%)	31 ( 43.7%)	71
Hepatitis C	0 ( 0.0%)	28 ( 39.4%)	41 ( 57.7%)	2 ( 2.8%)	71
Uterine leiomyoma	1 ( 1.4%)	47 ( 66.2%)	23 ( 32.4%)	0 ( 0.0%)	71
Asthenopia	1 ( 1.4%)	23 ( 32.4%)	36 ( 50.7%)	11 ( 15.5%)	71
Cachexia	2 ( 2.8%)	13 ( 18.3%)	40 ( 56.3%)	16 ( 22.5%)	71
Blindness transient	6 ( 8.5%)	25 ( 35.2%)	31 ( 43.7%)	9 ( 12.7%)	71
Oral infection	3 ( 4.2%)	22 ( 31.0%)	39 ( 54.9%)	7 ( 9.9%)	71
Umbilical hernia	11 ( 15.5%)	20 ( 28.2%)	35 ( 49.3%)	5 ( 7.0%)	71
Intestinal stenosis	6 ( 8.6%)	40 ( 57.1%)	22 ( 31.4%)	2 ( 2.9%)	70
Azotaemia	3 ( 4.3%)	16 ( 22.9%)	41 ( 58.6%)	10 ( 14.3%)	70
Muscle disorder	4 ( 5.7%)	10 ( 14.3%)	45 ( 64.3%)	11 ( 15.7%)	70
Application site pruritus	7 ( 10.0%)	26 ( 37.1%)	25 ( 35.7%)	12 ( 17.1%)	70
Hyperventilation	9 ( 12.9%)	34 ( 48.6%)	25 ( 35.7%)	2 ( 2.9%)	70
Colectomy	7 ( 10.0%)	28 ( 40.0%)	33 ( 47.1%)	2 ( 2.9%)	70
Abscess limb	2 ( 2.9%)	34 ( 48.6%)	32 ( 45.7%)	2 ( 2.9%)	70
Hypovolaemic shock	6 ( 8.6%)	15 ( 21.4%)	35 ( 50.0%)	14 ( 20.0%)	70
Hair texture abnormal	1 ( 1.4%)	9 ( 12.9%)	42 ( 60.0%)	18 ( 25.7%)	70
Cardiac pacemaker insertion	0 ( 0.0%)	4 ( 5.8%)	33 ( 47.8%)	32 ( 46.4%)	69
Fine motor skill dysfunction	2 ( 2.9%)	24 ( 34.8%)	32 ( 46.4%)	11 ( 15.9%)	69
Adrenocorticotrophic hormone deficiency	0 ( 0.0%)	12 ( 17.4%)	37 ( 53.6%)	20 ( 29.0%)	69
Hormone level abnormal	14 ( 20.3%)	26 ( 37.7%)	25 ( 36.2%)	4 ( 5.8%)	69
BK virus infection	25 ( 36.2%)	28 ( 40.6%)	16 ( 23.2%)	0 ( 0.0%)	69
Thermal burn	2 ( 2.9%)	18 ( 26.1%)	35 ( 50.7%)	14 ( 20.3%)	69
Wheelchair user	4 ( 5.8%)	15 ( 21.7%)	41 ( 59.4%)	9 ( 13.0%)	69



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Nasal obstruction	8 ( 11.6%)	34 ( 49.3%)	27 ( 39.1%)	0 ( 0.0%)	69
Abdominal tenderness	15 ( 21.7%)	22 ( 31.9%)	27 ( 39.1%)	5 ( 7.2%)	69
Petit mal epilepsy	35 ( 50.7%)	24 ( 34.8%)	5 ( 7.2%)	5 ( 7.2%)	69
Foetal death	1 ( 1.4%)	52 ( 75.4%)	16 ( 23.2%)	0 ( 0.0%)	69
Skin discomfort	19 ( 27.5%)	27 ( 39.1%)	21 ( 30.4%)	2 ( 2.9%)	69
Gastrointestinal toxicity	9 ( 13.0%)	10 ( 14.5%)	47 ( 68.1%)	3 ( 4.3%)	69
Pulmonary haemorrhage	15 ( 21.7%)	21 ( 30.4%)	25 ( 36.2%)	8 ( 11.6%)	69
Kounis syndrome	3 ( 4.3%)	31 ( 44.9%)	30 ( 43.5%)	5 ( 7.2%)	69
Hepatic pain	1 ( 1.4%)	21 ( 30.4%)	42 ( 60.9%)	5 ( 7.2%)	69
Adenovirus infection	49 ( 71.0%)	8 ( 11.6%)	11 ( 15.9%)	1 ( 1.4%)	69
Escherichia urinary tract infection	6 ( 8.7%)	12 ( 17.4%)	43 ( 62.3%)	8 ( 11.6%)	69
Vitamin B12 deficiency	6 ( 8.7%)	20 ( 29.0%)	31 ( 44.9%)	12 ( 17.4%)	69
Dysaesthesia	5 ( 7.2%)	30 ( 43.5%)	34 ( 49.3%)	0 ( 0.0%)	69
Creatinine renal clearance decreased	1 ( 1.4%)	6 ( 8.7%)	17 ( 24.6%)	45 ( 65.2%)	69
Blood creatinine abnormal	1 ( 1.4%)	12 ( 17.4%)	44 ( 63.8%)	12 ( 17.4%)	69
Device placement issue	11 ( 16.2%)	28 ( 41.2%)	22 ( 32.4%)	7 ( 10.3%)	68
Tearfulness	7 ( 10.3%)	16 ( 23.5%)	43 ( 63.2%)	2 ( 2.9%)	68
Hepatitis cholestatic	7 ( 10.3%)	14 ( 20.6%)	28 ( 41.2%)	19 ( 27.9%)	68
Muscle fatigue	1 ( 1.5%)	21 ( 30.9%)	40 ( 58.8%)	6 ( 8.8%)	68
Amylase increased	10 ( 14.7%)	15 ( 22.1%)	33 ( 48.5%)	10 ( 14.7%)	68
Labelled drug-drug interaction issue	7 ( 10.3%)	13 ( 19.1%)	35 ( 51.5%)	13 ( 19.1%)	68
Erythema of eyelid	31 ( 45.6%)	12 ( 17.6%)	19 ( 27.9%)	6 ( 8.8%)	68
Thyroid mass	4 ( 5.9%)	22 ( 32.4%)	38 ( 55.9%)	4 ( 5.9%)	68
Hallucinations, mixed	3 ( 4.5%)	17 ( 25.4%)	29 ( 43.3%)	18 ( 26.9%)	67
Nasal dryness	6 ( 9.0%)	19 ( 28.4%)	36 ( 53.7%)	6 ( 9.0%)	67
Aortic aneurysm	0 ( 0.0%)	2 ( 3.0%)	50 ( 74.6%)	15 ( 22.4%)	67
Periorbital oedema	11 ( 16.4%)	20 ( 29.9%)	33 ( 49.3%)	3 ( 4.5%)	67

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pre-existing condition improved	5 ( 7.5%)	27 ( 40.3%)	29 ( 43.3%)	6 ( 9.0%)	67
Hypersensitivity pneumonitis	1 ( 1.5%)	7 ( 10.4%)	40 ( 59.7%)	19 ( 28.4%)	67
Vulvovaginal mycotic infection	1 ( 1.5%)	21 ( 31.3%)	38 ( 56.7%)	7 ( 10.4%)	67
Dilated cardiomyopathy	1 ( 1.5%)	25 ( 37.3%)	22 ( 32.8%)	19 ( 28.4%)	67
Immune-mediated adrenal insufficiency	0 ( 0.0%)	12 ( 17.9%)	44 ( 65.7%)	11 ( 16.4%)	67
Apnoea	24 ( 35.8%)	20 ( 29.9%)	18 ( 26.9%)	5 ( 7.5%)	67
Cancer pain	1 ( 1.5%)	7 ( 10.4%)	49 ( 73.1%)	10 ( 14.9%)	67
Face injury	19 ( 28.8%)	12 ( 18.2%)	24 ( 36.4%)	11 ( 16.7%)	66
Atypical pneumonia	4 ( 6.1%)	26 ( 39.4%)	32 ( 48.5%)	4 ( 6.1%)	66
Mycobacterium haemophilum infection	1 ( 1.5%)	14 ( 21.2%)	39 ( 59.1%)	12 ( 18.2%)	66
Respiratory tract infection viral	13 ( 19.7%)	15 ( 22.7%)	34 ( 51.5%)	4 ( 6.1%)	66
Hyperacusis	9 ( 13.6%)	30 ( 45.5%)	25 ( 37.9%)	2 ( 3.0%)	66
Pulmonary pain	0 ( 0.0%)	15 ( 22.7%)	47 ( 71.2%)	4 ( 6.1%)	66
Pyoderma gangrenosum	7 ( 10.6%)	26 ( 39.4%)	32 ( 48.5%)	1 ( 1.5%)	66
Hair colour changes	5 ( 7.6%)	16 ( 24.2%)	31 ( 47.0%)	14 ( 21.2%)	66
Spinal fusion surgery	3 ( 4.5%)	21 ( 31.8%)	39 ( 59.1%)	3 ( 4.5%)	66
Intestinal resection	8 ( 12.1%)	23 ( 34.8%)	32 ( 48.5%)	3 ( 4.5%)	66
Ulcer haemorrhage	1 ( 1.5%)	14 ( 21.2%)	39 ( 59.1%)	12 ( 18.2%)	66
Coronary artery occlusion	0 ( 0.0%)	5 ( 7.6%)	49 ( 74.2%)	12 ( 18.2%)	66
Necrotising fasciitis	5 ( 7.7%)	16 ( 24.6%)	33 ( 50.8%)	11 ( 16.9%)	65
Cystitis haemorrhagic	12 ( 18.5%)	27 ( 41.5%)	18 ( 27.7%)	8 ( 12.3%)	65
Left ventricular dysfunction	18 ( 27.7%)	12 ( 18.5%)	28 ( 43.1%)	7 ( 10.8%)	65
Ecchymosis	8 ( 12.3%)	11 ( 16.9%)	35 ( 53.8%)	11 ( 16.9%)	65
Ovarian hyperstimulation syndrome	2 ( 3.1%)	63 ( 96.9%)	0 ( 0.0%)	0 ( 0.0%)	65
Self-medication	17 ( 26.2%)	18 ( 27.7%)	28 ( 43.1%)	2 ( 3.1%)	65
Normochromic normocytic anaemia	3 ( 4.6%)	7 ( 10.8%)	48 ( 73.8%)	7 ( 10.8%)	65
Tongue discomfort	2 ( 3.1%)	9 ( 13.8%)	42 ( 64.6%)	12 ( 18.5%)	65

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Trigeminal neuralgia	0 ( 0.0%)	23 ( 35.4%)	34 ( 52.3%)	8 ( 12.3%)	65
Hypertonic bladder	1 ( 1.5%)	16 ( 24.6%)	42 ( 64.6%)	6 ( 9.2%)	65
Tension headache	11 ( 16.9%)	28 ( 43.1%)	25 ( 38.5%)	1 ( 1.5%)	65
Diffuse large B-cell lymphoma recurrent	1 ( 1.5%)	15 ( 23.1%)	40 ( 61.5%)	9 ( 13.8%)	65
Type I hypersensitivity	11 ( 16.9%)	22 ( 33.8%)	29 ( 44.6%)	3 ( 4.6%)	65
Thrombocytosis	17 ( 26.2%)	20 ( 30.8%)	22 ( 33.8%)	6 ( 9.2%)	65
Yellow skin	4 ( 6.2%)	24 ( 36.9%)	26 ( 40.0%)	11 ( 16.9%)	65
Injection site nodule	8 ( 12.3%)	22 ( 33.8%)	30 ( 46.2%)	5 ( 7.7%)	65
Sinus pain	5 ( 7.7%)	19 ( 29.2%)	34 ( 52.3%)	7 ( 10.8%)	65
Product packaging issue	2 ( 3.1%)	9 ( 13.8%)	44 ( 67.7%)	10 ( 15.4%)	65
Product temperature excursion issue	10 ( 15.4%)	21 ( 32.3%)	28 ( 43.1%)	6 ( 9.2%)	65
Nail discolouration	5 ( 7.8%)	8 ( 12.5%)	30 ( 46.9%)	21 ( 32.8%)	64
Tongue oedema	0 ( 0.0%)	28 ( 43.8%)	27 ( 42.2%)	9 ( 14.1%)	64
Pneumonia viral	5 ( 7.8%)	7 ( 10.9%)	34 ( 53.1%)	18 ( 28.1%)	64
Muscle contractions involuntary	12 ( 18.8%)	27 ( 42.2%)	21 ( 32.8%)	4 ( 6.3%)	64
Disorganised speech	6 ( 9.4%)	22 ( 34.4%)	18 ( 28.1%)	18 ( 28.1%)	64
Visual field defect	5 ( 7.8%)	29 ( 45.3%)	24 ( 37.5%)	6 ( 9.4%)	64
Fournier's gangrene	1 ( 1.6%)	19 ( 29.7%)	41 ( 64.1%)	3 ( 4.7%)	64
Anorectal discomfort	6 ( 9.4%)	13 ( 20.3%)	39 ( 60.9%)	6 ( 9.4%)	64
Clavicle fracture	5 ( 7.8%)	7 ( 10.9%)	41 ( 64.1%)	11 ( 17.2%)	64
Enuresis	17 ( 26.6%)	24 ( 37.5%)	19 ( 29.7%)	4 ( 6.3%)	64
Deafness unilateral	5 ( 7.8%)	12 ( 18.8%)	42 ( 65.6%)	5 ( 7.8%)	64
Dry age-related macular degeneration	2 ( 3.1%)	9 ( 14.1%)	42 ( 65.6%)	11 ( 17.2%)	64
Aplastic anaemia	33 ( 51.6%)	3 ( 4.7%)	11 ( 17.2%)	17 ( 26.6%)	64
Female genital tract fistula	1 ( 1.6%)	9 ( 14.3%)	53 ( 84.1%)	0 ( 0.0%)	63
Eyelid margin crusting	9 ( 14.3%)	10 ( 15.9%)	38 ( 60.3%)	6 ( 9.5%)	63
Rehabilitation therapy	1 ( 1.6%)	7 ( 11.1%)	29 ( 46.0%)	26 ( 41.3%)	63

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Photopsia	0 ( 0.0%)	22 ( 34.9%)	33 ( 52.4%)	8 ( 12.7%)	63
Hepatitis B	0 ( 0.0%)	20 ( 31.7%)	38 ( 60.3%)	5 ( 7.9%)	63
Muscle rupture	1 ( 1.6%)	22 ( 34.9%)	36 ( 57.1%)	4 ( 6.3%)	63
Clostridium test positive	1 ( 1.6%)	7 ( 11.1%)	19 ( 30.2%)	36 ( 57.1%)	63
Gastrointestinal sounds abnormal	5 ( 7.9%)	10 ( 15.9%)	40 ( 63.5%)	8 ( 12.7%)	63
Slow speech	13 ( 20.6%)	24 ( 38.1%)	23 ( 36.5%)	3 ( 4.8%)	63
Drug tolerance decreased	0 ( 0.0%)	43 ( 68.3%)	16 ( 25.4%)	4 ( 6.3%)	63
Mean cell haemoglobin concentration decreased	2 ( 3.2%)	20 ( 31.7%)	37 ( 58.7%)	4 ( 6.3%)	63
Accidental exposure to product by child	63 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	63
Drug level above therapeutic	9 ( 14.3%)	10 ( 15.9%)	42 ( 66.7%)	2 ( 3.2%)	63
Acute pulmonary oedema	6 ( 9.7%)	17 ( 27.4%)	28 ( 45.2%)	11 ( 17.7%)	62
Eyelids pruritus	14 ( 22.6%)	12 ( 19.4%)	32 ( 51.6%)	4 ( 6.5%)	62
Faecal calprotectin increased	14 ( 22.6%)	25 ( 40.3%)	20 ( 32.3%)	3 ( 4.8%)	62
Traumatic haemorrhage	33 ( 53.2%)	18 ( 29.0%)	9 ( 14.5%)	2 ( 3.2%)	62
Cardiac flutter	3 ( 4.8%)	20 ( 32.3%)	28 ( 45.2%)	11 ( 17.7%)	62
Arterial occlusive disease	0 ( 0.0%)	4 ( 6.5%)	42 ( 67.7%)	16 ( 25.8%)	62
Paranasal sinus discomfort	3 ( 4.8%)	16 ( 25.8%)	41 ( 66.1%)	2 ( 3.2%)	62
Affect lability	10 ( 16.1%)	15 ( 24.2%)	29 ( 46.8%)	8 ( 12.9%)	62
Dust allergy	1 ( 1.6%)	12 ( 19.4%)	48 ( 77.4%)	1 ( 1.6%)	62
Necrosis	5 ( 8.1%)	10 ( 16.1%)	41 ( 66.1%)	6 ( 9.7%)	62
Nephritis	4 ( 6.5%)	17 ( 27.4%)	35 ( 56.5%)	6 ( 9.7%)	62
Endometriosis	13 ( 21.0%)	41 ( 66.1%)	7 ( 11.3%)	1 ( 1.6%)	62
Hyperlactacidaemia	17 ( 27.4%)	8 ( 12.9%)	36 ( 58.1%)	1 ( 1.6%)	62
Procedural complication	4 ( 6.5%)	17 ( 27.4%)	35 ( 56.5%)	6 ( 9.7%)	62
Gastrointestinal perforation	1 ( 1.6%)	12 ( 19.4%)	37 ( 59.7%)	12 ( 19.4%)	62
Haemorrhoidal haemorrhage	2 ( 3.2%)	10 ( 16.1%)	37 ( 59.7%)	13 ( 21.0%)	62
Glomerulonephritis	8 ( 13.1%)	17 ( 27.9%)	26 ( 42.6%)	10 ( 16.4%)	61

### Reaction Summary Table

#### Derived Age Group

	<i>Group1 (0-25)</i> (N=&AGEGRP1)	<i>Group2 (26-50)</i> (N=&AGEGRP2)	<i>Group3 (51-75)</i> (N=&AGEGRP3)	<i>Group4 (75+)</i> (N=&AGEGRP4)	<i>Total</i> (N=&AGEGRP5)
Shoulder arthroplasty	0 ( 0.0%)	3 ( 4.9%)	46 ( 75.4%)	12 ( 19.7%)	61
Substance-induced psychotic disorder	19 ( 31.1%)	16 ( 26.2%)	21 ( 34.4%)	5 ( 8.2%)	61
Subcutaneous abscess	8 ( 13.1%)	32 ( 52.5%)	14 ( 23.0%)	7 ( 11.5%)	61
Skin papilloma	13 ( 21.3%)	21 ( 34.4%)	22 ( 36.1%)	5 ( 8.2%)	61
Graves' disease	3 ( 4.9%)	27 ( 44.3%)	30 ( 49.2%)	1 ( 1.6%)	61
Neutrophil count abnormal	10 ( 16.4%)	10 ( 16.4%)	35 ( 57.4%)	6 ( 9.8%)	61
Joint noise	2 ( 3.3%)	25 ( 41.0%)	28 ( 45.9%)	6 ( 9.8%)	61
Abdominal abscess	7 ( 11.5%)	23 ( 37.7%)	28 ( 45.9%)	3 ( 4.9%)	61
Eosinophilic pneumonia	1 ( 1.6%)	10 ( 16.4%)	33 ( 54.1%)	17 ( 27.9%)	61
X-ray abnormal	3 ( 4.9%)	50 ( 82.0%)	8 ( 13.1%)	0 ( 0.0%)	61
Radiculopathy	1 ( 1.6%)	6 ( 9.8%)	53 ( 86.9%)	1 ( 1.6%)	61
Rhinalgia	2 ( 3.3%)	13 ( 21.3%)	38 ( 62.3%)	8 ( 13.1%)	61
Product dispensing issue	5 ( 8.2%)	13 ( 21.3%)	27 ( 44.3%)	16 ( 26.2%)	61
Renal tubular injury	0 ( 0.0%)	17 ( 27.9%)	34 ( 55.7%)	10 ( 16.4%)	61
Faecaloma	3 ( 5.0%)	6 ( 10.0%)	41 ( 68.3%)	10 ( 16.7%)	60
Incoherent	7 ( 11.7%)	14 ( 23.3%)	20 ( 33.3%)	19 ( 31.7%)	60
Humerus fracture	1 ( 1.7%)	6 ( 10.0%)	36 ( 60.0%)	17 ( 28.3%)	60
Body height increased	38 ( 63.3%)	12 ( 20.0%)	7 ( 11.7%)	3 ( 5.0%)	60
Lower gastrointestinal haemorrhage	0 ( 0.0%)	3 ( 5.0%)	34 ( 56.7%)	23 ( 38.3%)	60
Blood creatinine decreased	12 ( 20.0%)	18 ( 30.0%)	28 ( 46.7%)	2 ( 3.3%)	60
Procedural haemorrhage	10 ( 16.7%)	24 ( 40.0%)	21 ( 35.0%)	5 ( 8.3%)	60
Metabolic disorder	13 ( 21.7%)	21 ( 35.0%)	20 ( 33.3%)	6 ( 10.0%)	60
Craniofacial fracture	3 ( 5.0%)	12 ( 20.0%)	33 ( 55.0%)	12 ( 20.0%)	60
Retinal haemorrhage	2 ( 3.3%)	15 ( 25.0%)	29 ( 48.3%)	14 ( 23.3%)	60
Cervical vertebral fracture	0 ( 0.0%)	7 ( 11.7%)	33 ( 55.0%)	20 ( 33.3%)	60
Sinus headache	3 ( 5.0%)	12 ( 20.0%)	42 ( 70.0%)	3 ( 5.0%)	60
Fibrin D dimer increased	5 ( 8.5%)	12 ( 20.3%)	30 ( 50.8%)	12 ( 20.3%)	59

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hepatic neoplasm	2 ( 3.4%)	9 ( 15.3%)	43 ( 72.9%)	5 ( 8.5%)	59
Trigger finger	0 ( 0.0%)	7 ( 11.9%)	43 ( 72.9%)	9 ( 15.3%)	59
Feeling of body temperature change	8 ( 13.6%)	22 ( 37.3%)	28 ( 47.5%)	1 ( 1.7%)	59
Intestinal ischaemia	4 ( 6.8%)	11 ( 18.6%)	31 ( 52.5%)	13 ( 22.0%)	59
Skin hyperpigmentation	7 ( 11.9%)	24 ( 40.7%)	24 ( 40.7%)	4 ( 6.8%)	59
Psychiatric decompensation	4 ( 6.8%)	26 ( 44.1%)	29 ( 49.2%)	0 ( 0.0%)	59
Abnormal weight gain	18 ( 30.5%)	28 ( 47.5%)	11 ( 18.6%)	2 ( 3.4%)	59
Product size issue	2 ( 3.4%)	8 ( 13.6%)	31 ( 52.5%)	18 ( 30.5%)	59
Immunoglobulins decreased	5 ( 8.5%)	23 ( 39.0%)	26 ( 44.1%)	5 ( 8.5%)	59
Lip oedema	7 ( 11.9%)	18 ( 30.5%)	27 ( 45.8%)	7 ( 11.9%)	59
Stoma site erythema	6 ( 10.3%)	1 ( 1.7%)	36 ( 62.1%)	15 ( 25.9%)	58
Arthritis bacterial	2 ( 3.4%)	22 ( 37.9%)	30 ( 51.7%)	4 ( 6.9%)	58
Lyme disease	11 ( 19.0%)	18 ( 31.0%)	26 ( 44.8%)	3 ( 5.2%)	58
Hydrocephalus	18 ( 31.0%)	16 ( 27.6%)	15 ( 25.9%)	9 ( 15.5%)	58
Cataract operation	1 ( 1.7%)	1 ( 1.7%)	42 ( 72.4%)	14 ( 24.1%)	58
Choking sensation	6 ( 10.3%)	21 ( 36.2%)	28 ( 48.3%)	3 ( 5.2%)	58
Dacryostenosis acquired	2 ( 3.4%)	20 ( 34.5%)	33 ( 56.9%)	3 ( 5.2%)	58
Lupus nephritis	3 ( 5.2%)	33 ( 56.9%)	16 ( 27.6%)	6 ( 10.3%)	58
Food craving	4 ( 6.9%)	27 ( 46.6%)	25 ( 43.1%)	2 ( 3.4%)	58
Sarcoidosis	3 ( 5.2%)	17 ( 29.3%)	33 ( 56.9%)	5 ( 8.6%)	58
Pharyngeal paraesthesia	6 ( 10.3%)	32 ( 55.2%)	20 ( 34.5%)	0 ( 0.0%)	58
Meningioma	2 ( 3.4%)	18 ( 31.0%)	32 ( 55.2%)	6 ( 10.3%)	58
Autoimmune thyroiditis	8 ( 13.8%)	20 ( 34.5%)	27 ( 46.6%)	3 ( 5.2%)	58
Infection susceptibility increased	2 ( 3.4%)	34 ( 58.6%)	18 ( 31.0%)	4 ( 6.9%)	58
Pulse absent	4 ( 6.9%)	14 ( 24.1%)	31 ( 53.4%)	9 ( 15.5%)	58
Lupus vulgaris	0 ( 0.0%)	53 ( 91.4%)	5 ( 8.6%)	0 ( 0.0%)	58
Polymyalgia rheumatica	0 ( 0.0%)	0 ( 0.0%)	38 ( 65.5%)	20 ( 34.5%)	58

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Wound haemorrhage	4 ( 6.9%)	11 ( 19.0%)	25 ( 43.1%)	18 ( 31.0%)	58
Chapped lips	11 ( 19.0%)	21 ( 36.2%)	20 ( 34.5%)	6 ( 10.3%)	58
Varicella zoster virus infection	16 ( 27.6%)	13 ( 22.4%)	28 ( 48.3%)	1 ( 1.7%)	58
Plantar fasciitis	0 ( 0.0%)	8 ( 13.8%)	32 ( 55.2%)	18 ( 31.0%)	58
Animal bite	6 ( 10.3%)	21 ( 36.2%)	28 ( 48.3%)	3 ( 5.2%)	58
Near death experience	5 ( 8.6%)	8 ( 13.8%)	36 ( 62.1%)	9 ( 15.5%)	58
Vitamin B12 decreased	0 ( 0.0%)	16 ( 28.1%)	34 ( 59.6%)	7 ( 12.3%)	57
Methaemoglobinaemia	11 ( 19.3%)	16 ( 28.1%)	26 ( 45.6%)	4 ( 7.0%)	57
Blood creatine increased	4 ( 7.0%)	12 ( 21.1%)	28 ( 49.1%)	13 ( 22.8%)	57
Bone lesion	1 ( 1.8%)	12 ( 21.1%)	43 ( 75.4%)	1 ( 1.8%)	57
Hypovolaemia	3 ( 5.3%)	5 ( 8.8%)	29 ( 50.9%)	20 ( 35.1%)	57
Fungal skin infection	2 ( 3.5%)	13 ( 22.8%)	37 ( 64.9%)	5 ( 8.8%)	57
Autonomic nervous system imbalance	7 ( 12.3%)	13 ( 22.8%)	32 ( 56.1%)	5 ( 8.8%)	57
Monoplegia	7 ( 12.3%)	21 ( 36.8%)	22 ( 38.6%)	7 ( 12.3%)	57
Hyperphosphataemia	4 ( 7.0%)	10 ( 17.5%)	18 ( 31.6%)	25 ( 43.9%)	57
Bell's palsy	2 ( 3.5%)	15 ( 26.3%)	36 ( 63.2%)	4 ( 7.0%)	57
Guillain-Barre syndrome	2 ( 3.5%)	14 ( 24.6%)	34 ( 59.6%)	7 ( 12.3%)	57
Juvenile idiopathic arthritis	56 ( 98.2%)	1 ( 1.8%)	0 ( 0.0%)	0 ( 0.0%)	57
Clonus	21 ( 36.8%)	9 ( 15.8%)	24 ( 42.1%)	3 ( 5.3%)	57
Dermatomyositis	6 ( 10.5%)	12 ( 21.1%)	36 ( 63.2%)	3 ( 5.3%)	57
Norovirus infection	15 ( 26.3%)	16 ( 28.1%)	24 ( 42.1%)	2 ( 3.5%)	57
Paradoxical drug reaction	18 ( 31.6%)	15 ( 26.3%)	16 ( 28.1%)	8 ( 14.0%)	57
Thyroid cancer	0 ( 0.0%)	20 ( 35.1%)	33 ( 57.9%)	4 ( 7.0%)	57
Stress fracture	2 ( 3.5%)	14 ( 24.6%)	34 ( 59.6%)	7 ( 12.3%)	57
Foreign body sensation in eyes	3 ( 5.3%)	8 ( 14.0%)	34 ( 59.6%)	12 ( 21.1%)	57
Eye injury	12 ( 21.4%)	22 ( 39.3%)	16 ( 28.6%)	6 ( 10.7%)	56
Hypopnoea	3 ( 5.4%)	19 ( 33.9%)	30 ( 53.6%)	4 ( 7.1%)	56

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Gastric cancer	0 ( 0.0%)	3 ( 5.4%)	35 ( 62.5%)	18 ( 32.1%)	56
Feeling drunk	10 ( 17.9%)	23 ( 41.1%)	17 ( 30.4%)	6 ( 10.7%)	56
Heparin-induced thrombocytopenia	1 ( 1.8%)	7 ( 12.5%)	40 ( 71.4%)	8 ( 14.3%)	56
Mean cell haemoglobin increased	5 ( 8.9%)	14 ( 25.0%)	29 ( 51.8%)	8 ( 14.3%)	56
Chronic gastritis	3 ( 5.4%)	17 ( 30.4%)	28 ( 50.0%)	8 ( 14.3%)	56
Neck surgery	0 ( 0.0%)	13 ( 23.2%)	41 ( 73.2%)	2 ( 3.6%)	56
Normal newborn	15 ( 26.8%)	41 ( 73.2%)	0 ( 0.0%)	0 ( 0.0%)	56
Mucosal dryness	15 ( 26.8%)	16 ( 28.6%)	19 ( 33.9%)	6 ( 10.7%)	56
Energy increased	1 ( 1.8%)	17 ( 30.4%)	30 ( 53.6%)	8 ( 14.3%)	56
Acute graft versus host disease	28 ( 50.0%)	11 ( 19.6%)	15 ( 26.8%)	2 ( 3.6%)	56
Escherichia bacteraemia	13 ( 23.2%)	10 ( 17.9%)	24 ( 42.9%)	9 ( 16.1%)	56
Mycobacterium avium complex infection	0 ( 0.0%)	5 ( 8.9%)	47 ( 83.9%)	4 ( 7.1%)	56
C-reactive protein	0 ( 0.0%)	55 ( 98.2%)	1 ( 1.8%)	0 ( 0.0%)	56
Potentiating drug interaction	5 ( 8.9%)	17 ( 30.4%)	21 ( 37.5%)	13 ( 23.2%)	56
Deformity	3 ( 5.4%)	29 ( 51.8%)	19 ( 33.9%)	5 ( 8.9%)	56
Papilloedema	25 ( 44.6%)	8 ( 14.3%)	20 ( 35.7%)	3 ( 5.4%)	56
Menstrual disorder	8 ( 14.3%)	39 ( 69.6%)	9 ( 16.1%)	0 ( 0.0%)	56
Ileostomy	4 ( 7.3%)	28 ( 50.9%)	22 ( 40.0%)	1 ( 1.8%)	55
Bone cancer	0 ( 0.0%)	2 ( 3.6%)	43 ( 78.2%)	10 ( 18.2%)	55
Pneumonia klebsiella	5 ( 9.1%)	17 ( 30.9%)	26 ( 47.3%)	7 ( 12.7%)	55
Troponin I increased	33 ( 60.0%)	4 ( 7.3%)	14 ( 25.5%)	4 ( 7.3%)	55
Drug level below therapeutic	17 ( 30.9%)	22 ( 40.0%)	13 ( 23.6%)	3 ( 5.5%)	55
Cholestatic liver injury	0 ( 0.0%)	10 ( 18.2%)	34 ( 61.8%)	11 ( 20.0%)	55
Aplasia	8 ( 14.5%)	7 ( 12.7%)	37 ( 67.3%)	3 ( 5.5%)	55
Malabsorption	8 ( 14.5%)	24 ( 43.6%)	20 ( 36.4%)	3 ( 5.5%)	55
Carcinoembryonic antigen increased	0 ( 0.0%)	9 ( 16.7%)	40 ( 74.1%)	5 ( 9.3%)	54
Skin necrosis	4 ( 7.4%)	7 ( 13.0%)	36 ( 66.7%)	7 ( 13.0%)	54



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Erythema nodosum	5 ( 9.3%)	28 ( 51.9%)	21 ( 38.9%)	0 ( 0.0%)	54
Right ventricular failure	3 ( 5.6%)	12 ( 22.2%)	30 ( 55.6%)	9 ( 16.7%)	54
Localised oedema	5 ( 9.3%)	9 ( 16.7%)	33 ( 61.1%)	7 ( 13.0%)	54
Epigastric discomfort	1 ( 1.9%)	14 ( 25.9%)	33 ( 61.1%)	6 ( 11.1%)	54
Stoma complication	8 ( 14.8%)	14 ( 25.9%)	30 ( 55.6%)	2 ( 3.7%)	54
Skin erosion	7 ( 13.0%)	7 ( 13.0%)	30 ( 55.6%)	10 ( 18.5%)	54
Leukoencephalopathy	9 ( 16.7%)	8 ( 14.8%)	23 ( 42.6%)	14 ( 25.9%)	54
Tenosynovitis	5 ( 9.3%)	14 ( 25.9%)	31 ( 57.4%)	4 ( 7.4%)	54
Fluid intake reduced	6 ( 11.1%)	7 ( 13.0%)	28 ( 51.9%)	13 ( 24.1%)	54
Exposure to SARS-CoV-2	1 ( 1.9%)	13 ( 24.1%)	33 ( 61.1%)	7 ( 13.0%)	54
Anaphylactoid reaction	3 ( 5.6%)	12 ( 22.2%)	31 ( 57.4%)	8 ( 14.8%)	54
Renal tubular acidosis	8 ( 14.8%)	23 ( 42.6%)	15 ( 27.8%)	8 ( 14.8%)	54
Ocular icterus	9 ( 16.7%)	11 ( 20.4%)	23 ( 42.6%)	11 ( 20.4%)	54
Temperature regulation disorder	3 ( 5.6%)	28 ( 51.9%)	20 ( 37.0%)	3 ( 5.6%)	54
Abdominal mass	2 ( 3.7%)	15 ( 27.8%)	31 ( 57.4%)	6 ( 11.1%)	54
Product physical consistency issue	9 ( 16.7%)	6 ( 11.1%)	24 ( 44.4%)	15 ( 27.8%)	54
Hypopituitarism	3 ( 5.7%)	10 ( 18.9%)	28 ( 52.8%)	12 ( 22.6%)	53
Systemic inflammatory response syndrome	9 ( 17.0%)	12 ( 22.6%)	27 ( 50.9%)	5 ( 9.4%)	53
Recurrent cancer	2 ( 3.8%)	5 ( 9.4%)	39 ( 73.6%)	7 ( 13.2%)	53
Nystagmus	12 ( 22.6%)	17 ( 32.1%)	21 ( 39.6%)	3 ( 5.7%)	53
Abortion induced	22 ( 41.5%)	31 ( 58.5%)	0 ( 0.0%)	0 ( 0.0%)	53
Rash pustular	5 ( 9.4%)	14 ( 26.4%)	31 ( 58.5%)	3 ( 5.7%)	53
Oesophageal pain	1 ( 1.9%)	13 ( 24.5%)	36 ( 67.9%)	3 ( 5.7%)	53
Aneurysm	0 ( 0.0%)	13 ( 24.5%)	26 ( 49.1%)	14 ( 26.4%)	53
Hepatic cyst	0 ( 0.0%)	14 ( 26.4%)	34 ( 64.2%)	5 ( 9.4%)	53
Fulminant type 1 diabetes mellitus	0 ( 0.0%)	5 ( 9.4%)	37 ( 69.8%)	11 ( 20.8%)	53
Depression suicidal	8 ( 15.1%)	18 ( 34.0%)	27 ( 50.9%)	0 ( 0.0%)	53

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Chronic myeloid leukaemia	2 ( 3.8%)	18 ( 34.0%)	23 ( 43.4%)	10 ( 18.9%)	53
Sputum increased	5 ( 9.4%)	12 ( 22.6%)	28 ( 52.8%)	8 ( 15.1%)	53
Small for dates baby	53 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	53
Product label confusion	4 ( 7.5%)	31 ( 58.5%)	13 ( 24.5%)	5 ( 9.4%)	53
Eastern Cooperative Oncology Group performance status	0 ( 0.0%)	7 ( 13.2%)	30 ( 56.6%)	16 ( 30.2%)	53
Menopause	0 ( 0.0%)	26 ( 49.1%)	26 ( 49.1%)	1 ( 1.9%)	53
Large intestinal ulcer	1 ( 1.9%)	14 ( 26.9%)	29 ( 55.8%)	8 ( 15.4%)	52
Red blood cell count increased	5 ( 9.6%)	14 ( 26.9%)	29 ( 55.8%)	4 ( 7.7%)	52
Systemic candida	11 ( 21.2%)	11 ( 21.2%)	27 ( 51.9%)	3 ( 5.8%)	52
Therapeutic product effect variable	3 ( 5.8%)	21 ( 40.4%)	20 ( 38.5%)	8 ( 15.4%)	52
Venous thrombosis	7 ( 13.5%)	6 ( 11.5%)	34 ( 65.4%)	5 ( 9.6%)	52
Pustular psoriasis	4 ( 7.7%)	15 ( 28.8%)	31 ( 59.6%)	2 ( 3.8%)	52
Autoimmune haemolytic anaemia	7 ( 13.5%)	11 ( 21.2%)	27 ( 51.9%)	7 ( 13.5%)	52
Gallbladder operation	4 ( 7.7%)	15 ( 28.8%)	24 ( 46.2%)	9 ( 17.3%)	52
Polyomavirus viraemia	15 ( 28.8%)	11 ( 21.2%)	25 ( 48.1%)	1 ( 1.9%)	52
Neurological decompensation	2 ( 3.8%)	20 ( 38.5%)	23 ( 44.2%)	7 ( 13.5%)	52
Mean cell haemoglobin decreased	2 ( 3.8%)	32 ( 61.5%)	18 ( 34.6%)	0 ( 0.0%)	52
Bile duct stone	2 ( 3.8%)	8 ( 15.4%)	31 ( 59.6%)	11 ( 21.2%)	52
Increased upper airway secretion	8 ( 15.4%)	10 ( 19.2%)	24 ( 46.2%)	10 ( 19.2%)	52
Granuloma	7 ( 13.5%)	13 ( 25.0%)	29 ( 55.8%)	3 ( 5.8%)	52
Otitis media	18 ( 35.3%)	20 ( 39.2%)	9 ( 17.6%)	4 ( 7.8%)	51
Prostate cancer metastatic	0 ( 0.0%)	2 ( 3.9%)	23 ( 45.1%)	26 ( 51.0%)	51
Ear swelling	7 ( 13.7%)	20 ( 39.2%)	21 ( 41.2%)	3 ( 5.9%)	51
Blood immunoglobulin E increased	9 ( 17.6%)	16 ( 31.4%)	25 ( 49.0%)	1 ( 2.0%)	51
Peripheral ischaemia	5 ( 9.8%)	15 ( 29.4%)	22 ( 43.1%)	9 ( 17.6%)	51
Hepatic fibrosis	5 ( 9.8%)	19 ( 37.3%)	25 ( 49.0%)	2 ( 3.9%)	51
Pneumomediastinum	19 ( 37.3%)	18 ( 35.3%)	9 ( 17.6%)	5 ( 9.8%)	51

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Body temperature abnormal	15 ( 29.4%)	18 ( 35.3%)	13 ( 25.5%)	5 ( 9.8%)	51
Staphylococcal sepsis	11 ( 21.6%)	10 ( 19.6%)	24 ( 47.1%)	6 ( 11.8%)	51
Drug tolerance	5 ( 9.8%)	18 ( 35.3%)	26 ( 51.0%)	2 ( 3.9%)	51
Immune-mediated dermatitis	0 ( 0.0%)	6 ( 11.8%)	37 ( 72.5%)	8 ( 15.7%)	51
Bladder pain	4 ( 7.8%)	10 ( 19.6%)	28 ( 54.9%)	9 ( 17.6%)	51
Breast cancer stage II	0 ( 0.0%)	48 ( 94.1%)	3 ( 5.9%)	0 ( 0.0%)	51
Product residue present	3 ( 5.9%)	22 ( 43.1%)	22 ( 43.1%)	4 ( 7.8%)	51
Conjunctivitis allergic	1 ( 2.0%)	5 ( 9.8%)	43 ( 84.3%)	2 ( 3.9%)	51
Metastases to peritoneum	2 ( 4.0%)	11 ( 22.0%)	29 ( 58.0%)	8 ( 16.0%)	50
Central venous catheterisation	9 ( 18.0%)	16 ( 32.0%)	22 ( 44.0%)	3 ( 6.0%)	50
Bronchopulmonary aspergillosis allergic	0 ( 0.0%)	3 ( 6.0%)	21 ( 42.0%)	26 ( 52.0%)	50
Contraindicated product prescribed	1 ( 2.0%)	17 ( 34.0%)	24 ( 48.0%)	8 ( 16.0%)	50
Ingrowing nail	8 ( 16.0%)	12 ( 24.0%)	27 ( 54.0%)	3 ( 6.0%)	50
Vulvovaginal dryness	3 ( 6.0%)	11 ( 22.0%)	31 ( 62.0%)	5 ( 10.0%)	50
Haemorrhage subcutaneous	4 ( 8.0%)	5 ( 10.0%)	24 ( 48.0%)	17 ( 34.0%)	50
Drug delivery system malfunction	4 ( 8.0%)	16 ( 32.0%)	27 ( 54.0%)	3 ( 6.0%)	50
Snoring	8 ( 16.0%)	16 ( 32.0%)	23 ( 46.0%)	3 ( 6.0%)	50
Vulvovaginal pruritus	4 ( 8.0%)	8 ( 16.0%)	31 ( 62.0%)	7 ( 14.0%)	50
Stoma site pain	0 ( 0.0%)	6 ( 12.0%)	31 ( 62.0%)	13 ( 26.0%)	50
Injection site hypersensitivity	7 ( 14.0%)	14 ( 28.0%)	28 ( 56.0%)	1 ( 2.0%)	50
Immunisation reaction	3 ( 6.0%)	24 ( 48.0%)	19 ( 38.0%)	4 ( 8.0%)	50
Parainfluenzae virus infection	21 ( 42.0%)	5 ( 10.0%)	18 ( 36.0%)	6 ( 12.0%)	50
N-terminal prohormone brain natriuretic peptide incre	2 ( 4.0%)	14 ( 28.0%)	28 ( 56.0%)	6 ( 12.0%)	50
Seronegative arthritis	0 ( 0.0%)	42 ( 84.0%)	5 ( 10.0%)	3 ( 6.0%)	50
Limb mass	1 ( 2.0%)	10 ( 20.0%)	27 ( 54.0%)	12 ( 24.0%)	50
Ammonia increased	6 ( 12.0%)	5 ( 10.0%)	32 ( 64.0%)	7 ( 14.0%)	50
Pregnancy with contraceptive device	11 ( 22.0%)	39 ( 78.0%)	0 ( 0.0%)	0 ( 0.0%)	50

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Rash vesicular	7 ( 14.0%)	15 ( 30.0%)	22 ( 44.0%)	6 ( 12.0%)	50
Wound complication	4 ( 8.0%)	14 ( 28.0%)	27 ( 54.0%)	5 ( 10.0%)	50
Total lung capacity decreased	1 ( 2.0%)	7 ( 14.0%)	15 ( 30.0%)	27 ( 54.0%)	50
Cerebral ischaemia	5 ( 10.0%)	4 ( 8.0%)	32 ( 64.0%)	9 ( 18.0%)	50
Ophthalmic herpes zoster	2 ( 4.0%)	9 ( 18.0%)	29 ( 58.0%)	10 ( 20.0%)	50
Psychomotor skills impaired	7 ( 14.0%)	10 ( 20.0%)	30 ( 60.0%)	3 ( 6.0%)	50
Thoracic vertebral fracture	1 ( 2.0%)	9 ( 18.4%)	28 ( 57.1%)	11 ( 22.4%)	49
Lymphoproliferative disorder	5 ( 10.2%)	3 ( 6.1%)	23 ( 46.9%)	18 ( 36.7%)	49
Renal cell carcinoma	0 ( 0.0%)	6 ( 12.2%)	37 ( 75.5%)	6 ( 12.2%)	49
Phlebitis	0 ( 0.0%)	15 ( 30.6%)	27 ( 55.1%)	7 ( 14.3%)	49
Communication disorder	5 ( 10.2%)	11 ( 22.4%)	20 ( 40.8%)	13 ( 26.5%)	49
Blood thyroid stimulating hormone decreased	3 ( 6.1%)	16 ( 32.7%)	23 ( 46.9%)	7 ( 14.3%)	49
Infarction	1 ( 2.0%)	2 ( 4.1%)	33 ( 67.3%)	13 ( 26.5%)	49
Bundle branch block right	4 ( 8.2%)	12 ( 24.5%)	23 ( 46.9%)	10 ( 20.4%)	49
Functional gastrointestinal disorder	2 ( 4.1%)	22 ( 44.9%)	18 ( 36.7%)	7 ( 14.3%)	49
Hypertonia	14 ( 28.6%)	19 ( 38.8%)	9 ( 18.4%)	7 ( 14.3%)	49
Immune-mediated hypophysitis	0 ( 0.0%)	20 ( 40.8%)	21 ( 42.9%)	8 ( 16.3%)	49
Portal vein thrombosis	0 ( 0.0%)	8 ( 16.3%)	39 ( 79.6%)	2 ( 4.1%)	49
Cardiac valve disease	2 ( 4.1%)	3 ( 6.1%)	24 ( 49.0%)	20 ( 40.8%)	49
Prostatic disorder	0 ( 0.0%)	0 ( 0.0%)	31 ( 63.3%)	18 ( 36.7%)	49
Wrong patient received product	7 ( 14.6%)	8 ( 16.7%)	14 ( 29.2%)	19 ( 39.6%)	48
Acute myeloid leukaemia recurrent	8 ( 16.7%)	9 ( 18.8%)	26 ( 54.2%)	5 ( 10.4%)	48
Pulseless electrical activity	1 ( 2.1%)	10 ( 20.8%)	28 ( 58.3%)	9 ( 18.8%)	48
Wound secretion	2 ( 4.2%)	9 ( 18.8%)	30 ( 62.5%)	7 ( 14.6%)	48
Cortisol decreased	6 ( 12.5%)	14 ( 29.2%)	21 ( 43.8%)	7 ( 14.6%)	48
Oxygen saturation abnormal	10 ( 20.8%)	11 ( 22.9%)	21 ( 43.8%)	6 ( 12.5%)	48
Maternal exposure timing unspecified	6 ( 12.5%)	41 ( 85.4%)	1 ( 2.1%)	0 ( 0.0%)	48

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tongue ulceration	2 ( 4.2%)	8 ( 16.7%)	31 ( 64.6%)	7 ( 14.6%)	48
Body mass index increased	0 ( 0.0%)	20 ( 41.7%)	27 ( 56.3%)	1 ( 2.1%)	48
Compression fracture	0 ( 0.0%)	5 ( 10.4%)	27 ( 56.3%)	16 ( 33.3%)	48
Immunosuppressant drug level increased	4 ( 8.3%)	9 ( 18.8%)	32 ( 66.7%)	3 ( 6.3%)	48
Hyperphagia	13 ( 27.1%)	11 ( 22.9%)	19 ( 39.6%)	5 ( 10.4%)	48
Viral upper respiratory tract infection	14 ( 29.2%)	14 ( 29.2%)	18 ( 37.5%)	2 ( 4.2%)	48
Intervertebral discitis	0 ( 0.0%)	13 ( 27.1%)	34 ( 70.8%)	1 ( 2.1%)	48
Weight abnormal	5 ( 10.4%)	14 ( 29.2%)	22 ( 45.8%)	7 ( 14.6%)	48
Skin tightness	10 ( 20.8%)	12 ( 25.0%)	23 ( 47.9%)	3 ( 6.3%)	48
Deafness neurosensory	18 ( 37.5%)	11 ( 22.9%)	14 ( 29.2%)	5 ( 10.4%)	48
Gingival swelling	4 ( 8.3%)	13 ( 27.1%)	29 ( 60.4%)	2 ( 4.2%)	48
Haemorrhagic stroke	0 ( 0.0%)	12 ( 25.0%)	20 ( 41.7%)	16 ( 33.3%)	48
Pancreatic disorder	5 ( 10.4%)	5 ( 10.4%)	32 ( 66.7%)	6 ( 12.5%)	48
Prostatomegaly	0 ( 0.0%)	8 ( 17.0%)	31 ( 66.0%)	8 ( 17.0%)	47
Respiratory rate decreased	13 ( 27.7%)	12 ( 25.5%)	17 ( 36.2%)	5 ( 10.6%)	47
Oesophageal candidiasis	0 ( 0.0%)	13 ( 27.7%)	30 ( 63.8%)	4 ( 8.5%)	47
Oxygen therapy	3 ( 6.4%)	5 ( 10.6%)	24 ( 51.1%)	15 ( 31.9%)	47
Hypoventilation	13 ( 27.7%)	8 ( 17.0%)	24 ( 51.1%)	2 ( 4.3%)	47
Sialoadenitis	2 ( 4.3%)	14 ( 29.8%)	26 ( 55.3%)	5 ( 10.6%)	47
Lung adenocarcinoma	0 ( 0.0%)	4 ( 8.5%)	32 ( 68.1%)	11 ( 23.4%)	47
Mastication disorder	7 ( 14.9%)	14 ( 29.8%)	21 ( 44.7%)	5 ( 10.6%)	47
Glossitis	1 ( 2.1%)	9 ( 19.1%)	36 ( 76.6%)	1 ( 2.1%)	47
Mycotic allergy	3 ( 6.4%)	4 ( 8.5%)	38 ( 80.9%)	2 ( 4.3%)	47
Chest X-ray abnormal	5 ( 10.6%)	2 ( 4.3%)	37 ( 78.7%)	3 ( 6.4%)	47
Ischaemia	7 ( 14.9%)	8 ( 17.0%)	24 ( 51.1%)	8 ( 17.0%)	47
Nasal oedema	2 ( 4.3%)	12 ( 25.5%)	33 ( 70.2%)	0 ( 0.0%)	47
Cerebral atrophy	12 ( 25.5%)	6 ( 12.8%)	20 ( 42.6%)	9 ( 19.1%)	47

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tetany	10 ( 21.3%)	16 ( 34.0%)	20 ( 42.6%)	1 ( 2.1%)	47
Hodgkin's disease	6 ( 12.8%)	18 ( 38.3%)	20 ( 42.6%)	3 ( 6.4%)	47
Asthmatic crisis	9 ( 19.1%)	13 ( 27.7%)	23 ( 48.9%)	2 ( 4.3%)	47
Retinal artery occlusion	0 ( 0.0%)	14 ( 29.8%)	20 ( 42.6%)	13 ( 27.7%)	47
Adenocarcinoma of colon	0 ( 0.0%)	6 ( 12.8%)	35 ( 74.5%)	6 ( 12.8%)	47
Pulmonary function test decreased	6 ( 12.8%)	10 ( 21.3%)	22 ( 46.8%)	9 ( 19.1%)	47
Angiopathy	3 ( 6.4%)	12 ( 25.5%)	25 ( 53.2%)	7 ( 14.9%)	47
Product colour issue	4 ( 8.5%)	4 ( 8.5%)	30 ( 63.8%)	9 ( 19.1%)	47
Cholangitis sclerosing	7 ( 14.9%)	10 ( 21.3%)	25 ( 53.2%)	5 ( 10.6%)	47
Peritoneal cloudy effluent	7 ( 14.9%)	9 ( 19.1%)	22 ( 46.8%)	9 ( 19.1%)	47
Urinary tract disorder	4 ( 8.7%)	4 ( 8.7%)	30 ( 65.2%)	8 ( 17.4%)	46
Atypical mycobacterial infection	4 ( 8.7%)	12 ( 26.1%)	25 ( 54.3%)	5 ( 10.9%)	46
Eyelid skin dryness	21 ( 45.7%)	13 ( 28.3%)	10 ( 21.7%)	2 ( 4.3%)	46
Panniculitis	2 ( 4.3%)	10 ( 21.7%)	29 ( 63.0%)	5 ( 10.9%)	46
Contrast media reaction	4 ( 8.7%)	12 ( 26.1%)	24 ( 52.2%)	6 ( 13.0%)	46
Idiopathic intracranial hypertension	18 ( 39.1%)	27 ( 58.7%)	1 ( 2.2%)	0 ( 0.0%)	46
Mite allergy	1 ( 2.2%)	4 ( 8.7%)	40 ( 87.0%)	1 ( 2.2%)	46
Menopausal symptoms	0 ( 0.0%)	20 ( 43.5%)	25 ( 54.3%)	1 ( 2.2%)	46
Somnambulism	4 ( 8.7%)	17 ( 37.0%)	17 ( 37.0%)	8 ( 17.4%)	46
Underweight	13 ( 28.3%)	10 ( 21.7%)	13 ( 28.3%)	10 ( 21.7%)	46
Hyperaesthesia teeth	2 ( 4.3%)	16 ( 34.8%)	23 ( 50.0%)	5 ( 10.9%)	46
Biliary colic	3 ( 6.5%)	17 ( 37.0%)	21 ( 45.7%)	5 ( 10.9%)	46
Hepatic necrosis	3 ( 6.5%)	18 ( 39.1%)	22 ( 47.8%)	3 ( 6.5%)	46
Catheter site infection	6 ( 13.0%)	12 ( 26.1%)	24 ( 52.2%)	4 ( 8.7%)	46
Superficial vein thrombosis	1 ( 2.2%)	23 ( 50.0%)	19 ( 41.3%)	3 ( 6.5%)	46
Quadriparesis	11 ( 23.9%)	8 ( 17.4%)	17 ( 37.0%)	10 ( 21.7%)	46
Enthesopathy	3 ( 6.5%)	20 ( 43.5%)	18 ( 39.1%)	5 ( 10.9%)	46

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Neovascular age-related macular degeneration	0 ( 0.0%)	5 ( 10.9%)	25 ( 54.3%)	16 ( 34.8%)	46
Formication	7 ( 15.2%)	15 ( 32.6%)	20 ( 43.5%)	4 ( 8.7%)	46
Gastric perforation	4 ( 8.7%)	7 ( 15.2%)	25 ( 54.3%)	10 ( 21.7%)	46
Polyomavirus-associated nephropathy	11 ( 23.9%)	2 ( 4.3%)	33 ( 71.7%)	0 ( 0.0%)	46
Paranasal sinus hypersecretion	0 ( 0.0%)	5 ( 10.9%)	35 ( 76.1%)	6 ( 13.0%)	46
Bradypnoea	7 ( 15.2%)	14 ( 30.4%)	18 ( 39.1%)	7 ( 15.2%)	46
Priapism	3 ( 6.5%)	27 ( 58.7%)	16 ( 34.8%)	0 ( 0.0%)	46
Intervertebral disc disorder	0 ( 0.0%)	17 ( 37.0%)	27 ( 58.7%)	2 ( 4.3%)	46
Neck mass	0 ( 0.0%)	11 ( 23.9%)	31 ( 67.4%)	4 ( 8.7%)	46
Blood loss anaemia	5 ( 10.9%)	8 ( 17.4%)	18 ( 39.1%)	15 ( 32.6%)	46
Venous thrombosis limb	2 ( 4.4%)	18 ( 40.0%)	21 ( 46.7%)	4 ( 8.9%)	45
Oral surgery	1 ( 2.2%)	6 ( 13.3%)	29 ( 64.4%)	9 ( 20.0%)	45
Exposure via breast milk	42 ( 93.3%)	3 ( 6.7%)	0 ( 0.0%)	0 ( 0.0%)	45
Renal transplant	5 ( 11.1%)	12 ( 26.7%)	28 ( 62.2%)	0 ( 0.0%)	45
Infusion site mass	5 ( 11.1%)	7 ( 15.6%)	25 ( 55.6%)	8 ( 17.8%)	45
Vein rupture	7 ( 15.6%)	14 ( 31.1%)	20 ( 44.4%)	4 ( 8.9%)	45
Platelet disorder	0 ( 0.0%)	11 ( 24.4%)	28 ( 62.2%)	6 ( 13.3%)	45
Varices oesophageal	4 ( 8.9%)	9 ( 20.0%)	29 ( 64.4%)	3 ( 6.7%)	45
Sacroiliitis	7 ( 15.6%)	20 ( 44.4%)	18 ( 40.0%)	0 ( 0.0%)	45
Salmonellosis	7 ( 15.6%)	11 ( 24.4%)	24 ( 53.3%)	3 ( 6.7%)	45
Stridor	7 ( 15.6%)	7 ( 15.6%)	16 ( 35.6%)	15 ( 33.3%)	45
Patella fracture	2 ( 4.4%)	4 ( 8.9%)	31 ( 68.9%)	8 ( 17.8%)	45
Hypertrophic cardiomyopathy	11 ( 24.4%)	20 ( 44.4%)	10 ( 22.2%)	4 ( 8.9%)	45
Spinal cord compression	2 ( 4.4%)	7 ( 15.6%)	33 ( 73.3%)	3 ( 6.7%)	45
Brain abscess	8 ( 17.8%)	8 ( 17.8%)	20 ( 44.4%)	9 ( 20.0%)	45
Periarthritis	0 ( 0.0%)	15 ( 33.3%)	29 ( 64.4%)	1 ( 2.2%)	45
Tendon injury	7 ( 15.6%)	16 ( 35.6%)	19 ( 42.2%)	3 ( 6.7%)	45

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Terminal insomnia	2 ( 4.4%)	23 ( 51.1%)	17 ( 37.8%)	3 ( 6.7%)	45
Blood blister	3 ( 6.7%)	5 ( 11.1%)	30 ( 66.7%)	7 ( 15.6%)	45
Stent placement	0 ( 0.0%)	4 ( 8.9%)	32 ( 71.1%)	9 ( 20.0%)	45
Anxiety disorder	13 ( 28.9%)	14 ( 31.1%)	17 ( 37.8%)	1 ( 2.2%)	45
Suicidal behaviour	12 ( 26.7%)	30 ( 66.7%)	3 ( 6.7%)	0 ( 0.0%)	45
Persecutory delusion	6 ( 13.3%)	22 ( 48.9%)	10 ( 22.2%)	7 ( 15.6%)	45
Injection site extravasation	10 ( 22.2%)	4 ( 8.9%)	25 ( 55.6%)	6 ( 13.3%)	45
Gingival disorder	2 ( 4.4%)	11 ( 24.4%)	23 ( 51.1%)	9 ( 20.0%)	45
Sacral pain	0 ( 0.0%)	22 ( 50.0%)	19 ( 43.2%)	3 ( 6.8%)	44
Conjunctival hyperaemia	10 ( 22.7%)	14 ( 31.8%)	17 ( 38.6%)	3 ( 6.8%)	44
Activated partial thromboplastin time prolonged	16 ( 36.4%)	3 ( 6.8%)	13 ( 29.5%)	12 ( 27.3%)	44
Ovarian cancer	1 ( 2.3%)	6 ( 13.6%)	30 ( 68.2%)	7 ( 15.9%)	44
Self-injurious ideation	3 ( 6.8%)	33 ( 75.0%)	7 ( 15.9%)	1 ( 2.3%)	44
Pigmentary maculopathy	1 ( 2.3%)	13 ( 29.5%)	26 ( 59.1%)	4 ( 9.1%)	44
Pulse abnormal	4 ( 9.1%)	10 ( 22.7%)	25 ( 56.8%)	5 ( 11.4%)	44
Device related sepsis	10 ( 22.7%)	12 ( 27.3%)	19 ( 43.2%)	3 ( 6.8%)	44
Eye contusion	6 ( 13.6%)	5 ( 11.4%)	25 ( 56.8%)	8 ( 18.2%)	44
Bruxism	18 ( 40.9%)	12 ( 27.3%)	11 ( 25.0%)	3 ( 6.8%)	44
Metabolic alkalosis	4 ( 9.1%)	7 ( 15.9%)	24 ( 54.5%)	9 ( 20.5%)	44
Lower respiratory tract congestion	3 ( 6.8%)	15 ( 34.1%)	24 ( 54.5%)	2 ( 4.5%)	44
White blood cells urine positive	3 ( 6.8%)	16 ( 36.4%)	17 ( 38.6%)	8 ( 18.2%)	44
Appendectomy	4 ( 9.1%)	19 ( 43.2%)	21 ( 47.7%)	0 ( 0.0%)	44
Chorea	5 ( 11.4%)	16 ( 36.4%)	17 ( 38.6%)	6 ( 13.6%)	44
Extrasystoles	1 ( 2.3%)	14 ( 31.8%)	22 ( 50.0%)	7 ( 15.9%)	44
Alanine aminotransferase abnormal	5 ( 11.4%)	6 ( 13.6%)	27 ( 61.4%)	6 ( 13.6%)	44
Sinus operation	1 ( 2.3%)	14 ( 31.8%)	22 ( 50.0%)	7 ( 15.9%)	44
Neuritis	0 ( 0.0%)	7 ( 15.9%)	33 ( 75.0%)	4 ( 9.1%)	44



Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hypophysitis	0 ( 0.0%)	7 ( 15.9%)	29 ( 65.9%)	8 ( 18.2%)	44
Neutropenic colitis	8 ( 18.2%)	6 ( 13.6%)	24 ( 54.5%)	6 ( 13.6%)	44
Wrong dose	13 ( 29.5%)	5 ( 11.4%)	19 ( 43.2%)	7 ( 15.9%)	44
Tongue coated	0 ( 0.0%)	5 ( 11.4%)	35 ( 79.5%)	4 ( 9.1%)	44
Atrial septal defect	37 ( 84.1%)	5 ( 11.4%)	2 ( 4.5%)	0 ( 0.0%)	44
Urinary tract infection bacterial	1 ( 2.3%)	15 ( 34.1%)	18 ( 40.9%)	10 ( 22.7%)	44
Weight bearing difficulty	3 ( 6.8%)	15 ( 34.1%)	23 ( 52.3%)	3 ( 6.8%)	44
Volvulus	3 ( 6.8%)	5 ( 11.4%)	24 ( 54.5%)	12 ( 27.3%)	44
Anaemia macrocytic	4 ( 9.3%)	10 ( 23.3%)	16 ( 37.2%)	13 ( 30.2%)	43
Insulin-like growth factor increased	10 ( 23.3%)	13 ( 30.2%)	19 ( 44.2%)	1 ( 2.3%)	43
Carbohydrate antigen 15-3 increased	0 ( 0.0%)	15 ( 34.9%)	24 ( 55.8%)	4 ( 9.3%)	43
Fibrosis	1 ( 2.3%)	8 ( 18.6%)	20 ( 46.5%)	14 ( 32.6%)	43
Febrile infection	5 ( 11.6%)	13 ( 30.2%)	14 ( 32.6%)	11 ( 25.6%)	43
Dysphemia	4 ( 9.3%)	18 ( 41.9%)	19 ( 44.2%)	2 ( 4.7%)	43
Menstruation delayed	9 ( 20.9%)	33 ( 76.7%)	1 ( 2.3%)	0 ( 0.0%)	43
Protein total decreased	5 ( 11.6%)	7 ( 16.3%)	24 ( 55.8%)	7 ( 16.3%)	43
Prostatitis	1 ( 2.3%)	11 ( 25.6%)	27 ( 62.8%)	4 ( 9.3%)	43
Lung consolidation	6 ( 14.0%)	8 ( 18.6%)	20 ( 46.5%)	9 ( 20.9%)	43
Upper respiratory tract congestion	4 ( 9.3%)	11 ( 25.6%)	24 ( 55.8%)	4 ( 9.3%)	43
Neuromyelitis optica spectrum disorder	6 ( 14.0%)	12 ( 27.9%)	24 ( 55.8%)	1 ( 2.3%)	43
Hyperreflexia	19 ( 44.2%)	11 ( 25.6%)	9 ( 20.9%)	4 ( 9.3%)	43
Chronic spontaneous urticaria	4 ( 9.3%)	21 ( 48.8%)	15 ( 34.9%)	3 ( 7.0%)	43
Encephalitis autoimmune	9 ( 20.9%)	7 ( 16.3%)	22 ( 51.2%)	5 ( 11.6%)	43
Adrenocortical insufficiency acute	2 ( 4.7%)	5 ( 11.6%)	34 ( 79.1%)	2 ( 4.7%)	43
Therapeutic product ineffective	6 ( 14.0%)	9 ( 20.9%)	23 ( 53.5%)	5 ( 11.6%)	43
Thrombophlebitis	3 ( 7.0%)	20 ( 46.5%)	15 ( 34.9%)	5 ( 11.6%)	43
Vulvovaginal pain	3 ( 7.0%)	13 ( 30.2%)	23 ( 53.5%)	4 ( 9.3%)	43

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Foreign body in reproductive tract	5 ( 11.6%)	36 ( 83.7%)	2 ( 4.7%)	0 ( 0.0%)	43
Vitiligo	4 ( 9.3%)	7 ( 16.3%)	30 ( 69.8%)	2 ( 4.7%)	43
Blood prolactin increased	21 ( 48.8%)	14 ( 32.6%)	8 ( 18.6%)	0 ( 0.0%)	43
Tic	22 ( 51.2%)	10 ( 23.3%)	10 ( 23.3%)	1 ( 2.3%)	43
Urinary tract obstruction	7 ( 16.3%)	5 ( 11.6%)	19 ( 44.2%)	12 ( 27.9%)	43
Acute psychosis	8 ( 18.6%)	6 ( 14.0%)	28 ( 65.1%)	1 ( 2.3%)	43
Pneumonia cytomegaloviral	6 ( 14.0%)	11 ( 25.6%)	25 ( 58.1%)	1 ( 2.3%)	43
Gastrointestinal stoma output increased	8 ( 18.6%)	9 ( 20.9%)	24 ( 55.8%)	2 ( 4.7%)	43
JC polyomavirus test positive	0 ( 0.0%)	24 ( 55.8%)	18 ( 41.9%)	1 ( 2.3%)	43
Regurgitation	10 ( 23.3%)	9 ( 20.9%)	19 ( 44.2%)	5 ( 11.6%)	43
Joint lock	3 ( 7.1%)	11 ( 26.2%)	26 ( 61.9%)	2 ( 4.8%)	42
Lipoma	1 ( 2.4%)	12 ( 28.6%)	29 ( 69.0%)	0 ( 0.0%)	42
Eosinophilic oesophagitis	15 ( 35.7%)	16 ( 38.1%)	9 ( 21.4%)	2 ( 4.8%)	42
Embolic stroke	0 ( 0.0%)	4 ( 9.5%)	23 ( 54.8%)	15 ( 35.7%)	42
Skin hypertrophy	1 ( 2.4%)	20 ( 47.6%)	20 ( 47.6%)	1 ( 2.4%)	42
Catheterisation cardiac	3 ( 7.1%)	6 ( 14.3%)	26 ( 61.9%)	7 ( 16.7%)	42
Bone marrow disorder	1 ( 2.4%)	6 ( 14.3%)	32 ( 76.2%)	3 ( 7.1%)	42
Steroid dependence	21 ( 50.0%)	2 ( 4.8%)	19 ( 45.2%)	0 ( 0.0%)	42
Recalled product administered	14 ( 33.3%)	4 ( 9.5%)	22 ( 52.4%)	2 ( 4.8%)	42
Madarosis	5 ( 11.9%)	18 ( 42.9%)	17 ( 40.5%)	2 ( 4.8%)	42
Pneumonia pseudomonal	1 ( 2.4%)	7 ( 16.7%)	29 ( 69.0%)	5 ( 11.9%)	42
Aortic arteriosclerosis	0 ( 0.0%)	4 ( 9.5%)	25 ( 59.5%)	13 ( 31.0%)	42
Postural orthostatic tachycardia syndrome	10 ( 23.8%)	21 ( 50.0%)	11 ( 26.2%)	0 ( 0.0%)	42
Suspected suicide	1 ( 2.4%)	11 ( 26.2%)	24 ( 57.1%)	6 ( 14.3%)	42
Infrequent bowel movements	5 ( 11.9%)	15 ( 35.7%)	14 ( 33.3%)	8 ( 19.0%)	42
Skin injury	4 ( 9.5%)	9 ( 21.4%)	29 ( 69.0%)	0 ( 0.0%)	42
Vitreous haemorrhage	1 ( 2.4%)	6 ( 14.3%)	31 ( 73.8%)	4 ( 9.5%)	42

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Impulse-control disorder	4 ( 9.5%)	27 ( 64.3%)	9 ( 21.4%)	2 ( 4.8%)	42
Abdominal infection	2 ( 4.8%)	9 ( 21.4%)	26 ( 61.9%)	5 ( 11.9%)	42
Gastritis erosive	5 ( 11.9%)	6 ( 14.3%)	22 ( 52.4%)	9 ( 21.4%)	42
Injection site scar	4 ( 9.5%)	23 ( 54.8%)	14 ( 33.3%)	1 ( 2.4%)	42
Neck injury	7 ( 16.7%)	11 ( 26.2%)	20 ( 47.6%)	4 ( 9.5%)	42
Bacterial sepsis	10 ( 23.8%)	7 ( 16.7%)	21 ( 50.0%)	4 ( 9.5%)	42
Angina unstable	0 ( 0.0%)	12 ( 29.3%)	22 ( 53.7%)	7 ( 17.1%)	41
Jaundice cholestatic	0 ( 0.0%)	2 ( 4.9%)	26 ( 63.4%)	13 ( 31.7%)	41
Liver transplant	9 ( 22.0%)	11 ( 26.8%)	21 ( 51.2%)	0 ( 0.0%)	41
Pregnancy with implant contraceptive	17 ( 41.5%)	24 ( 58.5%)	0 ( 0.0%)	0 ( 0.0%)	41
Metastatic neoplasm	0 ( 0.0%)	3 ( 7.3%)	28 ( 68.3%)	10 ( 24.4%)	41
Hyperammonaemic encephalopathy	16 ( 39.0%)	17 ( 41.5%)	7 ( 17.1%)	1 ( 2.4%)	41
Adrenal disorder	0 ( 0.0%)	12 ( 29.3%)	25 ( 61.0%)	4 ( 9.8%)	41
Atrioventricular block second degree	9 ( 22.0%)	6 ( 14.6%)	14 ( 34.1%)	12 ( 29.3%)	41
Anaesthetic complication	5 ( 12.2%)	15 ( 36.6%)	19 ( 46.3%)	2 ( 4.9%)	41
Negative thoughts	6 ( 14.6%)	16 ( 39.0%)	18 ( 43.9%)	1 ( 2.4%)	41
Electrocardiogram ST segment elevation	3 ( 7.3%)	9 ( 22.0%)	25 ( 61.0%)	4 ( 9.8%)	41
Change in seizure presentation	30 ( 73.2%)	4 ( 9.8%)	6 ( 14.6%)	1 ( 2.4%)	41
Substance use	13 ( 31.7%)	23 ( 56.1%)	5 ( 12.2%)	0 ( 0.0%)	41
Cushingoid	11 ( 26.8%)	16 ( 39.0%)	12 ( 29.3%)	2 ( 4.9%)	41
Metabolic encephalopathy	4 ( 9.8%)	2 ( 4.9%)	22 ( 53.7%)	13 ( 31.7%)	41
Pneumonia staphylococcal	1 ( 2.4%)	21 ( 51.2%)	12 ( 29.3%)	7 ( 17.1%)	41
Trismus	7 ( 17.1%)	10 ( 24.4%)	19 ( 46.3%)	5 ( 12.2%)	41
Retinopathy	2 ( 4.9%)	6 ( 14.6%)	24 ( 58.5%)	9 ( 22.0%)	41
Decreased interest	4 ( 9.8%)	14 ( 34.1%)	19 ( 46.3%)	4 ( 9.8%)	41
Dental operation	4 ( 9.8%)	9 ( 22.0%)	26 ( 63.4%)	2 ( 4.9%)	41
Steroid diabetes	7 ( 17.1%)	10 ( 24.4%)	22 ( 53.7%)	2 ( 4.9%)	41

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Dengue fever	5 ( 12.2%)	18 ( 43.9%)	16 ( 39.0%)	2 ( 4.9%)	41
Allergy to animal	4 ( 9.8%)	11 ( 26.8%)	25 ( 61.0%)	1 ( 2.4%)	41
Product contamination	21 ( 51.2%)	5 ( 12.2%)	14 ( 34.1%)	1 ( 2.4%)	41
Oculogyric crisis	27 ( 65.9%)	11 ( 26.8%)	3 ( 7.3%)	0 ( 0.0%)	41
Retinal vein occlusion	0 ( 0.0%)	21 ( 51.2%)	16 ( 39.0%)	4 ( 9.8%)	41
Oesophageal stenosis	4 ( 9.8%)	8 ( 19.5%)	24 ( 58.5%)	5 ( 12.2%)	41
Monoparesis	3 ( 7.3%)	17 ( 41.5%)	18 ( 43.9%)	3 ( 7.3%)	41
SARS-CoV-2 antibody test negative	1 ( 2.4%)	22 ( 53.7%)	18 ( 43.9%)	0 ( 0.0%)	41
Atrioventricular block first degree	4 ( 10.0%)	2 ( 5.0%)	21 ( 52.5%)	13 ( 32.5%)	40
Gangrene	0 ( 0.0%)	3 ( 7.5%)	32 ( 80.0%)	5 ( 12.5%)	40
Pulmonary tuberculosis	2 ( 5.0%)	9 ( 22.5%)	19 ( 47.5%)	10 ( 25.0%)	40
Goitre	0 ( 0.0%)	13 ( 32.5%)	24 ( 60.0%)	3 ( 7.5%)	40
Product solubility abnormal	21 ( 52.5%)	5 ( 12.5%)	10 ( 25.0%)	4 ( 10.0%)	40
Cardiac amyloidosis	1 ( 2.5%)	1 ( 2.5%)	9 ( 22.5%)	29 ( 72.5%)	40
Noninfective gingivitis	4 ( 10.0%)	11 ( 27.5%)	24 ( 60.0%)	1 ( 2.5%)	40
Uterine cancer	1 ( 2.5%)	6 ( 15.0%)	29 ( 72.5%)	4 ( 10.0%)	40
Multiple use of single-use product	14 ( 35.0%)	5 ( 12.5%)	15 ( 37.5%)	6 ( 15.0%)	40
Dermal cyst	5 ( 12.5%)	14 ( 35.0%)	19 ( 47.5%)	2 ( 5.0%)	40
Aortic dissection	0 ( 0.0%)	4 ( 10.0%)	24 ( 60.0%)	12 ( 30.0%)	40
Supraventricular extrasystoles	0 ( 0.0%)	7 ( 17.5%)	22 ( 55.0%)	11 ( 27.5%)	40
Graft versus host disease in skin	14 ( 35.0%)	8 ( 20.0%)	16 ( 40.0%)	2 ( 5.0%)	40
Injection site haematoma	4 ( 10.0%)	12 ( 30.0%)	19 ( 47.5%)	5 ( 12.5%)	40
Macule	3 ( 7.5%)	13 ( 32.5%)	18 ( 45.0%)	6 ( 15.0%)	40
Sleep paralysis	7 ( 17.5%)	20 ( 50.0%)	13 ( 32.5%)	0 ( 0.0%)	40
Sternal fracture	0 ( 0.0%)	6 ( 15.0%)	28 ( 70.0%)	6 ( 15.0%)	40
Wound dehiscence	2 ( 5.0%)	8 ( 20.0%)	24 ( 60.0%)	6 ( 15.0%)	40
Ileal stenosis	5 ( 12.5%)	20 ( 50.0%)	14 ( 35.0%)	1 ( 2.5%)	40

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Respiratory alkalosis	0 ( 0.0%)	12 ( 30.0%)	23 ( 57.5%)	5 ( 12.5%)	40
Product formulation issue	6 ( 15.0%)	13 ( 32.5%)	15 ( 37.5%)	6 ( 15.0%)	40
Retinitis	1 ( 2.5%)	24 ( 60.0%)	14 ( 35.0%)	1 ( 2.5%)	40
Protein total increased	1 ( 2.5%)	14 ( 35.0%)	22 ( 55.0%)	3 ( 7.5%)	40
Biliary obstruction	1 ( 2.5%)	3 ( 7.5%)	32 ( 80.0%)	4 ( 10.0%)	40
Dyspnoea at rest	1 ( 2.6%)	7 ( 17.9%)	26 ( 66.7%)	5 ( 12.8%)	39
Dysphoria	2 ( 5.1%)	14 ( 35.9%)	13 ( 33.3%)	10 ( 25.6%)	39
Ear congestion	0 ( 0.0%)	10 ( 25.6%)	25 ( 64.1%)	4 ( 10.3%)	39
Abnormal uterine bleeding	21 ( 53.8%)	17 ( 43.6%)	1 ( 2.6%)	0 ( 0.0%)	39
Bicytopenia	3 ( 7.7%)	5 ( 12.8%)	25 ( 64.1%)	6 ( 15.4%)	39
Haematoma muscle	2 ( 5.1%)	2 ( 5.1%)	18 ( 46.2%)	17 ( 43.6%)	39
Polydipsia	1 ( 2.6%)	17 ( 43.6%)	19 ( 48.7%)	2 ( 5.1%)	39
Anti-cyclic citrullinated peptide antibody	0 ( 0.0%)	30 ( 76.9%)	9 ( 23.1%)	0 ( 0.0%)	39
Hangover	1 ( 2.6%)	21 ( 53.8%)	15 ( 38.5%)	2 ( 5.1%)	39
Panic disorder	8 ( 20.5%)	12 ( 30.8%)	14 ( 35.9%)	5 ( 12.8%)	39
Infusion site rash	7 ( 17.9%)	3 ( 7.7%)	21 ( 53.8%)	8 ( 20.5%)	39
Mucormycosis	5 ( 12.8%)	12 ( 30.8%)	20 ( 51.3%)	2 ( 5.1%)	39
Posture abnormal	3 ( 7.7%)	8 ( 20.5%)	18 ( 46.2%)	10 ( 25.6%)	39
Acute lymphocytic leukaemia	7 ( 17.9%)	11 ( 28.2%)	20 ( 51.3%)	1 ( 2.6%)	39
Vaccination failure	6 ( 15.4%)	6 ( 15.4%)	23 ( 59.0%)	4 ( 10.3%)	39
Application site rash	3 ( 7.7%)	16 ( 41.0%)	15 ( 38.5%)	5 ( 12.8%)	39
Diastolic dysfunction	2 ( 5.1%)	2 ( 5.1%)	22 ( 56.4%)	13 ( 33.3%)	39
Xerophthalmia	0 ( 0.0%)	9 ( 23.1%)	25 ( 64.1%)	5 ( 12.8%)	39
Dermatitis psoriasiform	4 ( 10.3%)	4 ( 10.3%)	28 ( 71.8%)	3 ( 7.7%)	39
Micturition disorder	4 ( 10.3%)	12 ( 30.8%)	15 ( 38.5%)	8 ( 20.5%)	39
Granulocyte count decreased	6 ( 15.4%)	4 ( 10.3%)	25 ( 64.1%)	4 ( 10.3%)	39
Aplasia pure red cell	4 ( 10.3%)	8 ( 20.5%)	20 ( 51.3%)	7 ( 17.9%)	39

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blood phosphorus decreased	5 ( 12.8%)	14 ( 35.9%)	17 ( 43.6%)	3 ( 7.7%)	39
Hypoproteinaemia	2 ( 5.1%)	10 ( 25.6%)	26 ( 66.7%)	1 ( 2.6%)	39
Radiation pneumonitis	1 ( 2.6%)	4 ( 10.3%)	32 ( 82.1%)	2 ( 5.1%)	39
Terminal state	1 ( 2.6%)	1 ( 2.6%)	19 ( 48.7%)	18 ( 46.2%)	39
Vulvovaginal burning sensation	3 ( 7.7%)	11 ( 28.2%)	22 ( 56.4%)	3 ( 7.7%)	39
Anal haemorrhage	2 ( 5.1%)	7 ( 17.9%)	25 ( 64.1%)	5 ( 12.8%)	39
Carbohydrate antigen 125 increased	0 ( 0.0%)	6 ( 15.8%)	29 ( 76.3%)	3 ( 7.9%)	38
Osteolysis	0 ( 0.0%)	10 ( 26.3%)	25 ( 65.8%)	3 ( 7.9%)	38
Auditory disorder	3 ( 7.9%)	5 ( 13.2%)	16 ( 42.1%)	14 ( 36.8%)	38
Cardiovascular insufficiency	4 ( 10.5%)	14 ( 36.8%)	17 ( 44.7%)	3 ( 7.9%)	38
Suspected counterfeit product	5 ( 13.2%)	15 ( 39.5%)	15 ( 39.5%)	3 ( 7.9%)	38
Skin wrinkling	0 ( 0.0%)	9 ( 23.7%)	13 ( 34.2%)	16 ( 42.1%)	38
Oesophageal carcinoma	0 ( 0.0%)	1 ( 2.6%)	27 ( 71.1%)	10 ( 26.3%)	38
Fixed eruption	2 ( 5.3%)	16 ( 42.1%)	12 ( 31.6%)	8 ( 21.1%)	38
Gene mutation	7 ( 18.4%)	7 ( 18.4%)	23 ( 60.5%)	1 ( 2.6%)	38
Myasthenia gravis crisis	3 ( 7.9%)	19 ( 50.0%)	12 ( 31.6%)	4 ( 10.5%)	38
Nasal discharge discolouration	3 ( 7.9%)	12 ( 31.6%)	23 ( 60.5%)	0 ( 0.0%)	38
Logorrhoea	11 ( 28.9%)	14 ( 36.8%)	10 ( 26.3%)	3 ( 7.9%)	38
Actinic keratosis	1 ( 2.6%)	1 ( 2.6%)	33 ( 86.8%)	3 ( 7.9%)	38
Pancreatic failure	4 ( 10.5%)	13 ( 34.2%)	18 ( 47.4%)	3 ( 7.9%)	38
Lacrimal structure injury	0 ( 0.0%)	17 ( 44.7%)	21 ( 55.3%)	0 ( 0.0%)	38
Keratitis	5 ( 13.2%)	8 ( 21.1%)	21 ( 55.3%)	4 ( 10.5%)	38
Tachyarrhythmia	5 ( 13.2%)	5 ( 13.2%)	17 ( 44.7%)	11 ( 28.9%)	38
Hypoxic-ischaemic encephalopathy	12 ( 31.6%)	2 ( 5.3%)	16 ( 42.1%)	8 ( 21.1%)	38
Plasma cell myeloma refractory	0 ( 0.0%)	1 ( 2.6%)	26 ( 68.4%)	11 ( 28.9%)	38
Blood phosphorus increased	2 ( 5.3%)	3 ( 7.9%)	9 ( 23.7%)	24 ( 63.2%)	38
Scleroderma	6 ( 15.8%)	10 ( 26.3%)	22 ( 57.9%)	0 ( 0.0%)	38

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Psychotic symptom	12 ( 31.6%)	11 ( 28.9%)	11 ( 28.9%)	4 ( 10.5%)	38
Craniocerebral injury	4 ( 10.5%)	6 ( 15.8%)	18 ( 47.4%)	10 ( 26.3%)	38
Arthropod sting	2 ( 5.3%)	8 ( 21.1%)	26 ( 68.4%)	2 ( 5.3%)	38
Acute graft versus host disease in skin	19 ( 50.0%)	15 ( 39.5%)	4 ( 10.5%)	0 ( 0.0%)	38
Pancreatitis necrotising	4 ( 10.5%)	13 ( 34.2%)	21 ( 55.3%)	0 ( 0.0%)	38
Tumour pseudoprogression	1 ( 2.6%)	8 ( 21.1%)	22 ( 57.9%)	7 ( 18.4%)	38
Intracranial aneurysm	0 ( 0.0%)	6 ( 15.8%)	29 ( 76.3%)	3 ( 7.9%)	38
Device alarm issue	5 ( 13.2%)	9 ( 23.7%)	18 ( 47.4%)	6 ( 15.8%)	38
Granulocytopenia	6 ( 15.8%)	10 ( 26.3%)	20 ( 52.6%)	2 ( 5.3%)	38
Hypothalamo-pituitary disorder	1 ( 2.6%)	6 ( 15.8%)	13 ( 34.2%)	18 ( 47.4%)	38
Cerebral haematoma	3 ( 7.9%)	3 ( 7.9%)	19 ( 50.0%)	13 ( 34.2%)	38
Oral mucosal eruption	4 ( 10.8%)	5 ( 13.5%)	24 ( 64.9%)	4 ( 10.8%)	37
Left ventricular hypertrophy	3 ( 8.1%)	10 ( 27.0%)	18 ( 48.6%)	6 ( 16.2%)	37
Metastases to meninges	1 ( 2.7%)	8 ( 21.6%)	20 ( 54.1%)	8 ( 21.6%)	37
Pericardial haemorrhage	0 ( 0.0%)	21 ( 56.8%)	10 ( 27.0%)	6 ( 16.2%)	37
Intentional underdose	5 ( 13.5%)	8 ( 21.6%)	17 ( 45.9%)	7 ( 18.9%)	37
Urine output increased	6 ( 16.2%)	5 ( 13.5%)	17 ( 45.9%)	9 ( 24.3%)	37
Blood potassium abnormal	2 ( 5.4%)	5 ( 13.5%)	25 ( 67.6%)	5 ( 13.5%)	37
Nocardiosis	0 ( 0.0%)	12 ( 32.4%)	16 ( 43.2%)	9 ( 24.3%)	37
Pruritus genital	3 ( 8.1%)	9 ( 24.3%)	22 ( 59.5%)	3 ( 8.1%)	37
Sensitisation	3 ( 8.1%)	3 ( 8.1%)	29 ( 78.4%)	2 ( 5.4%)	37
Hyperthermia malignant	10 ( 27.0%)	16 ( 43.2%)	11 ( 29.7%)	0 ( 0.0%)	37
Prostatic specific antigen abnormal	0 ( 0.0%)	2 ( 5.4%)	18 ( 48.6%)	17 ( 45.9%)	37
Unmasking of previously unidentified disease	14 ( 37.8%)	5 ( 13.5%)	17 ( 45.9%)	1 ( 2.7%)	37
Skin depigmentation	7 ( 18.9%)	12 ( 32.4%)	14 ( 37.8%)	4 ( 10.8%)	37
Purulent discharge	3 ( 8.1%)	12 ( 32.4%)	17 ( 45.9%)	5 ( 13.5%)	37
Endotracheal intubation	10 ( 27.0%)	10 ( 27.0%)	15 ( 40.5%)	2 ( 5.4%)	37

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Myoglobin blood increased	2 ( 5.4%)	5 ( 13.5%)	9 ( 24.3%)	21 ( 56.8%)	37
Large intestine infection	1 ( 2.7%)	6 ( 16.2%)	20 ( 54.1%)	10 ( 27.0%)	37
Colorectal cancer metastatic	0 ( 0.0%)	15 ( 40.5%)	20 ( 54.1%)	2 ( 5.4%)	37
Tumour haemorrhage	0 ( 0.0%)	6 ( 16.2%)	27 ( 73.0%)	4 ( 10.8%)	37
Aortic valve incompetence	6 ( 16.2%)	10 ( 27.0%)	15 ( 40.5%)	6 ( 16.2%)	37
Stoma site haemorrhage	2 ( 5.4%)	4 ( 10.8%)	18 ( 48.6%)	13 ( 35.1%)	37
Brain death	10 ( 27.0%)	16 ( 43.2%)	8 ( 21.6%)	3 ( 8.1%)	37
Drug diversion	1 ( 2.7%)	18 ( 48.6%)	15 ( 40.5%)	3 ( 8.1%)	37
Transplant	4 ( 10.8%)	12 ( 32.4%)	20 ( 54.1%)	1 ( 2.7%)	37
Visceral congestion	4 ( 10.8%)	27 ( 73.0%)	5 ( 13.5%)	1 ( 2.7%)	37
Implant site pain	11 ( 29.7%)	16 ( 43.2%)	9 ( 24.3%)	1 ( 2.7%)	37
Testicular pain	11 ( 29.7%)	18 ( 48.6%)	7 ( 18.9%)	1 ( 2.7%)	37
Jaw disorder	1 ( 2.7%)	5 ( 13.5%)	26 ( 70.3%)	5 ( 13.5%)	37
Strabismus	11 ( 29.7%)	8 ( 21.6%)	16 ( 43.2%)	2 ( 5.4%)	37
Pulmonary sepsis	2 ( 5.4%)	2 ( 5.4%)	24 ( 64.9%)	9 ( 24.3%)	37
Reduced facial expression	0 ( 0.0%)	5 ( 13.5%)	22 ( 59.5%)	10 ( 27.0%)	37
Infusion site discomfort	1 ( 2.7%)	12 ( 32.4%)	22 ( 59.5%)	2 ( 5.4%)	37
Onycholysis	0 ( 0.0%)	14 ( 37.8%)	21 ( 56.8%)	2 ( 5.4%)	37
JC virus infection	0 ( 0.0%)	11 ( 29.7%)	22 ( 59.5%)	4 ( 10.8%)	37
Labyrinthitis	1 ( 2.7%)	9 ( 24.3%)	24 ( 64.9%)	3 ( 8.1%)	37
Hypofibrinogenaemia	18 ( 48.6%)	8 ( 21.6%)	9 ( 24.3%)	2 ( 5.4%)	37
Radius fracture	3 ( 8.1%)	9 ( 24.3%)	18 ( 48.6%)	7 ( 18.9%)	37
Developmental delay	34 ( 91.9%)	2 ( 5.4%)	1 ( 2.7%)	0 ( 0.0%)	37
Joint arthroplasty	0 ( 0.0%)	11 ( 29.7%)	18 ( 48.6%)	8 ( 21.6%)	37
Disseminated aspergillosis	2 ( 5.6%)	11 ( 30.6%)	23 ( 63.9%)	0 ( 0.0%)	36
Pyroglutamic acidosis	0 ( 0.0%)	10 ( 27.8%)	19 ( 52.8%)	7 ( 19.4%)	36
Haemorrhage urinary tract	2 ( 5.6%)	7 ( 19.4%)	21 ( 58.3%)	6 ( 16.7%)	36



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Non-Hodgkin's lymphoma	3 ( 8.3%)	4 ( 11.1%)	25 ( 69.4%)	4 ( 11.1%)	36
Peripheral arterial occlusive disease	0 ( 0.0%)	2 ( 5.6%)	26 ( 72.2%)	8 ( 22.2%)	36
Ischaemic hepatitis	9 ( 25.0%)	5 ( 13.9%)	16 ( 44.4%)	6 ( 16.7%)	36
Antinuclear antibody positive	0 ( 0.0%)	16 ( 44.4%)	19 ( 52.8%)	1 ( 2.8%)	36
Mental fatigue	0 ( 0.0%)	16 ( 44.4%)	17 ( 47.2%)	3 ( 8.3%)	36
Stenosis	2 ( 5.6%)	13 ( 36.1%)	15 ( 41.7%)	6 ( 16.7%)	36
Lip haemorrhage	13 ( 36.1%)	13 ( 36.1%)	7 ( 19.4%)	3 ( 8.3%)	36
Pharyngeal erythema	10 ( 27.8%)	7 ( 19.4%)	16 ( 44.4%)	3 ( 8.3%)	36
Lymphadenitis	3 ( 8.3%)	18 ( 50.0%)	13 ( 36.1%)	2 ( 5.6%)	36
Thrombotic thrombocytopenic purpura	0 ( 0.0%)	5 ( 13.9%)	25 ( 69.4%)	6 ( 16.7%)	36
Vaginal flatulence	0 ( 0.0%)	0 ( 0.0%)	36 (100.0%)	0 ( 0.0%)	36
Injection site indentation	3 ( 8.3%)	9 ( 25.0%)	20 ( 55.6%)	4 ( 11.1%)	36
Intracardiac thrombus	6 ( 16.7%)	1 ( 2.8%)	19 ( 52.8%)	10 ( 27.8%)	36
Chronic inflammatory demyelinating polyradiculoneurop	1 ( 2.8%)	11 ( 30.6%)	22 ( 61.1%)	2 ( 5.6%)	36
Chronic lymphocytic leukaemia	0 ( 0.0%)	1 ( 2.8%)	28 ( 77.8%)	7 ( 19.4%)	36
Loose tooth	9 ( 25.0%)	2 ( 5.6%)	22 ( 61.1%)	3 ( 8.3%)	36
Portal hypertension	3 ( 8.3%)	9 ( 25.0%)	24 ( 66.7%)	0 ( 0.0%)	36
Neurogenic bladder	4 ( 11.1%)	6 ( 16.7%)	24 ( 66.7%)	2 ( 5.6%)	36
Gastrointestinal bacterial overgrowth	4 ( 11.1%)	18 ( 50.0%)	14 ( 38.9%)	0 ( 0.0%)	36
Epstein-Barr virus infection reactivation	13 ( 36.1%)	11 ( 30.6%)	12 ( 33.3%)	0 ( 0.0%)	36
Blood immunoglobulin G increased	8 ( 22.2%)	8 ( 22.2%)	16 ( 44.4%)	4 ( 11.1%)	36
Chondrocalcinosis	0 ( 0.0%)	1 ( 2.8%)	25 ( 69.4%)	10 ( 27.8%)	36
Vitritis	2 ( 5.6%)	6 ( 16.7%)	15 ( 41.7%)	13 ( 36.1%)	36
Oesophageal disorder	1 ( 2.8%)	6 ( 16.7%)	20 ( 55.6%)	9 ( 25.0%)	36
Duodenitis	4 ( 11.1%)	8 ( 22.2%)	21 ( 58.3%)	3 ( 8.3%)	36
Vitreous detachment	0 ( 0.0%)	6 ( 16.7%)	26 ( 72.2%)	4 ( 11.1%)	36
Meningitis cryptococcal	1 ( 2.8%)	14 ( 38.9%)	14 ( 38.9%)	7 ( 19.4%)	36

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Vomiting projectile	9 ( 25.0%)	11 ( 30.6%)	15 ( 41.7%)	1 ( 2.8%)	36
Hernia repair	1 ( 2.8%)	8 ( 22.2%)	24 ( 66.7%)	3 ( 8.3%)	36
Carcinoid tumour	0 ( 0.0%)	8 ( 22.9%)	26 ( 74.3%)	1 ( 2.9%)	35
Rebound eczema	14 ( 40.0%)	13 ( 37.1%)	6 ( 17.1%)	2 ( 5.7%)	35
Amyloid related imaging abnormality-oedema/effusion	0 ( 0.0%)	0 ( 0.0%)	21 ( 60.0%)	14 ( 40.0%)	35
Rheumatic disorder	0 ( 0.0%)	8 ( 22.9%)	24 ( 68.6%)	3 ( 8.6%)	35
Renal transplant failure	4 ( 11.4%)	13 ( 37.1%)	11 ( 31.4%)	7 ( 20.0%)	35
Ototoxicity	1 ( 2.9%)	3 ( 8.6%)	20 ( 57.1%)	11 ( 31.4%)	35
Lichen planus	0 ( 0.0%)	12 ( 34.3%)	20 ( 57.1%)	3 ( 8.6%)	35
Appendicitis perforated	4 ( 11.4%)	4 ( 11.4%)	18 ( 51.4%)	9 ( 25.7%)	35
Vasoplegia syndrome	20 ( 57.1%)	3 ( 8.6%)	12 ( 34.3%)	0 ( 0.0%)	35
Acute lymphocytic leukaemia recurrent	18 ( 51.4%)	6 ( 17.1%)	10 ( 28.6%)	1 ( 2.9%)	35
Fibula fracture	1 ( 2.9%)	9 ( 25.7%)	21 ( 60.0%)	4 ( 11.4%)	35
Clumsiness	5 ( 14.3%)	18 ( 51.4%)	10 ( 28.6%)	2 ( 5.7%)	35
Serous retinal detachment	1 ( 2.9%)	6 ( 17.1%)	21 ( 60.0%)	7 ( 20.0%)	35
Ear haemorrhage	8 ( 22.9%)	6 ( 17.1%)	15 ( 42.9%)	6 ( 17.1%)	35
Medical device discomfort	9 ( 25.7%)	17 ( 48.6%)	7 ( 20.0%)	2 ( 5.7%)	35
Mastitis	0 ( 0.0%)	15 ( 42.9%)	19 ( 54.3%)	1 ( 2.9%)	35
Body temperature fluctuation	4 ( 11.4%)	14 ( 40.0%)	14 ( 40.0%)	3 ( 8.6%)	35
Low birth weight baby	33 ( 94.3%)	2 ( 5.7%)	0 ( 0.0%)	0 ( 0.0%)	35
Abscess oral	1 ( 2.9%)	14 ( 40.0%)	18 ( 51.4%)	2 ( 5.7%)	35
Failure to thrive	10 ( 28.6%)	3 ( 8.6%)	11 ( 31.4%)	11 ( 31.4%)	35
Iritis	0 ( 0.0%)	13 ( 37.1%)	13 ( 37.1%)	9 ( 25.7%)	35
Subcutaneous emphysema	4 ( 11.4%)	19 ( 54.3%)	10 ( 28.6%)	2 ( 5.7%)	35
COVID-19 immunisation	0 ( 0.0%)	10 ( 28.6%)	22 ( 62.9%)	3 ( 8.6%)	35
Aortic stenosis	0 ( 0.0%)	2 ( 5.7%)	15 ( 42.9%)	18 ( 51.4%)	35
Abdominal rigidity	3 ( 8.6%)	12 ( 34.3%)	19 ( 54.3%)	1 ( 2.9%)	35

### Reaction Summary Table

#### Derived Age Group

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Deafness bilateral	5 ( 14.3%)	11 ( 31.4%)	17 ( 48.6%)	2 ( 5.7%)	35
Immobile	1 ( 2.9%)	12 ( 34.3%)	14 ( 40.0%)	8 ( 22.9%)	35
Polycythaemia	0 ( 0.0%)	4 ( 11.4%)	30 ( 85.7%)	1 ( 2.9%)	35
Hepatosplenomegaly	11 ( 31.4%)	11 ( 31.4%)	12 ( 34.3%)	1 ( 2.9%)	35
Gastric ulcer haemorrhage	4 ( 11.4%)	3 ( 8.6%)	13 ( 37.1%)	15 ( 42.9%)	35
Human chorionic gonadotropin increased	0 ( 0.0%)	29 ( 82.9%)	6 ( 17.1%)	0 ( 0.0%)	35
Small intestinal perforation	2 ( 5.7%)	7 ( 20.0%)	17 ( 48.6%)	9 ( 25.7%)	35
Blood testosterone decreased	1 ( 2.9%)	19 ( 54.3%)	13 ( 37.1%)	2 ( 5.7%)	35
Growth retardation	35 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	35
Graft versus host disease in gastrointestinal tract	9 ( 25.7%)	12 ( 34.3%)	12 ( 34.3%)	2 ( 5.7%)	35
Prothrombin time prolonged	7 ( 20.0%)	1 ( 2.9%)	16 ( 45.7%)	11 ( 31.4%)	35
Breast cancer recurrent	0 ( 0.0%)	10 ( 28.6%)	22 ( 62.9%)	3 ( 8.6%)	35
Hyperchlorhydria	1 ( 2.9%)	10 ( 28.6%)	24 ( 68.6%)	0 ( 0.0%)	35
Pleuritic pain	1 ( 2.9%)	10 ( 29.4%)	13 ( 38.2%)	10 ( 29.4%)	34
Fanconi syndrome acquired	2 ( 5.9%)	6 ( 17.6%)	24 ( 70.6%)	2 ( 5.9%)	34
Pneumatosis intestinalis	14 ( 41.2%)	2 ( 5.9%)	11 ( 32.4%)	7 ( 20.6%)	34
Bacterial vaginosis	2 ( 5.9%)	25 ( 73.5%)	7 ( 20.6%)	0 ( 0.0%)	34
Cardiac discomfort	3 ( 8.8%)	13 ( 38.2%)	15 ( 44.1%)	3 ( 8.8%)	34
Ventricular arrhythmia	9 ( 26.5%)	8 ( 23.5%)	8 ( 23.5%)	9 ( 26.5%)	34
Transplant dysfunction	5 ( 14.7%)	10 ( 29.4%)	19 ( 55.9%)	0 ( 0.0%)	34
Spirometry abnormal	0 ( 0.0%)	1 ( 2.9%)	33 ( 97.1%)	0 ( 0.0%)	34
Serum sickness	9 ( 26.5%)	9 ( 26.5%)	15 ( 44.1%)	1 ( 2.9%)	34
Rectal abscess	5 ( 14.7%)	18 ( 52.9%)	10 ( 29.4%)	1 ( 2.9%)	34
Oral pruritus	2 ( 5.9%)	15 ( 44.1%)	16 ( 47.1%)	1 ( 2.9%)	34
Stoma site infection	1 ( 2.9%)	5 ( 14.7%)	24 ( 70.6%)	4 ( 11.8%)	34
Miliaria	3 ( 8.8%)	11 ( 32.4%)	17 ( 50.0%)	3 ( 8.8%)	34
Bone contusion	1 ( 2.9%)	9 ( 26.5%)	15 ( 44.1%)	9 ( 26.5%)	34

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Coma scale abnormal	6 ( 17.6%)	6 ( 17.6%)	11 ( 32.4%)	11 ( 32.4%)	34
Suffocation feeling	0 ( 0.0%)	14 ( 41.2%)	14 ( 41.2%)	6 ( 17.6%)	34
Differential white blood cell count abnormal	1 ( 2.9%)	10 ( 29.4%)	23 ( 67.6%)	0 ( 0.0%)	34
Cardiopulmonary failure	5 ( 14.7%)	9 ( 26.5%)	12 ( 35.3%)	8 ( 23.5%)	34
Serum ferritin decreased	4 ( 11.8%)	15 ( 44.1%)	13 ( 38.2%)	2 ( 5.9%)	34
Lumbar spinal stenosis	0 ( 0.0%)	2 ( 5.9%)	21 ( 61.8%)	11 ( 32.4%)	34
Loss of control of legs	0 ( 0.0%)	5 ( 14.7%)	16 ( 47.1%)	13 ( 38.2%)	34
Diabetic foot	0 ( 0.0%)	1 ( 2.9%)	27 ( 79.4%)	6 ( 17.6%)	34
Axillary pain	3 ( 8.8%)	14 ( 41.2%)	16 ( 47.1%)	1 ( 2.9%)	34
Stenotrophomonas infection	16 ( 47.1%)	5 ( 14.7%)	13 ( 38.2%)	0 ( 0.0%)	34
B-cell lymphoma	2 ( 5.9%)	6 ( 17.6%)	24 ( 70.6%)	2 ( 5.9%)	34
Dactylitis	2 ( 5.9%)	18 ( 52.9%)	14 ( 41.2%)	0 ( 0.0%)	34
Middle ear effusion	3 ( 8.8%)	7 ( 20.6%)	19 ( 55.9%)	5 ( 14.7%)	34
Plasmacytoma	1 ( 2.9%)	4 ( 11.8%)	28 ( 82.4%)	1 ( 2.9%)	34
Chest injury	2 ( 5.9%)	8 ( 23.5%)	17 ( 50.0%)	7 ( 20.6%)	34
Eye allergy	5 ( 14.7%)	7 ( 20.6%)	21 ( 61.8%)	1 ( 2.9%)	34
Thyrotoxic crisis	5 ( 14.7%)	6 ( 17.6%)	20 ( 58.8%)	3 ( 8.8%)	34
Therapeutic response delayed	5 ( 14.7%)	8 ( 23.5%)	15 ( 44.1%)	6 ( 17.6%)	34
Poor peripheral circulation	4 ( 11.8%)	9 ( 26.5%)	15 ( 44.1%)	6 ( 17.6%)	34
Marasmus	0 ( 0.0%)	1 ( 2.9%)	14 ( 41.2%)	19 ( 55.9%)	34
Postmenopausal haemorrhage	0 ( 0.0%)	10 ( 29.4%)	23 ( 67.6%)	1 ( 2.9%)	34
Premature labour	10 ( 29.4%)	24 ( 70.6%)	0 ( 0.0%)	0 ( 0.0%)	34
Pyelonephritis acute	2 ( 5.9%)	5 ( 14.7%)	17 ( 50.0%)	10 ( 29.4%)	34
Rash morbilliform	8 ( 23.5%)	7 ( 20.6%)	11 ( 32.4%)	8 ( 23.5%)	34
Cerebrospinal fluid leakage	4 ( 11.8%)	11 ( 32.4%)	18 ( 52.9%)	1 ( 2.9%)	34
Intensive care	8 ( 23.5%)	5 ( 14.7%)	16 ( 47.1%)	5 ( 14.7%)	34
Pulmonary function test abnormal	0 ( 0.0%)	0 ( 0.0%)	30 ( 88.2%)	4 ( 11.8%)	34

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Chronic graft versus host disease	9 ( 26.5%)	10 ( 29.4%)	14 ( 41.2%)	1 ( 2.9%)	34
Genital herpes	0 ( 0.0%)	14 ( 41.2%)	18 ( 52.9%)	2 ( 5.9%)	34
Acidosis hyperchloreaemic	1 ( 3.0%)	12 ( 36.4%)	17 ( 51.5%)	3 ( 9.1%)	33
Cytomegalovirus colitis	0 ( 0.0%)	5 ( 15.2%)	23 ( 69.7%)	5 ( 15.2%)	33
Groin abscess	5 ( 15.2%)	18 ( 54.5%)	9 ( 27.3%)	1 ( 3.0%)	33
Renal neoplasm	0 ( 0.0%)	4 ( 12.1%)	19 ( 57.6%)	10 ( 30.3%)	33
Cholecystitis infective	0 ( 0.0%)	4 ( 12.1%)	23 ( 69.7%)	6 ( 18.2%)	33
Facial paresis	6 ( 18.2%)	7 ( 21.2%)	15 ( 45.5%)	5 ( 15.2%)	33
Cytomegalovirus chorioretinitis	4 ( 12.1%)	12 ( 36.4%)	14 ( 42.4%)	3 ( 9.1%)	33
Optic ischaemic neuropathy	0 ( 0.0%)	19 ( 57.6%)	10 ( 30.3%)	4 ( 12.1%)	33
Injection site infection	2 ( 6.1%)	10 ( 30.3%)	20 ( 60.6%)	1 ( 3.0%)	33
Red blood cell sedimentation rate abnormal	8 ( 24.2%)	5 ( 15.2%)	20 ( 60.6%)	0 ( 0.0%)	33
Multiple drug therapy	0 ( 0.0%)	3 ( 9.1%)	3 ( 9.1%)	27 ( 81.8%)	33
Follicular lymphoma	0 ( 0.0%)	9 ( 27.3%)	21 ( 63.6%)	3 ( 9.1%)	33
Drug titration error	2 ( 6.1%)	19 ( 57.6%)	7 ( 21.2%)	5 ( 15.2%)	33
Increased bronchial secretion	17 ( 51.5%)	4 ( 12.1%)	7 ( 21.2%)	5 ( 15.2%)	33
Injection related reaction	5 ( 15.2%)	16 ( 48.5%)	10 ( 30.3%)	2 ( 6.1%)	33
Disseminated mycobacterium avium complex infection	0 ( 0.0%)	13 ( 39.4%)	19 ( 57.6%)	1 ( 3.0%)	33
Lactose intolerance	4 ( 12.1%)	6 ( 18.2%)	20 ( 60.6%)	3 ( 9.1%)	33
Ulcerative keratitis	4 ( 12.1%)	7 ( 21.2%)	17 ( 51.5%)	5 ( 15.2%)	33
Conjunctival haemorrhage	1 ( 3.0%)	5 ( 15.2%)	23 ( 69.7%)	4 ( 12.1%)	33
IgA nephropathy	6 ( 18.2%)	11 ( 33.3%)	15 ( 45.5%)	1 ( 3.0%)	33
Diverticulum intestinal	0 ( 0.0%)	0 ( 0.0%)	26 ( 78.8%)	7 ( 21.2%)	33
Abnormal sensation in eye	0 ( 0.0%)	3 ( 9.1%)	22 ( 66.7%)	8 ( 24.2%)	33
Ketosis	3 ( 9.1%)	6 ( 18.2%)	12 ( 36.4%)	12 ( 36.4%)	33
Gastrointestinal stromal tumour	2 ( 6.1%)	6 ( 18.2%)	22 ( 66.7%)	3 ( 9.1%)	33
Henoch-Schonlein purpura	6 ( 18.2%)	7 ( 21.2%)	17 ( 51.5%)	3 ( 9.1%)	33

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bezoar	2 ( 6.1%)	8 ( 24.2%)	19 ( 57.6%)	4 ( 12.1%)	33
Cervix carcinoma	0 ( 0.0%)	18 ( 54.5%)	13 ( 39.4%)	2 ( 6.1%)	33
Barrett's oesophagus	1 ( 3.0%)	5 ( 15.2%)	26 ( 78.8%)	1 ( 3.0%)	33
Glomerular filtration rate increased	2 ( 6.1%)	12 ( 36.4%)	15 ( 45.5%)	4 ( 12.1%)	33
Malignant pleural effusion	0 ( 0.0%)	6 ( 18.8%)	23 ( 71.9%)	3 ( 9.4%)	32
Pneumocystis jirovecii infection	0 ( 0.0%)	4 ( 12.5%)	23 ( 71.9%)	5 ( 15.6%)	32
Chronic fatigue syndrome	1 ( 3.1%)	19 ( 59.4%)	8 ( 25.0%)	4 ( 12.5%)	32
Skin wound	4 ( 12.5%)	10 ( 31.3%)	14 ( 43.8%)	4 ( 12.5%)	32
Large intestinal haemorrhage	2 ( 6.3%)	6 ( 18.8%)	15 ( 46.9%)	9 ( 28.1%)	32
Oxygen consumption increased	5 ( 15.6%)	4 ( 12.5%)	18 ( 56.3%)	5 ( 15.6%)	32
Migraine with aura	6 ( 18.8%)	11 ( 34.4%)	14 ( 43.8%)	1 ( 3.1%)	32
Oesophageal ulcer	4 ( 12.5%)	3 ( 9.4%)	20 ( 62.5%)	5 ( 15.6%)	32
Heart valve incompetence	5 ( 15.6%)	5 ( 15.6%)	15 ( 46.9%)	7 ( 21.9%)	32
Hepatitis B reactivation	1 ( 3.1%)	6 ( 18.8%)	17 ( 53.1%)	8 ( 25.0%)	32
Nephrectomy	1 ( 3.1%)	1 ( 3.1%)	23 ( 71.9%)	7 ( 21.9%)	32
Myopericarditis	8 ( 25.0%)	9 ( 28.1%)	8 ( 25.0%)	7 ( 21.9%)	32
Motion sickness	3 ( 9.4%)	13 ( 40.6%)	15 ( 46.9%)	1 ( 3.1%)	32
Weight gain poor	16 ( 50.0%)	6 ( 18.8%)	8 ( 25.0%)	2 ( 6.3%)	32
Brain herniation	4 ( 12.5%)	11 ( 34.4%)	14 ( 43.8%)	3 ( 9.4%)	32
Secondary immunodeficiency	10 ( 31.3%)	11 ( 34.4%)	11 ( 34.4%)	0 ( 0.0%)	32
Histoplasmosis disseminated	14 ( 43.8%)	9 ( 28.1%)	6 ( 18.8%)	3 ( 9.4%)	32
Bone density abnormal	2 ( 6.3%)	7 ( 21.9%)	23 ( 71.9%)	0 ( 0.0%)	32
Lip blister	4 ( 12.5%)	12 ( 37.5%)	11 ( 34.4%)	5 ( 15.6%)	32
Bladder neoplasm	0 ( 0.0%)	1 ( 3.1%)	21 ( 65.6%)	10 ( 31.3%)	32
Tumour pain	6 ( 18.8%)	6 ( 18.8%)	19 ( 59.4%)	1 ( 3.1%)	32
Hyperparathyroidism secondary	3 ( 9.4%)	10 ( 31.3%)	16 ( 50.0%)	3 ( 9.4%)	32
Schizoffective disorder	2 ( 6.3%)	19 ( 59.4%)	11 ( 34.4%)	0 ( 0.0%)	32

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Social anxiety disorder	4 ( 12.5%)	24 ( 75.0%)	4 ( 12.5%)	0 ( 0.0%)	32
Microcytic anaemia	3 ( 9.4%)	6 ( 18.8%)	17 ( 53.1%)	6 ( 18.8%)	32
Cell death	4 ( 12.5%)	7 ( 21.9%)	17 ( 53.1%)	4 ( 12.5%)	32
Impetigo	12 ( 37.5%)	9 ( 28.1%)	9 ( 28.1%)	2 ( 6.3%)	32
Corneal disorder	2 ( 6.3%)	6 ( 18.8%)	14 ( 43.8%)	10 ( 31.3%)	32
Cystic fibrosis	9 ( 28.1%)	15 ( 46.9%)	8 ( 25.0%)	0 ( 0.0%)	32
Hypoglycaemic coma	0 ( 0.0%)	2 ( 6.3%)	13 ( 40.6%)	17 ( 53.1%)	32
Incorrect dose administered by product	1 ( 3.1%)	6 ( 18.8%)	14 ( 43.8%)	11 ( 34.4%)	32
Antipsychotic drug level increased	7 ( 21.9%)	18 ( 56.3%)	6 ( 18.8%)	1 ( 3.1%)	32
Foaming at mouth	7 ( 21.9%)	8 ( 25.0%)	15 ( 46.9%)	2 ( 6.3%)	32
Bacterial test positive	2 ( 6.3%)	10 ( 31.3%)	13 ( 40.6%)	7 ( 21.9%)	32
Gastrointestinal oedema	0 ( 0.0%)	16 ( 50.0%)	12 ( 37.5%)	4 ( 12.5%)	32
Escherichia sepsis	11 ( 34.4%)	1 ( 3.1%)	16 ( 50.0%)	4 ( 12.5%)	32
Haematocrit increased	2 ( 6.3%)	6 ( 18.8%)	22 ( 68.8%)	2 ( 6.3%)	32
White blood cell disorder	1 ( 3.1%)	3 ( 9.4%)	22 ( 68.8%)	6 ( 18.8%)	32
Psychomotor retardation	10 ( 31.3%)	8 ( 25.0%)	8 ( 25.0%)	6 ( 18.8%)	32
Pulmonary nocardiosis	0 ( 0.0%)	4 ( 12.5%)	28 ( 87.5%)	0 ( 0.0%)	32
Generalised bullous fixed drug eruption	1 ( 3.1%)	30 ( 93.8%)	1 ( 3.1%)	0 ( 0.0%)	32
Gastrointestinal obstruction	5 ( 15.6%)	4 ( 12.5%)	23 ( 71.9%)	0 ( 0.0%)	32
Central serous chorioretinopathy	1 ( 3.2%)	18 ( 58.1%)	11 ( 35.5%)	1 ( 3.2%)	31
Glomerular filtration rate abnormal	1 ( 3.2%)	7 ( 22.6%)	19 ( 61.3%)	4 ( 12.9%)	31
Pleural thickening	0 ( 0.0%)	7 ( 22.6%)	23 ( 74.2%)	1 ( 3.2%)	31
Pulmonary vasculitis	1 ( 3.2%)	0 ( 0.0%)	30 ( 96.8%)	0 ( 0.0%)	31
Eyelid irritation	5 ( 16.1%)	10 ( 32.3%)	12 ( 38.7%)	4 ( 12.9%)	31
Nephrogenic anaemia	1 ( 3.2%)	7 ( 22.6%)	14 ( 45.2%)	9 ( 29.0%)	31
Fear of death	0 ( 0.0%)	10 ( 32.3%)	15 ( 48.4%)	6 ( 19.4%)	31
Renal colic	0 ( 0.0%)	8 ( 25.8%)	22 ( 71.0%)	1 ( 3.2%)	31

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Amyloid related imaging abnormality-microhaemorrhages	0 ( 0.0%)	0 ( 0.0%)	13 ( 41.9%)	18 ( 58.1%)	31
Respiratory disorder neonatal	31 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	31
Hyperaemia	9 ( 29.0%)	6 ( 19.4%)	14 ( 45.2%)	2 ( 6.5%)	31
Accident at work	3 ( 9.7%)	13 ( 41.9%)	13 ( 41.9%)	2 ( 6.5%)	31
Aspartate aminotransferase abnormal	3 ( 9.7%)	4 ( 12.9%)	18 ( 58.1%)	6 ( 19.4%)	31
Pneumonia respiratory syncytial viral	11 ( 35.5%)	1 ( 3.2%)	17 ( 54.8%)	2 ( 6.5%)	31
Infective pulmonary exacerbation of cystic fibrosis	17 ( 54.8%)	9 ( 29.0%)	5 ( 16.1%)	0 ( 0.0%)	31
Hepatic mass	0 ( 0.0%)	5 ( 16.1%)	21 ( 67.7%)	5 ( 16.1%)	31
Sinus node dysfunction	0 ( 0.0%)	1 ( 3.2%)	16 ( 51.6%)	14 ( 45.2%)	31
Tongue haemorrhage	10 ( 32.3%)	2 ( 6.5%)	19 ( 61.3%)	0 ( 0.0%)	31
Rectal tenesmus	8 ( 25.8%)	13 ( 41.9%)	10 ( 32.3%)	0 ( 0.0%)	31
Drug detoxification	2 ( 6.5%)	22 ( 71.0%)	7 ( 22.6%)	0 ( 0.0%)	31
Periodontitis	0 ( 0.0%)	3 ( 9.7%)	22 ( 71.0%)	6 ( 19.4%)	31
Disease complication	2 ( 6.5%)	5 ( 16.1%)	13 ( 41.9%)	11 ( 35.5%)	31
Discharge	4 ( 12.9%)	9 ( 29.0%)	17 ( 54.8%)	1 ( 3.2%)	31
Perioral dermatitis	14 ( 45.2%)	12 ( 38.7%)	4 ( 12.9%)	1 ( 3.2%)	31
Catheter site haemorrhage	8 ( 25.8%)	10 ( 32.3%)	9 ( 29.0%)	4 ( 12.9%)	31
Retinal tear	1 ( 3.2%)	4 ( 12.9%)	25 ( 80.6%)	1 ( 3.2%)	31
Social problem	2 ( 6.5%)	12 ( 38.7%)	15 ( 48.4%)	2 ( 6.5%)	31
Kidney transplant rejection	8 ( 25.8%)	13 ( 41.9%)	9 ( 29.0%)	1 ( 3.2%)	31
Blood pressure inadequately controlled	0 ( 0.0%)	3 ( 9.7%)	24 ( 77.4%)	4 ( 12.9%)	31
Mycobacterium tuberculosis complex test positive	1 ( 3.2%)	11 ( 35.5%)	19 ( 61.3%)	0 ( 0.0%)	31
Stoma site hypergranulation	1 ( 3.2%)	1 ( 3.2%)	21 ( 67.7%)	8 ( 25.8%)	31
Ventricular septal defect	29 ( 93.5%)	1 ( 3.2%)	1 ( 3.2%)	0 ( 0.0%)	31
Hypomania	3 ( 9.7%)	12 ( 38.7%)	16 ( 51.6%)	0 ( 0.0%)	31
Blood HIV RNA increased	0 ( 0.0%)	22 ( 71.0%)	9 ( 29.0%)	0 ( 0.0%)	31
Galactorrhoea	19 ( 61.3%)	9 ( 29.0%)	2 ( 6.5%)	1 ( 3.2%)	31



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Rheumatoid nodule	0 ( 0.0%)	11 ( 35.5%)	19 ( 61.3%)	1 ( 3.2%)	31
Pneumonia legionella	0 ( 0.0%)	6 ( 19.4%)	23 ( 74.2%)	2 ( 6.5%)	31
Substance use disorder	10 ( 32.3%)	17 ( 54.8%)	4 ( 12.9%)	0 ( 0.0%)	31
Crepitations	2 ( 6.5%)	7 ( 22.6%)	17 ( 54.8%)	5 ( 16.1%)	31
Eye oedema	2 ( 6.5%)	13 ( 41.9%)	15 ( 48.4%)	1 ( 3.2%)	31
Mean cell volume decreased	1 ( 3.2%)	18 ( 58.1%)	11 ( 35.5%)	1 ( 3.2%)	31
Coccydynia	1 ( 3.2%)	8 ( 25.8%)	20 ( 64.5%)	2 ( 6.5%)	31
Reaction to excipient	2 ( 6.5%)	9 ( 29.0%)	19 ( 61.3%)	1 ( 3.2%)	31
Hyperglycaemic hyperosmolar nonketotic syndrome	0 ( 0.0%)	1 ( 3.2%)	25 ( 80.6%)	5 ( 16.1%)	31
Retinal pigmentation	1 ( 3.2%)	14 ( 45.2%)	14 ( 45.2%)	2 ( 6.5%)	31
Intra-abdominal fluid collection	3 ( 9.7%)	8 ( 25.8%)	17 ( 54.8%)	3 ( 9.7%)	31
Exposure to chemical pollution	1 ( 3.2%)	4 ( 12.9%)	12 ( 38.7%)	14 ( 45.2%)	31
Vulvovaginal discomfort	1 ( 3.2%)	4 ( 12.9%)	24 ( 77.4%)	2 ( 6.5%)	31
Device connection issue	6 ( 19.4%)	3 ( 9.7%)	15 ( 48.4%)	7 ( 22.6%)	31
Monocyte percentage increased	3 ( 10.0%)	6 ( 20.0%)	18 ( 60.0%)	3 ( 10.0%)	30
Coronary artery stenosis	0 ( 0.0%)	6 ( 20.0%)	17 ( 56.7%)	7 ( 23.3%)	30
Normocytic anaemia	0 ( 0.0%)	4 ( 13.3%)	21 ( 70.0%)	5 ( 16.7%)	30
Pharyngeal disorder	3 ( 10.0%)	11 ( 36.7%)	13 ( 43.3%)	3 ( 10.0%)	30
Otitis externa	9 ( 30.0%)	6 ( 20.0%)	15 ( 50.0%)	0 ( 0.0%)	30
Rectal cancer	0 ( 0.0%)	4 ( 13.3%)	23 ( 76.7%)	3 ( 10.0%)	30
SARS-CoV-2 test negative	13 ( 43.3%)	7 ( 23.3%)	10 ( 33.3%)	0 ( 0.0%)	30
Eosinophilic pneumonia acute	1 ( 3.3%)	7 ( 23.3%)	16 ( 53.3%)	6 ( 20.0%)	30
Bronchial secretion retention	3 ( 10.0%)	1 ( 3.3%)	15 ( 50.0%)	11 ( 36.7%)	30
Cutaneous T-cell lymphoma	1 ( 3.3%)	9 ( 30.0%)	13 ( 43.3%)	7 ( 23.3%)	30
Cataplexy	1 ( 3.3%)	14 ( 46.7%)	2 ( 6.7%)	13 ( 43.3%)	30
Tongue blistering	1 ( 3.3%)	7 ( 23.3%)	17 ( 56.7%)	5 ( 16.7%)	30
Lung abscess	0 ( 0.0%)	9 ( 30.0%)	17 ( 56.7%)	4 ( 13.3%)	30

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Food aversion	3 ( 10.0%)	8 ( 26.7%)	13 ( 43.3%)	6 ( 20.0%)	30
Lip injury	8 ( 26.7%)	12 ( 40.0%)	9 ( 30.0%)	1 ( 3.3%)	30
Dependence	4 ( 13.3%)	15 ( 50.0%)	10 ( 33.3%)	1 ( 3.3%)	30
Stoma site reaction	1 ( 3.3%)	0 ( 0.0%)	24 ( 80.0%)	5 ( 16.7%)	30
Abdominal adhesions	2 ( 6.7%)	10 ( 33.3%)	17 ( 56.7%)	1 ( 3.3%)	30
Abscess intestinal	4 ( 13.3%)	15 ( 50.0%)	9 ( 30.0%)	2 ( 6.7%)	30
Coronavirus test positive	0 ( 0.0%)	8 ( 26.7%)	21 ( 70.0%)	1 ( 3.3%)	30
Crystal nephropathy	0 ( 0.0%)	1 ( 3.3%)	16 ( 53.3%)	13 ( 43.3%)	30
Terminal ileitis	3 ( 10.0%)	14 ( 46.7%)	13 ( 43.3%)	0 ( 0.0%)	30
Ileal ulcer	2 ( 6.7%)	17 ( 56.7%)	8 ( 26.7%)	3 ( 10.0%)	30
Virologic failure	5 ( 16.7%)	11 ( 36.7%)	14 ( 46.7%)	0 ( 0.0%)	30
Tonic clonic movements	1 ( 3.3%)	13 ( 43.3%)	8 ( 26.7%)	8 ( 26.7%)	30
Nasal septum deviation	3 ( 10.0%)	19 ( 63.3%)	8 ( 26.7%)	0 ( 0.0%)	30
Treatment delayed	3 ( 10.0%)	7 ( 23.3%)	17 ( 56.7%)	3 ( 10.0%)	30
Mast cell activation syndrome	5 ( 16.7%)	17 ( 56.7%)	8 ( 26.7%)	0 ( 0.0%)	30
Infectious mononucleosis	17 ( 56.7%)	10 ( 33.3%)	3 ( 10.0%)	0 ( 0.0%)	30
White coat hypertension	0 ( 0.0%)	3 ( 10.0%)	23 ( 76.7%)	4 ( 13.3%)	30
Procalcitonin increased	5 ( 16.7%)	6 ( 20.0%)	18 ( 60.0%)	1 ( 3.3%)	30
Gastrointestinal ulcer	3 ( 10.0%)	14 ( 46.7%)	11 ( 36.7%)	2 ( 6.7%)	30
Blood chloride increased	1 ( 3.3%)	8 ( 26.7%)	17 ( 56.7%)	4 ( 13.3%)	30
Change of bowel habit	3 ( 10.0%)	3 ( 10.0%)	21 ( 70.0%)	3 ( 10.0%)	30
Cerebral thrombosis	1 ( 3.3%)	8 ( 26.7%)	17 ( 56.7%)	4 ( 13.3%)	30
Tympanic membrane perforation	8 ( 26.7%)	11 ( 36.7%)	10 ( 33.3%)	1 ( 3.3%)	30
Carotid artery stenosis	1 ( 3.3%)	2 ( 6.7%)	17 ( 56.7%)	10 ( 33.3%)	30
Intra-abdominal haemorrhage	3 ( 10.0%)	12 ( 40.0%)	13 ( 43.3%)	2 ( 6.7%)	30
Blood sodium increased	2 ( 6.7%)	5 ( 16.7%)	17 ( 56.7%)	6 ( 20.0%)	30
Lymphocyte count abnormal	2 ( 6.7%)	8 ( 26.7%)	20 ( 66.7%)	0 ( 0.0%)	30

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Capillary leak syndrome	6 ( 20.0%)	5 ( 16.7%)	16 ( 53.3%)	3 ( 10.0%)	30
Urinary bladder haemorrhage	1 ( 3.3%)	2 ( 6.7%)	19 ( 63.3%)	8 ( 26.7%)	30
Dyschromatopsia	2 ( 6.7%)	7 ( 23.3%)	17 ( 56.7%)	4 ( 13.3%)	30
Hair disorder	0 ( 0.0%)	9 ( 30.0%)	14 ( 46.7%)	7 ( 23.3%)	30
Cryptococcosis	0 ( 0.0%)	5 ( 16.7%)	22 ( 73.3%)	3 ( 10.0%)	30
Latent tuberculosis	0 ( 0.0%)	14 ( 48.3%)	13 ( 44.8%)	2 ( 6.9%)	29
Chemotherapy	0 ( 0.0%)	5 ( 17.2%)	19 ( 65.5%)	5 ( 17.2%)	29
Myocardial injury	6 ( 20.7%)	4 ( 13.8%)	14 ( 48.3%)	5 ( 17.2%)	29
Addison's disease	1 ( 3.4%)	7 ( 24.1%)	16 ( 55.2%)	5 ( 17.2%)	29
Granulomatosis with polyangiitis	2 ( 6.9%)	8 ( 27.6%)	18 ( 62.1%)	1 ( 3.4%)	29
Faeces pale	1 ( 3.4%)	2 ( 6.9%)	20 ( 69.0%)	6 ( 20.7%)	29
Osteitis	2 ( 6.9%)	8 ( 27.6%)	18 ( 62.1%)	1 ( 3.4%)	29
Peripheral motor neuropathy	10 ( 34.5%)	0 ( 0.0%)	15 ( 51.7%)	4 ( 13.8%)	29
Calculus urinary	4 ( 13.8%)	8 ( 27.6%)	13 ( 44.8%)	4 ( 13.8%)	29
Bronchial disorder	3 ( 10.3%)	4 ( 13.8%)	20 ( 69.0%)	2 ( 6.9%)	29
Nosocomial infection	12 ( 41.4%)	3 ( 10.3%)	11 ( 37.9%)	3 ( 10.3%)	29
B-cell type acute leukaemia	7 ( 24.1%)	6 ( 20.7%)	16 ( 55.2%)	0 ( 0.0%)	29
Hostility	4 ( 13.8%)	4 ( 13.8%)	21 ( 72.4%)	0 ( 0.0%)	29
Bundle branch block left	0 ( 0.0%)	4 ( 13.8%)	15 ( 51.7%)	10 ( 34.5%)	29
Age-related macular degeneration	0 ( 0.0%)	7 ( 24.1%)	14 ( 48.3%)	8 ( 27.6%)	29
Skin induration	0 ( 0.0%)	7 ( 24.1%)	20 ( 69.0%)	2 ( 6.9%)	29
Diffuse alveolar damage	2 ( 6.9%)	2 ( 6.9%)	22 ( 75.9%)	3 ( 10.3%)	29
Lymphocyte adoptive therapy	0 ( 0.0%)	3 ( 10.3%)	25 ( 86.2%)	1 ( 3.4%)	29
Lung neoplasm	1 ( 3.4%)	1 ( 3.4%)	21 ( 72.4%)	6 ( 20.7%)	29
Radiation necrosis	2 ( 6.9%)	3 ( 10.3%)	18 ( 62.1%)	6 ( 20.7%)	29
Spleen disorder	5 ( 17.2%)	8 ( 27.6%)	15 ( 51.7%)	1 ( 3.4%)	29
Mastectomy	0 ( 0.0%)	10 ( 34.5%)	15 ( 51.7%)	4 ( 13.8%)	29

**Reaction Summary Table**  
**Derived Age Group**

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Device loosening	2 ( 6.9%)	3 ( 10.3%)	20 ( 69.0%)	4 ( 13.8%)	29
Personality disorder	0 ( 0.0%)	3 ( 10.3%)	26 ( 89.7%)	0 ( 0.0%)	29
Gastrointestinal wall thickening	2 ( 6.9%)	10 ( 34.5%)	13 ( 44.8%)	4 ( 13.8%)	29
Subacute cutaneous lupus erythematosus	1 ( 3.4%)	6 ( 20.7%)	20 ( 69.0%)	2 ( 6.9%)	29
Vitamin B12 increased	1 ( 3.4%)	9 ( 31.0%)	14 ( 48.3%)	5 ( 17.2%)	29
Traumatic fracture	0 ( 0.0%)	5 ( 17.2%)	12 ( 41.4%)	12 ( 41.4%)	29
Walking disability	1 ( 3.4%)	6 ( 20.7%)	16 ( 55.2%)	6 ( 20.7%)	29
Subileus	6 ( 20.7%)	14 ( 48.3%)	8 ( 27.6%)	1 ( 3.4%)	29
Impulsive behaviour	17 ( 58.6%)	9 ( 31.0%)	3 ( 10.3%)	0 ( 0.0%)	29
Enterovirus infection	18 ( 62.1%)	8 ( 27.6%)	3 ( 10.3%)	0 ( 0.0%)	29
Anticholinergic syndrome	11 ( 37.9%)	4 ( 13.8%)	11 ( 37.9%)	3 ( 10.3%)	29
Antibiotic therapy	1 ( 3.4%)	4 ( 13.8%)	19 ( 65.5%)	5 ( 17.2%)	29
Brain operation	3 ( 10.3%)	6 ( 20.7%)	18 ( 62.1%)	2 ( 6.9%)	29
Allergic sinusitis	3 ( 10.3%)	5 ( 17.2%)	19 ( 65.5%)	2 ( 6.9%)	29
Nephrogenic diabetes insipidus	12 ( 41.4%)	7 ( 24.1%)	10 ( 34.5%)	0 ( 0.0%)	29
Oral mucosal erythema	5 ( 17.2%)	8 ( 27.6%)	14 ( 48.3%)	2 ( 6.9%)	29
Gastrointestinal necrosis	4 ( 13.8%)	8 ( 27.6%)	10 ( 34.5%)	7 ( 24.1%)	29
Prerenal failure	0 ( 0.0%)	1 ( 3.4%)	23 ( 79.3%)	5 ( 17.2%)	29
Bacterial disease carrier	6 ( 20.7%)	1 ( 3.4%)	13 ( 44.8%)	9 ( 31.0%)	29
Ventricular dysfunction	2 ( 6.9%)	9 ( 31.0%)	15 ( 51.7%)	3 ( 10.3%)	29
Cytokine storm	1 ( 3.4%)	3 ( 10.3%)	16 ( 55.2%)	9 ( 31.0%)	29
Choreoathetosis	9 ( 31.0%)	8 ( 27.6%)	6 ( 20.7%)	6 ( 20.7%)	29
Product packaging difficult to open	0 ( 0.0%)	1 ( 3.4%)	15 ( 51.7%)	13 ( 44.8%)	29
Glycosylated haemoglobin decreased	0 ( 0.0%)	3 ( 10.3%)	19 ( 65.5%)	7 ( 24.1%)	29
Ventricular hypokinesia	4 ( 13.8%)	4 ( 13.8%)	16 ( 55.2%)	5 ( 17.2%)	29
Oesophageal varices haemorrhage	2 ( 6.9%)	9 ( 31.0%)	17 ( 58.6%)	1 ( 3.4%)	29
Defaecation disorder	7 ( 24.1%)	8 ( 27.6%)	11 ( 37.9%)	3 ( 10.3%)	29

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Herpes ophthalmic	1 ( 3.6%)	6 ( 21.4%)	18 ( 64.3%)	3 ( 10.7%)	28
Hypercapnia	7 ( 25.0%)	4 ( 14.3%)	10 ( 35.7%)	7 ( 25.0%)	28
Renal mass	0 ( 0.0%)	1 ( 3.6%)	19 ( 67.9%)	8 ( 28.6%)	28
Chondropathy	0 ( 0.0%)	11 ( 39.3%)	13 ( 46.4%)	4 ( 14.3%)	28
Cytokine increased	1 ( 3.6%)	10 ( 35.7%)	17 ( 60.7%)	0 ( 0.0%)	28
Haemorrhagic diathesis	3 ( 10.7%)	1 ( 3.6%)	11 ( 39.3%)	13 ( 46.4%)	28
Infusion site infection	4 ( 14.3%)	12 ( 42.9%)	12 ( 42.9%)	0 ( 0.0%)	28
Nasal disorder	1 ( 3.6%)	11 ( 39.3%)	14 ( 50.0%)	2 ( 7.1%)	28
Torticollis	10 ( 35.7%)	7 ( 25.0%)	11 ( 39.3%)	0 ( 0.0%)	28
Tonsillar hypertrophy	17 ( 60.7%)	5 ( 17.9%)	6 ( 21.4%)	0 ( 0.0%)	28
Muscle strength abnormal	8 ( 28.6%)	6 ( 21.4%)	9 ( 32.1%)	5 ( 17.9%)	28
Emotional poverty	8 ( 28.6%)	18 ( 64.3%)	2 ( 7.1%)	0 ( 0.0%)	28
Seizure like phenomena	5 ( 17.9%)	5 ( 17.9%)	18 ( 64.3%)	0 ( 0.0%)	28
Brugada syndrome	11 ( 39.3%)	15 ( 53.6%)	2 ( 7.1%)	0 ( 0.0%)	28
Butterfly rash	3 ( 10.7%)	17 ( 60.7%)	8 ( 28.6%)	0 ( 0.0%)	28
Application site irritation	8 ( 28.6%)	10 ( 35.7%)	9 ( 32.1%)	1 ( 3.6%)	28
Disseminated tuberculosis	2 ( 7.1%)	6 ( 21.4%)	16 ( 57.1%)	4 ( 14.3%)	28
Spinal column injury	2 ( 7.1%)	3 ( 10.7%)	19 ( 67.9%)	4 ( 14.3%)	28
Spinal cord injury	2 ( 7.1%)	9 ( 32.1%)	12 ( 42.9%)	5 ( 17.9%)	28
Acute febrile neutrophilic dermatosis	1 ( 3.6%)	5 ( 17.9%)	20 ( 71.4%)	2 ( 7.1%)	28
Atrial thrombosis	3 ( 10.7%)	3 ( 10.7%)	11 ( 39.3%)	11 ( 39.3%)	28
Peripheral vascular disorder	1 ( 3.6%)	1 ( 3.6%)	21 ( 75.0%)	5 ( 17.9%)	28
Peritoneal dialysis complication	2 ( 7.1%)	8 ( 28.6%)	14 ( 50.0%)	4 ( 14.3%)	28
Large intestinal stenosis	9 ( 32.1%)	7 ( 25.0%)	8 ( 28.6%)	4 ( 14.3%)	28
Uterine perforation	2 ( 7.1%)	25 ( 89.3%)	1 ( 3.6%)	0 ( 0.0%)	28
Relapsing-remitting multiple sclerosis	1 ( 3.6%)	13 ( 46.4%)	14 ( 50.0%)	0 ( 0.0%)	28
White matter lesion	2 ( 7.1%)	10 ( 35.7%)	13 ( 46.4%)	3 ( 10.7%)	28

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Coronary arterial stent insertion	0 ( 0.0%)	1 ( 3.6%)	23 ( 82.1%)	4 ( 14.3%)	28
Ureterolithiasis	5 ( 17.9%)	4 ( 14.3%)	11 ( 39.3%)	8 ( 28.6%)	28
Blood calcium abnormal	0 ( 0.0%)	14 ( 50.0%)	13 ( 46.4%)	1 ( 3.6%)	28
Gastric polyps	1 ( 3.6%)	4 ( 14.3%)	21 ( 75.0%)	2 ( 7.1%)	28
Epstein-Barr viraemia	11 ( 39.3%)	10 ( 35.7%)	6 ( 21.4%)	1 ( 3.6%)	28
Post procedural swelling	4 ( 14.3%)	6 ( 21.4%)	18 ( 64.3%)	0 ( 0.0%)	28
Gastrointestinal stoma complication	5 ( 17.9%)	4 ( 14.3%)	11 ( 39.3%)	8 ( 28.6%)	28
Urine analysis abnormal	3 ( 10.7%)	8 ( 28.6%)	13 ( 46.4%)	4 ( 14.3%)	28
Reversible cerebral vasoconstriction syndrome	2 ( 7.1%)	18 ( 64.3%)	8 ( 28.6%)	0 ( 0.0%)	28
Restrictive pulmonary disease	6 ( 21.4%)	7 ( 25.0%)	13 ( 46.4%)	2 ( 7.1%)	28
Insulin resistance	9 ( 32.1%)	7 ( 25.0%)	11 ( 39.3%)	1 ( 3.6%)	28
Medical device site infection	9 ( 32.1%)	5 ( 17.9%)	12 ( 42.9%)	2 ( 7.1%)	28
Vertigo positional	0 ( 0.0%)	6 ( 21.4%)	17 ( 60.7%)	5 ( 17.9%)	28
Blood parathyroid hormone decreased	3 ( 10.7%)	4 ( 14.3%)	11 ( 39.3%)	10 ( 35.7%)	28
Cerebral venous thrombosis	15 ( 53.6%)	10 ( 35.7%)	3 ( 10.7%)	0 ( 0.0%)	28
Cerebral venous sinus thrombosis	14 ( 50.0%)	5 ( 17.9%)	8 ( 28.6%)	1 ( 3.6%)	28
Band sensation	0 ( 0.0%)	15 ( 53.6%)	13 ( 46.4%)	0 ( 0.0%)	28
Emergency care	8 ( 29.6%)	7 ( 25.9%)	9 ( 33.3%)	3 ( 11.1%)	27
Chronic cutaneous lupus erythematosus	0 ( 0.0%)	14 ( 51.9%)	12 ( 44.4%)	1 ( 3.7%)	27
Catheter site pain	7 ( 25.9%)	8 ( 29.6%)	11 ( 40.7%)	1 ( 3.7%)	27
Atypical femur fracture	0 ( 0.0%)	2 ( 7.4%)	20 ( 74.1%)	5 ( 18.5%)	27
Leg amputation	1 ( 3.7%)	3 ( 11.1%)	21 ( 77.8%)	2 ( 7.4%)	27
Laziness	5 ( 18.5%)	0 ( 0.0%)	15 ( 55.6%)	7 ( 25.9%)	27
Atypical haemolytic uraemic syndrome	5 ( 18.5%)	9 ( 33.3%)	11 ( 40.7%)	2 ( 7.4%)	27
Blood alkaline phosphatase abnormal	0 ( 0.0%)	2 ( 7.4%)	20 ( 74.1%)	5 ( 18.5%)	27
Osteosclerosis	0 ( 0.0%)	7 ( 25.9%)	16 ( 59.3%)	4 ( 14.8%)	27
Respiratory syncytial virus test positive	13 ( 48.1%)	2 ( 7.4%)	10 ( 37.0%)	2 ( 7.4%)	27

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Peptic ulcer	1 ( 3.7%)	10 ( 37.0%)	14 ( 51.9%)	2 ( 7.4%)	27
Ocular hypertension	7 ( 25.9%)	15 ( 55.6%)	4 ( 14.8%)	1 ( 3.7%)	27
Lip pain	2 ( 7.4%)	6 ( 22.2%)	14 ( 51.9%)	5 ( 18.5%)	27
Epicondylitis	0 ( 0.0%)	8 ( 29.6%)	16 ( 59.3%)	3 ( 11.1%)	27
Myocardial necrosis marker increased	5 ( 18.5%)	5 ( 18.5%)	13 ( 48.1%)	4 ( 14.8%)	27
Bronchitis chronic	1 ( 3.7%)	6 ( 22.2%)	13 ( 48.1%)	7 ( 25.9%)	27
Breast tenderness	5 ( 18.5%)	10 ( 37.0%)	9 ( 33.3%)	3 ( 11.1%)	27
Troponin T increased	5 ( 18.5%)	6 ( 22.2%)	10 ( 37.0%)	6 ( 22.2%)	27
Allergy to chemicals	4 ( 14.8%)	11 ( 40.7%)	9 ( 33.3%)	3 ( 11.1%)	27
Toe amputation	0 ( 0.0%)	7 ( 25.9%)	15 ( 55.6%)	5 ( 18.5%)	27
Mean platelet volume increased	1 ( 3.7%)	11 ( 40.7%)	11 ( 40.7%)	4 ( 14.8%)	27
Skin odour abnormal	3 ( 11.1%)	10 ( 37.0%)	11 ( 40.7%)	3 ( 11.1%)	27
Colorectal adenoma	0 ( 0.0%)	10 ( 37.0%)	14 ( 51.9%)	3 ( 11.1%)	27
Cartilage injury	1 ( 3.7%)	9 ( 33.3%)	16 ( 59.3%)	1 ( 3.7%)	27
Interleukin level increased	7 ( 25.9%)	6 ( 22.2%)	11 ( 40.7%)	3 ( 11.1%)	27
Long QT syndrome	0 ( 0.0%)	9 ( 33.3%)	9 ( 33.3%)	9 ( 33.3%)	27
Local anaesthetic systemic toxicity	8 ( 29.6%)	1 ( 3.7%)	18 ( 66.7%)	0 ( 0.0%)	27
Intrusive thoughts	4 ( 14.8%)	18 ( 66.7%)	4 ( 14.8%)	1 ( 3.7%)	27
Peripheral artery thrombosis	3 ( 11.1%)	6 ( 22.2%)	13 ( 48.1%)	5 ( 18.5%)	27
Appendicolith	0 ( 0.0%)	2 ( 7.4%)	0 ( 0.0%)	25 ( 92.6%)	27
Solar lentigo	1 ( 3.7%)	6 ( 22.2%)	16 ( 59.3%)	4 ( 14.8%)	27
Lymph node pain	4 ( 14.8%)	9 ( 33.3%)	12 ( 44.4%)	2 ( 7.4%)	27
Myopia	3 ( 11.1%)	9 ( 33.3%)	13 ( 48.1%)	2 ( 7.4%)	27
Kaposi's sarcoma	0 ( 0.0%)	10 ( 37.0%)	16 ( 59.3%)	1 ( 3.7%)	27
Still's disease	13 ( 48.1%)	11 ( 40.7%)	2 ( 7.4%)	1 ( 3.7%)	27
Invasive ductal breast carcinoma	0 ( 0.0%)	8 ( 29.6%)	18 ( 66.7%)	1 ( 3.7%)	27
Stress at work	3 ( 11.1%)	13 ( 48.1%)	11 ( 40.7%)	0 ( 0.0%)	27

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Intestinal operation	4 ( 14.8%)	6 ( 22.2%)	14 ( 51.9%)	3 ( 11.1%)	27
Lack of administration site rotation	4 ( 14.8%)	3 ( 11.1%)	19 ( 70.4%)	1 ( 3.7%)	27
Renal haemorrhage	2 ( 7.4%)	7 ( 25.9%)	11 ( 40.7%)	7 ( 25.9%)	27
Coronary artery bypass	0 ( 0.0%)	0 ( 0.0%)	22 ( 81.5%)	5 ( 18.5%)	27
Polycystic ovaries	5 ( 18.5%)	4 ( 14.8%)	18 ( 66.7%)	0 ( 0.0%)	27
High density lipoprotein decreased	4 ( 14.8%)	12 ( 44.4%)	7 ( 25.9%)	4 ( 14.8%)	27
Blood electrolytes decreased	1 ( 3.7%)	2 ( 7.4%)	20 ( 74.1%)	4 ( 14.8%)	27
Investigation abnormal	2 ( 7.4%)	5 ( 18.5%)	19 ( 70.4%)	1 ( 3.7%)	27
Scleritis	1 ( 3.7%)	10 ( 37.0%)	13 ( 48.1%)	3 ( 11.1%)	27
Vanishing bile duct syndrome	1 ( 3.7%)	5 ( 18.5%)	14 ( 51.9%)	7 ( 25.9%)	27
Intestinal mass	1 ( 3.7%)	2 ( 7.4%)	13 ( 48.1%)	11 ( 40.7%)	27
Temporomandibular joint syndrome	3 ( 11.1%)	10 ( 37.0%)	11 ( 40.7%)	3 ( 11.1%)	27
Neuroendocrine tumour	1 ( 3.7%)	6 ( 22.2%)	17 ( 63.0%)	3 ( 11.1%)	27
Dysentery	1 ( 3.7%)	12 ( 44.4%)	10 ( 37.0%)	4 ( 14.8%)	27
Acne cystic	6 ( 22.2%)	19 ( 70.4%)	2 ( 7.4%)	0 ( 0.0%)	27
Pneumonia cryptococcal	0 ( 0.0%)	3 ( 11.5%)	21 ( 80.8%)	2 ( 7.7%)	26
Purulence	5 ( 19.2%)	5 ( 19.2%)	12 ( 46.2%)	4 ( 15.4%)	26
Spondyloarthropathy	1 ( 3.8%)	13 ( 50.0%)	11 ( 42.3%)	1 ( 3.8%)	26
Metabolic syndrome	5 ( 19.2%)	14 ( 53.8%)	7 ( 26.9%)	0 ( 0.0%)	26
Laryngospasm	5 ( 19.2%)	7 ( 26.9%)	13 ( 50.0%)	1 ( 3.8%)	26
Ovarian cancer recurrent	0 ( 0.0%)	6 ( 23.1%)	20 ( 76.9%)	0 ( 0.0%)	26
Complications of transplanted kidney	5 ( 19.2%)	6 ( 23.1%)	13 ( 50.0%)	2 ( 7.7%)	26
Echocardiogram abnormal	17 ( 65.4%)	6 ( 23.1%)	3 ( 11.5%)	0 ( 0.0%)	26
Pancreatic enzymes increased	2 ( 7.7%)	5 ( 19.2%)	12 ( 46.2%)	7 ( 26.9%)	26
Intellectual disability	16 ( 61.5%)	2 ( 7.7%)	8 ( 30.8%)	0 ( 0.0%)	26
Rectal discharge	2 ( 7.7%)	8 ( 30.8%)	11 ( 42.3%)	5 ( 19.2%)	26
Pancreatic cyst	1 ( 3.8%)	0 ( 0.0%)	18 ( 69.2%)	7 ( 26.9%)	26



**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Intentional device misuse	11 ( 42.3%)	4 ( 15.4%)	8 ( 30.8%)	3 ( 11.5%)	26
Pancreatitis chronic	1 ( 3.8%)	6 ( 23.1%)	13 ( 50.0%)	6 ( 23.1%)	26
Campylobacter infection	0 ( 0.0%)	7 ( 26.9%)	14 ( 53.8%)	5 ( 19.2%)	26
Exfoliative rash	6 ( 23.1%)	5 ( 19.2%)	14 ( 53.8%)	1 ( 3.8%)	26
Muscle contracture	3 ( 11.5%)	7 ( 26.9%)	13 ( 50.0%)	3 ( 11.5%)	26
Enterobacter infection	8 ( 30.8%)	6 ( 23.1%)	11 ( 42.3%)	1 ( 3.8%)	26
Mucosal disorder	2 ( 7.7%)	8 ( 30.8%)	12 ( 46.2%)	4 ( 15.4%)	26
Multi-organ disorder	2 ( 7.7%)	3 ( 11.5%)	16 ( 61.5%)	5 ( 19.2%)	26
Electrocardiogram ST segment depression	7 ( 26.9%)	0 ( 0.0%)	14 ( 53.8%)	5 ( 19.2%)	26
Social avoidant behaviour	6 ( 23.1%)	11 ( 42.3%)	6 ( 23.1%)	3 ( 11.5%)	26
Ejection fraction abnormal	1 ( 3.8%)	4 ( 15.4%)	20 ( 76.9%)	1 ( 3.8%)	26
Sinusitis bacterial	3 ( 11.5%)	8 ( 30.8%)	14 ( 53.8%)	1 ( 3.8%)	26
Drug-genetic interaction	12 ( 46.2%)	4 ( 15.4%)	8 ( 30.8%)	2 ( 7.7%)	26
Gastrointestinal carcinoma	1 ( 3.8%)	4 ( 15.4%)	11 ( 42.3%)	10 ( 38.5%)	26
Radiotherapy	0 ( 0.0%)	8 ( 30.8%)	11 ( 42.3%)	7 ( 26.9%)	26
Bone marrow transplant	3 ( 11.5%)	7 ( 26.9%)	16 ( 61.5%)	0 ( 0.0%)	26
Livedo reticularis	6 ( 23.1%)	7 ( 26.9%)	13 ( 50.0%)	0 ( 0.0%)	26
Hypercoagulation	5 ( 19.2%)	3 ( 11.5%)	13 ( 50.0%)	5 ( 19.2%)	26
Induration	4 ( 15.4%)	6 ( 23.1%)	16 ( 61.5%)	0 ( 0.0%)	26
Tunnel vision	4 ( 15.4%)	8 ( 30.8%)	13 ( 50.0%)	1 ( 3.8%)	26
Hyperparathyroidism	0 ( 0.0%)	9 ( 34.6%)	14 ( 53.8%)	3 ( 11.5%)	26
Pharyngeal oedema	1 ( 3.8%)	7 ( 26.9%)	17 ( 65.4%)	1 ( 3.8%)	26
Subdural haemorrhage	0 ( 0.0%)	2 ( 7.7%)	9 ( 34.6%)	15 ( 57.7%)	26
Fungaemia	10 ( 38.5%)	3 ( 11.5%)	12 ( 46.2%)	1 ( 3.8%)	26
Pituitary tumour benign	4 ( 15.4%)	11 ( 42.3%)	8 ( 30.8%)	3 ( 11.5%)	26
Hepatic infection	3 ( 11.5%)	8 ( 30.8%)	13 ( 50.0%)	2 ( 7.7%)	26
Paraplegia	1 ( 3.8%)	14 ( 53.8%)	8 ( 30.8%)	3 ( 11.5%)	26

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Illusion	4 ( 15.4%)	8 ( 30.8%)	10 ( 38.5%)	4 ( 15.4%)	26
Immune-mediated thyroiditis	0 ( 0.0%)	4 ( 15.4%)	17 ( 65.4%)	5 ( 19.2%)	26
Lymphadenopathy mediastinal	0 ( 0.0%)	8 ( 30.8%)	17 ( 65.4%)	1 ( 3.8%)	26
Focal segmental glomerulosclerosis	10 ( 38.5%)	5 ( 19.2%)	10 ( 38.5%)	1 ( 3.8%)	26
Blood alkaline phosphatase decreased	9 ( 34.6%)	8 ( 30.8%)	8 ( 30.8%)	1 ( 3.8%)	26
Trichorrhexis	2 ( 7.7%)	10 ( 38.5%)	12 ( 46.2%)	2 ( 7.7%)	26
Mantle cell lymphoma	0 ( 0.0%)	1 ( 3.8%)	25 ( 96.2%)	0 ( 0.0%)	26
Cerebellar syndrome	1 ( 3.8%)	0 ( 0.0%)	8 ( 30.8%)	17 ( 65.4%)	26
Infectious pleural effusion	2 ( 7.7%)	4 ( 15.4%)	14 ( 53.8%)	6 ( 23.1%)	26
Post herpetic neuralgia	0 ( 0.0%)	2 ( 7.7%)	23 ( 88.5%)	1 ( 3.8%)	26
Herpes simplex reactivation	1 ( 3.8%)	9 ( 34.6%)	16 ( 61.5%)	0 ( 0.0%)	26
Hepatitis toxic	2 ( 7.7%)	6 ( 23.1%)	17 ( 65.4%)	1 ( 3.8%)	26
Retroperitoneal haemorrhage	1 ( 3.8%)	4 ( 15.4%)	16 ( 61.5%)	5 ( 19.2%)	26
Red blood cell count abnormal	1 ( 3.8%)	3 ( 11.5%)	18 ( 69.2%)	4 ( 15.4%)	26
Dandruff	5 ( 19.2%)	11 ( 42.3%)	8 ( 30.8%)	2 ( 7.7%)	26
Basophil count increased	3 ( 11.5%)	5 ( 19.2%)	17 ( 65.4%)	1 ( 3.8%)	26
Arterial disorder	1 ( 3.8%)	5 ( 19.2%)	16 ( 61.5%)	4 ( 15.4%)	26
Extravasation	5 ( 19.2%)	6 ( 23.1%)	9 ( 34.6%)	6 ( 23.1%)	26
Hyporeflexia	2 ( 8.0%)	3 ( 12.0%)	20 ( 80.0%)	0 ( 0.0%)	25
Orthopnoea	4 ( 16.0%)	12 ( 48.0%)	8 ( 32.0%)	1 ( 4.0%)	25
Peripheral artery occlusion	0 ( 0.0%)	3 ( 12.0%)	17 ( 68.0%)	5 ( 20.0%)	25
Axial spondyloarthritis	3 ( 12.0%)	18 ( 72.0%)	4 ( 16.0%)	0 ( 0.0%)	25
Embolism venous	0 ( 0.0%)	6 ( 24.0%)	18 ( 72.0%)	1 ( 4.0%)	25
Perforation	1 ( 4.0%)	12 ( 48.0%)	12 ( 48.0%)	0 ( 0.0%)	25
Otorrhoea	10 ( 40.0%)	3 ( 12.0%)	11 ( 44.0%)	1 ( 4.0%)	25
Blood iron increased	5 ( 20.0%)	5 ( 20.0%)	13 ( 52.0%)	2 ( 8.0%)	25
Papilloma viral infection	2 ( 8.0%)	17 ( 68.0%)	6 ( 24.0%)	0 ( 0.0%)	25

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Wrong patient	0 ( 0.0%)	3 ( 12.0%)	4 ( 16.0%)	18 ( 72.0%)	25
Vascular stent thrombosis	0 ( 0.0%)	6 ( 24.0%)	13 ( 52.0%)	6 ( 24.0%)	25
Minimal residual disease	4 ( 16.0%)	6 ( 24.0%)	14 ( 56.0%)	1 ( 4.0%)	25
Optic neuropathy	1 ( 4.0%)	11 ( 44.0%)	9 ( 36.0%)	4 ( 16.0%)	25
Ejaculation disorder	1 ( 4.0%)	21 ( 84.0%)	2 ( 8.0%)	1 ( 4.0%)	25
Off label use of device	14 ( 56.0%)	8 ( 32.0%)	2 ( 8.0%)	1 ( 4.0%)	25
Acquired gene mutation	1 ( 4.0%)	2 ( 8.0%)	19 ( 76.0%)	3 ( 12.0%)	25
Lip disorder	2 ( 8.0%)	11 ( 44.0%)	10 ( 40.0%)	2 ( 8.0%)	25
Calcinosis	0 ( 0.0%)	5 ( 20.0%)	17 ( 68.0%)	3 ( 12.0%)	25
Coagulation time prolonged	0 ( 0.0%)	3 ( 12.0%)	15 ( 60.0%)	7 ( 28.0%)	25
Papillary thyroid cancer	2 ( 8.0%)	16 ( 64.0%)	6 ( 24.0%)	1 ( 4.0%)	25
Monocyte count decreased	1 ( 4.0%)	6 ( 24.0%)	16 ( 64.0%)	2 ( 8.0%)	25
Injection site oedema	7 ( 28.0%)	6 ( 24.0%)	11 ( 44.0%)	1 ( 4.0%)	25
Rubber sensitivity	0 ( 0.0%)	8 ( 32.0%)	16 ( 64.0%)	1 ( 4.0%)	25
Nasal injury	5 ( 20.0%)	7 ( 28.0%)	10 ( 40.0%)	3 ( 12.0%)	25
Mouth injury	3 ( 12.0%)	4 ( 16.0%)	15 ( 60.0%)	3 ( 12.0%)	25
Meniere's disease	3 ( 12.0%)	5 ( 20.0%)	17 ( 68.0%)	0 ( 0.0%)	25
Medical procedure	1 ( 4.0%)	7 ( 28.0%)	14 ( 56.0%)	3 ( 12.0%)	25
Cutaneous lupus erythematosus	1 ( 4.0%)	11 ( 44.0%)	8 ( 32.0%)	5 ( 20.0%)	25
Soft tissue injury	1 ( 4.0%)	7 ( 28.0%)	16 ( 64.0%)	1 ( 4.0%)	25
Rotator cuff repair	0 ( 0.0%)	0 ( 0.0%)	25 (100.0%)	0 ( 0.0%)	25
Seborrhoeic keratosis	0 ( 0.0%)	2 ( 8.0%)	20 ( 80.0%)	3 ( 12.0%)	25
Diabetic retinopathy	2 ( 8.0%)	2 ( 8.0%)	21 ( 84.0%)	0 ( 0.0%)	25
Diabetic neuropathy	0 ( 0.0%)	8 ( 32.0%)	15 ( 60.0%)	2 ( 8.0%)	25
Immune-mediated myasthenia gravis	0 ( 0.0%)	4 ( 16.0%)	13 ( 52.0%)	8 ( 32.0%)	25
Computerised tomogram abnormal	0 ( 0.0%)	4 ( 16.0%)	14 ( 56.0%)	7 ( 28.0%)	25
Infected skin ulcer	2 ( 8.0%)	8 ( 32.0%)	14 ( 56.0%)	1 ( 4.0%)	25

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Large intestinal obstruction	1 ( 4.0%)	12 ( 48.0%)	9 ( 36.0%)	3 ( 12.0%)	25
Klebsiella bacteraemia	4 ( 16.0%)	10 ( 40.0%)	7 ( 28.0%)	4 ( 16.0%)	25
Jugular vein thrombosis	6 ( 24.0%)	6 ( 24.0%)	9 ( 36.0%)	4 ( 16.0%)	25
Joint destruction	5 ( 20.0%)	3 ( 12.0%)	17 ( 68.0%)	0 ( 0.0%)	25
Increased viscosity of upper respiratory secretion	9 ( 36.0%)	6 ( 24.0%)	6 ( 24.0%)	4 ( 16.0%)	25
Viral mutation identified	0 ( 0.0%)	15 ( 60.0%)	10 ( 40.0%)	0 ( 0.0%)	25
Pulmonary granuloma	0 ( 0.0%)	10 ( 40.0%)	15 ( 60.0%)	0 ( 0.0%)	25
Sudden hearing loss	0 ( 0.0%)	7 ( 28.0%)	12 ( 48.0%)	6 ( 24.0%)	25
Traumatic lung injury	1 ( 4.0%)	2 ( 8.0%)	18 ( 72.0%)	4 ( 16.0%)	25
Pituitary apoplexy	1 ( 4.0%)	11 ( 44.0%)	9 ( 36.0%)	4 ( 16.0%)	25
Tachyphrenia	1 ( 4.0%)	15 ( 60.0%)	9 ( 36.0%)	0 ( 0.0%)	25
Tongue discolouration	1 ( 4.0%)	8 ( 32.0%)	11 ( 44.0%)	5 ( 20.0%)	25
Infusion site induration	3 ( 12.0%)	5 ( 20.0%)	13 ( 52.0%)	4 ( 16.0%)	25
Small intestinal stenosis	1 ( 4.0%)	14 ( 56.0%)	9 ( 36.0%)	1 ( 4.0%)	25
Therapeutic product effect prolonged	2 ( 8.0%)	6 ( 24.0%)	14 ( 56.0%)	3 ( 12.0%)	25
Stillbirth	5 ( 20.0%)	20 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	25
Device kink	2 ( 8.0%)	8 ( 32.0%)	13 ( 52.0%)	2 ( 8.0%)	25
Xerosis	6 ( 24.0%)	9 ( 36.0%)	8 ( 32.0%)	2 ( 8.0%)	25
Asterixis	0 ( 0.0%)	4 ( 16.0%)	19 ( 76.0%)	2 ( 8.0%)	25
Accidental death	2 ( 8.0%)	12 ( 48.0%)	7 ( 28.0%)	4 ( 16.0%)	25
Stupor	2 ( 8.0%)	2 ( 8.0%)	14 ( 56.0%)	7 ( 28.0%)	25
Aortic valve stenosis	1 ( 4.0%)	1 ( 4.0%)	8 ( 32.0%)	15 ( 60.0%)	25
Soft tissue infection	1 ( 4.0%)	7 ( 28.0%)	15 ( 60.0%)	2 ( 8.0%)	25
Bipolar I disorder	7 ( 28.0%)	13 ( 52.0%)	5 ( 20.0%)	0 ( 0.0%)	25
Ankle operation	1 ( 4.0%)	9 ( 36.0%)	12 ( 48.0%)	3 ( 12.0%)	25
Wisdom teeth removal	12 ( 48.0%)	6 ( 24.0%)	7 ( 28.0%)	0 ( 0.0%)	25
Gastrointestinal viral infection	5 ( 20.0%)	10 ( 40.0%)	9 ( 36.0%)	1 ( 4.0%)	25

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Product contamination physical	9 ( 36.0%)	9 ( 36.0%)	4 ( 16.0%)	3 ( 12.0%)	25
Renal infarct	2 ( 8.0%)	5 ( 20.0%)	15 ( 60.0%)	3 ( 12.0%)	25
Weight loss poor	1 ( 4.0%)	12 ( 48.0%)	11 ( 44.0%)	1 ( 4.0%)	25
Pancreatic neoplasm	0 ( 0.0%)	3 ( 12.0%)	18 ( 72.0%)	4 ( 16.0%)	25
Mesothelioma	0 ( 0.0%)	1 ( 4.2%)	12 ( 50.0%)	11 ( 45.8%)	24
Cardioversion	0 ( 0.0%)	1 ( 4.2%)	15 ( 62.5%)	8 ( 33.3%)	24
Amyloidosis	2 ( 8.3%)	2 ( 8.3%)	11 ( 45.8%)	9 ( 37.5%)	24
Injection site cellulitis	3 ( 12.5%)	15 ( 62.5%)	5 ( 20.8%)	1 ( 4.2%)	24
Pancreatitis haemorrhagic	1 ( 4.2%)	0 ( 0.0%)	22 ( 91.7%)	1 ( 4.2%)	24
Cardiac hypertrophy	1 ( 4.2%)	9 ( 37.5%)	7 ( 29.2%)	7 ( 29.2%)	24
Blood immunoglobulin M decreased	1 ( 4.2%)	13 ( 54.2%)	10 ( 41.7%)	0 ( 0.0%)	24
Amyotrophic lateral sclerosis	0 ( 0.0%)	4 ( 16.7%)	17 ( 70.8%)	3 ( 12.5%)	24
Eyelid rash	11 ( 45.8%)	7 ( 29.2%)	6 ( 25.0%)	0 ( 0.0%)	24
Organ failure	1 ( 4.2%)	7 ( 29.2%)	9 ( 37.5%)	7 ( 29.2%)	24
Cystoid macular oedema	0 ( 0.0%)	8 ( 33.3%)	11 ( 45.8%)	5 ( 20.8%)	24
Resuscitation	5 ( 20.8%)	1 ( 4.2%)	17 ( 70.8%)	1 ( 4.2%)	24
Monkeypox	0 ( 0.0%)	15 ( 62.5%)	9 ( 37.5%)	0 ( 0.0%)	24
Lip erythema	6 ( 25.0%)	7 ( 29.2%)	9 ( 37.5%)	2 ( 8.3%)	24
Nipple pain	2 ( 8.3%)	4 ( 16.7%)	17 ( 70.8%)	1 ( 4.2%)	24
Vancomycin infusion reaction	2 ( 8.3%)	13 ( 54.2%)	7 ( 29.2%)	2 ( 8.3%)	24
Hypochloraemia	0 ( 0.0%)	9 ( 37.5%)	9 ( 37.5%)	6 ( 25.0%)	24
Application site burn	3 ( 12.5%)	12 ( 50.0%)	5 ( 20.8%)	4 ( 16.7%)	24
Pneumoperitoneum	1 ( 4.2%)	6 ( 25.0%)	14 ( 58.3%)	3 ( 12.5%)	24
Injection site dryness	5 ( 20.8%)	11 ( 45.8%)	7 ( 29.2%)	1 ( 4.2%)	24
Myofascial pain syndrome	1 ( 4.2%)	10 ( 41.7%)	13 ( 54.2%)	0 ( 0.0%)	24
Glomerulonephritis membranous	7 ( 29.2%)	5 ( 20.8%)	12 ( 50.0%)	0 ( 0.0%)	24
Dysbiosis	0 ( 0.0%)	12 ( 50.0%)	10 ( 41.7%)	2 ( 8.3%)	24

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Infusion site reaction	6 ( 25.0%)	3 ( 12.5%)	12 ( 50.0%)	3 ( 12.5%)	24
Ejection fraction	0 ( 0.0%)	2 ( 8.3%)	22 ( 91.7%)	0 ( 0.0%)	24
Antineutrophil cytoplasmic antibody positive	1 ( 4.2%)	3 ( 12.5%)	19 ( 79.2%)	1 ( 4.2%)	24
Metamorphopsia	3 ( 12.5%)	2 ( 8.3%)	11 ( 45.8%)	8 ( 33.3%)	24
Drug screen positive	4 ( 16.7%)	13 ( 54.2%)	7 ( 29.2%)	0 ( 0.0%)	24
Application site vesicles	8 ( 33.3%)	7 ( 29.2%)	7 ( 29.2%)	2 ( 8.3%)	24
Maternal exposure during delivery	7 ( 29.2%)	17 ( 70.8%)	0 ( 0.0%)	0 ( 0.0%)	24
Myelitis	2 ( 8.3%)	13 ( 54.2%)	9 ( 37.5%)	0 ( 0.0%)	24
Malignant catatonia	8 ( 33.3%)	8 ( 33.3%)	6 ( 25.0%)	2 ( 8.3%)	24
Magnetic resonance imaging abnormal	3 ( 12.5%)	11 ( 45.8%)	8 ( 33.3%)	2 ( 8.3%)	24
Small intestinal haemorrhage	1 ( 4.2%)	5 ( 20.8%)	12 ( 50.0%)	6 ( 25.0%)	24
Lymphocytosis	2 ( 8.3%)	2 ( 8.3%)	14 ( 58.3%)	6 ( 25.0%)	24
Bladder dysfunction	2 ( 8.3%)	13 ( 54.2%)	8 ( 33.3%)	1 ( 4.2%)	24
Macrocytosis	2 ( 8.3%)	3 ( 12.5%)	16 ( 66.7%)	3 ( 12.5%)	24
Alcoholism	2 ( 8.3%)	12 ( 50.0%)	8 ( 33.3%)	2 ( 8.3%)	24
Lipids increased	0 ( 0.0%)	7 ( 29.2%)	15 ( 62.5%)	2 ( 8.3%)	24
Infection reactivation	5 ( 20.8%)	10 ( 41.7%)	3 ( 12.5%)	6 ( 25.0%)	24
Seborrhoeic dermatitis	3 ( 12.5%)	11 ( 45.8%)	9 ( 37.5%)	1 ( 4.2%)	24
Dental implantation	0 ( 0.0%)	1 ( 4.2%)	19 ( 79.2%)	4 ( 16.7%)	24
Dark circles under eyes	7 ( 29.2%)	6 ( 25.0%)	9 ( 37.5%)	2 ( 8.3%)	24
Colorectal cancer	0 ( 0.0%)	9 ( 37.5%)	12 ( 50.0%)	3 ( 12.5%)	24
Hypochromic anaemia	1 ( 4.2%)	16 ( 66.7%)	6 ( 25.0%)	1 ( 4.2%)	24
Viral load increased	0 ( 0.0%)	13 ( 54.2%)	10 ( 41.7%)	1 ( 4.2%)	24
Glomerulonephritis rapidly progressive	1 ( 4.2%)	1 ( 4.2%)	19 ( 79.2%)	3 ( 12.5%)	24
Infected cyst	2 ( 8.3%)	9 ( 37.5%)	10 ( 41.7%)	3 ( 12.5%)	24
Psychogenic seizure	7 ( 29.2%)	12 ( 50.0%)	4 ( 16.7%)	1 ( 4.2%)	24
Blood chloride decreased	3 ( 12.5%)	5 ( 20.8%)	12 ( 50.0%)	4 ( 16.7%)	24

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Post procedural discomfort	8 ( 33.3%)	7 ( 29.2%)	8 ( 33.3%)	1 ( 4.2%)	24
Cerebellar infarction	1 ( 4.2%)	3 ( 12.5%)	14 ( 58.3%)	6 ( 25.0%)	24
Gastrointestinal bacterial infection	5 ( 20.8%)	8 ( 33.3%)	9 ( 37.5%)	2 ( 8.3%)	24
Cryptosporidiosis infection	1 ( 4.2%)	11 ( 45.8%)	12 ( 50.0%)	0 ( 0.0%)	24
Rhonchi	2 ( 8.3%)	9 ( 37.5%)	11 ( 45.8%)	2 ( 8.3%)	24
Pseudomeningocele	0 ( 0.0%)	6 ( 25.0%)	18 ( 75.0%)	0 ( 0.0%)	24
Testicular atrophy	5 ( 20.8%)	15 ( 62.5%)	4 ( 16.7%)	0 ( 0.0%)	24
Injection site paraesthesia	4 ( 16.7%)	12 ( 50.0%)	7 ( 29.2%)	1 ( 4.2%)	24
Cerebrospinal fistula	0 ( 0.0%)	6 ( 25.0%)	18 ( 75.0%)	0 ( 0.0%)	24
Hand-foot-and-mouth disease	12 ( 50.0%)	9 ( 37.5%)	3 ( 12.5%)	0 ( 0.0%)	24
Gestational diabetes	4 ( 16.7%)	20 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	24
Blood parathyroid hormone increased	2 ( 8.3%)	5 ( 20.8%)	14 ( 58.3%)	3 ( 12.5%)	24
Immune-mediated renal disorder	0 ( 0.0%)	3 ( 12.5%)	15 ( 62.5%)	6 ( 25.0%)	24
Non-small cell lung cancer metastatic	0 ( 0.0%)	4 ( 16.7%)	18 ( 75.0%)	2 ( 8.3%)	24
Bacillus infection	6 ( 26.1%)	4 ( 17.4%)	12 ( 52.2%)	1 ( 4.3%)	23
Oral fungal infection	1 ( 4.3%)	6 ( 26.1%)	14 ( 60.9%)	2 ( 8.7%)	23
Pupil fixed	8 ( 34.8%)	11 ( 47.8%)	4 ( 17.4%)	0 ( 0.0%)	23
Graft versus host disease in liver	3 ( 13.0%)	8 ( 34.8%)	10 ( 43.5%)	2 ( 8.7%)	23
Catheter site erythema	12 ( 52.2%)	4 ( 17.4%)	7 ( 30.4%)	0 ( 0.0%)	23
Eyelid disorder	1 ( 4.3%)	4 ( 17.4%)	15 ( 65.2%)	3 ( 13.0%)	23
Connective tissue disorder	1 ( 4.3%)	10 ( 43.5%)	7 ( 30.4%)	5 ( 21.7%)	23
Cardiac infection	10 ( 43.5%)	0 ( 0.0%)	10 ( 43.5%)	3 ( 13.0%)	23
Haemolytic uraemic syndrome	1 ( 4.3%)	3 ( 13.0%)	18 ( 78.3%)	1 ( 4.3%)	23
Polycythaemia vera	0 ( 0.0%)	4 ( 17.4%)	17 ( 73.9%)	2 ( 8.7%)	23
Ectopic pregnancy with contraceptive device	7 ( 30.4%)	16 ( 69.6%)	0 ( 0.0%)	0 ( 0.0%)	23
Suspected drug-induced liver injury	1 ( 4.3%)	2 ( 8.7%)	17 ( 73.9%)	3 ( 13.0%)	23
Urine ketone body present	2 ( 8.7%)	9 ( 39.1%)	10 ( 43.5%)	2 ( 8.7%)	23

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Biliary dilatation	3 ( 13.0%)	5 ( 21.7%)	14 ( 60.9%)	1 ( 4.3%)	23
Bronchial obstruction	9 ( 39.1%)	3 ( 13.0%)	9 ( 39.1%)	2 ( 8.7%)	23
Eosinophilic myocarditis	1 ( 4.3%)	15 ( 65.2%)	7 ( 30.4%)	0 ( 0.0%)	23
Neoplasm skin	2 ( 8.7%)	1 ( 4.3%)	17 ( 73.9%)	3 ( 13.0%)	23
Pulmonary cavitation	0 ( 0.0%)	15 ( 65.2%)	7 ( 30.4%)	1 ( 4.3%)	23
Subretinal fluid	1 ( 4.3%)	0 ( 0.0%)	15 ( 65.2%)	7 ( 30.4%)	23
Tongue dry	0 ( 0.0%)	5 ( 21.7%)	9 ( 39.1%)	9 ( 39.1%)	23
Embolia cutis medicamentosa	0 ( 0.0%)	16 ( 69.6%)	7 ( 30.4%)	0 ( 0.0%)	23
Drug specific antibody	11 ( 47.8%)	10 ( 43.5%)	2 ( 8.7%)	0 ( 0.0%)	23
Drug monitoring procedure not performed	1 ( 4.3%)	6 ( 26.1%)	11 ( 47.8%)	5 ( 21.7%)	23
Malignant melanoma in situ	0 ( 0.0%)	2 ( 8.7%)	4 ( 17.4%)	17 ( 73.9%)	23
Application site haemorrhage	1 ( 4.3%)	4 ( 17.4%)	14 ( 60.9%)	4 ( 17.4%)	23
Disability assessment scale score increased	0 ( 0.0%)	12 ( 52.2%)	11 ( 47.8%)	0 ( 0.0%)	23
Linear IgA disease	1 ( 4.3%)	14 ( 60.9%)	7 ( 30.4%)	1 ( 4.3%)	23
Hypereosinophilic syndrome	1 ( 4.3%)	1 ( 4.3%)	11 ( 47.8%)	10 ( 43.5%)	23
Device dispensing error	9 ( 39.1%)	5 ( 21.7%)	6 ( 26.1%)	3 ( 13.0%)	23
Kidney fibrosis	2 ( 8.7%)	1 ( 4.3%)	18 ( 78.3%)	2 ( 8.7%)	23
Depersonalisation/derealisation disorder	6 ( 26.1%)	13 ( 56.5%)	4 ( 17.4%)	0 ( 0.0%)	23
Blood pressure immeasurable	1 ( 4.3%)	7 ( 30.4%)	14 ( 60.9%)	1 ( 4.3%)	23
Strongyloidiasis	1 ( 4.3%)	6 ( 26.1%)	16 ( 69.6%)	0 ( 0.0%)	23
Immune-mediated cholangitis	0 ( 0.0%)	2 ( 8.7%)	16 ( 69.6%)	5 ( 21.7%)	23
Superinfection	6 ( 26.1%)	2 ( 8.7%)	4 ( 17.4%)	11 ( 47.8%)	23
Ophthalmic migraine	1 ( 4.3%)	7 ( 30.4%)	12 ( 52.2%)	3 ( 13.0%)	23
Piloerection	1 ( 4.3%)	12 ( 52.2%)	9 ( 39.1%)	1 ( 4.3%)	23
Amaurosis	1 ( 4.3%)	9 ( 39.1%)	11 ( 47.8%)	2 ( 8.7%)	23
Anorgasmia	6 ( 26.1%)	14 ( 60.9%)	3 ( 13.0%)	0 ( 0.0%)	23
Injection site hypoaesthesia	3 ( 13.0%)	12 ( 52.2%)	6 ( 26.1%)	2 ( 8.7%)	23



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Colostomy	2 ( 8.7%)	4 ( 17.4%)	16 ( 69.6%)	1 ( 4.3%)	23
Necrotising myositis	0 ( 0.0%)	2 ( 8.7%)	19 ( 82.6%)	2 ( 8.7%)	23
Glucose urine present	0 ( 0.0%)	5 ( 21.7%)	14 ( 60.9%)	4 ( 17.4%)	23
Pneumonia pneumococcal	2 ( 8.7%)	4 ( 17.4%)	15 ( 65.2%)	2 ( 8.7%)	23
Throat cancer	0 ( 0.0%)	0 ( 0.0%)	18 ( 78.3%)	5 ( 21.7%)	23
CD4 lymphocytes decreased	1 ( 4.3%)	7 ( 30.4%)	13 ( 56.5%)	2 ( 8.7%)	23
Small fibre neuropathy	3 ( 13.0%)	12 ( 52.2%)	7 ( 30.4%)	1 ( 4.3%)	23
Precancerous skin lesion	0 ( 0.0%)	3 ( 13.0%)	13 ( 56.5%)	7 ( 30.4%)	23
Pseudomonal sepsis	7 ( 30.4%)	2 ( 8.7%)	12 ( 52.2%)	2 ( 8.7%)	23
Gingival recession	1 ( 4.3%)	10 ( 43.5%)	9 ( 39.1%)	3 ( 13.0%)	23
Electric shock	2 ( 8.7%)	10 ( 43.5%)	9 ( 39.1%)	2 ( 8.7%)	23
Retinal disorder	1 ( 4.3%)	0 ( 0.0%)	12 ( 52.2%)	10 ( 43.5%)	23
Occult blood positive	1 ( 4.3%)	3 ( 13.0%)	16 ( 69.6%)	3 ( 13.0%)	23
Essential hypertension	0 ( 0.0%)	5 ( 21.7%)	9 ( 39.1%)	9 ( 39.1%)	23
Product selection error	8 ( 34.8%)	6 ( 26.1%)	5 ( 21.7%)	4 ( 17.4%)	23
Cervical dysplasia	3 ( 13.0%)	11 ( 47.8%)	8 ( 34.8%)	1 ( 4.3%)	23
Retinal vasculitis	3 ( 13.0%)	4 ( 17.4%)	12 ( 52.2%)	4 ( 17.4%)	23
Megacolon	4 ( 17.4%)	8 ( 34.8%)	8 ( 34.8%)	3 ( 13.0%)	23
Vocal cord paralysis	0 ( 0.0%)	6 ( 26.1%)	12 ( 52.2%)	5 ( 21.7%)	23
Intercepted product storage error	4 ( 17.4%)	4 ( 17.4%)	11 ( 47.8%)	4 ( 17.4%)	23
Adhesion	5 ( 22.7%)	4 ( 18.2%)	11 ( 50.0%)	2 ( 9.1%)	22
Atrophy	1 ( 4.5%)	5 ( 22.7%)	15 ( 68.2%)	1 ( 4.5%)	22
Catheter site swelling	5 ( 22.7%)	6 ( 27.3%)	11 ( 50.0%)	0 ( 0.0%)	22
Cardiac ablation	1 ( 4.5%)	0 ( 0.0%)	15 ( 68.2%)	6 ( 27.3%)	22
Reading disorder	5 ( 22.7%)	3 ( 13.6%)	8 ( 36.4%)	6 ( 27.3%)	22
Catarrh	4 ( 18.2%)	5 ( 22.7%)	13 ( 59.1%)	0 ( 0.0%)	22
Familial mediterranean fever	5 ( 22.7%)	11 ( 50.0%)	5 ( 22.7%)	1 ( 4.5%)	22

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Breast swelling	1 ( 4.5%)	7 ( 31.8%)	11 ( 50.0%)	3 ( 13.6%)	22
Vasodilatation	0 ( 0.0%)	6 ( 27.3%)	12 ( 54.5%)	4 ( 18.2%)	22
Osteoporotic fracture	1 ( 4.5%)	5 ( 22.7%)	12 ( 54.5%)	4 ( 18.2%)	22
Hepatitis fulminant	0 ( 0.0%)	8 ( 36.4%)	9 ( 40.9%)	5 ( 22.7%)	22
Hallucination, tactile	1 ( 4.5%)	9 ( 40.9%)	6 ( 27.3%)	6 ( 27.3%)	22
Pancreatic neuroendocrine tumour	0 ( 0.0%)	9 ( 40.9%)	13 ( 59.1%)	0 ( 0.0%)	22
Intercepted product prescribing error	1 ( 4.5%)	2 ( 9.1%)	14 ( 63.6%)	5 ( 22.7%)	22
Retinal degeneration	2 ( 9.1%)	7 ( 31.8%)	11 ( 50.0%)	2 ( 9.1%)	22
Enterocolitis haemorrhagic	1 ( 4.5%)	4 ( 18.2%)	11 ( 50.0%)	6 ( 27.3%)	22
Endodontic procedure	2 ( 9.1%)	4 ( 18.2%)	14 ( 63.6%)	2 ( 9.1%)	22
Uterine disorder	0 ( 0.0%)	12 ( 54.5%)	9 ( 40.9%)	1 ( 4.5%)	22
Muscle discomfort	1 ( 4.5%)	7 ( 31.8%)	13 ( 59.1%)	1 ( 4.5%)	22
Intestinal fistula	2 ( 9.1%)	14 ( 63.6%)	5 ( 22.7%)	1 ( 4.5%)	22
Spinal cord disorder	1 ( 4.5%)	8 ( 36.4%)	12 ( 54.5%)	1 ( 4.5%)	22
Monoclonal immunoglobulin present	0 ( 0.0%)	0 ( 0.0%)	11 ( 50.0%)	11 ( 50.0%)	22
Breath odour	4 ( 18.2%)	1 ( 4.5%)	13 ( 59.1%)	4 ( 18.2%)	22
Arterial thrombosis	1 ( 4.5%)	5 ( 22.7%)	11 ( 50.0%)	5 ( 22.7%)	22
Breast disorder	0 ( 0.0%)	9 ( 40.9%)	11 ( 50.0%)	2 ( 9.1%)	22
Bowen's disease	0 ( 0.0%)	6 ( 27.3%)	7 ( 31.8%)	9 ( 40.9%)	22
Lymphocyte percentage decreased	1 ( 4.5%)	4 ( 18.2%)	14 ( 63.6%)	3 ( 13.6%)	22
Bone marrow oedema	1 ( 4.5%)	10 ( 45.5%)	11 ( 50.0%)	0 ( 0.0%)	22
Myelopathy	0 ( 0.0%)	5 ( 22.7%)	14 ( 63.6%)	3 ( 13.6%)	22
Pharyngeal haemorrhage	4 ( 18.2%)	5 ( 22.7%)	9 ( 40.9%)	4 ( 18.2%)	22
Lymphadenectomy	4 ( 18.2%)	3 ( 13.6%)	11 ( 50.0%)	4 ( 18.2%)	22
Bladder spasm	1 ( 4.5%)	8 ( 36.4%)	11 ( 50.0%)	2 ( 9.1%)	22
Language disorder	8 ( 36.4%)	7 ( 31.8%)	4 ( 18.2%)	3 ( 13.6%)	22
Kyphosis	2 ( 9.1%)	4 ( 18.2%)	13 ( 59.1%)	3 ( 13.6%)	22

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Dermatitis diaper	20 ( 90.9%)	1 ( 4.5%)	1 ( 4.5%)	0 ( 0.0%)	22
Blood growth hormone increased	4 ( 18.2%)	8 ( 36.4%)	10 ( 45.5%)	0 ( 0.0%)	22
Dementia with Lewy bodies	0 ( 0.0%)	1 ( 4.5%)	14 ( 63.6%)	7 ( 31.8%)	22
Adverse food reaction	1 ( 4.5%)	4 ( 18.2%)	13 ( 59.1%)	4 ( 18.2%)	22
Hypersexuality	7 ( 31.8%)	10 ( 45.5%)	4 ( 18.2%)	1 ( 4.5%)	22
Decompensated hypothyroidism	9 ( 40.9%)	3 ( 13.6%)	9 ( 40.9%)	1 ( 4.5%)	22
Blast cell count increased	3 ( 13.6%)	3 ( 13.6%)	9 ( 40.9%)	7 ( 31.8%)	22
Blood bilirubin abnormal	3 ( 13.6%)	3 ( 13.6%)	13 ( 59.1%)	3 ( 13.6%)	22
Enteritis infectious	1 ( 4.5%)	6 ( 27.3%)	10 ( 45.5%)	5 ( 22.7%)	22
Cardiac ventricular thrombosis	1 ( 4.5%)	2 ( 9.1%)	15 ( 68.2%)	4 ( 18.2%)	22
Fungal foot infection	0 ( 0.0%)	1 ( 4.5%)	15 ( 68.2%)	6 ( 27.3%)	22
Antiphospholipid syndrome	3 ( 13.6%)	11 ( 50.0%)	8 ( 36.4%)	0 ( 0.0%)	22
Gastrointestinal injury	1 ( 4.5%)	8 ( 36.4%)	10 ( 45.5%)	3 ( 13.6%)	22
Ultrafiltration failure	1 ( 4.5%)	9 ( 40.9%)	10 ( 45.5%)	2 ( 9.1%)	22
Tonsillectomy	10 ( 45.5%)	10 ( 45.5%)	2 ( 9.1%)	0 ( 0.0%)	22
Hirsutism	3 ( 13.6%)	11 ( 50.0%)	8 ( 36.4%)	0 ( 0.0%)	22
Gallbladder enlargement	3 ( 13.6%)	2 ( 9.1%)	11 ( 50.0%)	6 ( 27.3%)	22
Heat stroke	0 ( 0.0%)	7 ( 31.8%)	14 ( 63.6%)	1 ( 4.5%)	22
Adjustment disorder	3 ( 13.6%)	1 ( 4.5%)	15 ( 68.2%)	3 ( 13.6%)	22
Sick leave	2 ( 9.1%)	12 ( 54.5%)	8 ( 36.4%)	0 ( 0.0%)	22
Non-cardiac chest pain	1 ( 4.5%)	6 ( 27.3%)	14 ( 63.6%)	1 ( 4.5%)	22
Noninfective encephalitis	6 ( 27.3%)	8 ( 36.4%)	6 ( 27.3%)	2 ( 9.1%)	22
Calciphylaxis	0 ( 0.0%)	5 ( 22.7%)	13 ( 59.1%)	4 ( 18.2%)	22
Alcohol abuse	2 ( 9.1%)	13 ( 59.1%)	6 ( 27.3%)	1 ( 4.5%)	22
Renal vein thrombosis	1 ( 4.5%)	7 ( 31.8%)	14 ( 63.6%)	0 ( 0.0%)	22
Lymphangiosis carcinomatosa	0 ( 0.0%)	4 ( 18.2%)	15 ( 68.2%)	3 ( 13.6%)	22
Product reconstitution quality issue	11 ( 50.0%)	4 ( 18.2%)	6 ( 27.3%)	1 ( 4.5%)	22

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Intestinal ulcer	1 ( 4.5%)	5 ( 22.7%)	15 ( 68.2%)	1 ( 4.5%)	22
Mycobacterium abscessus infection	1 ( 4.5%)	10 ( 45.5%)	9 ( 40.9%)	2 ( 9.1%)	22
Carbon dioxide decreased	4 ( 19.0%)	3 ( 14.3%)	12 ( 57.1%)	2 ( 9.5%)	21
Palmoplantar pustulosis	0 ( 0.0%)	4 ( 19.0%)	16 ( 76.2%)	1 ( 4.8%)	21
Oropharyngeal blistering	2 ( 9.5%)	2 ( 9.5%)	17 ( 81.0%)	0 ( 0.0%)	21
Infusion site irritation	3 ( 14.3%)	7 ( 33.3%)	7 ( 33.3%)	4 ( 19.0%)	21
Metastases to pelvis	0 ( 0.0%)	5 ( 23.8%)	13 ( 61.9%)	3 ( 14.3%)	21
Splenic infarction	1 ( 4.8%)	5 ( 23.8%)	8 ( 38.1%)	7 ( 33.3%)	21
Early satiety	1 ( 4.8%)	10 ( 47.6%)	10 ( 47.6%)	0 ( 0.0%)	21
Rectal prolapse	0 ( 0.0%)	5 ( 23.8%)	11 ( 52.4%)	5 ( 23.8%)	21
Haemophilus infection	4 ( 19.0%)	7 ( 33.3%)	9 ( 42.9%)	1 ( 4.8%)	21
Eczema eyelids	6 ( 28.6%)	9 ( 42.9%)	4 ( 19.0%)	2 ( 9.5%)	21
Painful respiration	2 ( 9.5%)	5 ( 23.8%)	13 ( 61.9%)	1 ( 4.8%)	21
Lip discolouration	7 ( 33.3%)	4 ( 19.0%)	6 ( 28.6%)	4 ( 19.0%)	21
Escherichia test positive	3 ( 14.3%)	2 ( 9.5%)	12 ( 57.1%)	4 ( 19.0%)	21
Lymphoma transformation	0 ( 0.0%)	5 ( 23.8%)	14 ( 66.7%)	2 ( 9.5%)	21
Acquired haemophilia	0 ( 0.0%)	12 ( 57.1%)	5 ( 23.8%)	4 ( 19.0%)	21
Paresis	1 ( 4.8%)	5 ( 23.8%)	11 ( 52.4%)	4 ( 19.0%)	21
Seborrhoea	4 ( 19.0%)	10 ( 47.6%)	7 ( 33.3%)	0 ( 0.0%)	21
Diverticular perforation	0 ( 0.0%)	6 ( 28.6%)	8 ( 38.1%)	7 ( 33.3%)	21
Mycobacterial infection	1 ( 4.8%)	5 ( 23.8%)	12 ( 57.1%)	3 ( 14.3%)	21
Empyema	0 ( 0.0%)	9 ( 42.9%)	9 ( 42.9%)	3 ( 14.3%)	21
Urine protein/creatinine ratio increased	3 ( 14.3%)	12 ( 57.1%)	5 ( 23.8%)	1 ( 4.8%)	21
Acarodermatitis	4 ( 19.0%)	5 ( 23.8%)	8 ( 38.1%)	4 ( 19.0%)	21
Metastatic malignant melanoma	0 ( 0.0%)	8 ( 38.1%)	9 ( 42.9%)	4 ( 19.0%)	21
Carotid artery occlusion	0 ( 0.0%)	0 ( 0.0%)	17 ( 81.0%)	4 ( 19.0%)	21
Drug clearance decreased	12 ( 57.1%)	1 ( 4.8%)	8 ( 38.1%)	0 ( 0.0%)	21

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Somatic symptom disorder	1 ( 4.8%)	14 ( 66.7%)	3 ( 14.3%)	3 ( 14.3%)	21
Blood culture positive	2 ( 9.5%)	5 ( 23.8%)	9 ( 42.9%)	5 ( 23.8%)	21
Blood thyroid stimulating hormone abnormal	0 ( 0.0%)	8 ( 38.1%)	8 ( 38.1%)	5 ( 23.8%)	21
Kidney enlargement	4 ( 19.0%)	10 ( 47.6%)	7 ( 33.3%)	0 ( 0.0%)	21
Joint instability	1 ( 4.8%)	9 ( 42.9%)	10 ( 47.6%)	1 ( 4.8%)	21
Blood pressure measurement	0 ( 0.0%)	11 ( 52.4%)	8 ( 38.1%)	2 ( 9.5%)	21
Phaeochromocytoma	0 ( 0.0%)	7 ( 33.3%)	14 ( 66.7%)	0 ( 0.0%)	21
Injection site abscess	5 ( 23.8%)	9 ( 42.9%)	6 ( 28.6%)	1 ( 4.8%)	21
Vital functions abnormal	4 ( 19.0%)	3 ( 14.3%)	12 ( 57.1%)	2 ( 9.5%)	21
Physical disability	1 ( 4.8%)	6 ( 28.6%)	12 ( 57.1%)	2 ( 9.5%)	21
Vascular pain	3 ( 14.3%)	9 ( 42.9%)	5 ( 23.8%)	4 ( 19.0%)	21
Pituitary tumour	0 ( 0.0%)	10 ( 47.6%)	9 ( 42.9%)	2 ( 9.5%)	21
Diverticulum intestinal haemorrhagic	0 ( 0.0%)	2 ( 9.5%)	5 ( 23.8%)	14 ( 66.7%)	21
Tooth discolouration	1 ( 4.8%)	9 ( 42.9%)	10 ( 47.6%)	1 ( 4.8%)	21
Daydreaming	2 ( 9.5%)	1 ( 4.8%)	12 ( 57.1%)	6 ( 28.6%)	21
Behcet's syndrome	1 ( 4.8%)	4 ( 19.0%)	14 ( 66.7%)	2 ( 9.5%)	21
Thyroidectomy	0 ( 0.0%)	7 ( 33.3%)	12 ( 57.1%)	2 ( 9.5%)	21
Immune-mediated nephritis	2 ( 9.5%)	2 ( 9.5%)	16 ( 76.2%)	1 ( 4.8%)	21
Ulna fracture	1 ( 4.8%)	5 ( 23.8%)	10 ( 47.6%)	5 ( 23.8%)	21
Cerebellar haemorrhage	2 ( 9.5%)	1 ( 4.8%)	11 ( 52.4%)	7 ( 33.3%)	21
Staphylococcal skin infection	1 ( 4.8%)	11 ( 52.4%)	8 ( 38.1%)	1 ( 4.8%)	21
Administration site pain	3 ( 14.3%)	12 ( 57.1%)	6 ( 28.6%)	0 ( 0.0%)	21
Gastrostomy	11 ( 52.4%)	2 ( 9.5%)	5 ( 23.8%)	3 ( 14.3%)	21
Respiratory tract infection bacterial	3 ( 14.3%)	7 ( 33.3%)	11 ( 52.4%)	0 ( 0.0%)	21
Respiratory syncytial virus bronchiolitis	20 ( 95.2%)	1 ( 4.8%)	0 ( 0.0%)	0 ( 0.0%)	21
Retinal oedema	0 ( 0.0%)	3 ( 14.3%)	12 ( 57.1%)	6 ( 28.6%)	21
Protein total abnormal	0 ( 0.0%)	5 ( 23.8%)	14 ( 66.7%)	2 ( 9.5%)	21

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Genital pain	4 ( 19.0%)	7 ( 33.3%)	7 ( 33.3%)	3 ( 14.3%)	21
Protein urine	1 ( 4.8%)	4 ( 19.0%)	15 ( 71.4%)	1 ( 4.8%)	21
Giant cell arteritis	0 ( 0.0%)	0 ( 0.0%)	7 ( 33.3%)	14 ( 66.7%)	21
Prolonged expiration	3 ( 14.3%)	1 ( 4.8%)	17 ( 81.0%)	0 ( 0.0%)	21
Product delivery mechanism issue	0 ( 0.0%)	1 ( 4.8%)	12 ( 57.1%)	8 ( 38.1%)	21
Gastrointestinal tract irritation	2 ( 9.5%)	4 ( 19.0%)	11 ( 52.4%)	4 ( 19.0%)	21
Analgesic drug level increased	15 ( 71.4%)	1 ( 4.8%)	5 ( 23.8%)	0 ( 0.0%)	21
Abdominal wall abscess	10 ( 47.6%)	5 ( 23.8%)	6 ( 28.6%)	0 ( 0.0%)	21
Post-traumatic neck syndrome	0 ( 0.0%)	6 ( 28.6%)	14 ( 66.7%)	1 ( 4.8%)	21
Central obesity	2 ( 10.0%)	15 ( 75.0%)	3 ( 15.0%)	0 ( 0.0%)	20
Gastric dilatation	1 ( 5.0%)	8 ( 40.0%)	9 ( 45.0%)	2 ( 10.0%)	20
Gastric bypass	0 ( 0.0%)	7 ( 35.0%)	13 ( 65.0%)	0 ( 0.0%)	20
Central hypothyroidism	7 ( 35.0%)	0 ( 0.0%)	13 ( 65.0%)	0 ( 0.0%)	20
Anal inflammation	13 ( 65.0%)	0 ( 0.0%)	6 ( 30.0%)	1 ( 5.0%)	20
Pulpitis dental	1 ( 5.0%)	14 ( 70.0%)	5 ( 25.0%)	0 ( 0.0%)	20
Pharyngeal abscess	12 ( 60.0%)	2 ( 10.0%)	6 ( 30.0%)	0 ( 0.0%)	20
Cytomegalovirus test positive	3 ( 15.0%)	2 ( 10.0%)	12 ( 60.0%)	3 ( 15.0%)	20
Perfume sensitivity	3 ( 15.0%)	8 ( 40.0%)	9 ( 45.0%)	0 ( 0.0%)	20
Periodontal disease	0 ( 0.0%)	1 ( 5.0%)	18 ( 90.0%)	1 ( 5.0%)	20
Abdominal wall haematoma	1 ( 5.0%)	1 ( 5.0%)	14 ( 70.0%)	4 ( 20.0%)	20
Fear of falling	0 ( 0.0%)	5 ( 25.0%)	10 ( 50.0%)	5 ( 25.0%)	20
Cytomegalovirus enterocolitis	0 ( 0.0%)	2 ( 10.0%)	11 ( 55.0%)	7 ( 35.0%)	20
Orchitis	0 ( 0.0%)	5 ( 25.0%)	15 ( 75.0%)	0 ( 0.0%)	20
Mitral valve prolapse	5 ( 25.0%)	7 ( 35.0%)	6 ( 30.0%)	2 ( 10.0%)	20
Haemothorax	0 ( 0.0%)	4 ( 20.0%)	8 ( 40.0%)	8 ( 40.0%)	20
Oligomenorrhoea	4 ( 20.0%)	15 ( 75.0%)	1 ( 5.0%)	0 ( 0.0%)	20
Enterococcal bacteraemia	2 ( 10.0%)	7 ( 35.0%)	10 ( 50.0%)	1 ( 5.0%)	20

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Arthrodesis	3 ( 15.0%)	4 ( 20.0%)	12 ( 60.0%)	1 ( 5.0%)	20
Hepatitis E	2 ( 10.0%)	7 ( 35.0%)	8 ( 40.0%)	3 ( 15.0%)	20
Allergy to plants	1 ( 5.0%)	5 ( 25.0%)	13 ( 65.0%)	1 ( 5.0%)	20
Drug dose titration not performed	3 ( 15.0%)	11 ( 55.0%)	4 ( 20.0%)	2 ( 10.0%)	20
Glioblastoma	1 ( 5.0%)	4 ( 20.0%)	13 ( 65.0%)	2 ( 10.0%)	20
Ureteric obstruction	3 ( 15.0%)	3 ( 15.0%)	12 ( 60.0%)	2 ( 10.0%)	20
Macular hole	1 ( 5.0%)	5 ( 25.0%)	9 ( 45.0%)	5 ( 25.0%)	20
Homicidal ideation	3 ( 15.0%)	13 ( 65.0%)	4 ( 20.0%)	0 ( 0.0%)	20
Histoplasmosis	2 ( 10.0%)	8 ( 40.0%)	10 ( 50.0%)	0 ( 0.0%)	20
Lung cancer metastatic	0 ( 0.0%)	2 ( 10.0%)	13 ( 65.0%)	5 ( 25.0%)	20
Diplegia	1 ( 5.0%)	7 ( 35.0%)	12 ( 60.0%)	0 ( 0.0%)	20
Lipodystrophy acquired	0 ( 0.0%)	7 ( 35.0%)	13 ( 65.0%)	0 ( 0.0%)	20
Libido increased	2 ( 10.0%)	3 ( 15.0%)	15 ( 75.0%)	0 ( 0.0%)	20
Hypercreatininaemia	1 ( 5.0%)	0 ( 0.0%)	17 ( 85.0%)	2 ( 10.0%)	20
Sputum retention	3 ( 15.0%)	1 ( 5.0%)	8 ( 40.0%)	8 ( 40.0%)	20
Soft tissue disorder	1 ( 5.0%)	6 ( 30.0%)	13 ( 65.0%)	0 ( 0.0%)	20
Aortic thrombosis	0 ( 0.0%)	4 ( 20.0%)	14 ( 70.0%)	2 ( 10.0%)	20
Delusion of grandeur	0 ( 0.0%)	0 ( 0.0%)	20 (100.0%)	0 ( 0.0%)	20
Blood corticotrophin decreased	2 ( 10.0%)	3 ( 15.0%)	11 ( 55.0%)	4 ( 20.0%)	20
Culture urine positive	3 ( 15.0%)	3 ( 15.0%)	5 ( 25.0%)	9 ( 45.0%)	20
Inappropriate schedule of product discontinuation	1 ( 5.0%)	5 ( 25.0%)	14 ( 70.0%)	0 ( 0.0%)	20
Immune-mediated pancreatitis	0 ( 0.0%)	3 ( 15.0%)	12 ( 60.0%)	5 ( 25.0%)	20
Tongue biting	8 ( 40.0%)	9 ( 45.0%)	3 ( 15.0%)	0 ( 0.0%)	20
Central nervous system infection	0 ( 0.0%)	5 ( 25.0%)	13 ( 65.0%)	2 ( 10.0%)	20
Retroperitoneal haematoma	0 ( 0.0%)	1 ( 5.0%)	13 ( 65.0%)	6 ( 30.0%)	20
Hypovitaminosis	1 ( 5.0%)	5 ( 25.0%)	13 ( 65.0%)	1 ( 5.0%)	20
Joint warmth	3 ( 15.0%)	1 ( 5.0%)	12 ( 60.0%)	4 ( 20.0%)	20

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Transitional cell carcinoma	0 ( 0.0%)	5 ( 25.0%)	10 ( 50.0%)	5 ( 25.0%)	20
Superinfection bacterial	1 ( 5.0%)	3 ( 15.0%)	11 ( 55.0%)	5 ( 25.0%)	20
Colonoscopy	0 ( 0.0%)	7 ( 35.0%)	12 ( 60.0%)	1 ( 5.0%)	20
Post procedural haematoma	0 ( 0.0%)	7 ( 35.0%)	8 ( 40.0%)	5 ( 25.0%)	20
Viraemia	6 ( 30.0%)	7 ( 35.0%)	7 ( 35.0%)	0 ( 0.0%)	20
Spondylolisthesis	1 ( 5.0%)	2 ( 10.0%)	15 ( 75.0%)	2 ( 10.0%)	20
Bladder catheterisation	0 ( 0.0%)	4 ( 20.0%)	13 ( 65.0%)	3 ( 15.0%)	20
Primary biliary cholangitis	2 ( 10.0%)	5 ( 25.0%)	8 ( 40.0%)	5 ( 25.0%)	20
Brain neoplasm malignant	1 ( 5.0%)	3 ( 15.0%)	14 ( 70.0%)	2 ( 10.0%)	20
Seizure cluster	15 ( 75.0%)	2 ( 10.0%)	2 ( 10.0%)	1 ( 5.0%)	20
Cluster headache	1 ( 5.0%)	13 ( 65.0%)	6 ( 30.0%)	0 ( 0.0%)	20
Anisocytosis	1 ( 5.0%)	2 ( 10.0%)	16 ( 80.0%)	1 ( 5.0%)	20
Vascular graft	0 ( 0.0%)	1 ( 5.0%)	17 ( 85.0%)	2 ( 10.0%)	20
Porphyria acute	1 ( 5.0%)	18 ( 90.0%)	1 ( 5.0%)	0 ( 0.0%)	20
Vena cava thrombosis	1 ( 5.0%)	8 ( 40.0%)	9 ( 45.0%)	2 ( 10.0%)	20
Areflexia	8 ( 40.0%)	7 ( 35.0%)	5 ( 25.0%)	0 ( 0.0%)	20
Oesophageal haemorrhage	3 ( 15.0%)	5 ( 25.0%)	10 ( 50.0%)	2 ( 10.0%)	20
Intestinal polyp	0 ( 0.0%)	4 ( 20.0%)	12 ( 60.0%)	4 ( 20.0%)	20
Pruritus allergic	4 ( 20.0%)	2 ( 10.0%)	11 ( 55.0%)	3 ( 15.0%)	20
Product used for unknown indication	3 ( 15.0%)	2 ( 10.0%)	14 ( 70.0%)	1 ( 5.0%)	20
Gastrointestinal tube insertion	9 ( 45.0%)	0 ( 0.0%)	6 ( 30.0%)	5 ( 25.0%)	20
Dyspareunia	7 ( 35.0%)	10 ( 50.0%)	3 ( 15.0%)	0 ( 0.0%)	20
Extremity necrosis	3 ( 15.8%)	6 ( 31.6%)	5 ( 26.3%)	5 ( 26.3%)	19
Anorectal disorder	2 ( 10.5%)	7 ( 36.8%)	9 ( 47.4%)	1 ( 5.3%)	19
Hyporesponsive to stimuli	4 ( 21.1%)	4 ( 21.1%)	5 ( 26.3%)	6 ( 31.6%)	19
Fusarium infection	2 ( 10.5%)	4 ( 21.1%)	13 ( 68.4%)	0 ( 0.0%)	19
Pilonidal disease	5 ( 26.3%)	10 ( 52.6%)	4 ( 21.1%)	0 ( 0.0%)	19



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Radiation injury	0 ( 0.0%)	1 ( 5.3%)	13 ( 68.4%)	5 ( 26.3%)	19
Cholangitis acute	0 ( 0.0%)	5 ( 26.3%)	11 ( 57.9%)	3 ( 15.8%)	19
Device related thrombosis	1 ( 5.3%)	9 ( 47.4%)	5 ( 26.3%)	4 ( 21.1%)	19
Vascular pseudoaneurysm	1 ( 5.3%)	8 ( 42.1%)	7 ( 36.8%)	3 ( 15.8%)	19
Choroidal effusion	0 ( 0.0%)	9 ( 47.4%)	6 ( 31.6%)	4 ( 21.1%)	19
Myeloproliferative neoplasm	1 ( 5.3%)	2 ( 10.5%)	12 ( 63.2%)	4 ( 21.1%)	19
Bladder discomfort	0 ( 0.0%)	3 ( 15.8%)	11 ( 57.9%)	5 ( 26.3%)	19
Carbon dioxide increased	2 ( 10.5%)	2 ( 10.5%)	15 ( 78.9%)	0 ( 0.0%)	19
Mitochondrial toxicity	1 ( 5.3%)	11 ( 57.9%)	7 ( 36.8%)	0 ( 0.0%)	19
Optic atrophy	2 ( 10.5%)	10 ( 52.6%)	6 ( 31.6%)	1 ( 5.3%)	19
Angioplasty	0 ( 0.0%)	2 ( 10.5%)	5 ( 26.3%)	12 ( 63.2%)	19
HIV infection	1 ( 5.3%)	8 ( 42.1%)	9 ( 47.4%)	1 ( 5.3%)	19
Head titubation	1 ( 5.3%)	3 ( 15.8%)	14 ( 73.7%)	1 ( 5.3%)	19
Heart rate	4 ( 21.1%)	6 ( 31.6%)	3 ( 15.8%)	6 ( 31.6%)	19
Reflux gastritis	0 ( 0.0%)	8 ( 42.1%)	8 ( 42.1%)	3 ( 15.8%)	19
Paraparesis	2 ( 10.5%)	6 ( 31.6%)	8 ( 42.1%)	3 ( 15.8%)	19
Astigmatism	3 ( 15.8%)	3 ( 15.8%)	11 ( 57.9%)	2 ( 10.5%)	19
Infusion site urticaria	2 ( 10.5%)	2 ( 10.5%)	14 ( 73.7%)	1 ( 5.3%)	19
Nephrocalcinosis	6 ( 31.6%)	7 ( 36.8%)	3 ( 15.8%)	3 ( 15.8%)	19
Bronchial wall thickening	0 ( 0.0%)	1 ( 5.3%)	14 ( 73.7%)	4 ( 21.1%)	19
Necrosis ischaemic	7 ( 36.8%)	1 ( 5.3%)	10 ( 52.6%)	1 ( 5.3%)	19
Burns second degree	2 ( 10.5%)	3 ( 15.8%)	13 ( 68.4%)	1 ( 5.3%)	19
Thyroid function test abnormal	1 ( 5.3%)	6 ( 31.6%)	9 ( 47.4%)	3 ( 15.8%)	19
Skin striae	7 ( 36.8%)	7 ( 36.8%)	4 ( 21.1%)	1 ( 5.3%)	19
Infusion site oedema	5 ( 26.3%)	6 ( 31.6%)	3 ( 15.8%)	5 ( 26.3%)	19
Mucosal ulceration	0 ( 0.0%)	13 ( 68.4%)	3 ( 15.8%)	3 ( 15.8%)	19
Alpha haemolytic streptococcal infection	6 ( 31.6%)	6 ( 31.6%)	6 ( 31.6%)	1 ( 5.3%)	19

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Monoclonal immunoglobulin increased	0 ( 0.0%)	0 ( 0.0%)	12 ( 63.2%)	7 ( 36.8%)	19
Effusion	1 ( 5.3%)	5 ( 26.3%)	8 ( 42.1%)	5 ( 26.3%)	19
Alopecia areata	7 ( 36.8%)	10 ( 52.6%)	2 ( 10.5%)	0 ( 0.0%)	19
Metastases to skin	0 ( 0.0%)	3 ( 15.8%)	15 ( 78.9%)	1 ( 5.3%)	19
Breast abscess	0 ( 0.0%)	14 ( 73.7%)	5 ( 26.3%)	0 ( 0.0%)	19
Breakthrough pain	0 ( 0.0%)	2 ( 10.5%)	15 ( 78.9%)	2 ( 10.5%)	19
Herpes zoster disseminated	1 ( 5.3%)	7 ( 36.8%)	9 ( 47.4%)	2 ( 10.5%)	19
Application site swelling	4 ( 21.1%)	7 ( 36.8%)	6 ( 31.6%)	2 ( 10.5%)	19
Cystocele	0 ( 0.0%)	3 ( 15.8%)	14 ( 73.7%)	2 ( 10.5%)	19
Bronchostenosis	1 ( 5.3%)	2 ( 10.5%)	16 ( 84.2%)	0 ( 0.0%)	19
Forced vital capacity decreased	0 ( 0.0%)	7 ( 36.8%)	10 ( 52.6%)	2 ( 10.5%)	19
Acute disseminated encephalomyelitis	15 ( 78.9%)	2 ( 10.5%)	2 ( 10.5%)	0 ( 0.0%)	19
Dermatitis infected	2 ( 10.5%)	2 ( 10.5%)	14 ( 73.7%)	1 ( 5.3%)	19
Dental discomfort	1 ( 5.3%)	5 ( 26.3%)	13 ( 68.4%)	0 ( 0.0%)	19
Staphylococcus test positive	4 ( 21.1%)	1 ( 5.3%)	13 ( 68.4%)	1 ( 5.3%)	19
Philadelphia chromosome positive	1 ( 5.3%)	9 ( 47.4%)	7 ( 36.8%)	2 ( 10.5%)	19
Full blood count increased	2 ( 10.5%)	2 ( 10.5%)	13 ( 68.4%)	2 ( 10.5%)	19
Hypogeusia	0 ( 0.0%)	4 ( 21.1%)	10 ( 52.6%)	5 ( 26.3%)	19
Hyperkinesia	0 ( 0.0%)	7 ( 36.8%)	8 ( 42.1%)	4 ( 21.1%)	19
Syphilis	0 ( 0.0%)	14 ( 73.7%)	5 ( 26.3%)	0 ( 0.0%)	19
Pulmonary valve incompetence	5 ( 26.3%)	2 ( 10.5%)	10 ( 52.6%)	2 ( 10.5%)	19
Coronary artery dissection	0 ( 0.0%)	13 ( 68.4%)	6 ( 31.6%)	0 ( 0.0%)	19
Urinary hesitation	1 ( 5.3%)	3 ( 15.8%)	8 ( 42.1%)	7 ( 36.8%)	19
Blood immunoglobulin A decreased	4 ( 21.1%)	4 ( 21.1%)	11 ( 57.9%)	0 ( 0.0%)	19
Acrochordon	2 ( 10.5%)	3 ( 15.8%)	13 ( 68.4%)	1 ( 5.3%)	19
Impatience	2 ( 10.5%)	6 ( 31.6%)	9 ( 47.4%)	2 ( 10.5%)	19
Immune-mediated adverse reaction	7 ( 36.8%)	1 ( 5.3%)	9 ( 47.4%)	2 ( 10.5%)	19

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cellulitis gangrenous	4 ( 21.1%)	0 ( 0.0%)	15 ( 78.9%)	0 ( 0.0%)	19
Stoma site inflammation	1 ( 5.3%)	1 ( 5.3%)	12 ( 63.2%)	5 ( 26.3%)	19
Bilirubin conjugated increased	3 ( 15.8%)	3 ( 15.8%)	12 ( 63.2%)	1 ( 5.3%)	19
Conversion disorder	7 ( 36.8%)	10 ( 52.6%)	2 ( 10.5%)	0 ( 0.0%)	19
Polymyositis	4 ( 21.1%)	7 ( 36.8%)	5 ( 26.3%)	3 ( 15.8%)	19
Varicella	9 ( 47.4%)	4 ( 21.1%)	4 ( 21.1%)	2 ( 10.5%)	19
Dental care	2 ( 10.5%)	2 ( 10.5%)	11 ( 57.9%)	4 ( 21.1%)	19
Anion gap increased	6 ( 31.6%)	6 ( 31.6%)	5 ( 26.3%)	2 ( 10.5%)	19
Wrong strength	0 ( 0.0%)	1 ( 5.3%)	12 ( 63.2%)	6 ( 31.6%)	19
Hormone-refractory prostate cancer	0 ( 0.0%)	0 ( 0.0%)	8 ( 42.1%)	11 ( 57.9%)	19
Psychotic behaviour	0 ( 0.0%)	16 ( 84.2%)	1 ( 5.3%)	2 ( 10.5%)	19
Skin oedema	2 ( 10.5%)	12 ( 63.2%)	4 ( 21.1%)	1 ( 5.3%)	19
Sinus arrest	1 ( 5.3%)	2 ( 10.5%)	8 ( 42.1%)	8 ( 42.1%)	19
Analgesic therapy	0 ( 0.0%)	1 ( 5.3%)	0 ( 0.0%)	18 ( 94.7%)	19
Non-alcoholic steatohepatitis	1 ( 5.3%)	8 ( 42.1%)	10 ( 52.6%)	0 ( 0.0%)	19
Abortion	4 ( 21.1%)	15 ( 78.9%)	0 ( 0.0%)	0 ( 0.0%)	19
Binge eating	2 ( 10.5%)	15 ( 78.9%)	2 ( 10.5%)	0 ( 0.0%)	19
Vaccination site pain	2 ( 10.5%)	2 ( 10.5%)	15 ( 78.9%)	0 ( 0.0%)	19
Rheumatoid factor increased	1 ( 5.3%)	8 ( 42.1%)	9 ( 47.4%)	1 ( 5.3%)	19
Medical device implantation	0 ( 0.0%)	3 ( 15.8%)	9 ( 47.4%)	7 ( 36.8%)	19
Essential tremor	0 ( 0.0%)	3 ( 15.8%)	12 ( 63.2%)	4 ( 21.1%)	19
Beta haemolytic streptococcal infection	1 ( 5.3%)	7 ( 36.8%)	10 ( 52.6%)	1 ( 5.3%)	19
Animal scratch	1 ( 5.3%)	0 ( 0.0%)	16 ( 84.2%)	2 ( 10.5%)	19
Prostatic pain	0 ( 0.0%)	11 ( 57.9%)	5 ( 26.3%)	3 ( 15.8%)	19
Vulvovaginal candidiasis	0 ( 0.0%)	9 ( 47.4%)	9 ( 47.4%)	1 ( 5.3%)	19
Product deposit	3 ( 15.8%)	3 ( 15.8%)	11 ( 57.9%)	2 ( 10.5%)	19
Device electrical finding	8 ( 42.1%)	3 ( 15.8%)	5 ( 26.3%)	3 ( 15.8%)	19

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Dysplasia	1 ( 5.6%)	4 ( 22.2%)	11 ( 61.1%)	2 ( 11.1%)	18
Breast discomfort	0 ( 0.0%)	9 ( 50.0%)	8 ( 44.4%)	1 ( 5.6%)	18
Polycystic ovarian syndrome	4 ( 22.2%)	11 ( 61.1%)	3 ( 16.7%)	0 ( 0.0%)	18
Circumstance or information capable of leading to dev	14 ( 77.8%)	2 ( 11.1%)	1 ( 5.6%)	1 ( 5.6%)	18
Abdominal lymphadenopathy	3 ( 16.7%)	10 ( 55.6%)	3 ( 16.7%)	2 ( 11.1%)	18
Cardiorenal syndrome	0 ( 0.0%)	1 ( 5.6%)	14 ( 77.8%)	3 ( 16.7%)	18
Haemangioma of liver	7 ( 38.9%)	7 ( 38.9%)	4 ( 22.2%)	0 ( 0.0%)	18
Adenocarcinoma pancreas	0 ( 0.0%)	0 ( 0.0%)	15 ( 83.3%)	3 ( 16.7%)	18
Fear of disease	0 ( 0.0%)	9 ( 50.0%)	7 ( 38.9%)	2 ( 11.1%)	18
Red blood cell transfusion	2 ( 11.1%)	0 ( 0.0%)	11 ( 61.1%)	5 ( 27.8%)	18
Coccidioidomycosis	2 ( 11.1%)	12 ( 66.7%)	4 ( 22.2%)	0 ( 0.0%)	18
Renal-limited thrombotic microangiopathy	0 ( 0.0%)	10 ( 55.6%)	8 ( 44.4%)	0 ( 0.0%)	18
Palliative care	0 ( 0.0%)	0 ( 0.0%)	6 ( 33.3%)	12 ( 66.7%)	18
Mixed anxiety and depressive disorder	1 ( 5.6%)	7 ( 38.9%)	9 ( 50.0%)	1 ( 5.6%)	18
Pancreatic carcinoma metastatic	0 ( 0.0%)	3 ( 16.7%)	6 ( 33.3%)	9 ( 50.0%)	18
Onychalgia	1 ( 5.6%)	3 ( 16.7%)	11 ( 61.1%)	3 ( 16.7%)	18
Oligohydramnios	6 ( 33.3%)	12 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	18
Oedematous pancreatitis	1 ( 5.6%)	12 ( 66.7%)	3 ( 16.7%)	2 ( 11.1%)	18
Abulia	4 ( 22.2%)	3 ( 16.7%)	9 ( 50.0%)	2 ( 11.1%)	18
Calcium deficiency	0 ( 0.0%)	4 ( 22.2%)	11 ( 61.1%)	3 ( 16.7%)	18
Neutrophil percentage decreased	2 ( 11.1%)	3 ( 16.7%)	12 ( 66.7%)	1 ( 5.6%)	18
Eosinophilic cellulitis	1 ( 5.6%)	7 ( 38.9%)	2 ( 11.1%)	8 ( 44.4%)	18
Nasal ulcer	2 ( 11.1%)	2 ( 11.1%)	12 ( 66.7%)	2 ( 11.1%)	18
Endocrine ophthalmopathy	0 ( 0.0%)	7 ( 38.9%)	9 ( 50.0%)	2 ( 11.1%)	18
Myasthenic syndrome	0 ( 0.0%)	0 ( 0.0%)	17 ( 94.4%)	1 ( 5.6%)	18
Spinal deformity	3 ( 16.7%)	4 ( 22.2%)	10 ( 55.6%)	1 ( 5.6%)	18
Narcolepsy	0 ( 0.0%)	11 ( 61.1%)	7 ( 38.9%)	0 ( 0.0%)	18

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Breast enlargement	5 ( 27.8%)	5 ( 27.8%)	5 ( 27.8%)	3 ( 16.7%)	18
Breast cyst	0 ( 0.0%)	11 ( 61.1%)	7 ( 38.9%)	0 ( 0.0%)	18
Tonsillar disorder	9 ( 50.0%)	4 ( 22.2%)	4 ( 22.2%)	1 ( 5.6%)	18
Mean platelet volume decreased	3 ( 16.7%)	7 ( 38.9%)	8 ( 44.4%)	0 ( 0.0%)	18
Skin texture abnormal	0 ( 0.0%)	9 ( 50.0%)	7 ( 38.9%)	2 ( 11.1%)	18
Drug delivery system issue	3 ( 16.7%)	5 ( 27.8%)	9 ( 50.0%)	1 ( 5.6%)	18
Bradyarrhythmia	0 ( 0.0%)	2 ( 11.1%)	6 ( 33.3%)	10 ( 55.6%)	18
Allergic reaction to excipient	0 ( 0.0%)	5 ( 27.8%)	12 ( 66.7%)	1 ( 5.6%)	18
Tryptase increased	1 ( 5.6%)	4 ( 22.2%)	9 ( 50.0%)	4 ( 22.2%)	18
Lower respiratory tract infection viral	0 ( 0.0%)	8 ( 44.4%)	9 ( 50.0%)	1 ( 5.6%)	18
Infertility	5 ( 27.8%)	13 ( 72.2%)	0 ( 0.0%)	0 ( 0.0%)	18
Ankle arthroplasty	0 ( 0.0%)	4 ( 22.2%)	14 ( 77.8%)	0 ( 0.0%)	18
Light chain analysis increased	0 ( 0.0%)	1 ( 5.6%)	11 ( 61.1%)	6 ( 33.3%)	18
Myelofibrosis	0 ( 0.0%)	2 ( 11.1%)	15 ( 83.3%)	1 ( 5.6%)	18
Uterine polyp	1 ( 5.6%)	8 ( 44.4%)	9 ( 50.0%)	0 ( 0.0%)	18
Leukaemia recurrent	9 ( 50.0%)	1 ( 5.6%)	6 ( 33.3%)	2 ( 11.1%)	18
Hyperferritinaemia	1 ( 5.6%)	4 ( 22.2%)	13 ( 72.2%)	0 ( 0.0%)	18
Creatinine renal clearance increased	2 ( 11.1%)	1 ( 5.6%)	3 ( 16.7%)	12 ( 66.7%)	18
Lacunar infarction	0 ( 0.0%)	2 ( 11.1%)	9 ( 50.0%)	7 ( 38.9%)	18
Foreign body in eye	0 ( 0.0%)	6 ( 33.3%)	10 ( 55.6%)	2 ( 11.1%)	18
Knee deformity	4 ( 22.2%)	3 ( 16.7%)	9 ( 50.0%)	2 ( 11.1%)	18
Derealisation	2 ( 11.1%)	8 ( 44.4%)	5 ( 27.8%)	3 ( 16.7%)	18
Adrenal haemorrhage	0 ( 0.0%)	5 ( 27.8%)	11 ( 61.1%)	2 ( 11.1%)	18
Autoimmune myositis	0 ( 0.0%)	1 ( 5.6%)	14 ( 77.8%)	3 ( 16.7%)	18
Corneal oedema	3 ( 16.7%)	4 ( 22.2%)	8 ( 44.4%)	3 ( 16.7%)	18
Nail ridging	0 ( 0.0%)	5 ( 27.8%)	2 ( 11.1%)	11 ( 61.1%)	18
Intervertebral disc operation	0 ( 0.0%)	3 ( 16.7%)	15 ( 83.3%)	0 ( 0.0%)	18

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blood cholesterol decreased	0 ( 0.0%)	0 ( 0.0%)	12 ( 66.7%)	6 ( 33.3%)	18
Ileocaecal resection	0 ( 0.0%)	14 ( 77.8%)	4 ( 22.2%)	0 ( 0.0%)	18
Pulmonary mucormycosis	0 ( 0.0%)	11 ( 61.1%)	6 ( 33.3%)	1 ( 5.6%)	18
Joint ankylosis	1 ( 5.6%)	7 ( 38.9%)	7 ( 38.9%)	3 ( 16.7%)	18
Systemic mycosis	3 ( 16.7%)	6 ( 33.3%)	6 ( 33.3%)	3 ( 16.7%)	18
Inflammatory pain	0 ( 0.0%)	7 ( 38.9%)	11 ( 61.1%)	0 ( 0.0%)	18
Tongue neoplasm malignant stage unspecified	0 ( 0.0%)	1 ( 5.6%)	13 ( 72.2%)	4 ( 22.2%)	18
Wound infection staphylococcal	0 ( 0.0%)	7 ( 38.9%)	9 ( 50.0%)	2 ( 11.1%)	18
Pulmonary arterial pressure increased	5 ( 27.8%)	4 ( 22.2%)	6 ( 33.3%)	3 ( 16.7%)	18
Neuroendocrine carcinoma of the skin	0 ( 0.0%)	5 ( 27.8%)	11 ( 61.1%)	2 ( 11.1%)	18
Post lumbar puncture syndrome	9 ( 50.0%)	4 ( 22.2%)	5 ( 27.8%)	0 ( 0.0%)	18
Stoma creation	3 ( 16.7%)	8 ( 44.4%)	6 ( 33.3%)	1 ( 5.6%)	18
Small intestine carcinoma	0 ( 0.0%)	1 ( 5.6%)	16 ( 88.9%)	1 ( 5.6%)	18
Wrong schedule	3 ( 16.7%)	4 ( 22.2%)	5 ( 27.8%)	6 ( 33.3%)	18
Postoperative wound complication	0 ( 0.0%)	3 ( 16.7%)	15 ( 83.3%)	0 ( 0.0%)	18
Mean cell haemoglobin concentration increased	5 ( 27.8%)	5 ( 27.8%)	8 ( 44.4%)	0 ( 0.0%)	18
Primary adrenal insufficiency	1 ( 5.6%)	1 ( 5.6%)	14 ( 77.8%)	2 ( 11.1%)	18
Uterine haemorrhage	0 ( 0.0%)	14 ( 77.8%)	4 ( 22.2%)	0 ( 0.0%)	18
Gastroduodenal ulcer	1 ( 5.6%)	0 ( 0.0%)	14 ( 77.8%)	3 ( 16.7%)	18
Pseudo Cushing's syndrome	2 ( 11.1%)	8 ( 44.4%)	8 ( 44.4%)	0 ( 0.0%)	18
Duodenal ulcer haemorrhage	3 ( 16.7%)	0 ( 0.0%)	11 ( 61.1%)	4 ( 22.2%)	18
Meibomian gland dysfunction	0 ( 0.0%)	7 ( 38.9%)	9 ( 50.0%)	2 ( 11.1%)	18
Gouty arthritis	0 ( 0.0%)	3 ( 16.7%)	11 ( 61.1%)	4 ( 22.2%)	18
Oesophageal spasm	2 ( 11.1%)	3 ( 16.7%)	13 ( 72.2%)	0 ( 0.0%)	18
Genital abscess	1 ( 5.6%)	9 ( 50.0%)	8 ( 44.4%)	0 ( 0.0%)	18
Product container seal issue	2 ( 11.1%)	1 ( 5.6%)	11 ( 61.1%)	4 ( 22.2%)	18
Inner ear disorder	0 ( 0.0%)	2 ( 11.1%)	14 ( 77.8%)	2 ( 11.1%)	18

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Prinzmetal angina	0 ( 0.0%)	5 ( 27.8%)	10 ( 55.6%)	3 ( 16.7%)	18
Cerebral mass effect	1 ( 5.6%)	3 ( 16.7%)	11 ( 61.1%)	3 ( 16.7%)	18
Premature rupture of membranes	4 ( 22.2%)	14 ( 77.8%)	0 ( 0.0%)	0 ( 0.0%)	18
Pseudomonal bacteraemia	2 ( 11.1%)	3 ( 16.7%)	10 ( 55.6%)	3 ( 16.7%)	18
Cerebellar atrophy	7 ( 38.9%)	7 ( 38.9%)	3 ( 16.7%)	1 ( 5.6%)	18
Optic nerve injury	1 ( 5.9%)	7 ( 41.2%)	8 ( 47.1%)	1 ( 5.9%)	17
Glycosylated haemoglobin abnormal	0 ( 0.0%)	2 ( 11.8%)	13 ( 76.5%)	2 ( 11.8%)	17
Fluid replacement	3 ( 17.6%)	2 ( 11.8%)	9 ( 52.9%)	3 ( 17.6%)	17
Radiation skin injury	1 ( 5.9%)	3 ( 17.6%)	13 ( 76.5%)	0 ( 0.0%)	17
Pelvic venous thrombosis	1 ( 5.9%)	4 ( 23.5%)	12 ( 70.6%)	0 ( 0.0%)	17
Fistula discharge	1 ( 5.9%)	5 ( 29.4%)	11 ( 64.7%)	0 ( 0.0%)	17
Ear inflammation	3 ( 17.6%)	5 ( 29.4%)	9 ( 52.9%)	0 ( 0.0%)	17
Febrile convulsion	13 ( 76.5%)	0 ( 0.0%)	2 ( 11.8%)	2 ( 11.8%)	17
Ovarian cyst ruptured	4 ( 23.5%)	12 ( 70.6%)	1 ( 5.9%)	0 ( 0.0%)	17
Osteochondrosis	5 ( 29.4%)	5 ( 29.4%)	6 ( 35.3%)	1 ( 5.9%)	17
Eyelid infection	5 ( 29.4%)	3 ( 17.6%)	9 ( 52.9%)	0 ( 0.0%)	17
Oral mucosal exfoliation	1 ( 5.9%)	4 ( 23.5%)	9 ( 52.9%)	3 ( 17.6%)	17
Hand dermatitis	1 ( 5.9%)	7 ( 41.2%)	9 ( 52.9%)	0 ( 0.0%)	17
Patient dissatisfaction with treatment	1 ( 5.9%)	7 ( 41.2%)	7 ( 41.2%)	2 ( 11.8%)	17
Nocturnal dyspnoea	0 ( 0.0%)	9 ( 52.9%)	8 ( 47.1%)	0 ( 0.0%)	17
Lip pruritus	7 ( 41.2%)	6 ( 35.3%)	4 ( 23.5%)	0 ( 0.0%)	17
Injection site necrosis	0 ( 0.0%)	10 ( 58.8%)	5 ( 29.4%)	2 ( 11.8%)	17
Blood immunoglobulin A increased	1 ( 5.9%)	10 ( 58.8%)	6 ( 35.3%)	0 ( 0.0%)	17
Enterococcal sepsis	11 ( 64.7%)	2 ( 11.8%)	3 ( 17.6%)	1 ( 5.9%)	17
Nasal pruritus	1 ( 5.9%)	5 ( 29.4%)	11 ( 64.7%)	0 ( 0.0%)	17
Scleroderma renal crisis	0 ( 0.0%)	4 ( 23.5%)	13 ( 76.5%)	0 ( 0.0%)	17
Vaccine interaction	3 ( 17.6%)	8 ( 47.1%)	4 ( 23.5%)	2 ( 11.8%)	17

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Endometrial cancer	0 ( 0.0%)	1 ( 5.9%)	14 ( 82.4%)	2 ( 11.8%)	17
Clostridial infection	1 ( 5.9%)	5 ( 29.4%)	6 ( 35.3%)	5 ( 29.4%)	17
Endocrine disorder	1 ( 5.9%)	10 ( 58.8%)	5 ( 29.4%)	1 ( 5.9%)	17
Patent ductus arteriosus	17 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	17
Patient uncooperative	5 ( 29.4%)	7 ( 41.2%)	5 ( 29.4%)	0 ( 0.0%)	17
Muscle abscess	2 ( 11.8%)	4 ( 23.5%)	7 ( 41.2%)	4 ( 23.5%)	17
Breathing-related sleep disorder	3 ( 17.6%)	11 ( 64.7%)	2 ( 11.8%)	1 ( 5.9%)	17
Pseudomembranous colitis	0 ( 0.0%)	4 ( 23.5%)	10 ( 58.8%)	3 ( 17.6%)	17
Carotid artery thrombosis	0 ( 0.0%)	4 ( 23.5%)	12 ( 70.6%)	1 ( 5.9%)	17
Colon cancer metastatic	0 ( 0.0%)	3 ( 17.6%)	10 ( 58.8%)	4 ( 23.5%)	17
Drug screen negative	0 ( 0.0%)	13 ( 76.5%)	4 ( 23.5%)	0 ( 0.0%)	17
Drug level abnormal	11 ( 64.7%)	1 ( 5.9%)	5 ( 29.4%)	0 ( 0.0%)	17
Distractibility	0 ( 0.0%)	4 ( 23.5%)	12 ( 70.6%)	1 ( 5.9%)	17
Cholangiocarcinoma	2 ( 11.8%)	5 ( 29.4%)	9 ( 52.9%)	1 ( 5.9%)	17
Disseminated cryptococcosis	0 ( 0.0%)	10 ( 58.8%)	4 ( 23.5%)	3 ( 17.6%)	17
Fracture pain	0 ( 0.0%)	0 ( 0.0%)	13 ( 76.5%)	4 ( 23.5%)	17
Acute graft versus host disease in intestine	8 ( 47.1%)	2 ( 11.8%)	7 ( 41.2%)	0 ( 0.0%)	17
Bone giant cell tumour	9 ( 52.9%)	5 ( 29.4%)	3 ( 17.6%)	0 ( 0.0%)	17
Soft tissue swelling	0 ( 0.0%)	5 ( 29.4%)	12 ( 70.6%)	0 ( 0.0%)	17
Diabetic metabolic decompensation	1 ( 5.9%)	2 ( 11.8%)	12 ( 70.6%)	2 ( 11.8%)	17
Leukocyturia	1 ( 5.9%)	2 ( 11.8%)	13 ( 76.5%)	1 ( 5.9%)	17
Stem cell transplant	0 ( 0.0%)	10 ( 58.8%)	7 ( 41.2%)	0 ( 0.0%)	17
Starvation	0 ( 0.0%)	4 ( 23.5%)	5 ( 29.4%)	8 ( 47.1%)	17
Keratopathy	0 ( 0.0%)	8 ( 47.1%)	5 ( 29.4%)	4 ( 23.5%)	17
Tumour necrosis	0 ( 0.0%)	2 ( 11.8%)	11 ( 64.7%)	4 ( 23.5%)	17
Catheter site discharge	2 ( 11.8%)	5 ( 29.4%)	10 ( 58.8%)	0 ( 0.0%)	17
Akinesia	4 ( 23.5%)	1 ( 5.9%)	6 ( 35.3%)	6 ( 35.3%)	17



**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Costochondritis	4 ( 23.5%)	9 ( 52.9%)	3 ( 17.6%)	1 ( 5.9%)	17
Vitreous opacities	1 ( 5.9%)	7 ( 41.2%)	5 ( 29.4%)	4 ( 23.5%)	17
Vascular device occlusion	4 ( 23.5%)	5 ( 29.4%)	7 ( 41.2%)	1 ( 5.9%)	17
Adulterated product	2 ( 11.8%)	13 ( 76.5%)	2 ( 11.8%)	0 ( 0.0%)	17
Thrombophlebitis migrans	0 ( 0.0%)	0 ( 0.0%)	12 ( 70.6%)	5 ( 29.4%)	17
Incision site impaired healing	0 ( 0.0%)	2 ( 11.8%)	14 ( 82.4%)	1 ( 5.9%)	17
Thyroid hormones decreased	2 ( 11.8%)	1 ( 5.9%)	12 ( 70.6%)	2 ( 11.8%)	17
Foetal growth restriction	14 ( 82.4%)	3 ( 17.6%)	0 ( 0.0%)	0 ( 0.0%)	17
Tinea pedis	1 ( 5.9%)	7 ( 41.2%)	8 ( 47.1%)	1 ( 5.9%)	17
Tongue erythema	1 ( 5.9%)	4 ( 23.5%)	9 ( 52.9%)	3 ( 17.6%)	17
Tendon discomfort	1 ( 5.9%)	10 ( 58.8%)	6 ( 35.3%)	0 ( 0.0%)	17
Hypertensive urgency	0 ( 0.0%)	7 ( 41.2%)	10 ( 58.8%)	0 ( 0.0%)	17
Streptococcal bacteraemia	8 ( 47.1%)	3 ( 17.6%)	4 ( 23.5%)	2 ( 11.8%)	17
Neuropsychological symptoms	2 ( 11.8%)	9 ( 52.9%)	6 ( 35.3%)	0 ( 0.0%)	17
Episcleritis	3 ( 17.6%)	2 ( 11.8%)	11 ( 64.7%)	1 ( 5.9%)	17
Brain hypoxia	2 ( 11.8%)	7 ( 41.2%)	8 ( 47.1%)	0 ( 0.0%)	17
Sleep talking	1 ( 5.9%)	6 ( 35.3%)	6 ( 35.3%)	4 ( 23.5%)	17
Nicotine dependence	0 ( 0.0%)	4 ( 23.5%)	9 ( 52.9%)	4 ( 23.5%)	17
Colonic abscess	1 ( 5.9%)	4 ( 23.5%)	11 ( 64.7%)	1 ( 5.9%)	17
Blood fibrinogen decreased	4 ( 23.5%)	3 ( 17.6%)	7 ( 41.2%)	3 ( 17.6%)	17
Ingrown hair	0 ( 0.0%)	16 ( 94.1%)	1 ( 5.9%)	0 ( 0.0%)	17
Ballismus	0 ( 0.0%)	10 ( 58.8%)	6 ( 35.3%)	1 ( 5.9%)	17
Heat exhaustion	1 ( 5.9%)	4 ( 23.5%)	11 ( 64.7%)	1 ( 5.9%)	17
Medical device removal	1 ( 5.9%)	3 ( 17.6%)	10 ( 58.8%)	3 ( 17.6%)	17
Calculus bladder	0 ( 0.0%)	3 ( 17.6%)	10 ( 58.8%)	4 ( 23.5%)	17
Genital burning sensation	2 ( 11.8%)	2 ( 11.8%)	13 ( 76.5%)	0 ( 0.0%)	17
Product packaging confusion	4 ( 23.5%)	1 ( 5.9%)	8 ( 47.1%)	4 ( 23.5%)	17

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cholinergic rebound syndrome	0 ( 0.0%)	0 ( 0.0%)	13 ( 76.5%)	4 ( 23.5%)	17
Campylobacter gastroenteritis	0 ( 0.0%)	2 ( 11.8%)	12 ( 70.6%)	3 ( 17.6%)	17
Incision site pain	0 ( 0.0%)	6 ( 35.3%)	11 ( 64.7%)	0 ( 0.0%)	17
Cancer surgery	0 ( 0.0%)	2 ( 11.8%)	13 ( 76.5%)	2 ( 11.8%)	17
Cervical spinal stenosis	0 ( 0.0%)	8 ( 47.1%)	7 ( 41.2%)	2 ( 11.8%)	17
Intra-abdominal haematoma	1 ( 5.9%)	4 ( 23.5%)	10 ( 58.8%)	2 ( 11.8%)	17
Anastomotic stenosis	0 ( 0.0%)	9 ( 52.9%)	8 ( 47.1%)	0 ( 0.0%)	17
Prolactin-producing pituitary tumour	0 ( 0.0%)	10 ( 58.8%)	4 ( 23.5%)	3 ( 17.6%)	17
Prostate infection	0 ( 0.0%)	4 ( 23.5%)	11 ( 64.7%)	2 ( 11.8%)	17
Prothrombin time shortened	9 ( 52.9%)	3 ( 17.6%)	3 ( 17.6%)	2 ( 11.8%)	17
Prostatic operation	0 ( 0.0%)	0 ( 0.0%)	14 ( 82.4%)	3 ( 17.6%)	17
Acute abdomen	4 ( 23.5%)	2 ( 11.8%)	5 ( 29.4%)	6 ( 35.3%)	17
Dyslexia	2 ( 11.8%)	2 ( 11.8%)	12 ( 70.6%)	1 ( 5.9%)	17
Wrist surgery	1 ( 5.9%)	3 ( 17.6%)	10 ( 58.8%)	3 ( 17.6%)	17
Anaesthesia	2 ( 11.8%)	11 ( 64.7%)	3 ( 17.6%)	1 ( 5.9%)	17
Dehiscence	0 ( 0.0%)	0 ( 0.0%)	5 ( 29.4%)	12 ( 70.6%)	17
Intussusception	3 ( 17.6%)	5 ( 29.4%)	8 ( 47.1%)	1 ( 5.9%)	17
Yawning	1 ( 5.9%)	12 ( 70.6%)	4 ( 23.5%)	0 ( 0.0%)	17
Poor feeding infant	16 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	16
Allodynia	1 ( 6.3%)	8 ( 50.0%)	5 ( 31.3%)	2 ( 12.5%)	16
Hyposmia	0 ( 0.0%)	7 ( 43.8%)	8 ( 50.0%)	1 ( 6.3%)	16
Teeth brittle	0 ( 0.0%)	9 ( 56.3%)	7 ( 43.8%)	0 ( 0.0%)	16
Anaemia megaloblastic	8 ( 50.0%)	0 ( 0.0%)	2 ( 12.5%)	6 ( 37.5%)	16
Hemihypoaesthesia	2 ( 12.5%)	7 ( 43.8%)	6 ( 37.5%)	1 ( 6.3%)	16
Pharyngeal ulceration	0 ( 0.0%)	3 ( 18.8%)	13 ( 81.3%)	0 ( 0.0%)	16
Fractured coccyx	0 ( 0.0%)	4 ( 25.0%)	4 ( 25.0%)	8 ( 50.0%)	16
Reproductive complication associated with device	2 ( 12.5%)	14 ( 87.5%)	0 ( 0.0%)	0 ( 0.0%)	16

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Food refusal	4 ( 25.0%)	0 ( 0.0%)	10 ( 62.5%)	2 ( 12.5%)	16
Metastases to the mediastinum	0 ( 0.0%)	2 ( 12.5%)	14 ( 87.5%)	0 ( 0.0%)	16
Rectal polyp	0 ( 0.0%)	1 ( 6.3%)	14 ( 87.5%)	1 ( 6.3%)	16
Cytomegalovirus oesophagitis	0 ( 0.0%)	1 ( 6.3%)	15 ( 93.8%)	0 ( 0.0%)	16
Facial discomfort	2 ( 12.5%)	4 ( 25.0%)	9 ( 56.3%)	1 ( 6.3%)	16
Diabetic coma	0 ( 0.0%)	5 ( 31.3%)	7 ( 43.8%)	4 ( 25.0%)	16
Alveolar proteinosis	0 ( 0.0%)	1 ( 6.3%)	15 ( 93.8%)	0 ( 0.0%)	16
Anaemia vitamin B12 deficiency	0 ( 0.0%)	0 ( 0.0%)	8 ( 50.0%)	8 ( 50.0%)	16
Aura	2 ( 12.5%)	4 ( 25.0%)	9 ( 56.3%)	1 ( 6.3%)	16
Anastomotic ulcer	3 ( 18.8%)	8 ( 50.0%)	4 ( 25.0%)	1 ( 6.3%)	16
Infusion site nodule	1 ( 6.3%)	3 ( 18.8%)	10 ( 62.5%)	2 ( 12.5%)	16
Angle closure glaucoma	0 ( 0.0%)	8 ( 50.0%)	5 ( 31.3%)	3 ( 18.8%)	16
Renal artery stenosis	5 ( 31.3%)	0 ( 0.0%)	10 ( 62.5%)	1 ( 6.3%)	16
Nutritional condition abnormal	4 ( 25.0%)	2 ( 12.5%)	8 ( 50.0%)	2 ( 12.5%)	16
Neutrophil percentage increased	3 ( 18.8%)	2 ( 12.5%)	9 ( 56.3%)	2 ( 12.5%)	16
Heart valve replacement	1 ( 6.3%)	0 ( 0.0%)	10 ( 62.5%)	5 ( 31.3%)	16
Epididymitis	3 ( 18.8%)	6 ( 37.5%)	5 ( 31.3%)	2 ( 12.5%)	16
Saliva altered	1 ( 6.3%)	4 ( 25.0%)	7 ( 43.8%)	4 ( 25.0%)	16
Haemangioma	3 ( 18.8%)	7 ( 43.8%)	4 ( 25.0%)	2 ( 12.5%)	16
Enterobacter pneumonia	1 ( 6.3%)	0 ( 0.0%)	5 ( 31.3%)	10 ( 62.5%)	16
Enteral nutrition	2 ( 12.5%)	3 ( 18.8%)	9 ( 56.3%)	2 ( 12.5%)	16
Parathyroid tumour benign	0 ( 0.0%)	3 ( 18.8%)	8 ( 50.0%)	5 ( 31.3%)	16
Nail infection	1 ( 6.3%)	6 ( 37.5%)	6 ( 37.5%)	3 ( 18.8%)	16
Sciatic nerve injury	0 ( 0.0%)	0 ( 0.0%)	13 ( 81.3%)	3 ( 18.8%)	16
Injection site coldness	2 ( 12.5%)	12 ( 75.0%)	2 ( 12.5%)	0 ( 0.0%)	16
Clostridium colitis	1 ( 6.3%)	6 ( 37.5%)	7 ( 43.8%)	2 ( 12.5%)	16
Encephalitis cytomegalovirus	0 ( 0.0%)	14 ( 87.5%)	2 ( 12.5%)	0 ( 0.0%)	16

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Self esteem decreased	6 ( 37.5%)	7 ( 43.8%)	2 ( 12.5%)	1 ( 6.3%)	16
Uterine enlargement	2 ( 12.5%)	14 ( 87.5%)	0 ( 0.0%)	0 ( 0.0%)	16
Multiple sclerosis pseudo relapse	2 ( 12.5%)	8 ( 50.0%)	6 ( 37.5%)	0 ( 0.0%)	16
Electroencephalogram abnormal	5 ( 31.3%)	4 ( 25.0%)	4 ( 25.0%)	3 ( 18.8%)	16
Uterine cervix stenosis	3 ( 18.8%)	12 ( 75.0%)	1 ( 6.3%)	0 ( 0.0%)	16
Mononeuropathy multiplex	0 ( 0.0%)	6 ( 37.5%)	5 ( 31.3%)	5 ( 31.3%)	16
Monocytosis	3 ( 18.8%)	6 ( 37.5%)	7 ( 43.8%)	0 ( 0.0%)	16
Hepatitis viral	0 ( 0.0%)	9 ( 56.3%)	7 ( 43.8%)	0 ( 0.0%)	16
Intercepted product dispensing error	3 ( 18.8%)	4 ( 25.0%)	8 ( 50.0%)	1 ( 6.3%)	16
Microangiopathy	1 ( 6.3%)	1 ( 6.3%)	9 ( 56.3%)	5 ( 31.3%)	16
Rebound atopic dermatitis	2 ( 12.5%)	4 ( 25.0%)	8 ( 50.0%)	2 ( 12.5%)	16
Meningitis bacterial	4 ( 25.0%)	3 ( 18.8%)	5 ( 31.3%)	4 ( 25.0%)	16
Dupuytren's contracture	0 ( 0.0%)	2 ( 12.5%)	13 ( 81.3%)	1 ( 6.3%)	16
Duodenal perforation	0 ( 0.0%)	0 ( 0.0%)	11 ( 68.8%)	5 ( 31.3%)	16
Apraxia	1 ( 6.3%)	4 ( 25.0%)	11 ( 68.8%)	0 ( 0.0%)	16
Infusion related hypersensitivity reaction	5 ( 31.3%)	2 ( 12.5%)	5 ( 31.3%)	4 ( 25.0%)	16
Drug administered in wrong device	12 ( 75.0%)	1 ( 6.3%)	3 ( 18.8%)	0 ( 0.0%)	16
Drainage	0 ( 0.0%)	8 ( 50.0%)	7 ( 43.8%)	1 ( 6.3%)	16
Lung transplant	3 ( 18.8%)	5 ( 31.3%)	8 ( 50.0%)	0 ( 0.0%)	16
Discontinued product administered	2 ( 12.5%)	2 ( 12.5%)	11 ( 68.8%)	1 ( 6.3%)	16
Compartment syndrome	2 ( 12.5%)	3 ( 18.8%)	11 ( 68.8%)	0 ( 0.0%)	16
Lip exfoliation	2 ( 12.5%)	3 ( 18.8%)	7 ( 43.8%)	4 ( 25.0%)	16
Infected bite	2 ( 12.5%)	4 ( 25.0%)	10 ( 62.5%)	0 ( 0.0%)	16
Spinal cord infection	0 ( 0.0%)	3 ( 18.8%)	12 ( 75.0%)	1 ( 6.3%)	16
Dependence on oxygen therapy	1 ( 6.3%)	0 ( 0.0%)	11 ( 68.8%)	4 ( 25.0%)	16
Aortic valve disease	2 ( 12.5%)	1 ( 6.3%)	6 ( 37.5%)	7 ( 43.8%)	16
Iron overload	3 ( 18.8%)	2 ( 12.5%)	6 ( 37.5%)	5 ( 31.3%)	16

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pharyngeal inflammation	3 ( 18.8%)	8 ( 50.0%)	5 ( 31.3%)	0 ( 0.0%)	16
Vocal cord dysfunction	1 ( 6.3%)	7 ( 43.8%)	7 ( 43.8%)	1 ( 6.3%)	16
Immune-mediated arthritis	1 ( 6.3%)	3 ( 18.8%)	12 ( 75.0%)	0 ( 0.0%)	16
Implantable defibrillator insertion	0 ( 0.0%)	1 ( 6.3%)	11 ( 68.8%)	4 ( 25.0%)	16
Antipsychotic drug level below therapeutic	1 ( 6.3%)	10 ( 62.5%)	5 ( 31.3%)	0 ( 0.0%)	16
Cystitis viral	3 ( 18.8%)	11 ( 68.8%)	2 ( 12.5%)	0 ( 0.0%)	16
Tumour flare	0 ( 0.0%)	3 ( 18.8%)	13 ( 81.3%)	0 ( 0.0%)	16
Inappropriate affect	3 ( 18.8%)	10 ( 62.5%)	3 ( 18.8%)	0 ( 0.0%)	16
Hypothalamic pituitary adrenal axis suppression	5 ( 31.3%)	8 ( 50.0%)	3 ( 18.8%)	0 ( 0.0%)	16
Cellulite	1 ( 6.3%)	8 ( 50.0%)	7 ( 43.8%)	0 ( 0.0%)	16
Immature granulocyte count increased	1 ( 6.3%)	7 ( 43.8%)	8 ( 50.0%)	0 ( 0.0%)	16
Agoraphobia	1 ( 6.3%)	13 ( 81.3%)	2 ( 12.5%)	0 ( 0.0%)	16
Tissue infiltration	1 ( 6.3%)	15 ( 93.8%)	0 ( 0.0%)	0 ( 0.0%)	16
Cellulitis orbital	0 ( 0.0%)	6 ( 37.5%)	7 ( 43.8%)	3 ( 18.8%)	16
Tonic convulsion	9 ( 56.3%)	4 ( 25.0%)	3 ( 18.8%)	0 ( 0.0%)	16
Polypectomy	1 ( 6.3%)	4 ( 25.0%)	8 ( 50.0%)	3 ( 18.8%)	16
Polymenorrhoea	4 ( 25.0%)	11 ( 68.8%)	1 ( 6.3%)	0 ( 0.0%)	16
Inadequate analgesia	1 ( 6.3%)	7 ( 43.8%)	7 ( 43.8%)	1 ( 6.3%)	16
Counterfeit product administered	4 ( 25.0%)	6 ( 37.5%)	5 ( 31.3%)	1 ( 6.3%)	16
Hyperleukocytosis	2 ( 12.5%)	6 ( 37.5%)	5 ( 31.3%)	3 ( 18.8%)	16
Staring	6 ( 37.5%)	1 ( 6.3%)	7 ( 43.8%)	2 ( 12.5%)	16
Asthma-chronic obstructive pulmonary disease overlap	0 ( 0.0%)	0 ( 0.0%)	16 (100.0%)	0 ( 0.0%)	16
Anosognosia	5 ( 31.3%)	2 ( 12.5%)	7 ( 43.8%)	2 ( 12.5%)	16
Congenital hiatus hernia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	16 (100.0%)	16
Upper respiratory tract infection bacterial	6 ( 37.5%)	4 ( 25.0%)	6 ( 37.5%)	0 ( 0.0%)	16
Right ventricular dysfunction	4 ( 25.0%)	3 ( 18.8%)	4 ( 25.0%)	5 ( 31.3%)	16
Erosive oesophagitis	4 ( 25.0%)	1 ( 6.3%)	7 ( 43.8%)	4 ( 25.0%)	16

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Injection site exfoliation	3 ( 18.8%)	5 ( 31.3%)	8 ( 50.0%)	0 ( 0.0%)	16
Intraductal proliferative breast lesion	0 ( 0.0%)	1 ( 6.3%)	14 ( 87.5%)	1 ( 6.3%)	16
Reversible airways obstruction	0 ( 0.0%)	3 ( 18.8%)	12 ( 75.0%)	1 ( 6.3%)	16
Vascular access complication	1 ( 6.3%)	1 ( 6.3%)	12 ( 75.0%)	2 ( 12.5%)	16
Angular cheilitis	3 ( 18.8%)	5 ( 31.3%)	8 ( 50.0%)	0 ( 0.0%)	16
Groin infection	2 ( 12.5%)	8 ( 50.0%)	5 ( 31.3%)	1 ( 6.3%)	16
Exophthalmos	0 ( 0.0%)	3 ( 18.8%)	9 ( 56.3%)	4 ( 25.0%)	16
Pyuria	6 ( 37.5%)	3 ( 18.8%)	2 ( 12.5%)	5 ( 31.3%)	16
Vitamin D increased	3 ( 18.8%)	1 ( 6.3%)	12 ( 75.0%)	0 ( 0.0%)	16
Vocal cord disorder	0 ( 0.0%)	4 ( 25.0%)	7 ( 43.8%)	5 ( 31.3%)	16
Bile duct stenosis	2 ( 12.5%)	2 ( 12.5%)	7 ( 43.8%)	5 ( 31.3%)	16
Aortic disorder	0 ( 0.0%)	4 ( 25.0%)	11 ( 68.8%)	1 ( 6.3%)	16
Neuroendocrine carcinoma	0 ( 0.0%)	0 ( 0.0%)	11 ( 68.8%)	5 ( 31.3%)	16
Symmetrical drug-related intertriginous and flexural	4 ( 25.0%)	0 ( 0.0%)	6 ( 37.5%)	6 ( 37.5%)	16
Generalised anxiety disorder	2 ( 12.5%)	8 ( 50.0%)	6 ( 37.5%)	0 ( 0.0%)	16
Product after taste	0 ( 0.0%)	3 ( 18.8%)	12 ( 75.0%)	1 ( 6.3%)	16
Product administered by wrong person	1 ( 6.3%)	7 ( 43.8%)	6 ( 37.5%)	2 ( 12.5%)	16
Precancerous condition	0 ( 0.0%)	2 ( 12.5%)	12 ( 75.0%)	2 ( 12.5%)	16
Pouchitis	2 ( 12.5%)	10 ( 62.5%)	3 ( 18.8%)	1 ( 6.3%)	16
Gastroenteritis salmonella	1 ( 6.3%)	5 ( 31.3%)	10 ( 62.5%)	0 ( 0.0%)	16
Pneumonia streptococcal	7 ( 46.7%)	3 ( 20.0%)	4 ( 26.7%)	1 ( 6.7%)	15
Eye infection toxoplasmal	5 ( 33.3%)	0 ( 0.0%)	10 ( 66.7%)	0 ( 0.0%)	15
Administration site extravasation	3 ( 20.0%)	3 ( 20.0%)	6 ( 40.0%)	3 ( 20.0%)	15
Metapneumovirus infection	12 ( 80.0%)	1 ( 6.7%)	2 ( 13.3%)	0 ( 0.0%)	15
Peritonsillar abscess	1 ( 6.7%)	9 ( 60.0%)	4 ( 26.7%)	1 ( 6.7%)	15
Eyelid exfoliation	8 ( 53.3%)	4 ( 26.7%)	1 ( 6.7%)	2 ( 13.3%)	15
Foreign body aspiration	0 ( 0.0%)	14 ( 93.3%)	1 ( 6.7%)	0 ( 0.0%)	15

# Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Peripheral sensorimotor neuropathy	0 ( 0.0%)	2 ( 13.3%)	6 ( 40.0%)	7 ( 46.7%)	15
Carotid arteriosclerosis	0 ( 0.0%)	1 ( 6.7%)	8 ( 53.3%)	6 ( 40.0%)	15
Crystalluria	0 ( 0.0%)	2 ( 13.3%)	10 ( 66.7%)	3 ( 20.0%)	15
Fat tissue increased	1 ( 6.7%)	1 ( 6.7%)	9 ( 60.0%)	4 ( 26.7%)	15
Faecal volume decreased	5 ( 33.3%)	2 ( 13.3%)	6 ( 40.0%)	2 ( 13.3%)	15
Pancreatic mass	0 ( 0.0%)	3 ( 20.0%)	9 ( 60.0%)	3 ( 20.0%)	15
Axillary mass	0 ( 0.0%)	9 ( 60.0%)	6 ( 40.0%)	0 ( 0.0%)	15
Expanded disability status scale score increased	0 ( 0.0%)	11 ( 73.3%)	4 ( 26.7%)	0 ( 0.0%)	15
Executive dysfunction	1 ( 6.7%)	4 ( 26.7%)	8 ( 53.3%)	2 ( 13.3%)	15
Agitated depression	0 ( 0.0%)	12 ( 80.0%)	3 ( 20.0%)	0 ( 0.0%)	15
Injection site papule	2 ( 13.3%)	6 ( 40.0%)	6 ( 40.0%)	1 ( 6.7%)	15
Chronic respiratory failure	2 ( 13.3%)	2 ( 13.3%)	7 ( 46.7%)	4 ( 26.7%)	15
Epstein-Barr virus associated lymphoma	2 ( 13.3%)	5 ( 33.3%)	7 ( 46.7%)	1 ( 6.7%)	15
Neurogenic shock	4 ( 26.7%)	4 ( 26.7%)	7 ( 46.7%)	0 ( 0.0%)	15
Ephelides	3 ( 20.0%)	4 ( 26.7%)	7 ( 46.7%)	1 ( 6.7%)	15
Electrocardiogram T wave abnormal	2 ( 13.3%)	6 ( 40.0%)	6 ( 40.0%)	1 ( 6.7%)	15
Enterocolitis infectious	0 ( 0.0%)	2 ( 13.3%)	13 ( 86.7%)	0 ( 0.0%)	15
Myocardial fibrosis	0 ( 0.0%)	8 ( 53.3%)	6 ( 40.0%)	1 ( 6.7%)	15
Myelitis transverse	1 ( 6.7%)	9 ( 60.0%)	4 ( 26.7%)	1 ( 6.7%)	15
Mycoplasma infection	4 ( 26.7%)	3 ( 20.0%)	8 ( 53.3%)	0 ( 0.0%)	15
Self-consciousness	0 ( 0.0%)	8 ( 53.3%)	7 ( 46.7%)	0 ( 0.0%)	15
Electrocardiogram ST-T segment abnormal	2 ( 13.3%)	2 ( 13.3%)	10 ( 66.7%)	1 ( 6.7%)	15
Septic embolus	7 ( 46.7%)	1 ( 6.7%)	7 ( 46.7%)	0 ( 0.0%)	15
Optic nerve disorder	2 ( 13.3%)	7 ( 46.7%)	5 ( 33.3%)	1 ( 6.7%)	15
Moaning	7 ( 46.7%)	2 ( 13.3%)	4 ( 26.7%)	2 ( 13.3%)	15
Ectopic pregnancy	2 ( 13.3%)	12 ( 80.0%)	1 ( 6.7%)	0 ( 0.0%)	15
Acute lung injury	2 ( 13.3%)	1 ( 6.7%)	11 ( 73.3%)	1 ( 6.7%)	15

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Metabolic surgery	1 ( 6.7%)	7 ( 46.7%)	7 ( 46.7%)	0 ( 0.0%)	15
Breast discharge	3 ( 20.0%)	4 ( 26.7%)	8 ( 53.3%)	0 ( 0.0%)	15
Sinusitis fungal	0 ( 0.0%)	6 ( 40.0%)	8 ( 53.3%)	1 ( 6.7%)	15
Penile size reduced	1 ( 6.7%)	8 ( 53.3%)	4 ( 26.7%)	2 ( 13.3%)	15
Mastoiditis	5 ( 33.3%)	3 ( 20.0%)	4 ( 26.7%)	3 ( 20.0%)	15
Application site exfoliation	4 ( 26.7%)	4 ( 26.7%)	7 ( 46.7%)	0 ( 0.0%)	15
Application site reaction	2 ( 13.3%)	8 ( 53.3%)	5 ( 33.3%)	0 ( 0.0%)	15
Slow response to stimuli	1 ( 6.7%)	1 ( 6.7%)	10 ( 66.7%)	3 ( 20.0%)	15
Fibroma	1 ( 6.7%)	2 ( 13.3%)	7 ( 46.7%)	5 ( 33.3%)	15
Smoke sensitivity	0 ( 0.0%)	4 ( 26.7%)	10 ( 66.7%)	1 ( 6.7%)	15
Disseminated varicella zoster virus infection	9 ( 60.0%)	1 ( 6.7%)	4 ( 26.7%)	1 ( 6.7%)	15
Disseminated strongyloidiasis	0 ( 0.0%)	4 ( 26.7%)	11 ( 73.3%)	0 ( 0.0%)	15
Lung operation	1 ( 6.7%)	3 ( 20.0%)	9 ( 60.0%)	2 ( 13.3%)	15
Disinhibition	3 ( 20.0%)	10 ( 66.7%)	2 ( 13.3%)	0 ( 0.0%)	15
Periorbital cellulitis	6 ( 40.0%)	4 ( 26.7%)	4 ( 26.7%)	1 ( 6.7%)	15
Human herpesvirus 6 infection	6 ( 40.0%)	2 ( 13.3%)	7 ( 46.7%)	0 ( 0.0%)	15
Lower respiratory tract infection bacterial	1 ( 6.7%)	9 ( 60.0%)	5 ( 33.3%)	0 ( 0.0%)	15
Bone neoplasm	1 ( 6.7%)	1 ( 6.7%)	11 ( 73.3%)	2 ( 13.3%)	15
Spinal cord neoplasm	1 ( 6.7%)	3 ( 20.0%)	11 ( 73.3%)	0 ( 0.0%)	15
Spinal laminectomy	1 ( 6.7%)	1 ( 6.7%)	8 ( 53.3%)	5 ( 33.3%)	15
Ligament injury	1 ( 6.7%)	2 ( 13.3%)	12 ( 80.0%)	0 ( 0.0%)	15
Peripheral nerve injury	0 ( 0.0%)	6 ( 40.0%)	9 ( 60.0%)	0 ( 0.0%)	15
Device wireless communication issue	1 ( 6.7%)	5 ( 33.3%)	9 ( 60.0%)	0 ( 0.0%)	15
Alcohol poisoning	4 ( 26.7%)	7 ( 46.7%)	4 ( 26.7%)	0 ( 0.0%)	15
Dermo-hypodermatitis	0 ( 0.0%)	0 ( 0.0%)	13 ( 86.7%)	2 ( 13.3%)	15
Dermatosis	1 ( 6.7%)	8 ( 53.3%)	4 ( 26.7%)	2 ( 13.3%)	15
Concomitant disease progression	0 ( 0.0%)	7 ( 46.7%)	3 ( 20.0%)	5 ( 33.3%)	15



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
KL-6 increased	0 ( 0.0%)	1 ( 6.7%)	10 ( 66.7%)	4 ( 26.7%)	15
Ischaemic cardiomyopathy	0 ( 0.0%)	1 ( 6.7%)	11 ( 73.3%)	3 ( 20.0%)	15
Trichodysplasia spinulosa	7 ( 46.7%)	8 ( 53.3%)	0 ( 0.0%)	0 ( 0.0%)	15
Transplant failure	4 ( 26.7%)	4 ( 26.7%)	7 ( 46.7%)	0 ( 0.0%)	15
Suspected product quality issue	1 ( 6.7%)	5 ( 33.3%)	8 ( 53.3%)	1 ( 6.7%)	15
Hypoglycaemic unconsciousness	1 ( 6.7%)	2 ( 13.3%)	7 ( 46.7%)	5 ( 33.3%)	15
Pertussis	6 ( 40.0%)	2 ( 13.3%)	7 ( 46.7%)	0 ( 0.0%)	15
Tracheobronchitis	0 ( 0.0%)	2 ( 13.3%)	12 ( 80.0%)	1 ( 6.7%)	15
Tenosynovitis stenosaurs	0 ( 0.0%)	9 ( 60.0%)	5 ( 33.3%)	1 ( 6.7%)	15
Toxic leukoencephalopathy	3 ( 20.0%)	5 ( 33.3%)	6 ( 40.0%)	1 ( 6.7%)	15
Topical steroid withdrawal reaction	4 ( 26.7%)	8 ( 53.3%)	3 ( 20.0%)	0 ( 0.0%)	15
Conjunctival oedema	4 ( 26.7%)	4 ( 26.7%)	6 ( 40.0%)	1 ( 6.7%)	15
Necrotising retinitis	0 ( 0.0%)	2 ( 13.3%)	13 ( 86.7%)	0 ( 0.0%)	15
Corneal opacity	3 ( 20.0%)	6 ( 40.0%)	6 ( 40.0%)	0 ( 0.0%)	15
Corneal abrasion	2 ( 13.3%)	5 ( 33.3%)	6 ( 40.0%)	2 ( 13.3%)	15
Transaminases abnormal	6 ( 40.0%)	8 ( 53.3%)	1 ( 6.7%)	0 ( 0.0%)	15
Biliary tract disorder	2 ( 13.3%)	8 ( 53.3%)	4 ( 26.7%)	1 ( 6.7%)	15
Blood bilirubin decreased	5 ( 33.3%)	4 ( 26.7%)	5 ( 33.3%)	1 ( 6.7%)	15
Tinea infection	1 ( 6.7%)	5 ( 33.3%)	8 ( 53.3%)	1 ( 6.7%)	15
Corneal perforation	0 ( 0.0%)	3 ( 20.0%)	9 ( 60.0%)	3 ( 20.0%)	15
Blood albumin increased	1 ( 6.7%)	3 ( 20.0%)	11 ( 73.3%)	0 ( 0.0%)	15
Drug dispensed to wrong patient	5 ( 33.3%)	1 ( 6.7%)	7 ( 46.7%)	2 ( 13.3%)	15
Hypoaesthesia eye	0 ( 0.0%)	8 ( 53.3%)	7 ( 46.7%)	0 ( 0.0%)	15
Gastroenteritis Escherichia coli	1 ( 6.7%)	0 ( 0.0%)	12 ( 80.0%)	2 ( 13.3%)	15
Subcutaneous haematoma	6 ( 40.0%)	0 ( 0.0%)	6 ( 40.0%)	3 ( 20.0%)	15
Intestinal dilatation	1 ( 6.7%)	8 ( 53.3%)	6 ( 40.0%)	0 ( 0.0%)	15
Globotriaosylsphingosine increased	5 ( 33.3%)	6 ( 40.0%)	4 ( 26.7%)	0 ( 0.0%)	15

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Sputum purulent	0 ( 0.0%)	4 ( 26.7%)	10 ( 66.7%)	1 ( 6.7%)	15
Small intestinal resection	2 ( 13.3%)	5 ( 33.3%)	8 ( 53.3%)	0 ( 0.0%)	15
Bite	2 ( 13.3%)	4 ( 26.7%)	9 ( 60.0%)	0 ( 0.0%)	15
High density lipoprotein increased	1 ( 6.7%)	4 ( 26.7%)	6 ( 40.0%)	4 ( 26.7%)	15
Skin sensitisation	0 ( 0.0%)	8 ( 53.3%)	7 ( 46.7%)	0 ( 0.0%)	15
Urine albumin/creatinine ratio increased	0 ( 0.0%)	5 ( 33.3%)	7 ( 46.7%)	3 ( 20.0%)	15
Drug therapy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	15 (100.0%)	15
Drug withdrawal convulsions	5 ( 33.3%)	6 ( 40.0%)	4 ( 26.7%)	0 ( 0.0%)	15
Anisocoria	7 ( 46.7%)	7 ( 46.7%)	0 ( 0.0%)	1 ( 6.7%)	15
Heat illness	1 ( 6.7%)	0 ( 0.0%)	6 ( 40.0%)	8 ( 53.3%)	15
Gaze palsy	4 ( 26.7%)	2 ( 13.3%)	5 ( 33.3%)	4 ( 26.7%)	15
Excessive cerumen production	0 ( 0.0%)	4 ( 26.7%)	9 ( 60.0%)	2 ( 13.3%)	15
Vascular purpura	0 ( 0.0%)	2 ( 13.3%)	5 ( 33.3%)	8 ( 53.3%)	15
Vein collapse	3 ( 20.0%)	3 ( 20.0%)	8 ( 53.3%)	1 ( 6.7%)	15
Renal haematoma	0 ( 0.0%)	4 ( 26.7%)	8 ( 53.3%)	3 ( 20.0%)	15
Haemodialysis	3 ( 20.0%)	1 ( 6.7%)	6 ( 40.0%)	5 ( 33.3%)	15
Blood iron abnormal	0 ( 0.0%)	2 ( 13.3%)	12 ( 80.0%)	1 ( 6.7%)	15
Insulinoma	0 ( 0.0%)	10 ( 66.7%)	1 ( 6.7%)	4 ( 26.7%)	15
Cystitis bacterial	4 ( 26.7%)	3 ( 20.0%)	5 ( 33.3%)	3 ( 20.0%)	15
Viral haemorrhagic cystitis	8 ( 53.3%)	2 ( 13.3%)	5 ( 33.3%)	0 ( 0.0%)	15
Proteus infection	3 ( 20.0%)	3 ( 20.0%)	7 ( 46.7%)	2 ( 13.3%)	15
Intestinal pseudo-obstruction	0 ( 0.0%)	4 ( 26.7%)	11 ( 73.3%)	0 ( 0.0%)	15
Genital hypoaesthesia	8 ( 53.3%)	7 ( 46.7%)	0 ( 0.0%)	0 ( 0.0%)	15
Intra-ocular injection complication	0 ( 0.0%)	0 ( 0.0%)	6 ( 40.0%)	9 ( 60.0%)	15
Cerebrovascular disorder	1 ( 6.7%)	4 ( 26.7%)	7 ( 46.7%)	3 ( 20.0%)	15
Gastrointestinal scarring	2 ( 13.3%)	3 ( 20.0%)	7 ( 46.7%)	3 ( 20.0%)	15
Intraventricular haemorrhage	2 ( 13.3%)	3 ( 20.0%)	4 ( 26.7%)	6 ( 40.0%)	15

### Reaction Summary Table Derived Age Group

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Intraventricular haemorrhage neonatal	15 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	15
Abscess drainage	1 ( 6.7%)	8 ( 53.3%)	5 ( 33.3%)	1 ( 6.7%)	15
Central nervous system vasculitis	0 ( 0.0%)	7 ( 50.0%)	7 ( 50.0%)	0 ( 0.0%)	14
Gastric pH decreased	1 ( 7.1%)	2 ( 14.3%)	11 ( 78.6%)	0 ( 0.0%)	14
Acinetobacter infection	2 ( 14.3%)	3 ( 21.4%)	9 ( 64.3%)	0 ( 0.0%)	14
Hepatorenal syndrome	4 ( 28.6%)	2 ( 14.3%)	7 ( 50.0%)	1 ( 7.1%)	14
Quadriplegia	3 ( 21.4%)	3 ( 21.4%)	7 ( 50.0%)	1 ( 7.1%)	14
Short-bowel syndrome	5 ( 35.7%)	1 ( 7.1%)	8 ( 57.1%)	0 ( 0.0%)	14
Ear operation	2 ( 14.3%)	2 ( 14.3%)	8 ( 57.1%)	2 ( 14.3%)	14
Autonomic neuropathy	1 ( 7.1%)	7 ( 50.0%)	3 ( 21.4%)	3 ( 21.4%)	14
Pelvic abscess	0 ( 0.0%)	3 ( 21.4%)	8 ( 57.1%)	3 ( 21.4%)	14
Eye ulcer	1 ( 7.1%)	5 ( 35.7%)	5 ( 35.7%)	3 ( 21.4%)	14
Breast operation	0 ( 0.0%)	3 ( 21.4%)	8 ( 57.1%)	3 ( 21.4%)	14
Faecal volume increased	2 ( 14.3%)	4 ( 28.6%)	6 ( 42.9%)	2 ( 14.3%)	14
Overlap syndrome	0 ( 0.0%)	6 ( 42.9%)	7 ( 50.0%)	1 ( 7.1%)	14
Blood insulin increased	0 ( 0.0%)	10 ( 71.4%)	3 ( 21.4%)	1 ( 7.1%)	14
Rectal adenocarcinoma	0 ( 0.0%)	3 ( 21.4%)	9 ( 64.3%)	2 ( 14.3%)	14
Limb deformity	1 ( 7.1%)	6 ( 42.9%)	4 ( 28.6%)	3 ( 21.4%)	14
Vascular rupture	0 ( 0.0%)	6 ( 42.9%)	6 ( 42.9%)	2 ( 14.3%)	14
Uhthoff's phenomenon	0 ( 0.0%)	12 ( 85.7%)	2 ( 14.3%)	0 ( 0.0%)	14
Oncologic complication	0 ( 0.0%)	2 ( 14.3%)	8 ( 57.1%)	4 ( 28.6%)	14
Chronic graft versus host disease in skin	6 ( 42.9%)	4 ( 28.6%)	4 ( 28.6%)	0 ( 0.0%)	14
Oedema mucosal	4 ( 28.6%)	2 ( 14.3%)	7 ( 50.0%)	1 ( 7.1%)	14
Occipital neuralgia	1 ( 7.1%)	7 ( 50.0%)	6 ( 42.9%)	0 ( 0.0%)	14
No device malfunction	11 ( 78.6%)	0 ( 0.0%)	3 ( 21.4%)	0 ( 0.0%)	14
Epstein Barr virus positive mucocutaneous ulcer	0 ( 0.0%)	0 ( 0.0%)	6 ( 42.9%)	8 ( 57.1%)	14
Neurologic neglect syndrome	0 ( 0.0%)	1 ( 7.1%)	12 ( 85.7%)	1 ( 7.1%)	14

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Feeding intolerance	13 ( 92.9%)	1 ( 7.1%)	0 ( 0.0%)	0 ( 0.0%)	14
SJS-TEN overlap	4 ( 28.6%)	6 ( 42.9%)	3 ( 21.4%)	1 ( 7.1%)	14
Circadian rhythm sleep disorder	0 ( 0.0%)	2 ( 14.3%)	12 ( 85.7%)	0 ( 0.0%)	14
Nail operation	0 ( 0.0%)	0 ( 0.0%)	13 ( 92.9%)	1 ( 7.1%)	14
Endometrial thickening	0 ( 0.0%)	4 ( 28.6%)	10 ( 71.4%)	0 ( 0.0%)	14
Myosclerosis	0 ( 0.0%)	8 ( 57.1%)	6 ( 42.9%)	0 ( 0.0%)	14
Encephalomalacia	1 ( 7.1%)	2 ( 14.3%)	10 ( 71.4%)	1 ( 7.1%)	14
Mutism	0 ( 0.0%)	3 ( 21.4%)	8 ( 57.1%)	3 ( 21.4%)	14
Electrocardiogram QRS complex shortened	6 ( 42.9%)	5 ( 35.7%)	1 ( 7.1%)	2 ( 14.3%)	14
Morton's neuralgia	0 ( 0.0%)	1 ( 7.1%)	13 ( 92.9%)	0 ( 0.0%)	14
Bronchial hyperreactivity	1 ( 7.1%)	3 ( 21.4%)	9 ( 64.3%)	1 ( 7.1%)	14
Alpha 1 foetoprotein increased	0 ( 0.0%)	0 ( 0.0%)	11 ( 78.6%)	3 ( 21.4%)	14
Monoclonal gammopathy	0 ( 0.0%)	4 ( 28.6%)	6 ( 42.9%)	4 ( 28.6%)	14
Metastatic renal cell carcinoma	0 ( 0.0%)	4 ( 28.6%)	8 ( 57.1%)	2 ( 14.3%)	14
Pelvic inflammatory disease	3 ( 21.4%)	7 ( 50.0%)	3 ( 21.4%)	1 ( 7.1%)	14
Urinary tract infection enterococcal	1 ( 7.1%)	1 ( 7.1%)	9 ( 64.3%)	3 ( 21.4%)	14
Mesenteric panniculitis	0 ( 0.0%)	7 ( 50.0%)	5 ( 35.7%)	2 ( 14.3%)	14
Meningitis pneumococcal	1 ( 7.1%)	3 ( 21.4%)	10 ( 71.4%)	0 ( 0.0%)	14
Skin bacterial infection	1 ( 7.1%)	4 ( 28.6%)	8 ( 57.1%)	1 ( 7.1%)	14
Penis disorder	4 ( 28.6%)	4 ( 28.6%)	5 ( 35.7%)	1 ( 7.1%)	14
Measles	8 ( 57.1%)	3 ( 21.4%)	3 ( 21.4%)	0 ( 0.0%)	14
Colon neoplasm	0 ( 0.0%)	3 ( 21.4%)	6 ( 42.9%)	5 ( 35.7%)	14
Colon operation	0 ( 0.0%)	3 ( 21.4%)	8 ( 57.1%)	3 ( 21.4%)	14
Drug level fluctuating	9 ( 64.3%)	2 ( 14.3%)	3 ( 21.4%)	0 ( 0.0%)	14
Brain contusion	0 ( 0.0%)	2 ( 14.3%)	7 ( 50.0%)	5 ( 35.7%)	14
Skull fracture	3 ( 21.4%)	4 ( 28.6%)	5 ( 35.7%)	2 ( 14.3%)	14
Sleep disorder therapy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	14 (100.0%)	14

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Drug abuser	7 ( 50.0%)	2 ( 14.3%)	5 ( 35.7%)	0 ( 0.0%)	14
Malignant ascites	1 ( 7.1%)	2 ( 14.3%)	6 ( 42.9%)	5 ( 35.7%)	14
Botulism	0 ( 0.0%)	9 ( 64.3%)	5 ( 35.7%)	0 ( 0.0%)	14
Disturbance in social behaviour	5 ( 35.7%)	5 ( 35.7%)	3 ( 21.4%)	1 ( 7.1%)	14
Soliloquy	0 ( 0.0%)	8 ( 57.1%)	5 ( 35.7%)	1 ( 7.1%)	14
Lung carcinoma cell type unspecified stage IV	0 ( 0.0%)	0 ( 0.0%)	11 ( 78.6%)	3 ( 21.4%)	14
Low density lipoprotein decreased	0 ( 0.0%)	0 ( 0.0%)	11 ( 78.6%)	3 ( 21.4%)	14
Application site discolouration	1 ( 7.1%)	4 ( 28.6%)	8 ( 57.1%)	1 ( 7.1%)	14
Cross sensitivity reaction	3 ( 21.4%)	1 ( 7.1%)	6 ( 42.9%)	4 ( 28.6%)	14
Lipoedema	1 ( 7.1%)	10 ( 71.4%)	2 ( 14.3%)	1 ( 7.1%)	14
Lipids abnormal	1 ( 7.1%)	5 ( 35.7%)	7 ( 50.0%)	1 ( 7.1%)	14
Lipid metabolism disorder	0 ( 0.0%)	3 ( 21.4%)	10 ( 71.4%)	1 ( 7.1%)	14
Critical illness	3 ( 21.4%)	2 ( 14.3%)	7 ( 50.0%)	2 ( 14.3%)	14
Foetal heart rate abnormal	1 ( 7.1%)	13 ( 92.9%)	0 ( 0.0%)	0 ( 0.0%)	14
Bladder operation	0 ( 0.0%)	2 ( 14.3%)	11 ( 78.6%)	1 ( 7.1%)	14
Infection parasitic	2 ( 14.3%)	7 ( 50.0%)	5 ( 35.7%)	0 ( 0.0%)	14
Catheter placement	2 ( 14.3%)	1 ( 7.1%)	7 ( 50.0%)	4 ( 28.6%)	14
Blood urea abnormal	1 ( 7.1%)	4 ( 28.6%)	6 ( 42.9%)	3 ( 21.4%)	14
Dissociative disorder	1 ( 7.1%)	12 ( 85.7%)	1 ( 7.1%)	0 ( 0.0%)	14
Dermatitis exfoliative	1 ( 7.1%)	2 ( 14.3%)	10 ( 71.4%)	1 ( 7.1%)	14
Klebsiella urinary tract infection	0 ( 0.0%)	3 ( 21.4%)	7 ( 50.0%)	4 ( 28.6%)	14
Klebsiella test positive	0 ( 0.0%)	5 ( 35.7%)	9 ( 64.3%)	0 ( 0.0%)	14
Klebsiella sepsis	2 ( 14.3%)	5 ( 35.7%)	5 ( 35.7%)	2 ( 14.3%)	14
Dental restoration failure	0 ( 0.0%)	2 ( 14.3%)	7 ( 50.0%)	5 ( 35.7%)	14
Pupillary reflex impaired	6 ( 42.9%)	4 ( 28.6%)	3 ( 21.4%)	1 ( 7.1%)	14
Stoma prolapse	4 ( 28.6%)	5 ( 35.7%)	5 ( 35.7%)	0 ( 0.0%)	14
Nail bed inflammation	0 ( 0.0%)	8 ( 57.1%)	5 ( 35.7%)	1 ( 7.1%)	14

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Injection site atrophy	5 ( 35.7%)	6 ( 42.9%)	3 ( 21.4%)	0 ( 0.0%)	14
Testicular swelling	0 ( 0.0%)	4 ( 28.6%)	8 ( 57.1%)	2 ( 14.3%)	14
Implant site infection	1 ( 7.1%)	8 ( 57.1%)	5 ( 35.7%)	0 ( 0.0%)	14
Infected fistula	4 ( 28.6%)	4 ( 28.6%)	5 ( 35.7%)	1 ( 7.1%)	14
Tumour marker abnormal	0 ( 0.0%)	2 ( 14.3%)	10 ( 71.4%)	2 ( 14.3%)	14
Needle fatigue	2 ( 14.3%)	2 ( 14.3%)	10 ( 71.4%)	0 ( 0.0%)	14
Incisional hernia	0 ( 0.0%)	6 ( 42.9%)	6 ( 42.9%)	2 ( 14.3%)	14
Thyroid hormones increased	0 ( 0.0%)	2 ( 14.3%)	10 ( 71.4%)	2 ( 14.3%)	14
Immune-mediated cystitis	0 ( 0.0%)	1 ( 7.1%)	12 ( 85.7%)	1 ( 7.1%)	14
Anticoagulant-related nephropathy	0 ( 0.0%)	0 ( 0.0%)	9 ( 64.3%)	5 ( 35.7%)	14
Dose calculation error	10 ( 71.4%)	2 ( 14.3%)	2 ( 14.3%)	0 ( 0.0%)	14
Cyanosis neonatal	14 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	14
Thyroiditis subacute	0 ( 0.0%)	4 ( 28.6%)	9 ( 64.3%)	1 ( 7.1%)	14
Immune-mediated hyperthyroidism	0 ( 0.0%)	3 ( 21.4%)	10 ( 71.4%)	1 ( 7.1%)	14
Immune-mediated encephalitis	0 ( 0.0%)	1 ( 7.1%)	10 ( 71.4%)	3 ( 21.4%)	14
Thrombocytopenic purpura	1 ( 7.1%)	3 ( 21.4%)	6 ( 42.9%)	4 ( 28.6%)	14
Pneumonia influenzal	3 ( 21.4%)	5 ( 35.7%)	6 ( 42.9%)	0 ( 0.0%)	14
Therapeutic response changed	4 ( 28.6%)	5 ( 35.7%)	5 ( 35.7%)	0 ( 0.0%)	14
Tracheitis	10 ( 71.4%)	2 ( 14.3%)	0 ( 0.0%)	2 ( 14.3%)	14
Post 5-alpha-reductase inhibitor syndrome	0 ( 0.0%)	10 ( 71.4%)	4 ( 28.6%)	0 ( 0.0%)	14
Epiglottitis	1 ( 7.1%)	1 ( 7.1%)	12 ( 85.7%)	0 ( 0.0%)	14
Hypertensive emergency	0 ( 0.0%)	1 ( 7.1%)	13 ( 92.9%)	0 ( 0.0%)	14
Tuberculin test positive	0 ( 0.0%)	4 ( 28.6%)	10 ( 71.4%)	0 ( 0.0%)	14
Computerised tomogram thorax abnormal	1 ( 7.1%)	7 ( 50.0%)	3 ( 21.4%)	3 ( 21.4%)	14
Coagulation factor deficiency	0 ( 0.0%)	0 ( 0.0%)	12 ( 85.7%)	2 ( 14.3%)	14
Infusion site warmth	4 ( 28.6%)	2 ( 14.3%)	7 ( 50.0%)	1 ( 7.1%)	14
Hepatitis A	0 ( 0.0%)	3 ( 21.4%)	11 ( 78.6%)	0 ( 0.0%)	14

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Urine flow decreased	0 ( 0.0%)	5 ( 35.7%)	7 ( 50.0%)	2 ( 14.3%)	14
Administration site swelling	1 ( 7.1%)	5 ( 35.7%)	5 ( 35.7%)	3 ( 21.4%)	14
Cortisol increased	0 ( 0.0%)	8 ( 57.1%)	6 ( 42.9%)	0 ( 0.0%)	14
Clear cell renal cell carcinoma	0 ( 0.0%)	9 ( 64.3%)	5 ( 35.7%)	0 ( 0.0%)	14
Injection site ulcer	2 ( 14.3%)	4 ( 28.6%)	8 ( 57.1%)	0 ( 0.0%)	14
Vascular occlusion	1 ( 7.1%)	2 ( 14.3%)	9 ( 64.3%)	2 ( 14.3%)	14
Whipple's disease	0 ( 0.0%)	4 ( 28.6%)	10 ( 71.4%)	0 ( 0.0%)	14
Haemorrhagic cyst	5 ( 35.7%)	4 ( 28.6%)	5 ( 35.7%)	0 ( 0.0%)	14
Chronic allograft nephropathy	1 ( 7.1%)	5 ( 35.7%)	8 ( 57.1%)	0 ( 0.0%)	14
Renal abscess	2 ( 14.3%)	5 ( 35.7%)	6 ( 42.9%)	1 ( 7.1%)	14
Ocular myasthenia	0 ( 0.0%)	0 ( 0.0%)	10 ( 71.4%)	4 ( 28.6%)	14
Angiocentric lymphoma	10 ( 71.4%)	0 ( 0.0%)	3 ( 21.4%)	1 ( 7.1%)	14
Cystitis interstitial	1 ( 7.1%)	3 ( 21.4%)	9 ( 64.3%)	1 ( 7.1%)	14
Vitamin B complex deficiency	0 ( 0.0%)	7 ( 50.0%)	5 ( 35.7%)	2 ( 14.3%)	14
Intestinal angioedema	0 ( 0.0%)	2 ( 14.3%)	7 ( 50.0%)	5 ( 35.7%)	14
Vulvovaginal swelling	1 ( 7.1%)	3 ( 21.4%)	10 ( 71.4%)	0 ( 0.0%)	14
Accidental poisoning	2 ( 14.3%)	6 ( 42.9%)	5 ( 35.7%)	1 ( 7.1%)	14
Gestational hypertension	1 ( 7.1%)	13 ( 92.9%)	0 ( 0.0%)	0 ( 0.0%)	14
Penile discomfort	0 ( 0.0%)	9 ( 64.3%)	4 ( 28.6%)	1 ( 7.1%)	14
Acute sinusitis	1 ( 7.1%)	5 ( 35.7%)	7 ( 50.0%)	1 ( 7.1%)	14
Cerebral toxoplasmosis	3 ( 21.4%)	1 ( 7.1%)	9 ( 64.3%)	1 ( 7.1%)	14
Cerebral microhaemorrhage	1 ( 7.1%)	4 ( 28.6%)	9 ( 64.3%)	0 ( 0.0%)	14
Postrenal failure	0 ( 0.0%)	1 ( 7.1%)	4 ( 28.6%)	9 ( 64.3%)	14
Haemobilia	1 ( 7.7%)	2 ( 15.4%)	4 ( 30.8%)	6 ( 46.2%)	13
Opportunistic infection	1 ( 7.7%)	8 ( 61.5%)	3 ( 23.1%)	1 ( 7.7%)	13
Death neonatal	8 ( 61.5%)	3 ( 23.1%)	2 ( 15.4%)	0 ( 0.0%)	13
Glycosuria	4 ( 30.8%)	2 ( 15.4%)	6 ( 46.2%)	1 ( 7.7%)	13

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Gait spastic	0 ( 0.0%)	2 ( 15.4%)	11 ( 84.6%)	0 ( 0.0%)	13
B-lymphocyte count increased	0 ( 0.0%)	8 ( 61.5%)	5 ( 38.5%)	0 ( 0.0%)	13
Food interaction	1 ( 7.7%)	6 ( 46.2%)	5 ( 38.5%)	1 ( 7.7%)	13
Renal vasculitis	1 ( 7.7%)	2 ( 15.4%)	9 ( 69.2%)	1 ( 7.7%)	13
Perineal abscess	1 ( 7.7%)	8 ( 61.5%)	4 ( 30.8%)	0 ( 0.0%)	13
Metastases to pleura	0 ( 0.0%)	4 ( 30.8%)	8 ( 61.5%)	1 ( 7.7%)	13
Ear injury	0 ( 0.0%)	1 ( 7.7%)	12 ( 92.3%)	0 ( 0.0%)	13
Paraesthesia ear	0 ( 0.0%)	3 ( 23.1%)	10 ( 76.9%)	0 ( 0.0%)	13
Vasospasm	1 ( 7.7%)	7 ( 53.8%)	5 ( 38.5%)	0 ( 0.0%)	13
Ovarian mass	0 ( 0.0%)	4 ( 30.8%)	8 ( 61.5%)	1 ( 7.7%)	13
Migraine without aura	1 ( 7.7%)	11 ( 84.6%)	1 ( 7.7%)	0 ( 0.0%)	13
Haemorrhage in pregnancy	3 ( 23.1%)	10 ( 76.9%)	0 ( 0.0%)	0 ( 0.0%)	13
Carbuncle	0 ( 0.0%)	2 ( 15.4%)	2 ( 15.4%)	9 ( 69.2%)	13
Renal tubular atrophy	2 ( 15.4%)	1 ( 7.7%)	7 ( 53.8%)	3 ( 23.1%)	13
Ophthalmoplegia	2 ( 15.4%)	2 ( 15.4%)	9 ( 69.2%)	0 ( 0.0%)	13
Ejaculation failure	0 ( 0.0%)	8 ( 61.5%)	5 ( 38.5%)	0 ( 0.0%)	13
Amniotic cavity infection	7 ( 53.8%)	6 ( 46.2%)	0 ( 0.0%)	0 ( 0.0%)	13
Obsessive-compulsive symptom	11 ( 84.6%)	1 ( 7.7%)	1 ( 7.7%)	0 ( 0.0%)	13
Essential thrombocythaemia	0 ( 0.0%)	2 ( 15.4%)	8 ( 61.5%)	3 ( 23.1%)	13
Non-cardiogenic pulmonary oedema	1 ( 7.7%)	10 ( 76.9%)	2 ( 15.4%)	0 ( 0.0%)	13
Non-alcoholic fatty liver	1 ( 7.7%)	6 ( 46.2%)	5 ( 38.5%)	1 ( 7.7%)	13
Neuromuscular toxicity	0 ( 0.0%)	2 ( 15.4%)	7 ( 53.8%)	4 ( 30.8%)	13
Feeling guilty	5 ( 38.5%)	5 ( 38.5%)	3 ( 23.1%)	0 ( 0.0%)	13
Parathyroid disorder	0 ( 0.0%)	2 ( 15.4%)	11 ( 84.6%)	0 ( 0.0%)	13
Bullous haemorrhagic dermatosis	0 ( 0.0%)	1 ( 7.7%)	5 ( 38.5%)	7 ( 53.8%)	13
Urticarial vasculitis	4 ( 30.8%)	3 ( 23.1%)	5 ( 38.5%)	1 ( 7.7%)	13
Bronchitis bacterial	2 ( 15.4%)	4 ( 30.8%)	7 ( 53.8%)	0 ( 0.0%)	13



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Multimorbidity	1 ( 7.7%)	1 ( 7.7%)	7 ( 53.8%)	4 ( 30.8%)	13
Mucosal haemorrhage	3 ( 23.1%)	5 ( 38.5%)	3 ( 23.1%)	2 ( 15.4%)	13
Hepatobiliary disease	1 ( 7.7%)	4 ( 30.8%)	8 ( 61.5%)	0 ( 0.0%)	13
Microangiopathic haemolytic anaemia	0 ( 0.0%)	4 ( 30.8%)	6 ( 46.2%)	3 ( 23.1%)	13
Metastatic squamous cell carcinoma	0 ( 0.0%)	2 ( 15.4%)	10 ( 76.9%)	1 ( 7.7%)	13
Blood folate decreased	1 ( 7.7%)	4 ( 30.8%)	6 ( 46.2%)	2 ( 15.4%)	13
Breast conserving surgery	0 ( 0.0%)	5 ( 38.5%)	7 ( 53.8%)	1 ( 7.7%)	13
Carotid artery disease	0 ( 0.0%)	1 ( 7.7%)	6 ( 46.2%)	6 ( 46.2%)	13
Dyshidrotic eczema	1 ( 7.7%)	7 ( 53.8%)	4 ( 30.8%)	1 ( 7.7%)	13
Meningitis viral	3 ( 23.1%)	7 ( 53.8%)	3 ( 23.1%)	0 ( 0.0%)	13
Medical device pain	3 ( 23.1%)	3 ( 23.1%)	4 ( 30.8%)	3 ( 23.1%)	13
Drug withdrawal syndrome neonatal	13 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	13
Mechanical ventilation	4 ( 30.8%)	1 ( 7.7%)	7 ( 53.8%)	1 ( 7.7%)	13
Mechanical ileus	0 ( 0.0%)	0 ( 0.0%)	7 ( 53.8%)	6 ( 46.2%)	13
Mastocytosis	2 ( 15.4%)	7 ( 53.8%)	3 ( 23.1%)	1 ( 7.7%)	13
Mammoplasty	0 ( 0.0%)	8 ( 61.5%)	5 ( 38.5%)	0 ( 0.0%)	13
Malocclusion	6 ( 46.2%)	1 ( 7.7%)	6 ( 46.2%)	0 ( 0.0%)	13
Intermittent claudication	0 ( 0.0%)	2 ( 15.4%)	8 ( 61.5%)	3 ( 23.1%)	13
Bladder dilatation	1 ( 7.7%)	8 ( 61.5%)	2 ( 15.4%)	2 ( 15.4%)	13
Allergic cough	1 ( 7.7%)	1 ( 7.7%)	10 ( 76.9%)	1 ( 7.7%)	13
Lung hyperinflation	0 ( 0.0%)	4 ( 30.8%)	7 ( 53.8%)	2 ( 15.4%)	13
Lung diffusion test decreased	0 ( 0.0%)	1 ( 7.7%)	10 ( 76.9%)	2 ( 15.4%)	13
Folate deficiency	0 ( 0.0%)	2 ( 15.4%)	4 ( 30.8%)	7 ( 53.8%)	13
Discoloured vomit	1 ( 7.7%)	0 ( 0.0%)	7 ( 53.8%)	5 ( 38.5%)	13
Myelodysplastic syndrome with excess blasts	1 ( 7.7%)	2 ( 15.4%)	9 ( 69.2%)	1 ( 7.7%)	13
Human rhinovirus test positive	7 ( 53.8%)	3 ( 23.1%)	3 ( 23.1%)	0 ( 0.0%)	13
Humidity intolerance	0 ( 0.0%)	2 ( 15.4%)	9 ( 69.2%)	2 ( 15.4%)	13

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Liver carcinoma ruptured	0 ( 0.0%)	2 ( 15.4%)	8 ( 61.5%)	3 ( 23.1%)	13
Croup infectious	11 ( 84.6%)	0 ( 0.0%)	1 ( 7.7%)	1 ( 7.7%)	13
Lip ulceration	2 ( 15.4%)	5 ( 38.5%)	4 ( 30.8%)	2 ( 15.4%)	13
Diaphragmalgia	0 ( 0.0%)	2 ( 15.4%)	11 ( 84.6%)	0 ( 0.0%)	13
Lip erosion	0 ( 0.0%)	3 ( 23.1%)	8 ( 61.5%)	2 ( 15.4%)	13
Appendix disorder	2 ( 15.4%)	1 ( 7.7%)	8 ( 61.5%)	2 ( 15.4%)	13
Body surface area increased	0 ( 0.0%)	5 ( 38.5%)	8 ( 61.5%)	0 ( 0.0%)	13
Anterior chamber inflammation	0 ( 0.0%)	1 ( 7.7%)	8 ( 61.5%)	4 ( 30.8%)	13
Device maintenance issue	3 ( 23.1%)	2 ( 15.4%)	5 ( 38.5%)	3 ( 23.1%)	13
Bloody discharge	2 ( 15.4%)	1 ( 7.7%)	6 ( 46.2%)	4 ( 30.8%)	13
Blood urea decreased	4 ( 30.8%)	5 ( 38.5%)	3 ( 23.1%)	1 ( 7.7%)	13
Granulocyte count increased	0 ( 0.0%)	7 ( 53.8%)	5 ( 38.5%)	1 ( 7.7%)	13
Apallic syndrome	2 ( 15.4%)	1 ( 7.7%)	8 ( 61.5%)	2 ( 15.4%)	13
Aortitis	0 ( 0.0%)	1 ( 7.7%)	9 ( 69.2%)	3 ( 23.1%)	13
Aortic valve replacement	0 ( 0.0%)	0 ( 0.0%)	6 ( 46.2%)	7 ( 53.8%)	13
Invasive breast carcinoma	0 ( 0.0%)	9 ( 69.2%)	4 ( 30.8%)	0 ( 0.0%)	13
Wrong drug	1 ( 7.7%)	0 ( 0.0%)	0 ( 0.0%)	12 ( 92.3%)	13
Intracranial mass	0 ( 0.0%)	1 ( 7.7%)	11 ( 84.6%)	1 ( 7.7%)	13
Stress urinary incontinence	0 ( 0.0%)	4 ( 30.8%)	6 ( 46.2%)	3 ( 23.1%)	13
Cryopyrin associated periodic syndrome	1 ( 7.7%)	10 ( 76.9%)	1 ( 7.7%)	1 ( 7.7%)	13
Nasal crusting	0 ( 0.0%)	3 ( 23.1%)	9 ( 69.2%)	1 ( 7.7%)	13
Puncture site pain	5 ( 38.5%)	2 ( 15.4%)	6 ( 46.2%)	0 ( 0.0%)	13
Venous injury	4 ( 30.8%)	1 ( 7.7%)	6 ( 46.2%)	2 ( 15.4%)	13
Coronary artery thrombosis	2 ( 15.4%)	1 ( 7.7%)	6 ( 46.2%)	4 ( 30.8%)	13
T-lymphocyte count decreased	2 ( 15.4%)	2 ( 15.4%)	5 ( 38.5%)	4 ( 30.8%)	13
Enterococcus test positive	2 ( 15.4%)	4 ( 30.8%)	6 ( 46.2%)	1 ( 7.7%)	13
Therapeutic product effect increased	2 ( 15.4%)	2 ( 15.4%)	6 ( 46.2%)	3 ( 23.1%)	13

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Amaurosis fugax	0 ( 0.0%)	3 ( 23.1%)	9 ( 69.2%)	1 ( 7.7%)	13
Abdominal symptom	3 ( 23.1%)	2 ( 15.4%)	7 ( 53.8%)	1 ( 7.7%)	13
Infection in an immunocompromised host	1 ( 7.7%)	4 ( 30.8%)	5 ( 38.5%)	3 ( 23.1%)	13
Jaw fracture	0 ( 0.0%)	0 ( 0.0%)	10 ( 76.9%)	3 ( 23.1%)	13
Pseudostroke	1 ( 7.7%)	1 ( 7.7%)	10 ( 76.9%)	1 ( 7.7%)	13
C-reactive protein decreased	0 ( 0.0%)	2 ( 15.4%)	10 ( 76.9%)	1 ( 7.7%)	13
Gambling disorder	1 ( 7.7%)	3 ( 23.1%)	9 ( 69.2%)	0 ( 0.0%)	13
Transient global amnesia	1 ( 7.7%)	1 ( 7.7%)	10 ( 76.9%)	1 ( 7.7%)	13
Total lung capacity abnormal	0 ( 0.0%)	1 ( 7.7%)	12 ( 92.3%)	0 ( 0.0%)	13
Fungal oesophagitis	0 ( 0.0%)	6 ( 46.2%)	5 ( 38.5%)	2 ( 15.4%)	13
Pneumonia mycoplasmal	7 ( 53.8%)	1 ( 7.7%)	4 ( 30.8%)	1 ( 7.7%)	13
Gastric fistula	0 ( 0.0%)	2 ( 15.4%)	10 ( 76.9%)	1 ( 7.7%)	13
Contrast encephalopathy	0 ( 0.0%)	3 ( 23.1%)	6 ( 46.2%)	4 ( 30.8%)	13
Central nervous system lupus	0 ( 0.0%)	13 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	13
Central nervous system lymphoma	0 ( 0.0%)	2 ( 15.4%)	9 ( 69.2%)	2 ( 15.4%)	13
Consciousness fluctuating	1 ( 7.7%)	0 ( 0.0%)	10 ( 76.9%)	2 ( 15.4%)	13
Tracheal stenosis	2 ( 15.4%)	2 ( 15.4%)	8 ( 61.5%)	1 ( 7.7%)	13
Anticoagulation drug level above therapeutic	1 ( 7.7%)	0 ( 0.0%)	8 ( 61.5%)	4 ( 30.8%)	13
Superior vena cava syndrome	2 ( 15.4%)	3 ( 23.1%)	6 ( 46.2%)	2 ( 15.4%)	13
Sudden cardiac death	1 ( 7.7%)	0 ( 0.0%)	9 ( 69.2%)	3 ( 23.1%)	13
Biliary tract infection	0 ( 0.0%)	4 ( 30.8%)	8 ( 61.5%)	1 ( 7.7%)	13
Streptococcus test positive	2 ( 15.4%)	4 ( 30.8%)	7 ( 53.8%)	0 ( 0.0%)	13
Splenic rupture	0 ( 0.0%)	2 ( 15.4%)	5 ( 38.5%)	6 ( 46.2%)	13
Gastrointestinal anastomotic leak	0 ( 0.0%)	1 ( 7.7%)	12 ( 92.3%)	0 ( 0.0%)	13
Hyperadrenocorticism	0 ( 0.0%)	1 ( 7.7%)	12 ( 92.3%)	0 ( 0.0%)	13
Soft tissue mass	0 ( 0.0%)	5 ( 38.5%)	6 ( 46.2%)	2 ( 15.4%)	13
Hilar lymphadenopathy	1 ( 7.7%)	4 ( 30.8%)	7 ( 53.8%)	1 ( 7.7%)	13

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Sitting disability	0 ( 0.0%)	8 ( 61.5%)	1 ( 7.7%)	4 ( 30.8%)	13
Heart sounds	0 ( 0.0%)	0 ( 0.0%)	13 (100.0%)	0 ( 0.0%)	13
Primary hypothyroidism	1 ( 7.7%)	0 ( 0.0%)	9 ( 69.2%)	3 ( 23.1%)	13
Biopsy	0 ( 0.0%)	2 ( 15.4%)	8 ( 61.5%)	3 ( 23.1%)	13
Proctectomy	1 ( 7.7%)	10 ( 76.9%)	2 ( 15.4%)	0 ( 0.0%)	13
Hemianopia	0 ( 0.0%)	10 ( 76.9%)	3 ( 23.1%)	0 ( 0.0%)	13
Chronic myelomonocytic leukaemia	0 ( 0.0%)	0 ( 0.0%)	8 ( 61.5%)	5 ( 38.5%)	13
Retinal pigment epitheliopathy	0 ( 0.0%)	4 ( 30.8%)	4 ( 30.8%)	5 ( 38.5%)	13
Blood triglycerides abnormal	1 ( 7.7%)	3 ( 23.1%)	8 ( 61.5%)	1 ( 7.7%)	13
Obstruction gastric	2 ( 15.4%)	1 ( 7.7%)	8 ( 61.5%)	2 ( 15.4%)	13
Retinal dystrophy	1 ( 7.7%)	7 ( 53.8%)	5 ( 38.5%)	0 ( 0.0%)	13
Product contamination microbial	3 ( 23.1%)	3 ( 23.1%)	6 ( 46.2%)	1 ( 7.7%)	13
Traumatic haematoma	4 ( 30.8%)	1 ( 7.7%)	5 ( 38.5%)	3 ( 23.1%)	13
Wernicke's encephalopathy	3 ( 23.1%)	1 ( 7.7%)	9 ( 69.2%)	0 ( 0.0%)	13
Abdominal operation	1 ( 7.7%)	4 ( 30.8%)	6 ( 46.2%)	2 ( 15.4%)	13
Intertrigo	1 ( 7.7%)	2 ( 15.4%)	9 ( 69.2%)	1 ( 7.7%)	13
Pulmonary infarction	2 ( 15.4%)	6 ( 46.2%)	3 ( 23.1%)	2 ( 15.4%)	13
Glomerulonephritis minimal lesion	0 ( 0.0%)	0 ( 0.0%)	13 (100.0%)	0 ( 0.0%)	13
Polyserositis	1 ( 7.7%)	10 ( 76.9%)	2 ( 15.4%)	0 ( 0.0%)	13
Viral diarrhoea	5 ( 38.5%)	1 ( 7.7%)	3 ( 23.1%)	4 ( 30.8%)	13
Acne pustular	2 ( 15.4%)	3 ( 23.1%)	7 ( 53.8%)	1 ( 7.7%)	13
Product tampering	0 ( 0.0%)	6 ( 46.2%)	7 ( 53.8%)	0 ( 0.0%)	13
Product package associated injury	0 ( 0.0%)	1 ( 7.7%)	7 ( 53.8%)	5 ( 38.5%)	13
Family stress	0 ( 0.0%)	3 ( 23.1%)	8 ( 61.5%)	2 ( 15.4%)	13
Defect conduction intraventricular	1 ( 7.7%)	6 ( 46.2%)	4 ( 30.8%)	2 ( 15.4%)	13
Breast cellulitis	0 ( 0.0%)	4 ( 30.8%)	8 ( 61.5%)	1 ( 7.7%)	13
Premature menopause	1 ( 7.7%)	12 ( 92.3%)	0 ( 0.0%)	0 ( 0.0%)	13

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Vascular injury	0 ( 0.0%)	2 ( 15.4%)	5 ( 38.5%)	6 ( 46.2%)	13
Delayed graft function	0 ( 0.0%)	5 ( 38.5%)	8 ( 61.5%)	0 ( 0.0%)	13
Intestinal infarction	0 ( 0.0%)	0 ( 0.0%)	9 ( 69.2%)	4 ( 30.8%)	13
Post-injection delirium sedation syndrome	3 ( 23.1%)	7 ( 53.8%)	3 ( 23.1%)	0 ( 0.0%)	13
International normalised ratio abnormal	1 ( 7.7%)	1 ( 7.7%)	9 ( 69.2%)	2 ( 15.4%)	13
Device ineffective	3 ( 25.0%)	1 ( 8.3%)	5 ( 41.7%)	3 ( 25.0%)	12
Gastric varices	0 ( 0.0%)	1 ( 8.3%)	11 ( 91.7%)	0 ( 0.0%)	12
Pneumonitis aspiration	1 ( 8.3%)	7 ( 58.3%)	1 ( 8.3%)	3 ( 25.0%)	12
Vascular calcification	2 ( 16.7%)	8 ( 66.7%)	2 ( 16.7%)	0 ( 0.0%)	12
Haemorrhagic infarction	0 ( 0.0%)	6 ( 50.0%)	2 ( 16.7%)	4 ( 33.3%)	12
Granulomatous liver disease	2 ( 16.7%)	4 ( 33.3%)	6 ( 50.0%)	0 ( 0.0%)	12
Ear neoplasm	0 ( 0.0%)	2 ( 16.7%)	6 ( 50.0%)	4 ( 33.3%)	12
Device related bacteraemia	5 ( 41.7%)	0 ( 0.0%)	7 ( 58.3%)	0 ( 0.0%)	12
Otitis media acute	7 ( 58.3%)	2 ( 16.7%)	3 ( 25.0%)	0 ( 0.0%)	12
Parotitis	0 ( 0.0%)	2 ( 16.7%)	10 ( 83.3%)	0 ( 0.0%)	12
Paraneoplastic syndrome	0 ( 0.0%)	3 ( 25.0%)	8 ( 66.7%)	1 ( 8.3%)	12
Renal amyloidosis	1 ( 8.3%)	2 ( 16.7%)	3 ( 25.0%)	6 ( 50.0%)	12
Anaemia of chronic disease	2 ( 16.7%)	4 ( 33.3%)	4 ( 33.3%)	2 ( 16.7%)	12
Cardiac fibrillation	0 ( 0.0%)	1 ( 8.3%)	9 ( 75.0%)	2 ( 16.7%)	12
Venous occlusion	0 ( 0.0%)	3 ( 25.0%)	6 ( 50.0%)	3 ( 25.0%)	12
Facial spasm	3 ( 25.0%)	5 ( 41.7%)	1 ( 8.3%)	3 ( 25.0%)	12
Ovarian disorder	0 ( 0.0%)	7 ( 58.3%)	4 ( 33.3%)	1 ( 8.3%)	12
Atrial tachycardia	0 ( 0.0%)	2 ( 16.7%)	8 ( 66.7%)	2 ( 16.7%)	12
Extradural haematoma	1 ( 8.3%)	3 ( 25.0%)	6 ( 50.0%)	2 ( 16.7%)	12
Oligoarthritis	1 ( 8.3%)	4 ( 33.3%)	7 ( 58.3%)	0 ( 0.0%)	12
Respiratory tract oedema	4 ( 33.3%)	3 ( 25.0%)	4 ( 33.3%)	1 ( 8.3%)	12
Oesophageal infection	1 ( 8.3%)	1 ( 8.3%)	8 ( 66.7%)	2 ( 16.7%)	12

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Injection site scab	0 ( 0.0%)	7 ( 58.3%)	5 ( 41.7%)	0 ( 0.0%)	12
Eschar	1 ( 8.3%)	2 ( 16.7%)	7 ( 58.3%)	2 ( 16.7%)	12
Neutropenic infection	1 ( 8.3%)	6 ( 50.0%)	4 ( 33.3%)	1 ( 8.3%)	12
Salpingectomy	1 ( 8.3%)	10 ( 83.3%)	1 ( 8.3%)	0 ( 0.0%)	12
Enzyme level increased	0 ( 0.0%)	6 ( 50.0%)	6 ( 50.0%)	0 ( 0.0%)	12
Infusion site scar	1 ( 8.3%)	1 ( 8.3%)	9 ( 75.0%)	1 ( 8.3%)	12
Sarcoid-like reaction	0 ( 0.0%)	3 ( 25.0%)	8 ( 66.7%)	1 ( 8.3%)	12
Enterovesical fistula	0 ( 0.0%)	5 ( 41.7%)	5 ( 41.7%)	2 ( 16.7%)	12
Nasal operation	1 ( 8.3%)	6 ( 50.0%)	5 ( 41.7%)	0 ( 0.0%)	12
Listeriosis	0 ( 0.0%)	1 ( 8.3%)	8 ( 66.7%)	3 ( 25.0%)	12
Violence-related symptom	1 ( 8.3%)	8 ( 66.7%)	3 ( 25.0%)	0 ( 0.0%)	12
Benign neoplasm of thyroid gland	0 ( 0.0%)	5 ( 41.7%)	7 ( 58.3%)	0 ( 0.0%)	12
Paroxysmal nocturnal haemoglobinuria	1 ( 8.3%)	4 ( 33.3%)	5 ( 41.7%)	2 ( 16.7%)	12
Endocarditis staphylococcal	0 ( 0.0%)	3 ( 25.0%)	4 ( 33.3%)	5 ( 41.7%)	12
Mycotic endophthalmitis	0 ( 0.0%)	1 ( 8.3%)	10 ( 83.3%)	1 ( 8.3%)	12
Clubbing	5 ( 41.7%)	1 ( 8.3%)	5 ( 41.7%)	1 ( 8.3%)	12
Uterine spasm	4 ( 33.3%)	5 ( 41.7%)	3 ( 25.0%)	0 ( 0.0%)	12
Muscle mass	0 ( 0.0%)	6 ( 50.0%)	5 ( 41.7%)	1 ( 8.3%)	12
Embolism arterial	2 ( 16.7%)	2 ( 16.7%)	8 ( 66.7%)	0 ( 0.0%)	12
Morphoea	0 ( 0.0%)	9 ( 75.0%)	3 ( 25.0%)	0 ( 0.0%)	12
Carditis	2 ( 16.7%)	3 ( 25.0%)	5 ( 41.7%)	2 ( 16.7%)	12
Arterial injury	0 ( 0.0%)	3 ( 25.0%)	5 ( 41.7%)	4 ( 33.3%)	12
Arrhythmic storm	0 ( 0.0%)	6 ( 50.0%)	6 ( 50.0%)	0 ( 0.0%)	12
Allergy to metals	1 ( 8.3%)	4 ( 33.3%)	6 ( 50.0%)	1 ( 8.3%)	12
Medication overuse headache	2 ( 16.7%)	6 ( 50.0%)	3 ( 25.0%)	1 ( 8.3%)	12
Muscle tension dysphonia	0 ( 0.0%)	11 ( 91.7%)	1 ( 8.3%)	0 ( 0.0%)	12
Drug-disease interaction	0 ( 0.0%)	8 ( 66.7%)	4 ( 33.3%)	0 ( 0.0%)	12

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Adnexa uteri pain	1 ( 8.3%)	7 ( 58.3%)	4 ( 33.3%)	0 ( 0.0%)	12
Mediastinitis	1 ( 8.3%)	0 ( 0.0%)	10 ( 83.3%)	1 ( 8.3%)	12
Mechanical urticaria	3 ( 25.0%)	7 ( 58.3%)	2 ( 16.7%)	0 ( 0.0%)	12
Drug monitoring procedure incorrectly performed	2 ( 16.7%)	5 ( 41.7%)	4 ( 33.3%)	1 ( 8.3%)	12
Skin neoplasm excision	0 ( 0.0%)	0 ( 0.0%)	7 ( 58.3%)	5 ( 41.7%)	12
Malignant neoplasm oligoprogession	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	0 ( 0.0%)	12
Male sexual dysfunction	3 ( 25.0%)	6 ( 50.0%)	3 ( 25.0%)	0 ( 0.0%)	12
Sleeve gastrectomy	1 ( 8.3%)	9 ( 75.0%)	2 ( 16.7%)	0 ( 0.0%)	12
Diverticulitis intestinal perforated	0 ( 0.0%)	5 ( 41.7%)	6 ( 50.0%)	1 ( 8.3%)	12
Lymphoid tissue hypoplasia	3 ( 25.0%)	9 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	12
Lymphocyte percentage increased	1 ( 8.3%)	3 ( 25.0%)	7 ( 58.3%)	1 ( 8.3%)	12
Unintentional use for unapproved indication	0 ( 0.0%)	6 ( 50.0%)	6 ( 50.0%)	0 ( 0.0%)	12
Periorbital irritation	6 ( 50.0%)	2 ( 16.7%)	3 ( 25.0%)	1 ( 8.3%)	12
Bone fissure	0 ( 0.0%)	1 ( 8.3%)	7 ( 58.3%)	4 ( 33.3%)	12
Bone deformity	2 ( 16.7%)	2 ( 16.7%)	8 ( 66.7%)	0 ( 0.0%)	12
Light chain disease	0 ( 0.0%)	0 ( 0.0%)	11 ( 91.7%)	1 ( 8.3%)	12
Inflammatory myofibroblastic tumour	0 ( 0.0%)	12 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	12
Lichen sclerosus	1 ( 8.3%)	1 ( 8.3%)	8 ( 66.7%)	2 ( 16.7%)	12
Diabetic complication	0 ( 0.0%)	2 ( 16.7%)	4 ( 33.3%)	6 ( 50.0%)	12
Libido disorder	2 ( 16.7%)	5 ( 41.7%)	4 ( 33.3%)	1 ( 8.3%)	12
Splenic abscess	3 ( 25.0%)	5 ( 41.7%)	4 ( 33.3%)	0 ( 0.0%)	12
QRS axis abnormal	0 ( 0.0%)	1 ( 8.3%)	8 ( 66.7%)	3 ( 25.0%)	12
Blood urea nitrogen/creatinine ratio increased	0 ( 0.0%)	1 ( 8.3%)	6 ( 50.0%)	5 ( 41.7%)	12
Detachment of retinal pigment epithelium	0 ( 0.0%)	0 ( 0.0%)	11 ( 91.7%)	1 ( 8.3%)	12
Infantile vomiting	12 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	12
Blood testosterone increased	2 ( 16.7%)	3 ( 25.0%)	5 ( 41.7%)	2 ( 16.7%)	12
Labile blood pressure	1 ( 8.3%)	1 ( 8.3%)	6 ( 50.0%)	4 ( 33.3%)	12

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Anterograde amnesia	4 ( 33.3%)	5 ( 41.7%)	1 ( 8.3%)	2 ( 16.7%)	12
Jugular vein distension	0 ( 0.0%)	4 ( 33.3%)	4 ( 33.3%)	4 ( 33.3%)	12
Vlth nerve paralysis	3 ( 25.0%)	3 ( 25.0%)	4 ( 33.3%)	2 ( 16.7%)	12
Conduction disorder	5 ( 41.7%)	3 ( 25.0%)	4 ( 33.3%)	0 ( 0.0%)	12
Bladder sphincter atony	1 ( 8.3%)	0 ( 0.0%)	11 ( 91.7%)	0 ( 0.0%)	12
Alanine aminotransferase decreased	0 ( 0.0%)	2 ( 16.7%)	6 ( 50.0%)	4 ( 33.3%)	12
Delusion of parasitosis	0 ( 0.0%)	3 ( 25.0%)	9 ( 75.0%)	0 ( 0.0%)	12
Tumour associated fever	1 ( 8.3%)	0 ( 0.0%)	9 ( 75.0%)	2 ( 16.7%)	12
Fractured sacrum	0 ( 0.0%)	4 ( 33.3%)	7 ( 58.3%)	1 ( 8.3%)	12
Hypervigilance	4 ( 33.3%)	3 ( 25.0%)	4 ( 33.3%)	1 ( 8.3%)	12
Phimosis	4 ( 33.3%)	1 ( 8.3%)	5 ( 41.7%)	2 ( 16.7%)	12
Nasal inflammation	2 ( 16.7%)	6 ( 50.0%)	3 ( 25.0%)	1 ( 8.3%)	12
Traumatic intracranial haemorrhage	1 ( 8.3%)	0 ( 0.0%)	4 ( 33.3%)	7 ( 58.3%)	12
Suture rupture	0 ( 0.0%)	1 ( 8.3%)	11 ( 91.7%)	0 ( 0.0%)	12
Suspected transmission of an infectious agent via pro	1 ( 8.3%)	4 ( 33.3%)	6 ( 50.0%)	1 ( 8.3%)	12
Blister infected	0 ( 0.0%)	1 ( 8.3%)	9 ( 75.0%)	2 ( 16.7%)	12
Vagal nerve stimulator implantation	9 ( 75.0%)	2 ( 16.7%)	1 ( 8.3%)	0 ( 0.0%)	12
Enterocolitis viral	4 ( 33.3%)	2 ( 16.7%)	5 ( 41.7%)	1 ( 8.3%)	12
Telangiectasia	2 ( 16.7%)	4 ( 33.3%)	6 ( 50.0%)	0 ( 0.0%)	12
Fractional exhaled nitric oxide increased	3 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	9 ( 75.0%)	12
Immediate post-injection reaction	0 ( 0.0%)	7 ( 58.3%)	5 ( 41.7%)	0 ( 0.0%)	12
Immune-mediated gastritis	0 ( 0.0%)	1 ( 8.3%)	10 ( 83.3%)	1 ( 8.3%)	12
Carpal tunnel decompression	0 ( 0.0%)	3 ( 25.0%)	8 ( 66.7%)	1 ( 8.3%)	12
Gamma-glutamyltransferase abnormal	1 ( 8.3%)	3 ( 25.0%)	8 ( 66.7%)	0 ( 0.0%)	12
Immunosuppressant drug level decreased	0 ( 0.0%)	5 ( 41.7%)	7 ( 58.3%)	0 ( 0.0%)	12
Tongue movement disturbance	4 ( 33.3%)	2 ( 16.7%)	4 ( 33.3%)	2 ( 16.7%)	12
Thymus hypoplasia	3 ( 25.0%)	9 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	12



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Ileostomy closure	1 ( 8.3%)	6 ( 50.0%)	5 ( 41.7%)	0 ( 0.0%)	12
Hypotonia neonatal	12 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	12
Systemic scleroderma	0 ( 0.0%)	5 ( 41.7%)	6 ( 50.0%)	1 ( 8.3%)	12
Surgical failure	0 ( 0.0%)	1 ( 8.3%)	10 ( 83.3%)	1 ( 8.3%)	12
Globulins decreased	1 ( 8.3%)	4 ( 33.3%)	4 ( 33.3%)	3 ( 25.0%)	12
Subclavian vein thrombosis	5 ( 41.7%)	3 ( 25.0%)	2 ( 16.7%)	2 ( 16.7%)	12
Streptococcal sepsis	3 ( 25.0%)	1 ( 8.3%)	4 ( 33.3%)	4 ( 33.3%)	12
Congenital anomaly	3 ( 25.0%)	4 ( 33.3%)	5 ( 41.7%)	0 ( 0.0%)	12
Anal ulcer	1 ( 8.3%)	4 ( 33.3%)	5 ( 41.7%)	2 ( 16.7%)	12
Postictal paralysis	1 ( 8.3%)	4 ( 33.3%)	7 ( 58.3%)	0 ( 0.0%)	12
Postoperative abscess	4 ( 33.3%)	5 ( 41.7%)	2 ( 16.7%)	1 ( 8.3%)	12
Spasmodic dysphonia	0 ( 0.0%)	10 ( 83.3%)	2 ( 16.7%)	0 ( 0.0%)	12
Gastrointestinal fistula	1 ( 8.3%)	0 ( 0.0%)	10 ( 83.3%)	1 ( 8.3%)	12
Infusion site discolouration	2 ( 16.7%)	3 ( 25.0%)	7 ( 58.3%)	0 ( 0.0%)	12
Sinus rhythm	0 ( 0.0%)	3 ( 25.0%)	5 ( 41.7%)	4 ( 33.3%)	12
Urinary tract pain	0 ( 0.0%)	0 ( 0.0%)	8 ( 66.7%)	4 ( 33.3%)	12
Seroma	1 ( 8.3%)	0 ( 0.0%)	7 ( 58.3%)	4 ( 33.3%)	12
Sense of oppression	0 ( 0.0%)	0 ( 0.0%)	11 ( 91.7%)	1 ( 8.3%)	12
Degenerative bone disease	0 ( 0.0%)	3 ( 25.0%)	8 ( 66.7%)	1 ( 8.3%)	12
Gastrointestinal stoma output decreased	6 ( 50.0%)	0 ( 0.0%)	6 ( 50.0%)	0 ( 0.0%)	12
Obliterative bronchiolitis	2 ( 16.7%)	3 ( 25.0%)	7 ( 58.3%)	0 ( 0.0%)	12
Instillation site irritation	0 ( 0.0%)	5 ( 41.7%)	2 ( 16.7%)	5 ( 41.7%)	12
Haematocrit abnormal	1 ( 8.3%)	3 ( 25.0%)	6 ( 50.0%)	2 ( 16.7%)	12
Blood ketone body increased	2 ( 16.7%)	4 ( 33.3%)	6 ( 50.0%)	0 ( 0.0%)	12
Rebound psoriasis	1 ( 8.3%)	8 ( 66.7%)	3 ( 25.0%)	0 ( 0.0%)	12
Granuloma annulare	0 ( 0.0%)	6 ( 50.0%)	6 ( 50.0%)	0 ( 0.0%)	12
Chlamydial infection	3 ( 25.0%)	4 ( 33.3%)	5 ( 41.7%)	0 ( 0.0%)	12

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Occupational exposure to product	0 ( 0.0%)	5 ( 41.7%)	5 ( 41.7%)	2 ( 16.7%)	12
Purpura fulminans	1 ( 8.3%)	3 ( 25.0%)	8 ( 66.7%)	0 ( 0.0%)	12
Punctate keratitis	0 ( 0.0%)	4 ( 33.3%)	8 ( 66.7%)	0 ( 0.0%)	12
Vital capacity decreased	0 ( 0.0%)	2 ( 16.7%)	8 ( 66.7%)	2 ( 16.7%)	12
Pulmonary histoplasmosis	8 ( 66.7%)	4 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	12
Retinal injury	1 ( 8.3%)	5 ( 41.7%)	6 ( 50.0%)	0 ( 0.0%)	12
Pseudoaldosteronism	0 ( 0.0%)	0 ( 0.0%)	10 ( 83.3%)	2 ( 16.7%)	12
Prothrombin time ratio decreased	8 ( 66.7%)	1 ( 8.3%)	0 ( 0.0%)	3 ( 25.0%)	12
Vulval abscess	1 ( 8.3%)	4 ( 33.3%)	7 ( 58.3%)	0 ( 0.0%)	12
Fanconi syndrome	0 ( 0.0%)	3 ( 25.0%)	6 ( 50.0%)	3 ( 25.0%)	12
Gingival abscess	0 ( 0.0%)	1 ( 8.3%)	11 ( 91.7%)	0 ( 0.0%)	12
General symptom	0 ( 0.0%)	1 ( 8.3%)	10 ( 83.3%)	1 ( 8.3%)	12
Intestinal metastasis	0 ( 0.0%)	1 ( 8.3%)	8 ( 66.7%)	3 ( 25.0%)	12
Cerebral nocardiosis	0 ( 0.0%)	3 ( 25.0%)	7 ( 58.3%)	2 ( 16.7%)	12
Gastrointestinal stoma output abnormal	3 ( 25.0%)	1 ( 8.3%)	3 ( 25.0%)	5 ( 41.7%)	12
Gastrointestinal stenosis	1 ( 8.3%)	6 ( 50.0%)	5 ( 41.7%)	0 ( 0.0%)	12
Bacterial vulvovaginitis	1 ( 8.3%)	7 ( 58.3%)	4 ( 33.3%)	0 ( 0.0%)	12
Gastrointestinal hypomotility	1 ( 8.3%)	4 ( 33.3%)	3 ( 25.0%)	4 ( 33.3%)	12
Anal stenosis	1 ( 8.3%)	6 ( 50.0%)	5 ( 41.7%)	0 ( 0.0%)	12
Positron emission tomogram abnormal	0 ( 0.0%)	3 ( 27.3%)	6 ( 54.5%)	2 ( 18.2%)	11
Central venous catheter removal	2 ( 18.2%)	6 ( 54.5%)	3 ( 27.3%)	0 ( 0.0%)	11
Positive airway pressure therapy	3 ( 27.3%)	1 ( 9.1%)	6 ( 54.5%)	1 ( 9.1%)	11
Pneumonia haemophilus	0 ( 0.0%)	4 ( 36.4%)	6 ( 54.5%)	1 ( 9.1%)	11
B-lymphocyte abnormalities	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	0 ( 0.0%)	11
Catheter site injury	0 ( 0.0%)	6 ( 54.5%)	5 ( 45.5%)	0 ( 0.0%)	11
Atypical fracture	0 ( 0.0%)	1 ( 9.1%)	7 ( 63.6%)	3 ( 27.3%)	11
Persistent depressive disorder	1 ( 9.1%)	7 ( 63.6%)	3 ( 27.3%)	0 ( 0.0%)	11

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Peripheral T-cell lymphoma unspecified	0 ( 0.0%)	1 ( 9.1%)	7 ( 63.6%)	3 ( 27.3%)	11
Cardiac septal defect	6 ( 54.5%)	0 ( 0.0%)	4 ( 36.4%)	1 ( 9.1%)	11
Cardiac output increased	8 ( 72.7%)	1 ( 9.1%)	2 ( 18.2%)	0 ( 0.0%)	11
Ovarian failure	2 ( 18.2%)	9 ( 81.8%)	0 ( 0.0%)	0 ( 0.0%)	11
Vasculitis necrotising	0 ( 0.0%)	2 ( 18.2%)	9 ( 81.8%)	0 ( 0.0%)	11
Haemoperitoneum	1 ( 9.1%)	4 ( 36.4%)	5 ( 45.5%)	1 ( 9.1%)	11
Insulin C-peptide decreased	0 ( 0.0%)	10 ( 90.9%)	1 ( 9.1%)	0 ( 0.0%)	11
Adenocarcinoma	1 ( 9.1%)	0 ( 0.0%)	6 ( 54.5%)	4 ( 36.4%)	11
Osteogenesis imperfecta	0 ( 0.0%)	2 ( 18.2%)	7 ( 63.6%)	2 ( 18.2%)	11
Oral mucosa erosion	2 ( 18.2%)	0 ( 0.0%)	5 ( 45.5%)	4 ( 36.4%)	11
Eye colour change	1 ( 9.1%)	4 ( 36.4%)	5 ( 45.5%)	1 ( 9.1%)	11
Omphalitis	1 ( 9.1%)	4 ( 36.4%)	6 ( 54.5%)	0 ( 0.0%)	11
Halo vision	1 ( 9.1%)	6 ( 54.5%)	4 ( 36.4%)	0 ( 0.0%)	11
Excessive granulation tissue	3 ( 27.3%)	1 ( 9.1%)	7 ( 63.6%)	0 ( 0.0%)	11
Atopy	3 ( 27.3%)	4 ( 36.4%)	4 ( 36.4%)	0 ( 0.0%)	11
Excessive eye blinking	6 ( 54.5%)	3 ( 27.3%)	2 ( 18.2%)	0 ( 0.0%)	11
Obstructive pancreatitis	0 ( 0.0%)	4 ( 36.4%)	5 ( 45.5%)	2 ( 18.2%)	11
Epstein-Barr virus associated lymphoproliferative dis	4 ( 36.4%)	0 ( 0.0%)	4 ( 36.4%)	3 ( 27.3%)	11
Helicobacter test positive	0 ( 0.0%)	3 ( 27.3%)	7 ( 63.6%)	1 ( 9.1%)	11
Nephrostomy	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Neonatal respiratory distress syndrome	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Eosinophil count abnormal	0 ( 0.0%)	3 ( 27.3%)	5 ( 45.5%)	3 ( 27.3%)	11
Hemiplegic migraine	1 ( 9.1%)	4 ( 36.4%)	5 ( 45.5%)	1 ( 9.1%)	11
Pancreatitis relapsing	5 ( 45.5%)	4 ( 36.4%)	2 ( 18.2%)	0 ( 0.0%)	11
Feelings of worthlessness	4 ( 36.4%)	3 ( 27.3%)	4 ( 36.4%)	0 ( 0.0%)	11
Scedosporium infection	4 ( 36.4%)	1 ( 9.1%)	6 ( 54.5%)	0 ( 0.0%)	11
Scapula fracture	0 ( 0.0%)	1 ( 9.1%)	7 ( 63.6%)	3 ( 27.3%)	11

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Uterine prolapse	0 ( 0.0%)	4 ( 36.4%)	7 ( 63.6%)	0 ( 0.0%)	11
Secondary progressive multiple sclerosis	0 ( 0.0%)	6 ( 54.5%)	5 ( 45.5%)	0 ( 0.0%)	11
Multisystem inflammatory syndrome	1 ( 9.1%)	7 ( 63.6%)	3 ( 27.3%)	0 ( 0.0%)	11
Multiple injuries	0 ( 0.0%)	6 ( 54.5%)	4 ( 36.4%)	1 ( 9.1%)	11
Electrocardiogram T wave inversion	2 ( 18.2%)	2 ( 18.2%)	3 ( 27.3%)	4 ( 36.4%)	11
Infusion site vesicles	1 ( 9.1%)	1 ( 9.1%)	8 ( 72.7%)	1 ( 9.1%)	11
Mouth breathing	1 ( 9.1%)	0 ( 0.0%)	9 ( 81.8%)	1 ( 9.1%)	11
Eczema herpeticum	4 ( 36.4%)	5 ( 45.5%)	2 ( 18.2%)	0 ( 0.0%)	11
Breath holding	5 ( 45.5%)	1 ( 9.1%)	5 ( 45.5%)	0 ( 0.0%)	11
Metastatic cutaneous Crohn's disease	4 ( 36.4%)	7 ( 63.6%)	0 ( 0.0%)	0 ( 0.0%)	11
Metastases to thorax	0 ( 0.0%)	3 ( 27.3%)	6 ( 54.5%)	2 ( 18.2%)	11
Recall phenomenon	0 ( 0.0%)	4 ( 36.4%)	7 ( 63.6%)	0 ( 0.0%)	11
Infusion site inflammation	2 ( 18.2%)	5 ( 45.5%)	3 ( 27.3%)	1 ( 9.1%)	11
Mesenteric vein thrombosis	0 ( 0.0%)	2 ( 18.2%)	8 ( 72.7%)	1 ( 9.1%)	11
Cold urticaria	0 ( 0.0%)	7 ( 63.6%)	2 ( 18.2%)	2 ( 18.2%)	11
Urinary tract discomfort	1 ( 9.1%)	1 ( 9.1%)	7 ( 63.6%)	2 ( 18.2%)	11
Dysmetria	1 ( 9.1%)	0 ( 0.0%)	10 ( 90.9%)	0 ( 0.0%)	11
Dyslalia	8 ( 72.7%)	1 ( 9.1%)	1 ( 9.1%)	1 ( 9.1%)	11
Bone infarction	2 ( 18.2%)	1 ( 9.1%)	8 ( 72.7%)	0 ( 0.0%)	11
Arrhythmia supraventricular	0 ( 0.0%)	1 ( 9.1%)	8 ( 72.7%)	2 ( 18.2%)	11
Anal cancer	0 ( 0.0%)	7 ( 63.6%)	4 ( 36.4%)	0 ( 0.0%)	11
Maternal drugs affecting foetus	5 ( 45.5%)	6 ( 54.5%)	0 ( 0.0%)	0 ( 0.0%)	11
Mammogram abnormal	0 ( 0.0%)	4 ( 36.4%)	6 ( 54.5%)	1 ( 9.1%)	11
Grimacing	1 ( 9.1%)	4 ( 36.4%)	2 ( 18.2%)	4 ( 36.4%)	11
Male orgasmic disorder	7 ( 63.6%)	3 ( 27.3%)	1 ( 9.1%)	0 ( 0.0%)	11
Malacoplakia	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Dizziness exertional	0 ( 0.0%)	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	11

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Borderline personality disorder	5 ( 45.5%)	6 ( 54.5%)	0 ( 0.0%)	0 ( 0.0%)	11
Mycoplasma test positive	1 ( 9.1%)	0 ( 0.0%)	9 ( 81.8%)	1 ( 9.1%)	11
Lymphocele	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Lymph gland infection	0 ( 0.0%)	3 ( 27.3%)	8 ( 72.7%)	0 ( 0.0%)	11
Dihydropyrimidine dehydrogenase deficiency	0 ( 0.0%)	5 ( 45.5%)	6 ( 54.5%)	0 ( 0.0%)	11
Loss of employment	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Humoral immune defect	1 ( 9.1%)	8 ( 72.7%)	2 ( 18.2%)	0 ( 0.0%)	11
Diffuse large B-cell lymphoma refractory	0 ( 0.0%)	0 ( 0.0%)	10 ( 90.9%)	1 ( 9.1%)	11
Bladder hypertrophy	1 ( 9.1%)	4 ( 36.4%)	4 ( 36.4%)	2 ( 18.2%)	11
Application site discomfort	1 ( 9.1%)	4 ( 36.4%)	4 ( 36.4%)	2 ( 18.2%)	11
Differentiation syndrome	0 ( 0.0%)	4 ( 36.4%)	4 ( 36.4%)	3 ( 27.3%)	11
Diarrhoea infectious	0 ( 0.0%)	4 ( 36.4%)	7 ( 63.6%)	0 ( 0.0%)	11
Diabetic ketoacidotic hyperglycaemic coma	2 ( 18.2%)	0 ( 0.0%)	5 ( 45.5%)	4 ( 36.4%)	11
Ligament disorder	1 ( 9.1%)	2 ( 18.2%)	6 ( 54.5%)	2 ( 18.2%)	11
Lichenification	1 ( 9.1%)	5 ( 45.5%)	5 ( 45.5%)	0 ( 0.0%)	11
Lentigo maligna	0 ( 0.0%)	1 ( 9.1%)	10 ( 90.9%)	0 ( 0.0%)	11
Splenic vein thrombosis	1 ( 9.1%)	2 ( 18.2%)	8 ( 72.7%)	0 ( 0.0%)	11
Body height abnormal	1 ( 9.1%)	5 ( 45.5%)	5 ( 45.5%)	0 ( 0.0%)	11
Device material issue	2 ( 18.2%)	3 ( 27.3%)	4 ( 36.4%)	2 ( 18.2%)	11
Left atrial enlargement	1 ( 9.1%)	2 ( 18.2%)	5 ( 45.5%)	3 ( 27.3%)	11
Perirectal abscess	1 ( 9.1%)	3 ( 27.3%)	7 ( 63.6%)	0 ( 0.0%)	11
Laryngeal stenosis	3 ( 27.3%)	3 ( 27.3%)	5 ( 45.5%)	0 ( 0.0%)	11
Hypergammaglobulinaemia benign monoclonal	0 ( 0.0%)	0 ( 0.0%)	9 ( 81.8%)	2 ( 18.2%)	11
Endometrial hyperplasia	0 ( 0.0%)	2 ( 18.2%)	8 ( 72.7%)	1 ( 9.1%)	11
Large granular lymphocytosis	0 ( 0.0%)	5 ( 45.5%)	6 ( 54.5%)	0 ( 0.0%)	11
Hyperhomocysteinaemia	2 ( 18.2%)	2 ( 18.2%)	7 ( 63.6%)	0 ( 0.0%)	11
Blood testosterone abnormal	0 ( 0.0%)	0 ( 0.0%)	9 ( 81.8%)	2 ( 18.2%)	11

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Joint space narrowing	0 ( 0.0%)	5 ( 45.5%)	6 ( 54.5%)	0 ( 0.0%)	11
Joint contracture	6 ( 54.5%)	2 ( 18.2%)	2 ( 18.2%)	1 ( 9.1%)	11
Demyelinating polyneuropathy	1 ( 9.1%)	2 ( 18.2%)	8 ( 72.7%)	0 ( 0.0%)	11
Nail bed bleeding	2 ( 18.2%)	4 ( 36.4%)	3 ( 27.3%)	2 ( 18.2%)	11
Stomach mass	1 ( 9.1%)	4 ( 36.4%)	6 ( 54.5%)	0 ( 0.0%)	11
Wrong device used	5 ( 45.5%)	1 ( 9.1%)	4 ( 36.4%)	1 ( 9.1%)	11
Nail psoriasis	0 ( 0.0%)	6 ( 54.5%)	5 ( 45.5%)	0 ( 0.0%)	11
Hypersensitivity vasculitis	1 ( 9.1%)	1 ( 9.1%)	8 ( 72.7%)	1 ( 9.1%)	11
Hypertrichosis	6 ( 54.5%)	2 ( 18.2%)	3 ( 27.3%)	0 ( 0.0%)	11
Intestinal anastomosis	1 ( 9.1%)	8 ( 72.7%)	1 ( 9.1%)	1 ( 9.1%)	11
Visceral leishmaniasis	0 ( 0.0%)	4 ( 36.4%)	7 ( 63.6%)	0 ( 0.0%)	11
Blood lactate dehydrogenase abnormal	0 ( 0.0%)	0 ( 0.0%)	4 ( 36.4%)	7 ( 63.6%)	11
Congestive hepatopathy	1 ( 9.1%)	4 ( 36.4%)	4 ( 36.4%)	2 ( 18.2%)	11
Vasogenic cerebral oedema	0 ( 0.0%)	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	11
Tracheostomy	1 ( 9.1%)	0 ( 0.0%)	8 ( 72.7%)	2 ( 18.2%)	11
Transfusion-related circulatory overload	1 ( 9.1%)	0 ( 0.0%)	7 ( 63.6%)	3 ( 27.3%)	11
Blister rupture	0 ( 0.0%)	6 ( 54.5%)	4 ( 36.4%)	1 ( 9.1%)	11
Talipes	10 ( 90.9%)	1 ( 9.1%)	0 ( 0.0%)	0 ( 0.0%)	11
Implant site swelling	4 ( 36.4%)	6 ( 54.5%)	0 ( 0.0%)	1 ( 9.1%)	11
Urinary tract infection fungal	0 ( 0.0%)	2 ( 18.2%)	8 ( 72.7%)	1 ( 9.1%)	11
Total lung capacity increased	1 ( 9.1%)	0 ( 0.0%)	10 ( 90.9%)	0 ( 0.0%)	11
Umbilical haemorrhage	0 ( 0.0%)	9 ( 81.8%)	1 ( 9.1%)	1 ( 9.1%)	11
Influenza A virus test positive	3 ( 27.3%)	3 ( 27.3%)	5 ( 45.5%)	0 ( 0.0%)	11
Toxic shock syndrome	1 ( 9.1%)	0 ( 0.0%)	10 ( 90.9%)	0 ( 0.0%)	11
Platelet transfusion	1 ( 9.1%)	1 ( 9.1%)	6 ( 54.5%)	3 ( 27.3%)	11
Toe operation	0 ( 0.0%)	2 ( 18.2%)	8 ( 72.7%)	1 ( 9.1%)	11
Immunodeficiency common variable	1 ( 9.1%)	3 ( 27.3%)	7 ( 63.6%)	0 ( 0.0%)	11

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Thyroxine increased	1 ( 9.1%)	4 ( 36.4%)	3 ( 27.3%)	3 ( 27.3%)	11
Thyroid neoplasm	0 ( 0.0%)	1 ( 9.1%)	9 ( 81.8%)	1 ( 9.1%)	11
Thrombosis in device	1 ( 9.1%)	6 ( 54.5%)	4 ( 36.4%)	0 ( 0.0%)	11
Polychondritis	0 ( 0.0%)	4 ( 36.4%)	7 ( 63.6%)	0 ( 0.0%)	11
Anal pruritus	2 ( 18.2%)	2 ( 18.2%)	7 ( 63.6%)	0 ( 0.0%)	11
Toxoplasmosis	2 ( 18.2%)	6 ( 54.5%)	2 ( 18.2%)	1 ( 9.1%)	11
Conjunctivitis viral	2 ( 18.2%)	5 ( 45.5%)	2 ( 18.2%)	2 ( 18.2%)	11
Takayasu's arteritis	8 ( 72.7%)	3 ( 27.3%)	0 ( 0.0%)	0 ( 0.0%)	11
Gastric ulcer perforation	0 ( 0.0%)	2 ( 18.2%)	7 ( 63.6%)	2 ( 18.2%)	11
Hypoparathyroidism	0 ( 0.0%)	4 ( 36.4%)	6 ( 54.5%)	1 ( 9.1%)	11
Congenital cystic kidney disease	1 ( 9.1%)	4 ( 36.4%)	5 ( 45.5%)	1 ( 9.1%)	11
Blood creatine phosphokinase MB increased	4 ( 36.4%)	1 ( 9.1%)	6 ( 54.5%)	0 ( 0.0%)	11
Infantile haemangioma	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Epithelioid mesothelioma	1 ( 9.1%)	1 ( 9.1%)	7 ( 63.6%)	2 ( 18.2%)	11
Glassy eyes	4 ( 36.4%)	1 ( 9.1%)	6 ( 54.5%)	0 ( 0.0%)	11
Hydrocele	1 ( 9.1%)	3 ( 27.3%)	7 ( 63.6%)	0 ( 0.0%)	11
Crush syndrome	0 ( 0.0%)	0 ( 0.0%)	5 ( 45.5%)	6 ( 54.5%)	11
Ureaplasma infection	4 ( 36.4%)	0 ( 0.0%)	7 ( 63.6%)	0 ( 0.0%)	11
Night blindness	1 ( 9.1%)	4 ( 36.4%)	5 ( 45.5%)	1 ( 9.1%)	11
Pregnancy on contraceptive	8 ( 72.7%)	3 ( 27.3%)	0 ( 0.0%)	0 ( 0.0%)	11
Pregnancy of partner	1 ( 9.1%)	9 ( 81.8%)	1 ( 9.1%)	0 ( 0.0%)	11
Silent thyroiditis	1 ( 9.1%)	2 ( 18.2%)	5 ( 45.5%)	3 ( 27.3%)	11
Nodal arrhythmia	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	0 ( 0.0%)	11
Antinuclear antibody increased	1 ( 9.1%)	3 ( 27.3%)	7 ( 63.6%)	0 ( 0.0%)	11
Salmonella bacteraemia	0 ( 0.0%)	3 ( 27.3%)	6 ( 54.5%)	2 ( 18.2%)	11
Root canal infection	1 ( 9.1%)	5 ( 45.5%)	4 ( 36.4%)	1 ( 9.1%)	11
Richter's syndrome	0 ( 0.0%)	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	11

**Reaction Summary Table**  
**Derived Age Group**

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Rhegmatogenous retinal detachment	0 ( 0.0%)	1 ( 9.1%)	9 ( 81.8%)	1 ( 9.1%)	11
Retroperitoneal fibrosis	0 ( 0.0%)	0 ( 0.0%)	4 ( 36.4%)	7 ( 63.6%)	11
Product closure removal difficult	1 ( 9.1%)	0 ( 0.0%)	4 ( 36.4%)	6 ( 54.5%)	11
Chronic kidney disease-mineral and bone disorder	2 ( 18.2%)	3 ( 27.3%)	5 ( 45.5%)	1 ( 9.1%)	11
Chronic idiopathic pain syndrome	0 ( 0.0%)	9 ( 81.8%)	2 ( 18.2%)	0 ( 0.0%)	11
Bile acid malabsorption	0 ( 0.0%)	6 ( 54.5%)	5 ( 45.5%)	0 ( 0.0%)	11
Haemorrhagic transformation stroke	0 ( 0.0%)	2 ( 18.2%)	4 ( 36.4%)	5 ( 45.5%)	11
Prothrombin level decreased	1 ( 9.1%)	3 ( 27.3%)	3 ( 27.3%)	4 ( 36.4%)	11
Agonal respiration	1 ( 9.1%)	4 ( 36.4%)	6 ( 54.5%)	0 ( 0.0%)	11
Greater trochanteric pain syndrome	0 ( 0.0%)	2 ( 18.2%)	8 ( 72.7%)	1 ( 9.1%)	11
Exposure to fungus	1 ( 9.1%)	6 ( 54.5%)	4 ( 36.4%)	0 ( 0.0%)	11
Cervical radiculopathy	0 ( 0.0%)	3 ( 27.3%)	8 ( 72.7%)	0 ( 0.0%)	11
Vitamin B1 decreased	8 ( 72.7%)	1 ( 9.1%)	2 ( 18.2%)	0 ( 0.0%)	11
Gingival ulceration	2 ( 18.2%)	0 ( 0.0%)	8 ( 72.7%)	1 ( 9.1%)	11
Candida sepsis	4 ( 36.4%)	3 ( 27.3%)	1 ( 9.1%)	3 ( 27.3%)	11
Aortic dilatation	1 ( 9.1%)	4 ( 36.4%)	6 ( 54.5%)	0 ( 0.0%)	11
Basal ganglion degeneration	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Giardiasis	2 ( 18.2%)	3 ( 27.3%)	6 ( 54.5%)	0 ( 0.0%)	11
Genital rash	0 ( 0.0%)	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	11
Product dose confusion	1 ( 9.1%)	1 ( 9.1%)	5 ( 45.5%)	4 ( 36.4%)	11
Proctitis ulcerative	1 ( 9.1%)	5 ( 45.5%)	4 ( 36.4%)	1 ( 9.1%)	11
Systemic infection	4 ( 36.4%)	3 ( 27.3%)	4 ( 36.4%)	0 ( 0.0%)	11
Post inflammatory pigmentation change	2 ( 20.0%)	4 ( 40.0%)	3 ( 30.0%)	1 ( 10.0%)	10
Post cholecystectomy syndrome	0 ( 0.0%)	7 ( 70.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Anal spasm	0 ( 0.0%)	0 ( 0.0%)	2 ( 20.0%)	8 ( 80.0%)	10
Pulmonary artery thrombosis	0 ( 0.0%)	4 ( 40.0%)	3 ( 30.0%)	3 ( 30.0%)	10
Cellulitis staphylococcal	0 ( 0.0%)	3 ( 30.0%)	3 ( 30.0%)	4 ( 40.0%)	10



**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Pneumococcal infection	1 ( 10.0%)	5 ( 50.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Anal infection	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Pulmonary sarcoidosis	0 ( 0.0%)	4 ( 40.0%)	4 ( 40.0%)	2 ( 20.0%)	10
Fungal peritonitis	1 ( 10.0%)	2 ( 20.0%)	5 ( 50.0%)	2 ( 20.0%)	10
Blood lactic acid decreased	8 ( 80.0%)	1 ( 10.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Pharyngeal operation	0 ( 0.0%)	3 ( 30.0%)	5 ( 50.0%)	2 ( 20.0%)	10
Pharyngeal hypoaesthesia	2 ( 20.0%)	2 ( 20.0%)	5 ( 50.0%)	1 ( 10.0%)	10
Phaeochromocytoma crisis	0 ( 0.0%)	2 ( 20.0%)	8 ( 80.0%)	0 ( 0.0%)	10
Peyronie's disease	1 ( 10.0%)	4 ( 40.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Victim of crime	1 ( 10.0%)	4 ( 40.0%)	4 ( 40.0%)	1 ( 10.0%)	10
Granuloma skin	0 ( 0.0%)	3 ( 30.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Gravitational oedema	0 ( 0.0%)	1 ( 10.0%)	2 ( 20.0%)	7 ( 70.0%)	10
Penile pain	2 ( 20.0%)	3 ( 30.0%)	2 ( 20.0%)	3 ( 30.0%)	10
Parkinsonian gait	0 ( 0.0%)	0 ( 0.0%)	8 ( 80.0%)	2 ( 20.0%)	10
Red blood cell abnormality	1 ( 10.0%)	5 ( 50.0%)	3 ( 30.0%)	1 ( 10.0%)	10
Cardioactive drug level increased	0 ( 0.0%)	0 ( 0.0%)	6 ( 60.0%)	4 ( 40.0%)	10
Intercepted medication error	3 ( 30.0%)	3 ( 30.0%)	3 ( 30.0%)	1 ( 10.0%)	10
Fat tissue decreased	1 ( 10.0%)	0 ( 0.0%)	7 ( 70.0%)	2 ( 20.0%)	10
Overgrowth bacterial	1 ( 10.0%)	3 ( 30.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Ostomy bag placement	0 ( 0.0%)	3 ( 30.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Orthostatic hypertension	0 ( 0.0%)	1 ( 10.0%)	2 ( 20.0%)	7 ( 70.0%)	10
Organic brain syndrome	3 ( 30.0%)	3 ( 30.0%)	3 ( 30.0%)	1 ( 10.0%)	10
Palmar erythema	0 ( 0.0%)	2 ( 20.0%)	8 ( 80.0%)	0 ( 0.0%)	10
Oral contusion	2 ( 20.0%)	1 ( 10.0%)	5 ( 50.0%)	2 ( 20.0%)	10
Serum amyloid A protein increased	3 ( 30.0%)	1 ( 10.0%)	4 ( 40.0%)	2 ( 20.0%)	10
Respiratory tract inflammation	1 ( 10.0%)	2 ( 20.0%)	6 ( 60.0%)	1 ( 10.0%)	10
Open angle glaucoma	0 ( 0.0%)	3 ( 30.0%)	7 ( 70.0%)	0 ( 0.0%)	10

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pancreatic carcinoma stage IV	0 ( 0.0%)	0 ( 0.0%)	7 ( 70.0%)	3 ( 30.0%)	10
Oophorectomy	0 ( 0.0%)	7 ( 70.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Pancreatic enlargement	1 ( 10.0%)	3 ( 30.0%)	5 ( 50.0%)	1 ( 10.0%)	10
Amputation	0 ( 0.0%)	3 ( 30.0%)	5 ( 50.0%)	2 ( 20.0%)	10
Chronic hepatitis	1 ( 10.0%)	3 ( 30.0%)	5 ( 50.0%)	1 ( 10.0%)	10
Hallucination, olfactory	0 ( 0.0%)	1 ( 10.0%)	9 ( 90.0%)	0 ( 0.0%)	10
Oesophageal obstruction	0 ( 0.0%)	3 ( 30.0%)	6 ( 60.0%)	1 ( 10.0%)	10
Oesophageal dilatation	0 ( 0.0%)	4 ( 40.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Retinogram abnormal	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Ocular vascular disorder	0 ( 0.0%)	6 ( 60.0%)	3 ( 30.0%)	1 ( 10.0%)	10
Obsessive thoughts	1 ( 10.0%)	5 ( 50.0%)	2 ( 20.0%)	2 ( 20.0%)	10
Atonic seizures	6 ( 60.0%)	4 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Heart transplant rejection	4 ( 40.0%)	2 ( 20.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Biliary sepsis	0 ( 0.0%)	4 ( 40.0%)	2 ( 20.0%)	4 ( 40.0%)	10
Paradoxical psoriasis	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Heart transplant	1 ( 10.0%)	2 ( 20.0%)	6 ( 60.0%)	1 ( 10.0%)	10
Helicobacter gastritis	3 ( 30.0%)	1 ( 10.0%)	5 ( 50.0%)	1 ( 10.0%)	10
Eosinophilic colitis	2 ( 20.0%)	1 ( 10.0%)	2 ( 20.0%)	5 ( 50.0%)	10
Eosinophil percentage increased	1 ( 10.0%)	3 ( 30.0%)	4 ( 40.0%)	2 ( 20.0%)	10
Acute painful neuropathy of rapid glycaemic control	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Bursitis infective	0 ( 0.0%)	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	10
Aspartate aminotransferase decreased	0 ( 0.0%)	1 ( 10.0%)	6 ( 60.0%)	3 ( 30.0%)	10
Claustrophobia	0 ( 0.0%)	4 ( 40.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Nail toxicity	1 ( 10.0%)	3 ( 30.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Engraftment syndrome	2 ( 20.0%)	4 ( 40.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Myoglobinuria	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Scrotal swelling	0 ( 0.0%)	4 ( 40.0%)	5 ( 50.0%)	1 ( 10.0%)	10

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Arthritis enteropathic	2 ( 20.0%)	5 ( 50.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Moyamoya disease	2 ( 20.0%)	5 ( 50.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Bronchial haemorrhage	0 ( 0.0%)	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	10
Milk-alkali syndrome	0 ( 0.0%)	2 ( 20.0%)	2 ( 20.0%)	6 ( 60.0%)	10
Ecthyma	1 ( 10.0%)	1 ( 10.0%)	3 ( 30.0%)	5 ( 50.0%)	10
Metastases to pancreas	0 ( 0.0%)	1 ( 10.0%)	6 ( 60.0%)	3 ( 30.0%)	10
Ear infection fungal	0 ( 0.0%)	2 ( 20.0%)	6 ( 60.0%)	2 ( 20.0%)	10
Acute leukaemia	0 ( 0.0%)	3 ( 30.0%)	6 ( 60.0%)	1 ( 10.0%)	10
Inhibitory drug interaction	1 ( 10.0%)	5 ( 50.0%)	3 ( 30.0%)	1 ( 10.0%)	10
Hernia pain	2 ( 20.0%)	0 ( 0.0%)	7 ( 70.0%)	1 ( 10.0%)	10
Duodenal polyp	0 ( 0.0%)	3 ( 30.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Brain stem infarction	0 ( 0.0%)	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	10
Administration site induration	1 ( 10.0%)	1 ( 10.0%)	7 ( 70.0%)	1 ( 10.0%)	10
Drug resistance mutation	0 ( 0.0%)	1 ( 10.0%)	9 ( 90.0%)	0 ( 0.0%)	10
Allergy test positive	0 ( 0.0%)	1 ( 10.0%)	9 ( 90.0%)	0 ( 0.0%)	10
Rapid eye movement sleep behaviour disorder	0 ( 0.0%)	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	10
Macroglossia	3 ( 30.0%)	1 ( 10.0%)	1 ( 10.0%)	5 ( 50.0%)	10
Lymphomatoid papulosis	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Bone swelling	0 ( 0.0%)	2 ( 20.0%)	8 ( 80.0%)	0 ( 0.0%)	10
Disseminated mucormycosis	9 ( 90.0%)	0 ( 0.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Smear cervix abnormal	1 ( 10.0%)	3 ( 30.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Lumbar radiculopathy	0 ( 0.0%)	4 ( 40.0%)	3 ( 30.0%)	3 ( 30.0%)	10
Periorbital inflammation	2 ( 20.0%)	4 ( 40.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Low density lipoprotein abnormal	0 ( 0.0%)	1 ( 10.0%)	9 ( 90.0%)	0 ( 0.0%)	10
Human polyomavirus infection	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Complex regional pain syndrome	0 ( 0.0%)	7 ( 70.0%)	2 ( 20.0%)	1 ( 10.0%)	10
Bone cyst	1 ( 10.0%)	2 ( 20.0%)	7 ( 70.0%)	0 ( 0.0%)	10

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Secondary hypertension	1 ( 10.0%)	3 ( 30.0%)	3 ( 30.0%)	3 ( 30.0%)	10
Foot amputation	0 ( 0.0%)	3 ( 30.0%)	5 ( 50.0%)	2 ( 20.0%)	10
Compulsive shopping	3 ( 30.0%)	1 ( 10.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Alcohol interaction	1 ( 10.0%)	5 ( 50.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Tumour rupture	1 ( 10.0%)	2 ( 20.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Abscess jaw	1 ( 10.0%)	3 ( 30.0%)	4 ( 40.0%)	2 ( 20.0%)	10
Blood sodium abnormal	1 ( 10.0%)	3 ( 30.0%)	3 ( 30.0%)	3 ( 30.0%)	10
Hypermagnesaemia	3 ( 30.0%)	3 ( 30.0%)	2 ( 20.0%)	2 ( 20.0%)	10
ADAMTS13 activity decreased	3 ( 30.0%)	4 ( 40.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Lymphocytic infiltration	0 ( 0.0%)	8 ( 80.0%)	2 ( 20.0%)	0 ( 0.0%)	10
Cranial nerve disorder	4 ( 40.0%)	1 ( 10.0%)	2 ( 20.0%)	3 ( 30.0%)	10
Stoma closure	2 ( 20.0%)	5 ( 50.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Activation syndrome	6 ( 60.0%)	1 ( 10.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Corynebacterium infection	1 ( 10.0%)	2 ( 20.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Superficial injury of eye	2 ( 20.0%)	1 ( 10.0%)	4 ( 40.0%)	3 ( 30.0%)	10
International normalised ratio decreased	1 ( 10.0%)	1 ( 10.0%)	3 ( 30.0%)	5 ( 50.0%)	10
Incision site swelling	0 ( 0.0%)	6 ( 60.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Intentional device use issue	2 ( 20.0%)	0 ( 0.0%)	2 ( 20.0%)	6 ( 60.0%)	10
Vascular pseudoaneurysm ruptured	0 ( 0.0%)	3 ( 30.0%)	4 ( 40.0%)	3 ( 30.0%)	10
Hypoosmolar state	0 ( 0.0%)	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	10
Systolic dysfunction	4 ( 40.0%)	1 ( 10.0%)	4 ( 40.0%)	1 ( 10.0%)	10
T-cell lymphoma	0 ( 0.0%)	4 ( 40.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Tourette's disorder	7 ( 70.0%)	1 ( 10.0%)	2 ( 20.0%)	0 ( 0.0%)	10
Uterine dilation and curettage	0 ( 0.0%)	6 ( 60.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Placental insufficiency	2 ( 20.0%)	8 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Urticaria thermal	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Creatinine renal clearance abnormal	0 ( 0.0%)	4 ( 40.0%)	3 ( 30.0%)	3 ( 30.0%)	10

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Triple negative breast cancer	0 ( 0.0%)	3 ( 30.0%)	6 ( 60.0%)	1 ( 10.0%)	10
Anticoagulation drug level increased	0 ( 0.0%)	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	10
Thermal burns of eye	0 ( 0.0%)	3 ( 30.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Gallbladder rupture	0 ( 0.0%)	0 ( 0.0%)	8 ( 80.0%)	2 ( 20.0%)	10
Transfusion-related acute lung injury	0 ( 0.0%)	2 ( 20.0%)	6 ( 60.0%)	2 ( 20.0%)	10
Pneumococcal sepsis	1 ( 10.0%)	1 ( 10.0%)	7 ( 70.0%)	1 ( 10.0%)	10
Thyroxine free decreased	2 ( 20.0%)	0 ( 0.0%)	5 ( 50.0%)	3 ( 30.0%)	10
Blood cholesterol	1 ( 10.0%)	3 ( 30.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Tongue pruritus	1 ( 10.0%)	7 ( 70.0%)	2 ( 20.0%)	0 ( 0.0%)	10
Tonsillar inflammation	3 ( 30.0%)	6 ( 60.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Immunoglobulins increased	1 ( 10.0%)	2 ( 20.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Tinea versicolour	1 ( 10.0%)	6 ( 60.0%)	1 ( 10.0%)	2 ( 20.0%)	10
Pneumothorax spontaneous	0 ( 0.0%)	1 ( 10.0%)	6 ( 60.0%)	3 ( 30.0%)	10
Thymus disorder	1 ( 10.0%)	3 ( 30.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Therapeutic procedure	1 ( 10.0%)	4 ( 40.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Implant site extravasation	3 ( 30.0%)	3 ( 30.0%)	3 ( 30.0%)	1 ( 10.0%)	10
Conjunctivitis bacterial	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Gliososis	1 ( 10.0%)	7 ( 70.0%)	2 ( 20.0%)	0 ( 0.0%)	10
Inadequate diet	2 ( 20.0%)	2 ( 20.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Hypometabolism	0 ( 0.0%)	2 ( 20.0%)	7 ( 70.0%)	1 ( 10.0%)	10
Hypomenorrhoea	1 ( 10.0%)	9 ( 90.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Adhesive tape use	3 ( 30.0%)	2 ( 20.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Post procedural diarrhoea	1 ( 10.0%)	2 ( 20.0%)	6 ( 60.0%)	1 ( 10.0%)	10
Subcapsular renal haematoma	0 ( 0.0%)	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	10
Gastroenteritis norovirus	4 ( 40.0%)	5 ( 50.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Tumour thrombosis	0 ( 0.0%)	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	10
Tumour marker decreased	0 ( 0.0%)	2 ( 20.0%)	6 ( 60.0%)	2 ( 20.0%)	10

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Complication of pregnancy	4 ( 40.0%)	6 ( 60.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Anterior chamber cell	0 ( 0.0%)	0 ( 0.0%)	7 ( 70.0%)	3 ( 30.0%)	10
Hungry bone syndrome	0 ( 0.0%)	4 ( 40.0%)	5 ( 50.0%)	1 ( 10.0%)	10
Cerebral artery occlusion	0 ( 0.0%)	1 ( 10.0%)	6 ( 60.0%)	3 ( 30.0%)	10
Colonic fistula	0 ( 0.0%)	4 ( 40.0%)	4 ( 40.0%)	2 ( 20.0%)	10
Herpes zoster reactivation	1 ( 10.0%)	3 ( 30.0%)	4 ( 40.0%)	2 ( 20.0%)	10
Infusion site cellulitis	5 ( 50.0%)	4 ( 40.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Skin fragility	0 ( 0.0%)	1 ( 10.0%)	3 ( 30.0%)	6 ( 60.0%)	10
Collagen disorder	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Sinus arrhythmia	2 ( 20.0%)	2 ( 20.0%)	4 ( 40.0%)	2 ( 20.0%)	10
Nodal rhythm	7 ( 70.0%)	0 ( 0.0%)	2 ( 20.0%)	1 ( 10.0%)	10
Nikolsky's sign	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	10
Anogenital warts	1 ( 10.0%)	5 ( 50.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Semen liquefaction	5 ( 50.0%)	2 ( 20.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Clostridium bacteriaemia	0 ( 0.0%)	1 ( 10.0%)	8 ( 80.0%)	1 ( 10.0%)	10
Balanoposthitis	0 ( 0.0%)	1 ( 10.0%)	3 ( 30.0%)	6 ( 60.0%)	10
Hepatic adenoma	6 ( 60.0%)	4 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Vaginal disorder	0 ( 0.0%)	4 ( 40.0%)	4 ( 40.0%)	2 ( 20.0%)	10
Anion gap decreased	0 ( 0.0%)	2 ( 20.0%)	6 ( 60.0%)	2 ( 20.0%)	10
Retinal toxicity	0 ( 0.0%)	7 ( 70.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Reticulocyte count increased	3 ( 30.0%)	0 ( 0.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Respiratory fume inhalation disorder	0 ( 0.0%)	5 ( 50.0%)	4 ( 40.0%)	1 ( 10.0%)	10
Renal tubular disorder	6 ( 60.0%)	3 ( 30.0%)	0 ( 0.0%)	1 ( 10.0%)	10
Renal ischaemia	1 ( 10.0%)	4 ( 40.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Chorioretinitis	3 ( 30.0%)	3 ( 30.0%)	3 ( 30.0%)	1 ( 10.0%)	10
Genital atrophy	4 ( 40.0%)	5 ( 50.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Brain stem syndrome	0 ( 0.0%)	5 ( 50.0%)	4 ( 40.0%)	1 ( 10.0%)	10

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Intentional medical device removal by patient	2 ( 20.0%)	2 ( 20.0%)	5 ( 50.0%)	1 ( 10.0%)	10
Rectal perforation	0 ( 0.0%)	4 ( 40.0%)	5 ( 50.0%)	1 ( 10.0%)	10
Recalled product	0 ( 0.0%)	6 ( 60.0%)	3 ( 30.0%)	1 ( 10.0%)	10
Interferon gamma release assay positive	1 ( 10.0%)	7 ( 70.0%)	1 ( 10.0%)	1 ( 10.0%)	10
Vestibular neuronitis	0 ( 0.0%)	3 ( 30.0%)	4 ( 40.0%)	3 ( 30.0%)	10
Flat affect	3 ( 30.0%)	4 ( 40.0%)	2 ( 20.0%)	1 ( 10.0%)	10
Pulmonary resection	0 ( 0.0%)	4 ( 40.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Vulvovaginal rash	1 ( 10.0%)	1 ( 10.0%)	8 ( 80.0%)	0 ( 0.0%)	10
Chemical burn	1 ( 10.0%)	2 ( 20.0%)	6 ( 60.0%)	1 ( 10.0%)	10
Volume blood decreased	0 ( 0.0%)	0 ( 0.0%)	7 ( 70.0%)	3 ( 30.0%)	10
Gingival discolouration	0 ( 0.0%)	3 ( 30.0%)	6 ( 60.0%)	1 ( 10.0%)	10
Vulval cancer	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	10
Vulval disorder	2 ( 20.0%)	2 ( 20.0%)	5 ( 50.0%)	1 ( 10.0%)	10
Vulvovaginal inflammation	1 ( 10.0%)	6 ( 60.0%)	2 ( 20.0%)	1 ( 10.0%)	10
Prostate cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	10
Protein induced by vitamin K absence or antagonist II	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	10
Genital tract inflammation	0 ( 0.0%)	2 ( 20.0%)	7 ( 70.0%)	1 ( 10.0%)	10
Administration site bruise	0 ( 0.0%)	2 ( 20.0%)	4 ( 40.0%)	4 ( 40.0%)	10
Anastomotic leak	2 ( 20.0%)	3 ( 30.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Product use in unapproved therapeutic environment	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Product confusion	1 ( 10.0%)	1 ( 10.0%)	7 ( 70.0%)	1 ( 10.0%)	10
Blood magnesium increased	1 ( 10.0%)	2 ( 20.0%)	6 ( 60.0%)	1 ( 10.0%)	10
Gastrointestinal ulcer haemorrhage	0 ( 0.0%)	1 ( 10.0%)	8 ( 80.0%)	1 ( 10.0%)	10
Menstrual clots	2 ( 20.0%)	8 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Cerebral aspergillosis	4 ( 40.0%)	0 ( 0.0%)	5 ( 50.0%)	1 ( 10.0%)	10
Gitelman's syndrome	6 ( 60.0%)	0 ( 0.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Iris adhesions	4 ( 40.0%)	0 ( 0.0%)	5 ( 50.0%)	1 ( 10.0%)	10

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
T-cell type acute leukaemia	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	0 ( 0.0%)	9
Gastric operation	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Polyarteritis nodosa	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	9
Pulmonary calcification	1 ( 11.1%)	0 ( 0.0%)	7 ( 77.8%)	1 ( 11.1%)	9
Gastric hypomotility	4 ( 44.4%)	3 ( 33.3%)	2 ( 22.2%)	0 ( 0.0%)	9
Pneumonia necrotising	0 ( 0.0%)	4 ( 44.4%)	3 ( 33.3%)	2 ( 22.2%)	9
Pneumonia acinetobacter	0 ( 0.0%)	1 ( 11.1%)	2 ( 22.2%)	6 ( 66.7%)	9
Gallbladder polyp	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Catheter site related reaction	3 ( 33.3%)	1 ( 11.1%)	5 ( 55.6%)	0 ( 0.0%)	9
Pulmonary veno-occlusive disease	1 ( 11.1%)	0 ( 0.0%)	7 ( 77.8%)	1 ( 11.1%)	9
Shunt occlusion	4 ( 44.4%)	3 ( 33.3%)	2 ( 22.2%)	0 ( 0.0%)	9
Eye symptom	1 ( 11.1%)	4 ( 44.4%)	4 ( 44.4%)	0 ( 0.0%)	9
Pernicious anaemia	0 ( 0.0%)	0 ( 0.0%)	3 ( 33.3%)	6 ( 66.7%)	9
Metastases to bone marrow	0 ( 0.0%)	4 ( 44.4%)	4 ( 44.4%)	1 ( 11.1%)	9
Forearm fracture	3 ( 33.3%)	2 ( 22.2%)	4 ( 44.4%)	0 ( 0.0%)	9
Axonal neuropathy	2 ( 22.2%)	0 ( 0.0%)	6 ( 66.7%)	1 ( 11.1%)	9
Periorbital pain	0 ( 0.0%)	5 ( 55.6%)	2 ( 22.2%)	2 ( 22.2%)	9
Adenomyosis	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	0 ( 0.0%)	9
Cholangitis infective	0 ( 0.0%)	2 ( 22.2%)	5 ( 55.6%)	2 ( 22.2%)	9
Metastases to ovary	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	9
Guttate psoriasis	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Autoinflammatory disease	2 ( 22.2%)	3 ( 33.3%)	3 ( 33.3%)	1 ( 11.1%)	9
Patient elopement	0 ( 0.0%)	0 ( 0.0%)	5 ( 55.6%)	4 ( 44.4%)	9
Facial asymmetry	0 ( 0.0%)	3 ( 33.3%)	4 ( 44.4%)	2 ( 22.2%)	9
Cardiac stress test abnormal	0 ( 0.0%)	2 ( 22.2%)	5 ( 55.6%)	2 ( 22.2%)	9
Activated partial thromboplastin time shortened	7 ( 77.8%)	1 ( 11.1%)	1 ( 11.1%)	0 ( 0.0%)	9
Faecal calprotectin abnormal	1 ( 11.1%)	3 ( 33.3%)	5 ( 55.6%)	0 ( 0.0%)	9



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Factor V Leiden mutation	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Factitious disorder	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	9
PO2 decreased	1 ( 11.1%)	4 ( 44.4%)	3 ( 33.3%)	1 ( 11.1%)	9
Osteonecrosis of external auditory canal	0 ( 0.0%)	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	9
Osteomalacia	0 ( 0.0%)	3 ( 33.3%)	5 ( 55.6%)	1 ( 11.1%)	9
Eyelid pain	1 ( 11.1%)	1 ( 11.1%)	5 ( 55.6%)	2 ( 22.2%)	9
Oropharyngeal candidiasis	1 ( 11.1%)	1 ( 11.1%)	5 ( 55.6%)	2 ( 22.2%)	9
Amyloid arthropathy	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Oral lichenoid reaction	0 ( 0.0%)	1 ( 11.1%)	4 ( 44.4%)	4 ( 44.4%)	9
Eye infection bacterial	3 ( 33.3%)	2 ( 22.2%)	4 ( 44.4%)	0 ( 0.0%)	9
Capillary disorder	1 ( 11.1%)	2 ( 22.2%)	6 ( 66.7%)	0 ( 0.0%)	9
Oesophageal discomfort	1 ( 11.1%)	1 ( 11.1%)	7 ( 77.8%)	0 ( 0.0%)	9
Oesophageal achalasia	0 ( 0.0%)	3 ( 33.3%)	4 ( 44.4%)	2 ( 22.2%)	9
Athetosis	0 ( 0.0%)	4 ( 44.4%)	3 ( 33.3%)	2 ( 22.2%)	9
Heart disease congenital	4 ( 44.4%)	1 ( 11.1%)	2 ( 22.2%)	2 ( 22.2%)	9
Non-Hodgkin's lymphoma recurrent	0 ( 0.0%)	0 ( 0.0%)	8 ( 88.9%)	1 ( 11.1%)	9
Nitrite urine present	3 ( 33.3%)	0 ( 0.0%)	4 ( 44.4%)	2 ( 22.2%)	9
Neuropathic arthropathy	0 ( 0.0%)	4 ( 44.4%)	4 ( 44.4%)	1 ( 11.1%)	9
Nephrosclerosis	2 ( 22.2%)	2 ( 22.2%)	5 ( 55.6%)	0 ( 0.0%)	9
Nephritic syndrome	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Eosinophil percentage decreased	2 ( 22.2%)	3 ( 33.3%)	3 ( 33.3%)	1 ( 11.1%)	9
Neonatal hypoxia	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Enterocutaneous fistula	1 ( 11.1%)	4 ( 44.4%)	3 ( 33.3%)	1 ( 11.1%)	9
Burns third degree	1 ( 11.1%)	0 ( 0.0%)	7 ( 77.8%)	1 ( 11.1%)	9
Enterobacter bacteraemia	2 ( 22.2%)	1 ( 11.1%)	5 ( 55.6%)	1 ( 11.1%)	9
Alveolar osteitis	0 ( 0.0%)	3 ( 33.3%)	6 ( 66.7%)	0 ( 0.0%)	9
Arthroscopy	2 ( 22.2%)	1 ( 11.1%)	6 ( 66.7%)	0 ( 0.0%)	9

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Mycobacterium test positive	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Muscle necrosis	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Electrolyte depletion	0 ( 0.0%)	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	9
Mucosal erosion	1 ( 11.1%)	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	9
Mucocutaneous ulceration	0 ( 0.0%)	0 ( 0.0%)	8 ( 88.9%)	1 ( 11.1%)	9
Motor neurone disease	2 ( 22.2%)	0 ( 0.0%)	7 ( 77.8%)	0 ( 0.0%)	9
Electrocardiogram J wave	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Bronchial carcinoma	0 ( 0.0%)	0 ( 0.0%)	8 ( 88.9%)	1 ( 11.1%)	9
Elbow operation	1 ( 11.1%)	2 ( 22.2%)	6 ( 66.7%)	0 ( 0.0%)	9
Ejaculation delayed	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	0 ( 0.0%)	9
Breast neoplasm	0 ( 0.0%)	2 ( 22.2%)	7 ( 77.8%)	0 ( 0.0%)	9
Arterial stenosis	0 ( 0.0%)	2 ( 22.2%)	4 ( 44.4%)	3 ( 33.3%)	9
Metastases to spinal cord	0 ( 0.0%)	2 ( 22.2%)	7 ( 77.8%)	0 ( 0.0%)	9
Metastases to adrenals	0 ( 0.0%)	1 ( 11.1%)	6 ( 66.7%)	2 ( 22.2%)	9
Coital bleeding	3 ( 33.3%)	6 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	9
Metapneumovirus pneumonia	1 ( 11.1%)	4 ( 44.4%)	4 ( 44.4%)	0 ( 0.0%)	9
EGFR gene mutation	0 ( 0.0%)	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	9
Metabolic function test abnormal	0 ( 0.0%)	3 ( 33.3%)	6 ( 66.7%)	0 ( 0.0%)	9
Arterial haemorrhage	0 ( 0.0%)	2 ( 22.2%)	3 ( 33.3%)	4 ( 44.4%)	9
Mesenteric artery thrombosis	0 ( 0.0%)	0 ( 0.0%)	8 ( 88.9%)	1 ( 11.1%)	9
Cholecystitis chronic	2 ( 22.2%)	4 ( 44.4%)	3 ( 33.3%)	0 ( 0.0%)	9
Cold-stimulus headache	0 ( 0.0%)	2 ( 22.2%)	7 ( 77.8%)	0 ( 0.0%)	9
Autoimmune pancreatitis	1 ( 11.1%)	2 ( 22.2%)	5 ( 55.6%)	1 ( 11.1%)	9
Meningoencephalitis herpetic	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Breast cancer stage I	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Acute left ventricular failure	2 ( 22.2%)	1 ( 11.1%)	4 ( 44.4%)	2 ( 22.2%)	9
Carotid artery dissection	0 ( 0.0%)	7 ( 77.8%)	2 ( 22.2%)	0 ( 0.0%)	9

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Duodenal stenosis	0 ( 0.0%)	1 ( 11.1%)	6 ( 66.7%)	2 ( 22.2%)	9
Aptyalism	1 ( 11.1%)	3 ( 33.3%)	4 ( 44.4%)	1 ( 11.1%)	9
Mean cell volume abnormal	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Drug screen false positive	1 ( 11.1%)	4 ( 44.4%)	4 ( 44.4%)	0 ( 0.0%)	9
Bradycardia neonatal	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Brachiocephalic vein thrombosis	1 ( 11.1%)	4 ( 44.4%)	4 ( 44.4%)	0 ( 0.0%)	9
Encephalitis viral	1 ( 11.1%)	1 ( 11.1%)	5 ( 55.6%)	2 ( 22.2%)	9
Small cell lung cancer	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Magnetic resonance imaging spinal abnormal	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	9
Hepatitis B core antibody positive	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Borrelia infection	0 ( 0.0%)	1 ( 11.1%)	4 ( 44.4%)	4 ( 44.4%)	9
Boredom	3 ( 33.3%)	1 ( 11.1%)	4 ( 44.4%)	1 ( 11.1%)	9
Retrograde ejaculation	1 ( 11.1%)	5 ( 55.6%)	3 ( 33.3%)	0 ( 0.0%)	9
Lymph node tuberculosis	2 ( 22.2%)	4 ( 44.4%)	2 ( 22.2%)	1 ( 11.1%)	9
Upper airway obstruction	1 ( 11.1%)	3 ( 33.3%)	5 ( 55.6%)	0 ( 0.0%)	9
Disease risk factor	0 ( 0.0%)	5 ( 55.6%)	4 ( 44.4%)	0 ( 0.0%)	9
Periorbital haematoma	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Lung carcinoma cell type unspecified recurrent	0 ( 0.0%)	3 ( 33.3%)	4 ( 44.4%)	2 ( 22.2%)	9
Locked-in syndrome	0 ( 0.0%)	5 ( 55.6%)	3 ( 33.3%)	1 ( 11.1%)	9
Local reaction	2 ( 22.2%)	3 ( 33.3%)	3 ( 33.3%)	1 ( 11.1%)	9
Diaphragmatic hernia	0 ( 0.0%)	3 ( 33.3%)	5 ( 55.6%)	1 ( 11.1%)	9
Dialysis related complication	0 ( 0.0%)	1 ( 11.1%)	6 ( 66.7%)	2 ( 22.2%)	9
Diabetic hyperosmolar coma	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Device use confusion	3 ( 33.3%)	0 ( 0.0%)	5 ( 55.6%)	1 ( 11.1%)	9
Complications of transplanted lung	1 ( 11.1%)	3 ( 33.3%)	5 ( 55.6%)	0 ( 0.0%)	9
Splenic lesion	1 ( 11.1%)	0 ( 0.0%)	7 ( 77.8%)	1 ( 11.1%)	9
Splenic artery aneurysm	1 ( 11.1%)	1 ( 11.1%)	7 ( 77.8%)	0 ( 0.0%)	9

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Lentigo	0 ( 0.0%)	3 ( 33.3%)	6 ( 66.7%)	0 ( 0.0%)	9
Left atrial dilatation	1 ( 11.1%)	0 ( 0.0%)	4 ( 44.4%)	4 ( 44.4%)	9
Laryngopharyngitis	1 ( 11.1%)	6 ( 66.7%)	2 ( 22.2%)	0 ( 0.0%)	9
Apnoeic attack	3 ( 33.3%)	4 ( 44.4%)	2 ( 22.2%)	0 ( 0.0%)	9
Laryngeal discomfort	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Bladder tamponade	0 ( 0.0%)	2 ( 22.2%)	3 ( 33.3%)	4 ( 44.4%)	9
Acute myelomonocytic leukaemia	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Albumin globulin ratio increased	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Judgement impaired	0 ( 0.0%)	4 ( 44.4%)	4 ( 44.4%)	1 ( 11.1%)	9
Perinatal depression	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Job dissatisfaction	1 ( 11.1%)	5 ( 55.6%)	3 ( 33.3%)	0 ( 0.0%)	9
Jaw fistula	0 ( 0.0%)	2 ( 22.2%)	7 ( 77.8%)	0 ( 0.0%)	9
Tumour excision	1 ( 11.1%)	4 ( 44.4%)	3 ( 33.3%)	1 ( 11.1%)	9
Ischaemic cerebral infarction	1 ( 11.1%)	1 ( 11.1%)	4 ( 44.4%)	3 ( 33.3%)	9
Pyelocaliectasis	4 ( 44.4%)	1 ( 11.1%)	3 ( 33.3%)	1 ( 11.1%)	9
Iodine allergy	1 ( 11.1%)	1 ( 11.1%)	4 ( 44.4%)	3 ( 33.3%)	9
Blood oestrogen increased	0 ( 0.0%)	7 ( 77.8%)	0 ( 0.0%)	2 ( 22.2%)	9
Antipsychotic drug level above therapeutic	2 ( 22.2%)	4 ( 44.4%)	2 ( 22.2%)	1 ( 11.1%)	9
Ventricular tachyarrhythmia	3 ( 33.3%)	0 ( 0.0%)	6 ( 66.7%)	0 ( 0.0%)	9
Ventilation perfusion mismatch	0 ( 0.0%)	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	9
Suture insertion	2 ( 22.2%)	4 ( 44.4%)	1 ( 11.1%)	2 ( 22.2%)	9
Insulin-like growth factor abnormal	1 ( 11.1%)	3 ( 33.3%)	5 ( 55.6%)	0 ( 0.0%)	9
Anticoagulation drug level below therapeutic	0 ( 0.0%)	1 ( 11.1%)	4 ( 44.4%)	4 ( 44.4%)	9
Vascular access site pain	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Transient acantholytic dermatosis	0 ( 0.0%)	1 ( 11.1%)	5 ( 55.6%)	3 ( 33.3%)	9
Cyst rupture	0 ( 0.0%)	3 ( 33.3%)	6 ( 66.7%)	0 ( 0.0%)	9
Cutaneous symptom	0 ( 0.0%)	4 ( 44.4%)	4 ( 44.4%)	1 ( 11.1%)	9

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Urticaria chronic	1 ( 11.1%)	5 ( 55.6%)	2 ( 22.2%)	1 ( 11.1%)	9
Tender joint count increased	0 ( 0.0%)	0 ( 0.0%)	7 ( 77.8%)	2 ( 22.2%)	9
Toxic neuropathy	0 ( 0.0%)	3 ( 33.3%)	6 ( 66.7%)	0 ( 0.0%)	9
Blood fibrinogen increased	0 ( 0.0%)	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	9
Idiopathic interstitial pneumonia	0 ( 0.0%)	1 ( 11.1%)	6 ( 66.7%)	2 ( 22.2%)	9
Adult failure to thrive	0 ( 0.0%)	0 ( 0.0%)	3 ( 33.3%)	6 ( 66.7%)	9
Upper respiratory tract inflammation	1 ( 11.1%)	2 ( 22.2%)	6 ( 66.7%)	0 ( 0.0%)	9
Blood electrolytes abnormal	2 ( 22.2%)	0 ( 0.0%)	6 ( 66.7%)	1 ( 11.1%)	9
Thalamus haemorrhage	0 ( 0.0%)	1 ( 11.1%)	5 ( 55.6%)	3 ( 33.3%)	9
Type V hyperlipidaemia	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Aspergillus test positive	3 ( 33.3%)	2 ( 22.2%)	3 ( 33.3%)	1 ( 11.1%)	9
Incorrect product formulation administered	2 ( 22.2%)	5 ( 55.6%)	2 ( 22.2%)	0 ( 0.0%)	9
Pleurothotonus	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Blood corticotrophin increased	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Thunderclap headache	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	9
Tobacco user	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	9
Corneal lesion	0 ( 0.0%)	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	9
Immune-mediated pericarditis	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Tonsil cancer	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Adrenomegaly	0 ( 0.0%)	0 ( 0.0%)	8 ( 88.9%)	1 ( 11.1%)	9
Thyroxine free increased	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	9
Antibiotic level above therapeutic	0 ( 0.0%)	5 ( 55.6%)	4 ( 44.4%)	0 ( 0.0%)	9
Thyroid operation	1 ( 11.1%)	3 ( 33.3%)	5 ( 55.6%)	0 ( 0.0%)	9
Immune-mediated endocrinopathy	0 ( 0.0%)	2 ( 22.2%)	5 ( 55.6%)	2 ( 22.2%)	9
Antibody test positive	6 ( 66.7%)	2 ( 22.2%)	1 ( 11.1%)	0 ( 0.0%)	9
Aspiration pleural cavity	0 ( 0.0%)	1 ( 11.1%)	5 ( 55.6%)	3 ( 33.3%)	9
Immobilisation syndrome	0 ( 0.0%)	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	9

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Abortion missed	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	0 ( 0.0%)	9
Thalamic infarction	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Corneal transplant	1 ( 11.1%)	2 ( 22.2%)	5 ( 55.6%)	1 ( 11.1%)	9
Epidermal necrosis	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Imprisonment	2 ( 22.2%)	5 ( 55.6%)	2 ( 22.2%)	0 ( 0.0%)	9
Gastric stenosis	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Hypospadias	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Transferrin saturation decreased	0 ( 0.0%)	1 ( 11.1%)	6 ( 66.7%)	2 ( 22.2%)	9
Synovial disorder	0 ( 0.0%)	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	9
Symptom masked	2 ( 22.2%)	5 ( 55.6%)	1 ( 11.1%)	1 ( 11.1%)	9
Coronavirus pneumonia	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Portal hypertensive gastropathy	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Gastritis bacterial	0 ( 0.0%)	7 ( 77.8%)	2 ( 22.2%)	0 ( 0.0%)	9
Neuroblastoma recurrent	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Sudden unexplained death in epilepsy	4 ( 44.4%)	4 ( 44.4%)	1 ( 11.1%)	0 ( 0.0%)	9
Bleeding time prolonged	2 ( 22.2%)	4 ( 44.4%)	2 ( 22.2%)	1 ( 11.1%)	9
Subdiaphragmatic abscess	0 ( 0.0%)	0 ( 0.0%)	8 ( 88.9%)	1 ( 11.1%)	9
Gastroenteritis rotavirus	7 ( 77.8%)	0 ( 0.0%)	2 ( 22.2%)	0 ( 0.0%)	9
Increased viscosity of bronchial secretion	2 ( 22.2%)	2 ( 22.2%)	5 ( 55.6%)	0 ( 0.0%)	9
Stoma site discomfort	0 ( 0.0%)	3 ( 33.3%)	4 ( 44.4%)	2 ( 22.2%)	9
Acute polyneuropathy	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Sticky skin	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Steroid withdrawal syndrome	2 ( 22.2%)	1 ( 11.1%)	6 ( 66.7%)	0 ( 0.0%)	9
Blood creatine phosphokinase abnormal	0 ( 0.0%)	2 ( 22.2%)	2 ( 22.2%)	5 ( 55.6%)	9
Steatohepatitis	5 ( 55.6%)	0 ( 0.0%)	4 ( 44.4%)	0 ( 0.0%)	9
Sprue-like enteropathy	0 ( 0.0%)	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	9
Epiretinal membrane	1 ( 11.1%)	1 ( 11.1%)	5 ( 55.6%)	2 ( 22.2%)	9

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Splenectomy	1 ( 11.1%)	1 ( 11.1%)	5 ( 55.6%)	2 ( 22.2%)	9
Sleep-related eating disorder	2 ( 22.2%)	4 ( 44.4%)	3 ( 33.3%)	0 ( 0.0%)	9
Colon injury	0 ( 0.0%)	2 ( 22.2%)	7 ( 77.8%)	0 ( 0.0%)	9
Sinus polyp	1 ( 11.1%)	2 ( 22.2%)	6 ( 66.7%)	0 ( 0.0%)	9
Herbal interaction	0 ( 0.0%)	4 ( 44.4%)	2 ( 22.2%)	3 ( 33.3%)	9
Secondary hypogonadism	1 ( 11.1%)	0 ( 0.0%)	8 ( 88.9%)	0 ( 0.0%)	9
Uterine infection	0 ( 0.0%)	8 ( 88.9%)	1 ( 11.1%)	0 ( 0.0%)	9
Hepatic enzyme decreased	1 ( 11.1%)	2 ( 22.2%)	3 ( 33.3%)	3 ( 33.3%)	9
Injection site eczema	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	0 ( 0.0%)	9
Injection site erosion	3 ( 33.3%)	3 ( 33.3%)	3 ( 33.3%)	0 ( 0.0%)	9
Citrobacter infection	4 ( 44.4%)	3 ( 33.3%)	1 ( 11.1%)	1 ( 11.1%)	9
Salivary gland disorder	1 ( 11.1%)	2 ( 22.2%)	4 ( 44.4%)	2 ( 22.2%)	9
Cystic lung disease	0 ( 0.0%)	6 ( 66.7%)	2 ( 22.2%)	1 ( 11.1%)	9
Rheumatoid lung	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Hearing aid user	0 ( 0.0%)	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	9
Retroperitoneal lymphadenopathy	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Retinitis pigmentosa	0 ( 0.0%)	3 ( 33.3%)	5 ( 55.6%)	1 ( 11.1%)	9
Bile duct cancer	0 ( 0.0%)	1 ( 11.1%)	5 ( 55.6%)	3 ( 33.3%)	9
Acquired factor V deficiency	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Vasoconstriction	4 ( 44.4%)	3 ( 33.3%)	2 ( 22.2%)	0 ( 0.0%)	9
Renal cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	8 ( 88.9%)	1 ( 11.1%)	9
Haematoma infection	0 ( 0.0%)	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	9
Haematological malignancy	0 ( 0.0%)	0 ( 0.0%)	8 ( 88.9%)	1 ( 11.1%)	9
Vertebral lesion	0 ( 0.0%)	2 ( 22.2%)	5 ( 55.6%)	2 ( 22.2%)	9
Interchange of vaccine products	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	9
Growth failure	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Abnormal sleep-related event	1 ( 11.1%)	4 ( 44.4%)	4 ( 44.4%)	0 ( 0.0%)	9

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Oesophageal motility disorder	0 ( 0.0%)	3 ( 33.3%)	4 ( 44.4%)	2 ( 22.2%)	9
Gluten sensitivity	2 ( 22.2%)	4 ( 44.4%)	2 ( 22.2%)	1 ( 11.1%)	9
Administration site erythema	0 ( 0.0%)	3 ( 33.3%)	6 ( 66.7%)	0 ( 0.0%)	9
Basophil percentage increased	1 ( 11.1%)	3 ( 33.3%)	5 ( 55.6%)	0 ( 0.0%)	9
Pseudopolyp	2 ( 22.2%)	1 ( 11.1%)	6 ( 66.7%)	0 ( 0.0%)	9
Chalazion	2 ( 22.2%)	1 ( 11.1%)	6 ( 66.7%)	0 ( 0.0%)	9
Blood oestrogen decreased	0 ( 0.0%)	4 ( 44.4%)	4 ( 44.4%)	1 ( 11.1%)	9
Basal ganglia haemorrhage	0 ( 0.0%)	2 ( 22.2%)	5 ( 55.6%)	2 ( 22.2%)	9
Genital ulceration	1 ( 11.1%)	3 ( 33.3%)	5 ( 55.6%)	0 ( 0.0%)	9
Propofol infusion syndrome	2 ( 22.2%)	7 ( 77.8%)	0 ( 0.0%)	0 ( 0.0%)	9
Abdominal neoplasm	1 ( 11.1%)	1 ( 11.1%)	5 ( 55.6%)	2 ( 22.2%)	9
Genital erosion	0 ( 0.0%)	0 ( 0.0%)	2 ( 22.2%)	7 ( 77.8%)	9
Genital anaesthesia	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	0 ( 0.0%)	9
West Nile viral infection	1 ( 11.1%)	5 ( 55.6%)	3 ( 33.3%)	0 ( 0.0%)	9
Product design issue	4 ( 44.4%)	0 ( 0.0%)	1 ( 11.1%)	4 ( 44.4%)	9
Gingival hypertrophy	2 ( 22.2%)	3 ( 33.3%)	4 ( 44.4%)	0 ( 0.0%)	9
Gene mutation identification test positive	0 ( 0.0%)	4 ( 44.4%)	2 ( 22.2%)	3 ( 33.3%)	9
Vogt-Koyanagi-Harada disease	0 ( 0.0%)	4 ( 44.4%)	4 ( 44.4%)	1 ( 11.1%)	9
Primary amyloidosis	0 ( 0.0%)	0 ( 0.0%)	2 ( 22.2%)	7 ( 77.8%)	9
Wound necrosis	3 ( 33.3%)	1 ( 11.1%)	5 ( 55.6%)	0 ( 0.0%)	9
Gastrointestinal mucormycosis	4 ( 44.4%)	2 ( 22.2%)	2 ( 22.2%)	1 ( 11.1%)	9
Precancerous cells present	0 ( 0.0%)	4 ( 44.4%)	4 ( 44.4%)	1 ( 11.1%)	9
Gastrointestinal fungal infection	2 ( 22.2%)	1 ( 11.1%)	5 ( 55.6%)	1 ( 11.1%)	9
Glare	2 ( 22.2%)	4 ( 44.4%)	2 ( 22.2%)	1 ( 11.1%)	9
Infusion site haematoma	1 ( 11.1%)	3 ( 33.3%)	2 ( 22.2%)	3 ( 33.3%)	9
Autoscopy	0 ( 0.0%)	5 ( 55.6%)	3 ( 33.3%)	1 ( 11.1%)	9
Adjusted calcium decreased	0 ( 0.0%)	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	9



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Psychological trauma	2 ( 25.0%)	3 ( 37.5%)	2 ( 25.0%)	1 ( 12.5%)	8
Portal venous gas	0 ( 0.0%)	0 ( 0.0%)	3 ( 37.5%)	5 ( 62.5%)	8
Globulins increased	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8
Gastric mucosal lesion	1 ( 12.5%)	1 ( 12.5%)	4 ( 50.0%)	2 ( 25.0%)	8
Polychromasia	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Gallbladder cancer	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8
Fungal disease carrier	2 ( 25.0%)	0 ( 0.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Catheter site pruritus	1 ( 12.5%)	2 ( 25.0%)	5 ( 62.5%)	0 ( 0.0%)	8
Physical assault	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	0 ( 0.0%)	8
International normalised ratio fluctuation	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Viral rash	3 ( 37.5%)	0 ( 0.0%)	5 ( 62.5%)	0 ( 0.0%)	8
Pyelitis	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Pelvic neoplasm	1 ( 12.5%)	1 ( 12.5%)	6 ( 75.0%)	0 ( 0.0%)	8
Q fever	0 ( 0.0%)	6 ( 75.0%)	1 ( 12.5%)	1 ( 12.5%)	8
Cataract subcapsular	3 ( 37.5%)	2 ( 25.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Penile infection	1 ( 12.5%)	1 ( 12.5%)	4 ( 50.0%)	2 ( 25.0%)	8
Penile haemorrhage	2 ( 25.0%)	1 ( 12.5%)	3 ( 37.5%)	2 ( 25.0%)	8
Abdominal injury	0 ( 0.0%)	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	8
Pelvic fluid collection	1 ( 12.5%)	5 ( 62.5%)	2 ( 25.0%)	0 ( 0.0%)	8
HER2 positive breast cancer	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	0 ( 0.0%)	8
Adenocarcinoma gastric	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Cardiac procedure complication	1 ( 12.5%)	0 ( 0.0%)	7 ( 87.5%)	0 ( 0.0%)	8
Autoimmune colitis	0 ( 0.0%)	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	8
Palatal disorder	1 ( 12.5%)	1 ( 12.5%)	4 ( 50.0%)	2 ( 25.0%)	8
Faecal vomiting	2 ( 25.0%)	3 ( 37.5%)	2 ( 25.0%)	1 ( 12.5%)	8
Haemophilic arthropathy	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Acetabulum fracture	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Osmotic demyelination syndrome	2 ( 25.0%)	0 ( 0.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Orthostatic intolerance	1 ( 12.5%)	0 ( 0.0%)	4 ( 50.0%)	3 ( 37.5%)	8
Orthopaedic procedure	0 ( 0.0%)	1 ( 12.5%)	5 ( 62.5%)	2 ( 25.0%)	8
Oropharyngeal swelling	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Palatal oedema	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8
Carcinoid crisis	0 ( 0.0%)	3 ( 37.5%)	4 ( 50.0%)	1 ( 12.5%)	8
Orbital oedema	2 ( 25.0%)	2 ( 25.0%)	3 ( 37.5%)	1 ( 12.5%)	8
Carbon dioxide abnormal	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Oppositional defiant disorder	6 ( 75.0%)	1 ( 12.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Mixed hepatocellular cholangiocarcinoma	1 ( 12.5%)	3 ( 37.5%)	3 ( 37.5%)	1 ( 12.5%)	8
Oesophageal rupture	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Cancer fatigue	1 ( 12.5%)	1 ( 12.5%)	5 ( 62.5%)	1 ( 12.5%)	8
Exostosis of jaw	0 ( 0.0%)	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	8
Ocular toxicity	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8
Ocular lymphoma	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	0 ( 0.0%)	8
Erythema induratum	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Nipple swelling	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
CSF protein increased	5 ( 62.5%)	1 ( 12.5%)	1 ( 12.5%)	1 ( 12.5%)	8
Neutrophil count	1 ( 12.5%)	3 ( 37.5%)	4 ( 50.0%)	0 ( 0.0%)	8
Neutralising antibodies positive	2 ( 25.0%)	3 ( 37.5%)	3 ( 37.5%)	0 ( 0.0%)	8
Neurosarcoidosis	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Epiploic appendagitis	0 ( 0.0%)	2 ( 25.0%)	4 ( 50.0%)	2 ( 25.0%)	8
Neuromyopathy	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Nephritis allergic	0 ( 0.0%)	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	8
Acute phase reaction	1 ( 12.5%)	0 ( 0.0%)	7 ( 87.5%)	0 ( 0.0%)	8
Necrotising soft tissue infection	1 ( 12.5%)	2 ( 25.0%)	4 ( 50.0%)	1 ( 12.5%)	8
Entropion	0 ( 0.0%)	2 ( 25.0%)	3 ( 37.5%)	3 ( 37.5%)	8

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Enterobiasis	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Binocular eye movement disorder	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	0 ( 0.0%)	8
Vaccination complication	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Endoscopy	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Scleral hyperaemia	1 ( 12.5%)	2 ( 25.0%)	3 ( 37.5%)	2 ( 25.0%)	8
Myoclonic epilepsy	6 ( 75.0%)	0 ( 0.0%)	2 ( 25.0%)	0 ( 0.0%)	8
Scrotal abscess	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Fibroadenoma of breast	0 ( 0.0%)	4 ( 50.0%)	1 ( 12.5%)	3 ( 37.5%)	8
Endometrial ablation	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	0 ( 0.0%)	8
Mycobacterium fortuitum infection	6 ( 75.0%)	1 ( 12.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Encephalomyelitis	5 ( 62.5%)	0 ( 0.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Emphysematous cystitis	0 ( 0.0%)	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	8
Bronchitis viral	1 ( 12.5%)	2 ( 25.0%)	4 ( 50.0%)	1 ( 12.5%)	8
Pasteurella infection	1 ( 12.5%)	0 ( 0.0%)	5 ( 62.5%)	2 ( 25.0%)	8
Parvovirus B19 infection	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Morning sickness	1 ( 12.5%)	5 ( 62.5%)	2 ( 25.0%)	0 ( 0.0%)	8
Electrocardiogram PR prolongation	0 ( 0.0%)	4 ( 50.0%)	1 ( 12.5%)	3 ( 37.5%)	8
Mole excision	1 ( 12.5%)	3 ( 37.5%)	4 ( 50.0%)	0 ( 0.0%)	8
Serratia infection	1 ( 12.5%)	3 ( 37.5%)	3 ( 37.5%)	1 ( 12.5%)	8
Ehlers-Danlos syndrome	1 ( 12.5%)	3 ( 37.5%)	4 ( 50.0%)	0 ( 0.0%)	8
Educational problem	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Mitral valve disease	0 ( 0.0%)	0 ( 0.0%)	3 ( 37.5%)	5 ( 62.5%)	8
Alopecia scarring	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Metastatic lymphoma	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
Ear tube insertion	7 ( 87.5%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 12.5%)	8
Metastatic bronchial carcinoma	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
Breast haemorrhage	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> (N=&AGEGRP1)	<i>Group2 (26-50)</i> (N=&AGEGRP2)	<i>Group3 (51-75)</i> (N=&AGEGRP3)	<i>Group4 (75+)</i> (N=&AGEGRP4)	<i>Total</i> (N=&AGEGRP5)
Metastases to breast	1 ( 12.5%)	2 ( 25.0%)	5 ( 62.5%)	0 ( 0.0%)	8
Vitreous degeneration	0 ( 0.0%)	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	8
Dysmorphism	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Breakthrough haemolysis	2 ( 25.0%)	1 ( 12.5%)	4 ( 50.0%)	1 ( 12.5%)	8
Muscular dystrophy	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8
Skin candida	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	0 ( 0.0%)	8
Dry gangrene	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Fluid imbalance	0 ( 0.0%)	2 ( 25.0%)	3 ( 37.5%)	3 ( 37.5%)	8
Medical device site discomfort	2 ( 25.0%)	2 ( 25.0%)	3 ( 37.5%)	1 ( 12.5%)	8
Allergy to arthropod sting	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Allergy to arthropod bite	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Mean cell haemoglobin	1 ( 12.5%)	3 ( 37.5%)	3 ( 37.5%)	1 ( 12.5%)	8
Mallory-Weiss syndrome	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
Autophobia	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Drowning	2 ( 25.0%)	1 ( 12.5%)	2 ( 25.0%)	3 ( 37.5%)	8
Documented hypersensitivity to administered product	1 ( 12.5%)	3 ( 37.5%)	4 ( 50.0%)	0 ( 0.0%)	8
Smooth muscle cell neoplasm	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Speech disorder developmental	6 ( 75.0%)	0 ( 0.0%)	2 ( 25.0%)	0 ( 0.0%)	8
Bone hypertrophy	1 ( 12.5%)	5 ( 62.5%)	1 ( 12.5%)	1 ( 12.5%)	8
Lipohypertrophy	2 ( 25.0%)	4 ( 50.0%)	2 ( 25.0%)	0 ( 0.0%)	8
Lip infection	6 ( 75.0%)	1 ( 12.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Diabetic nephropathy	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Limb reduction defect	7 ( 87.5%)	1 ( 12.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Bone cancer metastatic	0 ( 0.0%)	1 ( 12.5%)	3 ( 37.5%)	4 ( 50.0%)	8
Body temperature	5 ( 62.5%)	1 ( 12.5%)	1 ( 12.5%)	1 ( 12.5%)	8
Body mass index decreased	1 ( 12.5%)	3 ( 37.5%)	4 ( 50.0%)	0 ( 0.0%)	8
Legal problem	0 ( 0.0%)	4 ( 50.0%)	2 ( 25.0%)	2 ( 25.0%)	8

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Left ventricular dilatation	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Alcohol use	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	0 ( 0.0%)	8
Laryngeal cancer	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Alcohol intolerance	1 ( 12.5%)	3 ( 37.5%)	3 ( 37.5%)	1 ( 12.5%)	8
Dermatophytosis	1 ( 12.5%)	1 ( 12.5%)	5 ( 62.5%)	1 ( 12.5%)	8
Labelled drug-food interaction issue	3 ( 37.5%)	3 ( 37.5%)	2 ( 25.0%)	0 ( 0.0%)	8
Albuminuria	0 ( 0.0%)	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	8
Blood stem cell transplant failure	7 ( 87.5%)	1 ( 12.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Acute chest syndrome	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Keratouveitis	1 ( 12.5%)	0 ( 0.0%)	5 ( 62.5%)	2 ( 25.0%)	8
Jaw operation	2 ( 25.0%)	2 ( 25.0%)	3 ( 37.5%)	1 ( 12.5%)	8
Delivery	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Nail growth abnormal	0 ( 0.0%)	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	8
Wolff-Parkinson-White syndrome	0 ( 0.0%)	5 ( 62.5%)	2 ( 25.0%)	1 ( 12.5%)	8
Congenital central nervous system anomaly	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Intraductal papillary mucinous neoplasm	0 ( 0.0%)	2 ( 25.0%)	4 ( 50.0%)	2 ( 25.0%)	8
Hypertensive heart disease	1 ( 12.5%)	0 ( 0.0%)	6 ( 75.0%)	1 ( 12.5%)	8
Air embolism	0 ( 0.0%)	3 ( 37.5%)	2 ( 25.0%)	3 ( 37.5%)	8
Vulvovaginal erythema	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Vertebral foraminal stenosis	1 ( 12.5%)	1 ( 12.5%)	5 ( 62.5%)	1 ( 12.5%)	8
Agnosia	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Incarcerated hernia	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Blood immunoglobulin M increased	1 ( 12.5%)	1 ( 12.5%)	3 ( 37.5%)	3 ( 37.5%)	8
Blood immunoglobulin G abnormal	2 ( 25.0%)	2 ( 25.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Use of accessory respiratory muscles	3 ( 37.5%)	3 ( 37.5%)	2 ( 25.0%)	0 ( 0.0%)	8
Teething	6 ( 75.0%)	2 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Implant site necrosis	6 ( 75.0%)	2 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	8

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Implant site erythema	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	0 ( 0.0%)	8
UGT1A1 gene mutation	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Blood creatine phosphokinase decreased	1 ( 12.5%)	3 ( 37.5%)	3 ( 37.5%)	1 ( 12.5%)	8
Thrombotic cerebral infarction	0 ( 0.0%)	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	8
Thyrototoxic periodic paralysis	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Antibody test abnormal	2 ( 25.0%)	2 ( 25.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Corneal epithelium defect	2 ( 25.0%)	2 ( 25.0%)	2 ( 25.0%)	2 ( 25.0%)	8
Nephroangiosclerosis	0 ( 0.0%)	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	8
Testicular seminoma (pure)	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Tooth socket haemorrhage	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Blood 25-hydroxycholecalciferol decreased	3 ( 37.5%)	0 ( 0.0%)	4 ( 50.0%)	1 ( 12.5%)	8
Transcription medication error	2 ( 25.0%)	2 ( 25.0%)	3 ( 37.5%)	1 ( 12.5%)	8
Systemic lupus erythematosus rash	0 ( 0.0%)	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	8
Hypophosphataemic osteomalacia	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
Hypoperfusion	0 ( 0.0%)	3 ( 37.5%)	4 ( 50.0%)	1 ( 12.5%)	8
Swollen joint count	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	0 ( 0.0%)	8
Suture related complication	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Hypoaldosteronism	2 ( 25.0%)	0 ( 0.0%)	1 ( 12.5%)	5 ( 62.5%)	8
Anti factor VIII antibody positive	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Stubbornness	1 ( 12.5%)	5 ( 62.5%)	1 ( 12.5%)	1 ( 12.5%)	8
Post procedural discharge	0 ( 0.0%)	2 ( 25.0%)	2 ( 25.0%)	4 ( 50.0%)	8
Cranial nerve paralysis	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Tumefactive multiple sclerosis	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Stoma site dermatitis	0 ( 0.0%)	2 ( 25.0%)	1 ( 12.5%)	5 ( 62.5%)	8
Stoma obstruction	0 ( 0.0%)	3 ( 37.5%)	4 ( 50.0%)	1 ( 12.5%)	8
Indifference	3 ( 37.5%)	0 ( 0.0%)	5 ( 62.5%)	0 ( 0.0%)	8
Tumour hyperprogression	0 ( 0.0%)	2 ( 25.0%)	3 ( 37.5%)	3 ( 37.5%)	8

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Stasis dermatitis	0 ( 0.0%)	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	8
Stab wound	1 ( 12.5%)	5 ( 62.5%)	2 ( 25.0%)	0 ( 0.0%)	8
Twin pregnancy	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Sputum abnormal	0 ( 0.0%)	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	8
Infected neoplasm	1 ( 12.5%)	4 ( 50.0%)	2 ( 25.0%)	1 ( 12.5%)	8
Neurosyphilis	3 ( 37.5%)	1 ( 12.5%)	4 ( 50.0%)	0 ( 0.0%)	8
Ulcerative gastritis	0 ( 0.0%)	6 ( 75.0%)	0 ( 0.0%)	2 ( 25.0%)	8
Infective aneurysm	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Hydrothorax	0 ( 0.0%)	3 ( 37.5%)	3 ( 37.5%)	2 ( 25.0%)	8
Infective keratitis	6 ( 75.0%)	2 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Spinal cord abscess	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Soft tissue necrosis	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Horner's syndrome	0 ( 0.0%)	4 ( 50.0%)	3 ( 37.5%)	1 ( 12.5%)	8
Colour blindness	0 ( 0.0%)	4 ( 50.0%)	2 ( 25.0%)	2 ( 25.0%)	8
Small intestine ulcer	0 ( 0.0%)	2 ( 25.0%)	4 ( 50.0%)	2 ( 25.0%)	8
Cerebral artery stenosis	0 ( 0.0%)	4 ( 50.0%)	3 ( 37.5%)	1 ( 12.5%)	8
Ureteric compression	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
Adnexal torsion	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Cerebral amyloid angiopathy	0 ( 0.0%)	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	8
Skin discharge	2 ( 25.0%)	2 ( 25.0%)	2 ( 25.0%)	2 ( 25.0%)	8
Serum serotonin decreased	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Coagulation test abnormal	1 ( 12.5%)	2 ( 25.0%)	4 ( 50.0%)	1 ( 12.5%)	8
Hepatic vein thrombosis	3 ( 37.5%)	2 ( 25.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Hepatic infarction	0 ( 0.0%)	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	8
Scleroderma-like reaction	1 ( 12.5%)	4 ( 50.0%)	2 ( 25.0%)	1 ( 12.5%)	8
Procedural dizziness	0 ( 0.0%)	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	8
Sciatic nerve neuropathy	1 ( 12.5%)	1 ( 12.5%)	6 ( 75.0%)	0 ( 0.0%)	8

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Procedural headache	2 ( 25.0%)	2 ( 25.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Sarcoma	0 ( 0.0%)	4 ( 50.0%)	2 ( 25.0%)	2 ( 25.0%)	8
Cyst removal	1 ( 12.5%)	3 ( 37.5%)	4 ( 50.0%)	0 ( 0.0%)	8
Administration site pruritus	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	0 ( 0.0%)	8
Chronic myeloid leukaemia recurrent	0 ( 0.0%)	3 ( 37.5%)	4 ( 50.0%)	1 ( 12.5%)	8
Head banging	4 ( 50.0%)	1 ( 12.5%)	2 ( 25.0%)	1 ( 12.5%)	8
Anaplastic large cell lymphoma T- and null-cell types	0 ( 0.0%)	3 ( 37.5%)	4 ( 50.0%)	1 ( 12.5%)	8
Product closure issue	0 ( 0.0%)	3 ( 37.5%)	3 ( 37.5%)	2 ( 25.0%)	8
Retinal vascular disorder	2 ( 25.0%)	2 ( 25.0%)	2 ( 25.0%)	2 ( 25.0%)	8
Chronic hepatitis B	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Retinal operation	0 ( 0.0%)	1 ( 12.5%)	5 ( 62.5%)	2 ( 25.0%)	8
Haemorrhagic disorder	0 ( 0.0%)	2 ( 25.0%)	3 ( 37.5%)	3 ( 37.5%)	8
Cytogenetic abnormality	1 ( 12.5%)	1 ( 12.5%)	6 ( 75.0%)	0 ( 0.0%)	8
Renal surgery	0 ( 0.0%)	1 ( 12.5%)	5 ( 62.5%)	2 ( 25.0%)	8
Insulin autoimmune syndrome	0 ( 0.0%)	4 ( 50.0%)	3 ( 37.5%)	1 ( 12.5%)	8
Renal hypertension	6 ( 75.0%)	1 ( 12.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Remission not achieved	0 ( 0.0%)	5 ( 62.5%)	1 ( 12.5%)	2 ( 25.0%)	8
Genital blister	3 ( 37.5%)	1 ( 12.5%)	4 ( 50.0%)	0 ( 0.0%)	8
Reflux laryngitis	0 ( 0.0%)	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	8
Rectal fissure	3 ( 37.5%)	2 ( 25.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Reaction to colouring	3 ( 37.5%)	2 ( 25.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Benign neoplasm	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Growth disorder	6 ( 75.0%)	0 ( 0.0%)	2 ( 25.0%)	0 ( 0.0%)	8
Vestibular disorder	1 ( 12.5%)	3 ( 37.5%)	1 ( 12.5%)	3 ( 37.5%)	8
Radiation oesophagitis	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8
Pyoderma	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Exposure to communicable disease	1 ( 12.5%)	5 ( 62.5%)	2 ( 25.0%)	0 ( 0.0%)	8



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Aneurysm ruptured	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8
Aortic aneurysm rupture	0 ( 0.0%)	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	8
Chemotherapeutic drug level increased	7 ( 87.5%)	0 ( 0.0%)	1 ( 12.5%)	0 ( 0.0%)	8
Intestinal fibrosis	0 ( 0.0%)	2 ( 25.0%)	3 ( 37.5%)	3 ( 37.5%)	8
Vitamin D abnormal	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Pterygium	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Prostatectomy	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
Protothecosis	0 ( 0.0%)	5 ( 62.5%)	0 ( 0.0%)	3 ( 37.5%)	8
Gingival erythema	2 ( 25.0%)	0 ( 0.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Product expiration date issue	1 ( 12.5%)	2 ( 25.0%)	4 ( 50.0%)	1 ( 12.5%)	8
Product blister packaging issue	0 ( 0.0%)	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	8
Defiant behaviour	7 ( 87.5%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 12.5%)	8
Pseudocirrhosis	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Gastrointestinal procedural complication	0 ( 0.0%)	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	8
Gastrointestinal polyp haemorrhage	0 ( 0.0%)	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	8
Presbyopia	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Gastrointestinal neoplasm	0 ( 0.0%)	1 ( 12.5%)	5 ( 62.5%)	2 ( 25.0%)	8
Pregnenolone deficiency	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Bacterial translocation	2 ( 25.0%)	1 ( 12.5%)	1 ( 12.5%)	4 ( 50.0%)	8
Postoperative ileus	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8
Postoperative adhesion	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	0 ( 0.0%)	8
Extravasation blood	0 ( 0.0%)	4 ( 50.0%)	3 ( 37.5%)	1 ( 12.5%)	8
Iris atrophy	6 ( 75.0%)	1 ( 12.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Bacterial endophthalmitis	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Central sleep apnoea syndrome	1 ( 14.3%)	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	7
Pleural disorder	1 ( 14.3%)	1 ( 14.3%)	4 ( 57.1%)	1 ( 14.3%)	7
Cauda equina syndrome	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Fungal pharyngitis	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Personality change due to a general medical condition	2 ( 28.6%)	0 ( 0.0%)	5 ( 71.4%)	0 ( 0.0%)	7
Peritoneal disorder	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Adenoidectomy	6 ( 85.7%)	1 ( 14.3%)	0 ( 0.0%)	0 ( 0.0%)	7
Grief reaction	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Paternal exposure during pregnancy	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	0 ( 0.0%)	7
Fibrocystic breast disease	0 ( 0.0%)	4 ( 57.1%)	0 ( 0.0%)	3 ( 42.9%)	7
Fibroblast growth factor 23 increased	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Femoroacetabular impingement	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	0 ( 0.0%)	7
Parasomnia	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Paraneoplastic neurological syndrome	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Acquired diaphragmatic eventration	1 ( 14.3%)	3 ( 42.9%)	2 ( 28.6%)	1 ( 14.3%)	7
Paranasal sinus inflammation	0 ( 0.0%)	4 ( 57.1%)	2 ( 28.6%)	1 ( 14.3%)	7
Autoimmune heparin-induced thrombocytopenia	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Red blood cells urine positive	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	0 ( 0.0%)	7
Anaemia of malignant disease	1 ( 14.3%)	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	7
Pancreatic neuroendocrine tumour metastatic	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Cardiac pacemaker replacement	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7
PCO2 increased	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	7
Oxygen consumption decreased	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Factor VIII inhibition	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	0 ( 0.0%)	7
Anaemia folate deficiency	0 ( 0.0%)	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	7
Facial nerve disorder	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7
Resorption bone increased	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Eyelid cyst	1 ( 14.3%)	4 ( 57.1%)	0 ( 0.0%)	2 ( 28.6%)	7
Oral lichen planus	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Oral blood blister	1 ( 14.3%)	0 ( 0.0%)	5 ( 71.4%)	1 ( 14.3%)	7

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
False negative investigation result	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Injury corneal	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Extra-axial haemorrhage	6 ( 85.7%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 14.3%)	7
Oesophagitis ulcerative	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	7
Candida pneumonia	1 ( 14.3%)	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	7
Fascicular block	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Atrial appendage closure	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Occult blood	1 ( 14.3%)	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	7
Atonic urinary bladder	0 ( 0.0%)	2 ( 28.6%)	3 ( 42.9%)	2 ( 28.6%)	7
Chronic myeloid leukaemia transformation	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	7
Erythromelalgia	1 ( 14.3%)	0 ( 0.0%)	5 ( 71.4%)	1 ( 14.3%)	7
Morganella infection	0 ( 0.0%)	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	7
Cardiac sarcoidosis	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	7
Abdominoplasty	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	0 ( 0.0%)	7
Acute promyelocytic leukaemia	0 ( 0.0%)	3 ( 42.9%)	2 ( 28.6%)	2 ( 28.6%)	7
Neutropenia neonatal	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Vaginal odour	1 ( 14.3%)	3 ( 42.9%)	2 ( 28.6%)	1 ( 14.3%)	7
Eosinophilic fasciitis	1 ( 14.3%)	1 ( 14.3%)	3 ( 42.9%)	2 ( 28.6%)	7
Autoimmune hypothyroidism	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Needle track marks	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Enterovirus test positive	5 ( 71.4%)	1 ( 14.3%)	1 ( 14.3%)	0 ( 0.0%)	7
Nasal turbinate hypertrophy	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Burnout syndrome	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	0 ( 0.0%)	7
Enlarged uvula	1 ( 14.3%)	2 ( 28.6%)	4 ( 57.1%)	0 ( 0.0%)	7
Nail pigmentation	1 ( 14.3%)	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	7
Nail injury	1 ( 14.3%)	2 ( 28.6%)	4 ( 57.1%)	0 ( 0.0%)	7
Rectal stenosis	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	7

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Endometritis	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	0 ( 0.0%)	7
Myoglobinaemia	5 ( 71.4%)	1 ( 14.3%)	1 ( 14.3%)	0 ( 0.0%)	7
Accident at home	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Endocarditis bacterial	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Arthritis reactive	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Bronchospasm paradoxical	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Emergency care examination	0 ( 0.0%)	4 ( 57.1%)	1 ( 14.3%)	2 ( 28.6%)	7
Coagulation factor V level abnormal	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Electrocardiogram change	0 ( 0.0%)	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	7
Electrocardiogram T wave amplitude decreased	1 ( 14.3%)	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	7
Mucosal discolouration	0 ( 0.0%)	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	7
Moraxella infection	4 ( 57.1%)	1 ( 14.3%)	2 ( 28.6%)	0 ( 0.0%)	7
Coating in mouth	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Serum serotonin increased	1 ( 14.3%)	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	7
Eczema asteatotic	3 ( 42.9%)	1 ( 14.3%)	3 ( 42.9%)	0 ( 0.0%)	7
Ectropion	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Micturition frequency decreased	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	7
Breast reconstruction	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	7
Microcephaly	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Microalbuminuria	0 ( 0.0%)	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	7
Metatarsalgia	0 ( 0.0%)	3 ( 42.9%)	2 ( 28.6%)	2 ( 28.6%)	7
Urinary tract inflammation	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Ear infection bacterial	3 ( 42.9%)	2 ( 28.6%)	2 ( 28.6%)	0 ( 0.0%)	7
Mesothelioma malignant	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Mesenteric artery stenosis	0 ( 0.0%)	1 ( 14.3%)	2 ( 28.6%)	4 ( 57.1%)	7
Urinary sediment present	0 ( 0.0%)	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	7
Mental disability	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	0 ( 0.0%)	7

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Menopausal disorder	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Meningitis listeria	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Colectomy total	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	0 ( 0.0%)	7
Melanoma recurrent	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Duodenogastric reflux	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	0 ( 0.0%)	7
Simple partial seizures	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Medical device site haemorrhage	1 ( 14.3%)	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	7
Mediastinal mass	2 ( 28.6%)	1 ( 14.3%)	1 ( 14.3%)	3 ( 42.9%)	7
Skin hypopigmentation	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7
Marginal zone lymphoma	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Skin squamous cell carcinoma recurrent	0 ( 0.0%)	3 ( 42.9%)	0 ( 0.0%)	4 ( 57.1%)	7
Allergic transfusion reaction	2 ( 28.6%)	3 ( 42.9%)	2 ( 28.6%)	0 ( 0.0%)	7
Malignant hypertension	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	7
Male reproductive tract disorder	5 ( 71.4%)	1 ( 14.3%)	0 ( 0.0%)	1 ( 14.3%)	7
Malacoplakia gastrointestinal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	7
Double stranded DNA antibody positive	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Intermittent explosive disorder	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	0 ( 0.0%)	7
Perineal pain	1 ( 14.3%)	2 ( 28.6%)	3 ( 42.9%)	1 ( 14.3%)	7
Bone scan abnormal	0 ( 0.0%)	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	7
Bone operation	0 ( 0.0%)	2 ( 28.6%)	3 ( 42.9%)	2 ( 28.6%)	7
Lung transplant rejection	2 ( 28.6%)	1 ( 14.3%)	4 ( 57.1%)	0 ( 0.0%)	7
Acute graft versus host disease in liver	3 ( 42.9%)	1 ( 14.3%)	3 ( 42.9%)	0 ( 0.0%)	7
Lung perforation	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Avulsion fracture	2 ( 28.6%)	2 ( 28.6%)	3 ( 42.9%)	0 ( 0.0%)	7
Lumbar hernia	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Lower urinary tract symptoms	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Liver transplant rejection	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7

**Reaction Summary Table**  
**Derived Age Group**

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Antimicrobial susceptibility test resistant	3 ( 42.9%)	0 ( 0.0%)	4 ( 57.1%)	0 ( 0.0%)	7
Bone graft	2 ( 28.6%)	3 ( 42.9%)	1 ( 14.3%)	1 ( 14.3%)	7
Diffuse alopecia	1 ( 14.3%)	2 ( 28.6%)	2 ( 28.6%)	2 ( 28.6%)	7
Lithiasis	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	0 ( 0.0%)	7
Adrenal cyst	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Application site bruise	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Lip squamous cell carcinoma	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Limb crushing injury	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	7
Body tinea	1 ( 14.3%)	3 ( 42.9%)	0 ( 0.0%)	3 ( 42.9%)	7
Body surface area decreased	0 ( 0.0%)	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	7
Leukoerythroblastosis	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	7
Body mass index	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	7
Hypercalciuria	4 ( 57.1%)	1 ( 14.3%)	2 ( 28.6%)	0 ( 0.0%)	7
Left ventricle outflow tract obstruction	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Abscess neck	1 ( 14.3%)	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	7
Learning disability	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	0 ( 0.0%)	7
Typhoid fever	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Blood urine	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7
Squamous cell carcinoma of lung	0 ( 0.0%)	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	7
Blood uric acid abnormal	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Large intestine erosion	0 ( 0.0%)	4 ( 57.1%)	1 ( 14.3%)	2 ( 28.6%)	7
Lagophthalmos	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Dermoid cyst	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Steatorrhoea	1 ( 14.3%)	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	7
Ketonuria	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	0 ( 0.0%)	7
Keratitis bacterial	2 ( 28.6%)	2 ( 28.6%)	3 ( 42.9%)	0 ( 0.0%)	7
Blood prolactin decreased	1 ( 14.3%)	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	7

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> (N=&AGEGRP1)	<i>Group2 (26-50)</i> (N=&AGEGRP2)	<i>Group3 (51-75)</i> (N=&AGEGRP3)	<i>Group4 (75+)</i> (N=&AGEGRP4)	<i>Total</i> (N=&AGEGRP5)
Blood prolactin abnormal	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	0 ( 0.0%)	7
Dental prosthesis placement	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Joint hyperextension	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7
Jaw cyst	1 ( 14.3%)	2 ( 28.6%)	4 ( 57.1%)	0 ( 0.0%)	7
Delayed recovery from anaesthesia	1 ( 14.3%)	2 ( 28.6%)	1 ( 14.3%)	3 ( 42.9%)	7
B-cell lymphoma recurrent	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	7
Blood pH decreased	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7
Intracardiac mass	0 ( 0.0%)	1 ( 14.3%)	2 ( 28.6%)	4 ( 57.1%)	7
Waist circumference increased	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Blood creatine abnormal	1 ( 14.3%)	2 ( 28.6%)	3 ( 42.9%)	1 ( 14.3%)	7
Subcutaneous drug absorption impaired	2 ( 28.6%)	2 ( 28.6%)	3 ( 42.9%)	0 ( 0.0%)	7
Substance abuser	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	0 ( 0.0%)	7
Hyphaema	0 ( 0.0%)	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	7
Visual brightness	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	1 ( 14.3%)	7
Burning mouth syndrome	1 ( 14.3%)	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	7
Viral pharyngitis	2 ( 28.6%)	3 ( 42.9%)	2 ( 28.6%)	0 ( 0.0%)	7
Superior sagittal sinus thrombosis	4 ( 57.1%)	2 ( 28.6%)	1 ( 14.3%)	0 ( 0.0%)	7
Blood ketone body present	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	0 ( 0.0%)	7
Alveolitis	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Hypoglycaemic seizure	3 ( 42.9%)	0 ( 0.0%)	0 ( 0.0%)	4 ( 57.1%)	7
Cytomegalovirus enteritis	0 ( 0.0%)	4 ( 57.1%)	1 ( 14.3%)	2 ( 28.6%)	7
Insulin-like growth factor decreased	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	0 ( 0.0%)	7
Vein discolouration	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	0 ( 0.0%)	7
Cyclic vomiting syndrome	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	0 ( 0.0%)	7
Catheter site thrombosis	1 ( 14.3%)	1 ( 14.3%)	3 ( 42.9%)	2 ( 28.6%)	7
Tachycardia induced cardiomyopathy	4 ( 57.1%)	0 ( 0.0%)	1 ( 14.3%)	2 ( 28.6%)	7
Uterine pain	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	0 ( 0.0%)	7

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Placenta praevia	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	0 ( 0.0%)	7
Urticaria pressure	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Tenoplasty	1 ( 14.3%)	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	7
Testis discomfort	4 ( 57.1%)	1 ( 14.3%)	2 ( 28.6%)	0 ( 0.0%)	7
Ureteric stenosis	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Infective myositis	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	0 ( 0.0%)	7
Blood catecholamines increased	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Illness anxiety disorder	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Tooth erosion	0 ( 0.0%)	5 ( 71.4%)	1 ( 14.3%)	1 ( 14.3%)	7
Cough decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	7
Corneal deposits	5 ( 71.4%)	0 ( 0.0%)	1 ( 14.3%)	1 ( 14.3%)	7
Toxic shock syndrome streptococcal	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	7
Tongue fungal infection	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Tongue injury	2 ( 28.6%)	1 ( 14.3%)	4 ( 57.1%)	0 ( 0.0%)	7
Gastrectomy	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Immune-mediated pancytopenia	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Tissue injury	2 ( 28.6%)	3 ( 42.9%)	2 ( 28.6%)	0 ( 0.0%)	7
Thyroxine decreased	2 ( 28.6%)	2 ( 28.6%)	2 ( 28.6%)	1 ( 14.3%)	7
Thrombotic stroke	1 ( 14.3%)	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	7
Abdominal sepsis	1 ( 14.3%)	4 ( 57.1%)	1 ( 14.3%)	1 ( 14.3%)	7
Convulsions local	1 ( 14.3%)	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	7
Therapeutic product ineffective for unapproved indica	1 ( 14.3%)	3 ( 42.9%)	1 ( 14.3%)	2 ( 28.6%)	7
Ileal perforation	1 ( 14.3%)	3 ( 42.9%)	2 ( 28.6%)	1 ( 14.3%)	7
Idiopathic orbital inflammation	0 ( 0.0%)	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	7
Tracheal disorder	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	7
Hypotensive crisis	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Syndactyly	6 ( 85.7%)	1 ( 14.3%)	0 ( 0.0%)	0 ( 0.0%)	7



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blindness day	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Epidural injection	0 ( 0.0%)	4 ( 57.1%)	2 ( 28.6%)	1 ( 14.3%)	7
Blood chromogranin A increased	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Sudden onset of sleep	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7
Tri-iodothyronine free decreased	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Trichoglossia	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Post procedural contusion	1 ( 14.3%)	0 ( 0.0%)	4 ( 57.1%)	2 ( 28.6%)	7
Increased need for sleep	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Stoma site extravasation	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Stiff person syndrome	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	7
Hypermetropia	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	0 ( 0.0%)	7
Hypermetabolism	1 ( 14.3%)	1 ( 14.3%)	4 ( 57.1%)	1 ( 14.3%)	7
Hypercreatinaemia	1 ( 14.3%)	1 ( 14.3%)	2 ( 28.6%)	3 ( 42.9%)	7
Splenic cyst	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Hyperaldosteronism	1 ( 14.3%)	2 ( 28.6%)	3 ( 42.9%)	1 ( 14.3%)	7
Spinal cord haemorrhage	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	0 ( 0.0%)	7
Soft tissue haemorrhage	4 ( 57.1%)	0 ( 0.0%)	3 ( 42.9%)	0 ( 0.0%)	7
Gastrointestinal hypermotility	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	0 ( 0.0%)	7
Influenza immunisation	0 ( 0.0%)	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	7
Colorectal cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	7
Adrenal adenoma	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Colony stimulating factor therapy	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Skin turgor decreased	5 ( 71.4%)	0 ( 0.0%)	2 ( 28.6%)	0 ( 0.0%)	7
Urethral pain	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Herpes zoster oticus	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Right ventricle outflow tract obstruction	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Sinonasal obstruction	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Culture positive	1 ( 14.3%)	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	7
Urinary bladder suspension	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	7
Serositis	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Erythrodermic psoriasis	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	7
Senile dementia	0 ( 0.0%)	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	7
Selective eating disorder	4 ( 57.1%)	2 ( 28.6%)	1 ( 14.3%)	0 ( 0.0%)	7
Gastrointestinal surgery	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Hepatic cyst infection	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Hepatic cancer metastatic	0 ( 0.0%)	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	7
Procedural nausea	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	0 ( 0.0%)	7
Scan abnormal	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Hepatectomy	1 ( 14.3%)	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	7
Heparin resistance	1 ( 14.3%)	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	7
Chylothorax	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Varicella zoster pneumonia	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	7
Injection site pustule	2 ( 28.6%)	3 ( 42.9%)	2 ( 28.6%)	0 ( 0.0%)	7
Chronic lymphocytic leukaemia recurrent	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Retinitis viral	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	0 ( 0.0%)	7
Retinal thickening	0 ( 0.0%)	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	7
Resting tremor	0 ( 0.0%)	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	7
Haemorrhoids thrombosed	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	7
Respiratory rate	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Residual urine volume increased	0 ( 0.0%)	4 ( 57.1%)	1 ( 14.3%)	2 ( 28.6%)	7
Renal atrophy	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Cytomegalovirus duodenitis	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Hanging	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	0 ( 0.0%)	7
Refusal of examination	2 ( 28.6%)	3 ( 42.9%)	1 ( 14.3%)	1 ( 14.3%)	7

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Recurrence of neuromuscular blockade	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	0 ( 0.0%)	7
Administration site infection	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	7
Benign neoplasm of adrenal gland	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	7
Very low density lipoprotein increased	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	7
Chloasma	0 ( 0.0%)	4 ( 57.1%)	2 ( 28.6%)	1 ( 14.3%)	7
Pulpless tooth	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Pulmonary vascular disorder	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Pulmonary renal syndrome	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Vitamin B6 deficiency	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Globotriaosylceramide increased	2 ( 28.6%)	2 ( 28.6%)	3 ( 42.9%)	0 ( 0.0%)	7
Vitamin B6 decreased	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	7
Psoas abscess	0 ( 0.0%)	2 ( 28.6%)	3 ( 42.9%)	2 ( 28.6%)	7
Pseudomonas test positive	1 ( 14.3%)	3 ( 42.9%)	2 ( 28.6%)	1 ( 14.3%)	7
Gingival discomfort	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Extensor plantar response	0 ( 0.0%)	4 ( 57.1%)	2 ( 28.6%)	1 ( 14.3%)	7
Vulval ulceration	4 ( 57.1%)	2 ( 28.6%)	1 ( 14.3%)	0 ( 0.0%)	7
Genital swelling	1 ( 14.3%)	1 ( 14.3%)	3 ( 42.9%)	2 ( 28.6%)	7
Prolapse	1 ( 14.3%)	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	7
Genital lesion	2 ( 28.6%)	0 ( 0.0%)	3 ( 42.9%)	2 ( 28.6%)	7
Genital infection fungal	0 ( 0.0%)	2 ( 28.6%)	3 ( 42.9%)	2 ( 28.6%)	7
Genital infection	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Administration site discolouration	2 ( 28.6%)	1 ( 14.3%)	3 ( 42.9%)	1 ( 14.3%)	7
Cerebral small vessel ischaemic disease	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Intraocular pressure test abnormal	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Preterm premature rupture of membranes	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Premenstrual syndrome	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	0 ( 0.0%)	7
Precancerous lesion of digestive tract	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cerebral calcification	2 ( 28.6%)	0 ( 0.0%)	5 ( 71.4%)	0 ( 0.0%)	7
Postural tremor	0 ( 0.0%)	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	7
Postpartum haemorrhage	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	0 ( 0.0%)	7
Postoperative thrombosis	1 ( 14.3%)	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	7
Xeroderma	1 ( 14.3%)	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	7
Cerebellar stroke	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Wound abscess	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Post procedural sepsis	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Gastroenteritis radiation	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7
Post concussion syndrome	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	1 ( 16.7%)	6
Gastritis haemorrhagic	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Central nervous system viral infection	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Pulmonary artery stenosis	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Bacterial abdominal infection	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Glomerulonephritis membranoproliferative	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Poikilocytosis	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Pneumonia parainfluenzae viral	1 ( 16.7%)	2 ( 33.3%)	2 ( 33.3%)	1 ( 16.7%)	6
Babesiosis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Pneumobilia	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Pneumatosis	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Pleuropericarditis	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Pleural mesothelioma	0 ( 0.0%)	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	6
BCG related cystitis	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Plasma cell leukaemia	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Chest wall haematoma	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Pituitary-dependent Cushing's syndrome	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Fungal endocarditis	1 ( 16.7%)	1 ( 16.7%)	2 ( 33.3%)	2 ( 33.3%)	6

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Pica	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	6
Catheter site irritation	3 ( 50.0%)	0 ( 0.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Catheter site inflammation	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	6
Fracture nonunion	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Adenotonsillectomy	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
B-cell aplasia	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Periprosthetic fracture	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Peripheral nerve lesion	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Anal cyst	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Granulomatous dermatitis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Penile ulceration	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Pelvic haematoma	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Peak expiratory flow rate decreased	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Viral test positive	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Parathyroidectomy	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Autoimmune lung disease	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Paraneoplastic pemphigus	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Cardiac ventricular disorder	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Fear-related avoidance of activities	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Cytomegalovirus gastritis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Fat necrosis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Blood insulin abnormal	4 ( 66.7%)	1 ( 16.7%)	0 ( 0.0%)	1 ( 16.7%)	6
Fallopian tube disorder	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Angiosarcoma	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Pachymeningitis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Oxygen saturation increased	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Cardiac function test abnormal	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Overflow diarrhoea	2 ( 33.3%)	2 ( 33.3%)	2 ( 33.3%)	0 ( 0.0%)	6
Cardiac failure high output	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Ovarian granulosa cell tumour	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Amyotrophy	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Atypical mycobacterium test positive	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Osteosarcoma	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Osteomyelitis chronic	2 ( 33.3%)	2 ( 33.3%)	2 ( 33.3%)	0 ( 0.0%)	6
Eyelid operation	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Carcinoid tumour pulmonary	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Orthosis user	3 ( 50.0%)	1 ( 16.7%)	1 ( 16.7%)	1 ( 16.7%)	6
Eye infection viral	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Eye infection fungal	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Optic nerve neoplasm	0 ( 0.0%)	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	6
Cardiac output decreased	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Open fracture	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Extranodal marginal zone B-cell lymphoma (MALT type)	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Capillary fragility	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Capillaritis	2 ( 33.3%)	1 ( 16.7%)	3 ( 50.0%)	0 ( 0.0%)	6
Candida test positive	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Oesophageal perforation	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Exposure to household chemicals	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Oesophageal irritation	1 ( 16.7%)	0 ( 0.0%)	4 ( 66.7%)	1 ( 16.7%)	6
Oesophageal injury	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Oesophageal food impaction	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Oedema genital	0 ( 0.0%)	3 ( 50.0%)	1 ( 16.7%)	2 ( 33.3%)	6
Ocular neoplasm	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Pancreatic atrophy	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Chronic left ventricular failure	0 ( 0.0%)	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	6
Obstructive defaecation	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	6
Hearing disability	1 ( 16.7%)	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	6
Erythematotelangiectatic rosacea	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Neurofibroma	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Neuroendocrine tumour of the rectum	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Epidural analgesia	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Hemiparaesthesia	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Amimia	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	6
CD19 lymphocytes decreased	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Neovascularisation	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Neonatal respiratory acidosis	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Buttock injury	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Enterostomy	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Neck deformity	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Acute on chronic liver failure	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Nasal septum perforation	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Nasal polypectomy	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Nasal mucosal disorder	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Nasal cavity cancer	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Nail dystrophy	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Nail bed disorder	2 ( 33.3%)	2 ( 33.3%)	2 ( 33.3%)	0 ( 0.0%)	6
NSAID exacerbated respiratory disease	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Myxoedema	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Hepatic haemorrhage	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Myocardial strain imaging abnormal	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Myocardial oedema	2 ( 33.3%)	2 ( 33.3%)	1 ( 16.7%)	1 ( 16.7%)	6

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Budd-Chiari syndrome	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Myeloid leukaemia	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Rectal ulcer	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Alternaria infection	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Mycobacterium marinum infection	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Altered visual depth perception	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Muscle swelling	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Elliptocytosis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Bronchiolitis obliterans syndrome	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Mucosal hypertrophy	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	1 ( 16.7%)	6
Arteriovenous malformation	1 ( 16.7%)	1 ( 16.7%)	2 ( 33.3%)	2 ( 33.3%)	6
Electrocardiogram ST-T change	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Muckle-Wells syndrome	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Electrocardiogram QT shortened	2 ( 33.3%)	1 ( 16.7%)	1 ( 16.7%)	2 ( 33.3%)	6
Electrocardiogram QT interval abnormal	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Morbid thoughts	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Patient isolation	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Elbow deformity	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Brief psychotic disorder with marked stressors	0 ( 0.0%)	3 ( 50.0%)	0 ( 0.0%)	3 ( 50.0%)	6
Mitral valve thickening	4 ( 66.7%)	0 ( 0.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Eczema weeping	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Mitochondrial encephalomyopathy	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Acute macular neuroretinopathy	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Breast ulceration	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Arterial therapeutic procedure	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Eating disorder symptom	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Ear neoplasm malignant	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	6



Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Shock symptom	0 ( 0.0%)	2 ( 33.3%)	2 ( 33.3%)	2 ( 33.3%)	6
Breast feeding	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Pelvic mass	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Shunt malfunction	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	6
Meningococcal sepsis	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Dysdiadochokinesis	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Dysaesthesia pharynx	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Arnold-Chiari malformation	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	0 ( 0.0%)	6
Breast calcifications	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Anal blister	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Medical induction of coma	1 ( 16.7%)	2 ( 33.3%)	2 ( 33.3%)	1 ( 16.7%)	6
Penile curvature	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Medical device site pain	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Medical device change	2 ( 33.3%)	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	6
Flashback	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Acute hepatitis B	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Drug rechallenge positive	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Application site scab	3 ( 50.0%)	1 ( 16.7%)	1 ( 16.7%)	1 ( 16.7%)	6
Brain cancer metastatic	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Dropped head syndrome	2 ( 33.3%)	1 ( 16.7%)	2 ( 33.3%)	1 ( 16.7%)	6
Male genital atrophy	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Pericarditis fungal	0 ( 0.0%)	3 ( 50.0%)	0 ( 0.0%)	3 ( 50.0%)	6
Macrocephaly	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Uraemic encephalopathy	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Foetal hypokinesia	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	6
Disseminated toxoplasmosis	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Foetal malformation	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	6

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Lung diffusion test abnormal	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Lung cyst	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Ludwig angina	1 ( 16.7%)	1 ( 16.7%)	2 ( 33.3%)	2 ( 33.3%)	6
Unexpected vaginal bleeding on hormonal IUD	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Diffuse large B-cell lymphoma stage IV	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Application site dryness	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Liver function test decreased	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Diet refusal	2 ( 33.3%)	0 ( 0.0%)	2 ( 33.3%)	2 ( 33.3%)	6
Complicated appendicitis	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Bone fragmentation	1 ( 16.7%)	0 ( 0.0%)	4 ( 66.7%)	1 ( 16.7%)	6
Infective exacerbation of chronic obstructive airways	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	6
Diaphragmatic paralysis	1 ( 16.7%)	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	6
Bladder irritation	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Limb asymmetry	0 ( 0.0%)	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	6
Leukoplakia oral	0 ( 0.0%)	2 ( 33.3%)	2 ( 33.3%)	2 ( 33.3%)	6
Leukoderma	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Leukaemoid reaction	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Splenic infection viral	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Apparent death	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Left atrial appendage closure implant	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Bloody peritoneal effluent	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Learning disorder	4 ( 66.7%)	0 ( 0.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Blood zinc decreased	0 ( 0.0%)	2 ( 33.3%)	2 ( 33.3%)	2 ( 33.3%)	6
Spontaneous bacterial peritonitis	2 ( 33.3%)	0 ( 0.0%)	4 ( 66.7%)	0 ( 0.0%)	6
Blood viscosity decreased	0 ( 0.0%)	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	6
Laryngeal inflammation	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Laryngeal disorder	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blood uric acid decreased	1 ( 16.7%)	2 ( 33.3%)	2 ( 33.3%)	1 ( 16.7%)	6
Device colour issue	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Developmental hip dysplasia	3 ( 50.0%)	0 ( 0.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Lactation insufficiency	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Lactation disorder	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Lack of spontaneous speech	3 ( 50.0%)	0 ( 0.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Labelled drug-food interaction medication error	4 ( 66.7%)	0 ( 0.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Kwashiorkor	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Keratoacanthoma	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Keratic precipitates	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Dependence on respirator	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Catheter site bruise	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Jaundice neonatal	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Irregular sleep wake rhythm disorder	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Irregular breathing	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Anal fissure haemorrhage	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Stomatitis haemorrhagic	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Deja vu	4 ( 66.7%)	0 ( 0.0%)	1 ( 16.7%)	1 ( 16.7%)	6
Intravascular haemolysis	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Wound sepsis	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Pharyngeal mass	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	1 ( 16.7%)	6
Deep brain stimulation	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Blood osmolarity decreased	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Blood magnesium abnormal	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Vitamin C deficiency	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Deafness transitory	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Vitamin B1 deficiency	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Intervertebral disc injury	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Graft complication	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Viral skin infection	3 ( 50.0%)	0 ( 0.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Incision site haemorrhage	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Benign breast neoplasm	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Adrenal neoplasm	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Cytomegalovirus gastrointestinal infection	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	1 ( 16.7%)	6
Nasal neoplasm	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Vascular stenosis	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Vascular malformation	2 ( 33.3%)	1 ( 16.7%)	3 ( 50.0%)	0 ( 0.0%)	6
Vascular hyalinosis	0 ( 0.0%)	2 ( 33.3%)	0 ( 0.0%)	4 ( 66.7%)	6
Hypopyon	0 ( 0.0%)	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	6
Vaginal abscess	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	0 ( 0.0%)	6
VEXAS syndrome	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Cutaneous nocardiosis	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Toxic cardiomyopathy	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Infusion site injury	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Idiopathic environmental intolerance	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Testicular disorder	0 ( 0.0%)	2 ( 33.3%)	0 ( 0.0%)	4 ( 66.7%)	6
Urinary bladder polyp	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Contraindication to medical treatment	2 ( 33.3%)	0 ( 0.0%)	3 ( 50.0%)	1 ( 16.7%)	6
Tethered oral tissue	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	6
Tumour compression	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Tubulointerstitial nephritis and uveitis syndrome	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Trigger points	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Trichophytosis	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Transplantation complication	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	6

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Nematodiasis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Transferrin decreased	0 ( 0.0%)	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	6
Tractional retinal detachment	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Toxic nodular goitre	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Corneal toxicity	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Tooth avulsion	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Tongue spasm	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	0 ( 0.0%)	6
Tongue rough	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Corneal infection	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Immune-mediated neuropathy	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Cor pulmonale	0 ( 0.0%)	2 ( 33.3%)	1 ( 16.7%)	3 ( 50.0%)	6
Tooth deposit	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Coombs positive haemolytic anaemia	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Coombs negative haemolytic anaemia	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Thoracic cavity drainage	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Iliotibial band syndrome	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Therapeutic response increased	1 ( 16.7%)	2 ( 33.3%)	0 ( 0.0%)	3 ( 50.0%)	6
Testis cancer	2 ( 33.3%)	2 ( 33.3%)	1 ( 16.7%)	1 ( 16.7%)	6
Testicular mass	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Toxicologic test abnormal	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Iatrogenic injury	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	1 ( 16.7%)	6
Contact lens intolerance	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Illrd nerve paralysis	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Blood albumin abnormal	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Tracheal injury	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	6
Transfusion reaction	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Synovial rupture	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hypohidrosis	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Hypogonadism male	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Suspected product tampering	1 ( 16.7%)	1 ( 16.7%)	2 ( 33.3%)	2 ( 33.3%)	6
Suspected product contamination	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	1 ( 16.7%)	6
Adrenal mass	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Hypnagogic hallucination	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)	4 ( 66.7%)	6
Trisomy 18	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Hypersensitivity myocarditis	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Stoma site oedema	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Hyperplasia	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Bladder ulcer	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Hyperinsulinaemic hypoglycaemia	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Computerised tomogram thorax	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Hypergammaglobulinaemia	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Sports injury	3 ( 50.0%)	1 ( 16.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Spontaneous haematoma	0 ( 0.0%)	2 ( 33.3%)	2 ( 33.3%)	2 ( 33.3%)	6
Type III immune complex mediated reaction	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Hyperchloraemia	4 ( 66.7%)	0 ( 0.0%)	1 ( 16.7%)	1 ( 16.7%)	6
Hypercalcaemia of malignancy	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Posthaemorrhagic hydrocephalus	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Spinal nerve stimulator implantation	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Spinal flattening	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Spinal epidural haemorrhage	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	6
Complement factor decreased	3 ( 50.0%)	1 ( 16.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Solar dermatitis	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Sodium retention	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Cryptitis	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cryptococcal fungaemia	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Histone antibody positive	0 ( 0.0%)	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	6
Tumour invasion	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Colonoscopy abnormal	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Urethral obstruction	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Infusion	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Colon dysplasia	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Herpes zoster meningoencephalitis	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Urethral haemorrhage	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Anorectal infection	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Shock hypoglycaemic	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Sexually inappropriate behaviour	0 ( 0.0%)	2 ( 33.3%)	1 ( 16.7%)	3 ( 50.0%)	6
Hepatitis alcoholic	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Septic pulmonary embolism	2 ( 33.3%)	2 ( 33.3%)	2 ( 33.3%)	0 ( 0.0%)	6
Septic arthritis staphylococcal	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Sensorimotor disorder	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Inguinal mass	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Biopsy kidney	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Secondary syphilis	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Hepatic vascular thrombosis	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Secondary amyloidosis	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Uterine cyst	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Second degree chemical burn of skin	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Seasonal affective disorder	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Scrotal oedema	1 ( 16.7%)	2 ( 33.3%)	2 ( 33.3%)	1 ( 16.7%)	6
Scrotal cellulitis	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Clonic convulsion	3 ( 50.0%)	1 ( 16.7%)	1 ( 16.7%)	1 ( 16.7%)	6

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Abnormal menstrual clots	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Scleral discolouration	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Schizoaffective disorder bipolar type	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Scarlet fever	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	6
Hepatic atrophy	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Sarcopenia	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Salpingo-oophorectomy bilateral	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Salivary gland enlargement	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Injection site nerve damage	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Right ventricular dilatation	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Right atrial dilatation	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	3 ( 50.0%)	6
Injection site laceration	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Retinal occlusive vasculitis	0 ( 0.0%)	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	6
Chronic hepatic failure	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Vascular dementia	0 ( 0.0%)	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	6
Rest regimen	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Vascular stent stenosis	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Renal tubular dysfunction	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Beta 2 microglobulin increased	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Haemochromatosis	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Reflexes abnormal	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Haemangioma of skin	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Product monitoring error	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Cholinergic syndrome	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	6
Vertebrobasilar artery dissection	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Radioisotope scan abnormal	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Grip strength	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6



Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Victim of sexual abuse	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Chloroma	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Pyomyositis	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Oedema mouth	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Graft versus host disease oral	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Interstitial lung abnormality	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Child abuse	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Intervertebral disc compression	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Glucocorticoid deficiency	0 ( 0.0%)	3 ( 50.0%)	1 ( 16.7%)	2 ( 33.3%)	6
Glomerulosclerosis	3 ( 50.0%)	0 ( 0.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Pulmonary blastomycosis	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Pulmonary angioplasty	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Gingivitis ulcerative	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Basophil count decreased	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Androgenetic alopecia	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Protrusion tongue	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Gingival blister	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Protein deficiency	1 ( 16.7%)	1 ( 16.7%)	2 ( 33.3%)	2 ( 33.3%)	6
Cervix disorder	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Vulvovaginitis	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Genital ulcer syndrome	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Progressive multiple sclerosis	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Cervical polyp	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Genital discomfort	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
General physical condition	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Product commingling	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Product coating issue	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Gastrostomy tube site complication	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	6
Gastrooesophageal reflux in neonate	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Change in sustained attention	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Withdrawal catatonia	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Cerebral palsy	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Cerebral microinfarction	0 ( 0.0%)	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	6
Cerebral microangiopathy	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Wound infection bacterial	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Wrist deformity	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Cerebral cyst	3 ( 50.0%)	1 ( 16.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Aortic occlusion	0 ( 0.0%)	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	6
Gastrointestinal candidiasis	2 ( 33.3%)	0 ( 0.0%)	4 ( 66.7%)	0 ( 0.0%)	6
Posterior capsule opacification	2 ( 33.3%)	1 ( 16.7%)	1 ( 16.7%)	2 ( 33.3%)	6
Acinetobacter test positive	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Post procedural fistula	1 ( 16.7%)	0 ( 0.0%)	4 ( 66.7%)	1 ( 16.7%)	6
Anal squamous cell carcinoma	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Central vision loss	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Post infection glomerulonephritis	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Polypoidal choroidal vasculopathy	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Polymerase chain reaction positive	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Gastric neoplasm	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Bed bug infestation	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Pneumonia lipid	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Plicated tongue	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Pleural fibrosis	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Pleocytosis	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Platelet count	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pulmonary venous thrombosis	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Frostbite	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Frontotemporal dementia	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Pharyngitis bacterial	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Free fatty acids increased	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Catheter site extravasation	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Phaeohyphomycosis	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Pyloric stenosis	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Foreign body in respiratory tract	1 ( 20.0%)	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	5
Granulomatous lymphadenitis	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Periostitis	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Follicular lymphoma stage IV	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Catabolic state	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Foetal disorder	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Breast injury	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Autonomic dysreflexia	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Penile erythema	1 ( 20.0%)	1 ( 20.0%)	1 ( 20.0%)	2 ( 40.0%)	5
Pelvic discomfort	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Finger amputation	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Pelvi-ureteric obstruction	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Fibrous histiocytoma	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Fibromuscular dysplasia	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Patellofemoral pain syndrome	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
HLA marker study positive	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Parapsoriasis	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Paraproteinaemia	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Paraphimosis	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Paranasal sinus hyposecretion	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Feeding tube user	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Febrile nonhaemolytic transfusion reaction	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Pancreatolithiasis	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Autoimmune dermatitis	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Pancreatic duct dilatation	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Pancreatic carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Autoimmune arthritis	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Palmoplantar keratoderma	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Adenocarcinoma of appendix	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Palatal swelling	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Faecaluria	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	5
PIK3CA-activated mutation	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Adenocarcinoma metastatic	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Ovarian cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Atypical mycobacterial pneumonia	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Choroiditis	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Repetitive speech	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Eyelid injury	1 ( 20.0%)	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Carcinoma in situ	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Bickerstaff's encephalitis	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Carcinoid tumour of the small bowel	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Oropharyngeal plaque	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Oropharyngeal cancer	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Eye paraesthesia	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Respiratory paralysis	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Carboxyhaemoglobin increased	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Respiratory muscle weakness	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Carbon monoxide poisoning	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Eye haematoma	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Oral administration complication	1 ( 20.0%)	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Optic perineuritis	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Acute stress disorder	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	2 ( 40.0%)	5
Opisthotonus	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Extremity contracture	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Ophthalmic herpes simplex	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Oophorectomy bilateral	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Retinal exudates	0 ( 0.0%)	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Oesophagogastroduodenoscopy	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Exposure via eye contact	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Exposure via direct contact	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Pancreatic toxicity	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Exposure to allergen	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Oesophageal cancer metastatic	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Expiratory reserve volume decreased	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Retracted nipple	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Haptoglobin decreased	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Exercise lack of	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Nuchal rigidity	1 ( 20.0%)	1 ( 20.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Norepinephrine decreased	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Erythema annulare	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Nodal osteoarthritis	0 ( 0.0%)	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Chronic rhinosinusitis with nasal polyps	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Neurosurgery	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5

**Reaction Summary Table**  
**Derived Age Group**

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Neurosis	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Epidural haemorrhage	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Neurodegenerative disorder	3 ( 60.0%)	1 ( 20.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Saccadic eye movement	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Neuroblastoma	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Hemianopia homonymous	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Nerve block	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
American trypanosomiasis	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
C3 glomerulopathy	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Salivary gland calculus	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Negative symptoms in schizophrenia	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Necrotising oesophagitis	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Enthesophyte	0 ( 0.0%)	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	5
Near drowning	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Felty's syndrome	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Enterobacter sepsis	0 ( 0.0%)	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	5
Nasal herpes	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Burning sensation mucosal	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Vaccination site erythema	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Asocial behaviour	0 ( 0.0%)	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Nail pitting	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Burn oesophageal	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Endotracheal intubation complication	1 ( 20.0%)	1 ( 20.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Artificial crown procedure	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Burkitt's lymphoma recurrent	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Nail bed infection	1 ( 20.0%)	2 ( 40.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Endoscopy upper gastrointestinal tract	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	0 ( 0.0%)	5

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bunion operation	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Bundle branch block	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Parkinsonian crisis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	5
Bulbar palsy	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Brow ptosis	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Myelin oligodendrocyte glycoprotein antibody-associa	3 ( 60.0%)	1 ( 20.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Encephalomyelitis viral	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Mycobacterium chelonae infection	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Partial seizures with secondary generalisation	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Enanthema	1 ( 20.0%)	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Bronchopleural fistula	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Muscle hypertrophy	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Muscle enzyme increased	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Embolic cerebral infarction	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Artery dissection	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Inguinal hernia repair	1 ( 20.0%)	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Alpha tumour necrosis factor increased	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Biopsy lung	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Mood disorder due to a general medical condition	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Cutaneous calcification	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Septic cerebral embolism	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Monocyte chemotactic protein-1 increased	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Arteriovenous fistula	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Mixed connective tissue disease	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Breech presentation	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Eczema infected	2 ( 40.0%)	1 ( 20.0%)	0 ( 0.0%)	2 ( 40.0%)	5
Mineral supplementation	2 ( 40.0%)	1 ( 20.0%)	1 ( 20.0%)	1 ( 20.0%)	5

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Milk allergy	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Middle ear inflammation	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Microsporidia infection	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Ear, nose and throat infection	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Metastases to stomach	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Metastases to spleen	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Breast inflammation	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Metastases to neck	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Allogenic stem cell transplantation	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Metastases to eye	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Metastases to chest wall	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Metastases to abdominal cavity	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Dyspnoea paroxysmal nocturnal	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Dysplastic naevus	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Meralgia paraesthetica	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Seminoma	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Meniscus operation	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Meningoradiculitis	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Meningoencephalitis bacterial	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Dyscalculia	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Meningitis enterococcal	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Dysania	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Meningitis Escherichia	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Melanoderma	1 ( 20.0%)	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Duplicate therapy error	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	5
Ductus arteriosus stenosis foetal	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Medical device site joint infection	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	5



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Brain stem haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Herpes zoster meningitis	1 ( 20.0%)	1 ( 20.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Brain neoplasm benign	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Drug metabolite level high	1 ( 20.0%)	1 ( 20.0%)	1 ( 20.0%)	2 ( 40.0%)	5
Brain compression	2 ( 40.0%)	0 ( 0.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Periarticular thenar erythema with onycholysis	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Drain placement	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Magnesium deficiency	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Macular ischaemia	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
MELAS syndrome	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Diverticulitis intestinal haemorrhagic	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	5
Lymphocytic hypophysitis	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Dissociative amnesia	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Lymphatic disorder	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Lymphangitis	0 ( 0.0%)	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Disseminated varicella zoster vaccine virus infection	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Application site hypoaesthesia	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Disseminated coccidioidomycosis	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Disseminated Bacillus Calmette-Guerin infection	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Lumbar puncture	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Alkalosis hypochloraemic	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Loss of proprioception	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Abdominal wall haemorrhage	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Long QT syndrome congenital	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Follicular thyroid cancer	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Lipoprotein (a) increased	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Lipoatrophy	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bone density increased	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Diagnostic procedure	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Lineage switch leukaemia	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Appendix cancer	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Diabetic ketosis	1 ( 20.0%)	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Light chain analysis abnormal	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Ligament operation	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Follicular lymphoma stage III	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Alcoholic hangover	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Body mass index abnormal	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Lenticular opacities	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Leiomyoma	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Alcohol withdrawal syndrome	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Legionella infection	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Apoptotic colonopathy	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Laryngitis bacterial	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Blood viscosity increased	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Laryngeal pain	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Device deposit issue	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Device calibration failure	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Lacunar stroke	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Laboratory test interference	1 ( 20.0%)	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Foreign body	2 ( 40.0%)	1 ( 20.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Blood product transfusion dependent	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
B precursor type acute leukaemia	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Joint abscess	1 ( 20.0%)	2 ( 40.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Jealous delusion	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Jaw clicking	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Wound drainage	0 ( 0.0%)	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	5
Airway complication of anaesthesia	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Intracranial infection	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Intracranial haematoma	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Vulvovaginal injury	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Vulvitis	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Blood oestrogen abnormal	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Death of relative	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Vitamin B6 increased	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Puncture site swelling	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Superficial siderosis of central nervous system	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Cytotoxic oedema	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Interleukin-2 receptor increased	1 ( 20.0%)	1 ( 20.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Intercepted product selection error	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	5
Vertebral end plate inflammation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	5
Ventricular hypertrophy	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Physical product label issue	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Agitation neonatal	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Vascular insufficiency	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Cystitis radiation	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Varicose vein operation	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Varicella virus test positive	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Cystic fibrosis respiratory infection suppression	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Antipsychotic drug level decreased	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Vaginal cyst	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
T-lymphocyte count increased	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Tracheostomy infection	2 ( 40.0%)	1 ( 20.0%)	0 ( 0.0%)	2 ( 40.0%)	5
In vitro fertilisation	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Uterine neoplasm	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Urine calcium increased	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Cubital tunnel syndrome	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Tooth impacted	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Tumour perforation	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Infantile diarrhoea	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Tumour inflammation	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Thrombectomy	1 ( 20.0%)	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Tubo-ovarian abscess	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Tuberculous pleurisy	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Blood creatine decreased	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Adverse event following immunisation	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Trichiasis	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Cor pulmonale chronic	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Incision site haematoma	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Incision site complication	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Thyroid cyst	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Coronary angioplasty	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Blood catecholamines decreased	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Tonsillitis bacterial	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Tongue eruption	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Immunology test abnormal	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Immune-mediated uveitis	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Thyroxine abnormal	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Blood bilirubin unconjugated decreased	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Thyroid cancer metastatic	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Immune reconstitution inflammatory syndrome associate	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Antiacetylcholine receptor antibody positive	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Blood bicarbonate increased	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Blood bicarbonate decreased	3 ( 60.0%)	0 ( 0.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Coombs direct test positive	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Blood beta-D-glucan increased	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Corneal thinning	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	5
Anti-thyroid antibody increased	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Contrast media deposition	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Idiopathic urticaria	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Polymers allergy	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Ichthyosis	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Tooth development disorder	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Hypotony of eye	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Symblepharon	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Conjunctival bleb	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Hypogonadism	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Hypoglycaemic encephalopathy	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Incarcerated inguinal hernia	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Cortical visual impairment	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Suprapubic pain	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Suicide threat	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Neurogenic bowel	0 ( 0.0%)	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Acquired tracheo-oesophageal fistula	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Substance dependence	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Bleeding varicose vein	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Subchorionic haematoma	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Post procedural erythema	1 ( 20.0%)	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Blast crisis in myelogenous leukaemia	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Streptococcal endocarditis	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Blast cells present	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Stomatitis necrotising	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Hyperproteinaemia	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Stoma site induration	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Conductive deafness	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Stent removal	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Antidepressant discontinuation syndrome	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Hyperlipasaemia	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Bladder transitional cell carcinoma	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Hyperkinetic heart syndrome	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Tumour ulceration	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Sputum culture positive	1 ( 20.0%)	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	5
Splenic haemorrhage	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Spinal synovial cyst	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Spinal fusion acquired	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Spinal decompression	1 ( 20.0%)	1 ( 20.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Spinal cord operation	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Spinal cord herniation	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Anoxia	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Human papilloma virus test positive	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Human herpesvirus 6 infection reactivation	3 ( 60.0%)	0 ( 0.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Specific gravity urine abnormal	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Comminuted fracture	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Human antichimeric antibody positive	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Housebound	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Small intestine neuroendocrine tumour	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Small cell carcinoma	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Bladder cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Cryptorchism	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Colon cancer stage IV	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Skin graft	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Single functional kidney	2 ( 40.0%)	0 ( 0.0%)	1 ( 20.0%)	2 ( 40.0%)	5
Urinary tract candidiasis	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Hepatosplenic candidiasis	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Cogwheel rigidity	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	5
Short stature	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Gastrointestinal mucosa hyperaemia	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Acquired left ventricle outflow tract obstruction	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Serum ferritin abnormal	2 ( 40.0%)	0 ( 0.0%)	1 ( 20.0%)	2 ( 40.0%)	5
Actinomycosis	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Blood follicle stimulating hormone increased	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Hepatitis B surface antigen positive	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Coagulation factor decreased	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Selenium deficiency	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Biopsy bone marrow	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	5
Clostridial sepsis	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Scrotal infection	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Injection site cyst	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Uterine scar	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Ankle deformity	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Gingival operation	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Circumcision	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Vaginal prolapse	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
SARS-CoV-2 antibody test positive	0 ( 0.0%)	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	5
SARS-CoV-2 RNA increased	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
SAPHO syndrome	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Ruptured cerebral aneurysm	0 ( 0.0%)	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	5
Rotavirus infection	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Right-to-left cardiac shunt	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Heart valve operation	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Chronic recurrent multifocal osteomyelitis	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Varicose veins vulval	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Rhinocerebral mucormycosis	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Biliary fistula	0 ( 0.0%)	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Cystitis escherichia	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Bile duct stent insertion	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Anhidrosis	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Bile acids increased	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Respiratory tract irritation	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Respiratory tract haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Respiratory syncytial virus bronchitis	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Bifidobacterium infection	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Chromatopsia	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Renal salt-wasting syndrome	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Choroidal detachment	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Renal failure neonatal	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Haemofiltration	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5



Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Haemospermia	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Renal aplasia	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Refeeding syndrome	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Cholestasis of pregnancy	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Vertebrobasilar stroke	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Angiogram	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Rebound acid hypersecretion	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Reactive gastropathy	0 ( 0.0%)	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Genital erythema	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Anastomotic infection	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Radicular pain	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Radial nerve compression	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Pyogenic granuloma	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Pyelonephritis fungal	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Puncture site haemorrhage	2 ( 40.0%)	0 ( 0.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Intervertebral disc displacement	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Pulmonary valve stenosis	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Intervertebral disc space narrowing	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Pulmonary haematoma	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Pulmonary contusion	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Pulmonary arterial pressure abnormal	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Psychosexual disorder	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Vitreous cells	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Psoriasis area severity index increased	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Prurigo	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Cervix dystocia	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Gilbert's syndrome	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Prostatic mass	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Prostate cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Cervicitis	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Prolonged labour	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Walking distance test abnormal	1 ( 20.0%)	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Progesterone decreased	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Product substitution	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Product outer packaging issue	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Product counterfeit	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Intracranial tumour haemorrhage	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Cerebral salt-wasting syndrome	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Procedural vomiting	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Procedural pneumothorax	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Procedural hypotension	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Procedural failure	2 ( 40.0%)	0 ( 0.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Primary immunodeficiency syndrome	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Bacteroides infection	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Pressure of speech	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Gastrointestinal polyp	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Bacteriuria	3 ( 60.0%)	0 ( 0.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Premature separation of placenta	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Pregnancy test positive	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Pregnancy on oral contraceptive	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Pseudopapilloedema	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Cerebral artery embolism	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Xanthoma	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Zinc deficiency	2 ( 40.0%)	0 ( 0.0%)	2 ( 40.0%)	1 ( 20.0%)	5

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Post procedural oedema	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Post procedural inflammation	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Post procedural fever	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Portal vein occlusion	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Poor school attendance	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Pulmonary artery dilatation	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Central nervous system neoplasm	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Gastric pneumatosis	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Acinetobacter sepsis	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Anal rash	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Central nervous system inflammation	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	4
Gastric antral vascular ectasia	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Pneumonia escherichia	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Ganglioglioma	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Gamma-glutamyltransferase	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Gambling	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Gallbladder hypofunction	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Adenovirus interstitial nephritis	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Plasmapheresis	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Gadolinium deposition disease	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Placental disorder	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Pituitary tumour recurrent	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Physiotherapy	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Physical examination abnormal	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Catheter site oedema	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Pharyngeal injury	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Catheter site granuloma	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	4

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Fracture displacement	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Fracture delayed union	1 ( 25.0%)	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Foreign body ingestion	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Foreign body in skin or subcutaneous tissue	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Azoospermia	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Peritoneal effluent abnormal	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Catheter management	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Axonal and demyelinating polyneuropathy	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Peripheral vein occlusion	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Rabbit syndrome	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Peripheral paralysis	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Cataract operation complication	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Peripheral embolism	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Peripheral circulatory failure	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Peripancreatic fluid collection	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Periorbital dermatitis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Cat scratch disease	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Graft thrombosis	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Periodic limb movement disorder	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Foetal heart rate decreased	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Anal cancer stage 0	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Foetal growth abnormality	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Perichondritis	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Pericarditis infective	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Pericarditis constrictive	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Focal peritonitis	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Peptic ulcer perforation	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Penile swelling	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Adenoma benign	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Penile blister	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Penicillium infection	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Fistula of small intestine	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Pelvic bone injury	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Rectal cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Autoimmune thyroid disorder	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Patient-device incompatibility	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Cardiospasm	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Adenoidal hypertrophy	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Partner stress	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Fibrinolysis	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Autoimmune neutropenia	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Fibrin degradation products increased	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Parotid gland enlargement	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Parkinson's disease psychosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Parenteral nutrition	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Adenoidal disorder	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Paratracheal lymphadenopathy	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Parathyroid tumour malignant	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Female orgasmic disorder	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Paraspinal abscess	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Parasitic gastroenteritis	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Paraneoplastic dermatomyositis	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Inspiratory capacity decreased	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Paracentesis	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Cardiac therapeutic procedure	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Autoimmune eye disorder	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Cardiac steatosis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Pancreatic steatosis	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
False positive investigation result	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Pancreatectomy	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Cardiac neoplasm unspecified	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Painful erection	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Painful ejaculation	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Venous haemorrhage	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
POEMS syndrome	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Oxygen saturation	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Cardiac fibroma	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Ovarian vein thrombosis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Ovarian rupture	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Ovarian haemorrhage	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Facial wasting	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Ovarian abscess	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Cardiac death	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Fabry's disease	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
FEV1/FVC ratio decreased	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Eyelid thickening	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Renovascular hypertension	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Oscillopsia	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Oroticaciduria	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Pain management	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Amyloid related imaging abnormalities	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Orgasm abnormal	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Oral neoplasm	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Carbohydrate antigen 27.29 increased	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Carbohydrate antigen 19-9 increased	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Amylase abnormal	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Extradural abscess	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Atrial standstill	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Oestradiol decreased	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Hair injury	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Cancer with a high tumour mutational burden	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Cancer in remission	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Amniotic fluid volume decreased	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Injection site thrombosis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Campylobacter colitis	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Atrial conduction time prolongation	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	4
Euthanasia	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Eustachian tube dysfunction	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Obsessive rumination	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Nucleated red cells	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Norovirus test positive	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Calcification metastatic	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	4
Non-small cell lung cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Non-pitting oedema	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Non-cirrhotic portal hypertension	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Non-Hodgkin's lymphoma stage IV	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
CSF volume increased	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Asymptomatic bacteriuria	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
CSF test abnormal	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Erosive duodenitis	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Nipple disorder	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Astrocytoma malignant	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Erection increased	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Newborn persistent pulmonary hypertension	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
CSF pressure increased	2 ( 50.0%)	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	4
New onset diabetes after transplantation	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Epstein-Barr virus test positive	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Neuropsychiatric syndrome	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Neuromuscular blockade	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
CNS ventriculitis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Neurological examination abnormal	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Paranasal cyst	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Epidural lipomatosis	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Hemianaesthesia	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
CD4/CD8 ratio decreased	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
CD4 lymphocytes increased	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Nerve root injury lumbar	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Eosinophilic pneumonia chronic	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Eosinophilic pleural effusion	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Eosinophilic bronchitis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Aspiration bone marrow	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Enzyme level abnormal	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Harlequin syndrome	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Enzyme abnormality	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Environmental exposure	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Vaccination site swelling	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Necrotic lymphadenopathy	1 ( 25.0%)	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Enterocolonic fistula	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Natural killer cell count decreased	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Bursa disorder	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Aspartate aminotransferase	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Nasal mucosal blistering	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Autoimmune myocarditis	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Scar pain	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Female sterilisation	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Nail hypertrophy	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Articular calcification	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Mycobacterial peritonitis	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Bronchopulmonary disease	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Acute myeloid leukaemia refractory	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Empty sella syndrome	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Emphysematous pyelonephritis	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Muscle tone disorder	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Passenger lymphocyte syndrome	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Rectal ulcer haemorrhage	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Electrocardiogram repolarisation abnormality	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Retroperitoneal abscess	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Mucosal toxicity	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Electrocardiogram ST segment abnormal	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Mucocutaneous haemorrhage	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Mucocutaneous disorder	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Bronchial neoplasm	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Electrocardiogram Q wave abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Electrocardiogram PR shortened	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Mitral valve calcification	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Mitochondrial cytopathy	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Alopecia universalis	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Alopecia totalis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Ectopic ACTH syndrome	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Microvascular coronary artery disease	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Echocardiogram	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Metastases to thyroid	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Arterial rupture	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Metastases to soft tissue	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Arterial repair	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Ear infection viral	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Breast haematoma	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Breast fibrosis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Metaplasia	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Breast disorder male	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Metal poisoning	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Dystrophic calcification	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Breast disorder female	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Cold type haemolytic anaemia	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Allergy to vaccine	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Breast cancer stage IV	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Meningoencephalitis viral	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Meningococcal infection	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Dysacusis	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Medullary thyroid cancer	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Breakthrough COVID-19	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Medical diet	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Medical device site swelling	1 ( 25.0%)	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Acute interstitial pneumonitis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Arachnoiditis	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Medical device site erosion	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Medical device battery replacement	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Drug tolerance increased	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Meconium in amniotic fluid	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Mechanical ventilation complication	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Application site warmth	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Drug specific antibody absent	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Mean arterial pressure decreased	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Masked fever	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Marrow hyperplasia	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Manufacturing product shipping issue	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	4
Mantle cell lymphoma recurrent	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Adenomatous polyposis coli	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Malignant polyp	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Malignant peritoneal neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Malignant neoplasm of unknown primary site	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Malignant neoplasm of pleura	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Malignant neoplasm of eyelid	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Malignant neoplasm of eye	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Application site oedema	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Malabsorption from injection site	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Allergic respiratory symptom	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Dopamine dysregulation syndrome	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Dolichocolon	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Application site mass	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Allergic oedema	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Lymphoplasmacytoid lymphoma/immunocytoma	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Lymphocytic leukaemia	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Borderline leprosy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Lymphocyte stimulation test positive	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Distal intestinal obstruction syndrome	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Lymphadenitis bacterial	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Lymph nodes scan abnormal	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Lymph node abscess	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Disseminated cytomegaloviral infection	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Abscess rupture	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Bone metabolism biochemical marker increased	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Lung lobectomy	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Lung carcinoma cell type unspecified stage III	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Lung adenocarcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Lumbosacral radiculopathy	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Bone marrow infiltration	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Cytotoxic lesions of corpus callosum	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Application site erosion	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Crowned dens syndrome	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Alkalosis	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Diffuse axonal injury	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Application site discharge	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4

**Reaction Summary Table**  
**Derived Age Group**

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Application site dermatitis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Liposuction	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Bone formation decreased	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Lipoprotein (a) decreased	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Diaphragmatic rupture	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Diaphragmatic disorder	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Lip scab	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Limb traumatic amputation	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Limb reconstructive surgery	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Limb hypoplasia congenital	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Diabetic gastroparesis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Lid sulcus deepened	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Diabetic eye disease	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Abscess of eyelid	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Device temperature issue	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Leukaemic infiltration extramedullary	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Compulsions	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Body height below normal	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Body fat disorder	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Acute encephalitis with refractory, repetitive partia	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Alcohol use disorder	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Laser therapy	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Laryngitis fungal	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Large intestine operation	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Large intestine benign neoplasm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Large intestinal polypectomy	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Apical granuloma	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Laparoscopic surgery	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Lacrimation disorder	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Lacrimation decreased	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Desmoplastic small round cell tumour	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Peritoneal mesothelioma malignant	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Peritoneal tuberculosis	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Koebner phenomenon	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Klippel-Feil syndrome	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Dermatillomania	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Albumin urine present	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Joint injection	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	4
Blood pressure orthostatic decreased	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Jejunostomy	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Delusional perception	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Aortic surgery	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Itching scar	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Irregular sleep phase	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Delirium febrile	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	4
Delayed light adaptation	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
pH urine increased	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Tuberculosis of central nervous system	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Invasive lobular breast carcinoma	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Wrong rate	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Wrong dosage formulation	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Intrauterine infection	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Blood phosphorus abnormal	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Intracranial haemangioma	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	4

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Intra-abdominal pressure increased	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Waldenstrom's macroglobulinaemia	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
WT1 gene mutation	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Intestinal metaplasia	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Vocal cord inflammation	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Vitamin A increased	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Vitamin A deficiency	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Visual snow syndrome	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Viral sinusitis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Viral load abnormal	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Vesical fistula	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Hypoglobulinaemia	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Intentional misuse of drug delivery system	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Vasculitic rash	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Vascular operation	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Vascular encephalopathy	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Antisynthetase syndrome	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Vascular access site bruising	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Uterine rupture	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Uterine mass	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Uterine contractions during pregnancy	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Cutaneous mucormycosis	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Urogenital fistula	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Testicular cyst	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Urinary tract infection pseudomonal	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Plasma cells increased	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Urinary retention postoperative	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Crystal urine present	2 ( 50.0%)	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Urge incontinence	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Crystal arthropathy	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Total cholesterol/HDL ratio decreased	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Influenza virus test positive	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Ureteritis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Ureteric dilatation	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Antimitochondrial antibody positive	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Cryoglobulinaemia	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Plantar erythema	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Infective tenosynovitis	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Umbilical hernia repair	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Craniopharyngioma	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Infantile apnoea	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Tumour embolism	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Tumour cavitation	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Anticonvulsant drug level increased	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Tuberculosis liver	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Tryptase	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Anticonvulsant drug level below therapeutic	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Incision site discharge	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Traumatic haemothorax	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Transfusion-associated dyspnoea	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Transferrin saturation increased	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Tracheal obstruction	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Toxic optic neuropathy	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Implant site inflammation	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4



Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Implant site haematoma	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Corneal reflex decreased	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Imperception	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Immunoglobulin G4 related disease	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	4
Tongue paralysis	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Immunoglobulins abnormal	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Tongue geographic	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Tongue exfoliation	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Antibody test negative	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Tobacco abuse	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Immune-mediated neurological disorder	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Cornea verticillata	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Thyroid calcification	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Thyroglobulin increased	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Corneal neovascularisation	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Immature granulocyte percentage increased	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Thrombin time prolonged	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Thought blocking	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Thirst decreased	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
ADAMTS13 activity abnormal	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Contrast media toxicity	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Therapeutic product effective for unapproved indicati	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Therapeutic nerve ablation	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Idiosyncratic drug reaction	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Idiopathic pneumonia syndrome	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Testicular neoplasm	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Blood alcohol increased	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Teratoma	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Tender joint count decreased	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Hypotrichosis	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Tanning	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Coronary artery embolism	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Blood 1,25-dihydroxycholecalciferol increased	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	4
Tracheostomy malfunction	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Blood cholinesterase decreased	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Conjunctival pallor	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Anti-glomerular basement membrane disease	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Hypophosphatasia	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Transformation to acute myeloid leukaemia	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Conjunctival disorder	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Swollen joint count decreased	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Sweat gland infection	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Abortion infected	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Sudden visual loss	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Tri-iodothyronine decreased	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Congenital multiplex arthrogryposis	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Blastomycosis	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Gastroenteritis eosinophilic	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	4
Blastocystis infection	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Hypertensive encephalopathy	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Hyperresponsive to stimuli	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Stoma site irritation	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Stoma site abscess	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Hyperparathyroidism primary	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hyperosmolar state	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Hypermobility syndrome	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Abdominal cavity drainage	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Infantile spasms	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Starvation ketoacidosis	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Squamous cell carcinoma of the tongue	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Adrenal gland cancer metastatic	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Squamous cell carcinoma of head and neck	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Infected dermal cyst	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Computerised tomogram abdomen abnormal	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Hyperdynamic left ventricle	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Splinter	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Splenic infection fungal	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Hyperamylasaemia	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Aeromonas infection	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Spinal muscular atrophy	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Spinal instability	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Spinal cord oedema	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Infective corneal ulcer	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Hydrocholecystis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Undifferentiated connective tissue disease	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Spinal X-ray abnormal	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Spina bifida	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Complement factor C3 increased	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Spermatozoa abnormal	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Human metapneumovirus test positive	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Human herpesvirus 8 infection	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Human ehrlichiosis	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Inflammation of wound	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Human bocavirus infection	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Solar urticaria	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Coma hepatic	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Bladder cyst	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Ureteral stent insertion	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Blood ethanol increased	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Sleep disorder due to general medical condition, hype	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
High-pitched crying	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Acquired oesophageal web	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
High density lipoprotein abnormal	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Skin operation	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Urethral stenosis	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Antineutrophil cytoplasmic antibody increased	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Bipolar II disorder	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Colon cancer stage II	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Herpes zoster cutaneous disseminated	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Herpes simplex viraemia	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Herpes simplex test positive	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Acquired macroglossia	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Adnexa uteri mass	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Sinoatrial block	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Shunt stenosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Urine albumin/creatinine ratio abnormal	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	4
Severe cutaneous adverse reaction	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Serum sickness-like reaction	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cutaneous T-cell lymphoma stage IV	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Serous retinopathy	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Hepatitis G	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Hepatitis C virus test positive	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Administration site warmth	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Sepsis neonatal	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Semen volume decreased	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Semen liquefaction abnormal	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Acquired immunodeficiency syndrome	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Uterine hypertonus	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Biopsy bone marrow abnormal	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Injection site dermatitis	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Urethral disorder	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Sclerodactylia	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Schwannoma	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Hepatic cancer recurrent	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Administration site rash	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Salivary gland neoplasm	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
SLE arthritis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Heavy metal increased	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Cystatin C increased	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Rouleaux formation	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Rocky mountain spotted fever	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Right ventricular hypertrophy	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Heart valve calcification	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Varicose ulceration	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Chronic respiratory disease	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Heart sounds abnormal	1 ( 25.0%)	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Antisocial behaviour	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Anion gap	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Head deformity	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Retrognathia	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Retinal vascular thrombosis	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Retinal vascular occlusion	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Hand amputation	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Vascular compression	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Haemorrhoid operation	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Haemorrhagic occlusive retinal vasculitis	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Bifascicular block	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Repetitive strain injury	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Haemophilus test positive	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Choroidal neovascularisation	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Cytogenetic analysis abnormal	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Choroidal haemorrhage	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Renal hamartoma	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Administration site irritation	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Venous aneurysm	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Choroid melanoma	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Haemoconcentration	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Blood insulin decreased	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Refractoriness to platelet transfusion	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Refraction disorder	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Chondrolysis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Red blood cell sedimentation rate decreased	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Red blood cell nucleated morphology present	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Red blood cell elliptocytes present	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Benign ovarian tumour	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Rectocele	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Angioimmunoblastic T-cell lymphoma	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Growth hormone-producing pituitary tumour	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Rash papulosquamous	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Rapid eye movements sleep abnormal	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Raoultella ornithinolytica infection	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Vibratory sense increased	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Chloropsia	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Vesicoureteric reflux	2 ( 50.0%)	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Benign familial pemphigus	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Gram stain positive	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Pupillary disorder	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Benign ear neoplasm	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Graft infection	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Puncture site injury	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Puncture site induration	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Puncture site erythema	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Dairy intolerance	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Chest wall mass	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Chest wall abscess	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Acquired apparent mineralocorticoid excess	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	4
Pulmonary septal thickening	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Pulmonary radiation injury	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Pulmonary imaging procedure abnormal	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pulmonary hypertensive crisis	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Vitamin B12 abnormal	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Intestinal barrier dysfunction	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Pseudoporphyria	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Pseudolymphoma	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Pseudohallucination	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Pseudocyst	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Vocal cord polyp	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Prothrombin level increased	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Proteus test positive	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Acoustic neuroma	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Protein-losing gastroenteropathy	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	4
Prosthesis implantation	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Prostatic haemorrhage	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Genotype drug resistance test positive	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Cervicobrachial syndrome	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Decompression sickness	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Cervical incompetence	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Bartholinitis	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Cervical conisation	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Product shape issue	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Anastomotic haemorrhage	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Genital candidiasis	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Product name confusion	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Product measured potency issue	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Product lot number issue	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Cerebral vasoconstriction	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4



**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Cerebral vascular occlusion	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Product appearance confusion	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Product advertising issue	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Proctitis bacterial	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Procedure aborted	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Intraductal papilloma of breast	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	4
Gastrointestinal tract mucosal pigmentation	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Procedural anxiety	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Intracranial hypotension	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Primary syphilis	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Balamuthia infection	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Gastrointestinal submucosal tumour	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Cerebral hypoperfusion	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Premature ejaculation	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Pregnancy test false positive	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Precocious puberty	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Gastrointestinal ischaemia	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Cerebral artery thrombosis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Abscess fungal	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Postprandial hypoglycaemia	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Postmortem blood drug level abnormal	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Cerebellar tumour	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Postictal state	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Postictal psychosis	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	4
Gastrointestinal angiectasia	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Post-traumatic pain	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Gastroenteropancreatic neuroendocrine tumour disease	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Cerebellar cognitive affective syndrome	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Post procedural haematuria	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Cerebellar ataxia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Gastroenteritis cryptosporidial	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Gastroenteritis astroviral	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Post procedural bile leak	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Portosplenomesenteric venous thrombosis	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Central pain syndrome	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Gastric volvulus	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Gastric varices haemorrhage	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Poor personal hygiene	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Central nervous system necrosis	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Central nervous system mass	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Polymorphic light eruption	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Polydactyly	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Anal prolapse	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Central nervous system haemorrhage	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Bacillus bacteraemia	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Anal polyp	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Central nervous system abscess	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Gamma-glutamyltransferase decreased	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Anal injury	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Gaming disorder	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Pneumocephalus	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Gallbladder injury	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Pleural adhesion	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Platelet dysfunction	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Plasmablastic lymphoma	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Placenta accreta	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Pituitary enlargement	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
B-lymphocyte count abnormal	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Pinguecula	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Adenoviral haemorrhagic cystitis	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Functional residual capacity decreased	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Photodermatitis	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Anal fistula infection	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
B-cell small lymphocytic lymphoma	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Phlebotomy	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Philadelphia positive acute lymphocytic leukaemia	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Pharyngotonsillitis	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Pharyngolaryngeal abscess	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Pharyngeal haematoma	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Catheter site discolouration	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Personal relationship issue	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Persistent genital arousal disorder	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Peritoneal perforation	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Foreign body in gastrointestinal tract	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Peritoneal fluid analysis abnormal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Anal erosion	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Peritoneal abscess	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Forced expiratory volume abnormal	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Catastrophic reaction	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Peripheral artery aneurysm	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Axillary lymphadenectomy	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Periorbital haemorrhage	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Perinephric abscess	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Cast application	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Perineal cellulitis	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Cartilage atrophy	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Pericarditis malignant	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Foetal exposure during delivery	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Foetal distress syndrome	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Foetal cardiac disorder	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Carotid pulse decreased	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Pericardial disease	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Pericardial calcification	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Periarthritis calcarea	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Focal dyscognitive seizures	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Performance enhancing product use	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Perforated ulcer	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Fluid intake restriction	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Penis injury	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Penile vascular disorder	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Carotid artery stent insertion	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Acid fast bacilli infection	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Penile dermatitis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Pelvic organ prolapse	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Pelvic operation	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Fistula inflammation	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Pelvic infection	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Pelvic haemorrhage	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pelvic congestion	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Peau d'orange	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Abnormal clotting factor	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Anaesthesia oral	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Parophthalmia	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Autoimmune neuropathy	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Parkinsonian rest tremor	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Parechovirus infection	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Red blood cell morphology abnormal	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Parathyroid gland enlargement	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Paranoid personality disorder	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Paradoxical psoriatic arthritis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Paradoxical pain	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Papulopustular rosacea	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Papillary renal cell carcinoma	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Autoimmune enteropathy	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Autoimmune encephalopathy	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Fasciitis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Pancreatic injury	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Autoimmune blistering disease	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Pancreatic abscess	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Pancreas infection	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Palpable purpura	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Fallopian tube cancer	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Palate injury	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Pain threshold decreased	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Autoantibody positive	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cardiac monitoring	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Paediatric acute-onset neuropsychiatric syndrome	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Auricular swelling	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Oxygen saturation immeasurable	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Ovarian neoplasm	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Ovarian enlargement	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Ovarian cystectomy	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Ovarian cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Cardiac device implantation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Osteosarcoma recurrent	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Atypical mycobacterial lower respiratory tract infect	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Osteoporosis postmenopausal	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Cardiac arrest neonatal	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Osteomyelitis fungal	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Failed induction of labour	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Osteomyelitis acute	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Orthodontic procedure	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Oropharyngeal surgery	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Carcinoid syndrome	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Eyelash changes	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Oropharyngeal discolouration	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Oromandibular dystonia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Orchitis noninfective	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Carcinoembryonic antigen decreased	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Atrophic vulvovaginitis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Oral mucosal discolouration	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Atrioventricular septal defect	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Eye infection staphylococcal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Oral herpes zoster	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Oral discharge	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Amylase decreased	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Oral bacterial infection	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Eye abscess	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Optic disc disorder	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Opsoclonus myoclonus	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Opiates positive	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Extravascular haemolysis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Ophthalmological examination abnormal	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Ophthalmic vascular thrombosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Onychophagia	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Omental infarction	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Retinal deposits	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Cannabinoid hyperemesis syndrome	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Oesophagitis haemorrhagic	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Venous pressure increased	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Oesophageal ulcer haemorrhage	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Amphetamines positive	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Oesophageal polyp	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Exposure to extreme temperature	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Amoebic dysentery	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Oesophageal fistula	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Oesophageal carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Exposed bone in jaw	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Amoebiasis	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Oedema due to cardiac disease	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Atrial enlargement	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
AST/ALT ratio abnormal	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Camptocormia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Ocular ischaemic syndrome	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Excessive skin	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Excessive masturbation	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Ochronosis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Evans syndrome	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Calcium metabolism disorder	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Eustachian tube disorder	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Normal pressure hydrocephalus	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Noonan syndrome	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Escherichia peritonitis	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Noninfective sialoadenitis	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Noninfectious peritonitis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Atheroembolism	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Non-small cell lung cancer stage II	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Chronic myocarditis	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Erythroopenia	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Non-scarring alopecia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Non-high-density lipoprotein cholesterol increased	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Non-consummation	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Nodular vasculitis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Nodular rash	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Amnestic disorder	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
CSF protein abnormal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3



### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Epstein-Barr virus antigen positive	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Neurotrophic keratopathy	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
CREST syndrome	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Neurorrhaphy	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Neuroprosthesis implantation	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Asthma exercise induced	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Ammonia decreased	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Epiphysiolysis	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Epileptic psychosis	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	3
Neuroma	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Ammonia abnormal	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Neurological infection	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
CFTR gene mutation	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Neurofibrosarcoma	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Neuroendocrine carcinoma metastatic	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Epidermolysis bullosa	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
CD4/CD8 ratio increased	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Epidermodysplasia verruciformis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
CD4 lymphocyte percentage decreased	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Nephrogenic systemic fibrosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Aspiration joint	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Neoplasm of thymus	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Neonatal infection	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Eosinopenia	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Neonatal asphyxia	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Enzyme inhibition	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Negative pressure pulmonary oedema	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Necrotising scleritis	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Necrotising enterocolitis neonatal	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Necrobiosis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Nasopharyngeal cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Nasal septal operation	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Enterobacter test positive	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Nasal abscess	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Nail discomfort	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Myxoid liposarcoma	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Myringitis	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Myotonia	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Bullous erysipelas	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Endometrial adenocarcinoma	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Myocardial calcification	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Myiasis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Myelodysplastic syndrome with single lineage dysplasi	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Myelocyte count increased	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	3
Mycetoma mycotic	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Bronchopulmonary dysplasia	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Musculoskeletal toxicity	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Bronchopneumopathy	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Muscle operation	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Muscle fibrosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Alport's syndrome	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Mumps	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Alpha-1 antitrypsin deficiency	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Multifocal motor neuropathy	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Electrocardiogram T wave peaked	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Arteritis	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Cutaneous contour deformity	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Mucocutaneous toxicity	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Acute motor-sensory axonal neuropathy	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Electrocardiogram QRS complex abnormal	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Electrocardiogram P wave abnormal	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Monocyte percentage decreased	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Arteriovenous fistula site complication	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Acute monocytic leukaemia	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Accelerated hypertension	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Brief resolved unexplained event	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Mitral valve stenosis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Mitral valve replacement	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Mitral valve repair	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Eczema nummular	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Minimum inhibitory concentration	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Mineral metabolism disorder	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Miller Fisher syndrome	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Milia	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Eclampsia	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Microcytosis	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Metastatic carcinoma of the bladder	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Metastases to salivary gland	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Breast hyperplasia	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Ear dryness	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Mesenteritis	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Mesenteric lymphadenitis	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Mesenteric haemorrhage	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Merycism	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Dysphotopsia	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Menometrorrhagia	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Meningorrhagia	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Abdominal hernia obstructive	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Meningitis tuberculous	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Breast cancer in situ	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Breast atrophy	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Medical observation abnormal	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Allergy to immunoglobulin therapy	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Medical device site thrombosis	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Dumping syndrome	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Medical device site scab	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Medical device site rash	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Ductus arteriosus premature closure	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Arachnoid cyst	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Brain stem haematoma	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Medical device site abscess	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Brain sarcoma	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Acute hepatitis C	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Medial tibial stress syndrome	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Application site wound	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Brain natriuretic peptide abnormal	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Mean cell haemoglobin concentration abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Mean cell haemoglobin concentration	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
May-Thurner syndrome	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Drug exposure before pregnancy	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Malignant urinary tract neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Malignant neoplasm of spinal cord	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Malignant neoplasm of renal pelvis	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Angiodysplasia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Malignant melanoma stage I	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Brachiocephalic artery stenosis	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Malignant anorectal neoplasm	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Drain site complication	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Malaria	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Macular pigmentation	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Macular detachment	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Abdominal wall infection	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Bordetella infection	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Lymphocytic lymphoma	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Lymphocyte morphology abnormal	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Application site inflammation	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Lymphocyte count	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Aversion	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Application site infection	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Lymphangioma	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Disseminated varicella	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Lymph node palpable	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Lymph node fibrosis	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Lung squamous cell carcinoma stage III	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Disorder of sex development	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Application site haematoma	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Lung adenocarcinoma stage IV	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Alkalosis hypokalaemic	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Application site extravasation	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Low lung compliance	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Dilatation ventricular	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Dilatation intrahepatic duct acquired	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Low cardiac output syndrome	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Loss of visual contrast sensitivity	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Bone lesion excision	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Loose body in joint	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Liver operation	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Listeria sepsis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Lipase abnormal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Lip neoplasm malignant stage unspecified	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Application site acne	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Limb immobilisation	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Bone abscess	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Ligamentitis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Lichen planus pemphigoides	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Anterior chamber cleavage syndrome	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Abdominal fat apron	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Lichen nitidus	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Lhermitte's sign	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Leukostasis syndrome	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Appendiceal abscess	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Device programming error	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Leishmaniasis	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Leiomyosarcoma metastatic	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Leiomyosarcoma	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Body dysmorphic disorder	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Left ventricular enlargement	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Blunted affect	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Apoptosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Laryngomalacia	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Laryngitis allergic	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Laryngeal obstruction	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Laryngeal neoplasm	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Abdominal wall disorder	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Large intestinal ulcer haemorrhage	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Device audio issue	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Device allergy	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Laparotomy	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Desmoid tumour	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Lack of satiety	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Lack of infusion site rotation	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Dermatoporosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Dermatofibrosarcoma protuberans	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Dermatochalasis	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Kyphoscoliosis	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Blood test	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Aortoenteric fistula	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Ketosis-prone diabetes mellitus	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Keratosis pilaris	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Keratosis follicular	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Keratomileusis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Aortic valve thickening	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Deprescribing error	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Juvenile chronic myelomonocytic leukaemia	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Joint tuberculosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Albumin globulin ratio decreased	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Joint surgery	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Aortic valve sclerosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Dental plaque	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Blood pressure systolic	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Joint fluid drainage	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Jessner's lymphocytic infiltration	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Abdominal wall cyst	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Aortic valve calcification	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Ischaemic enteritis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Delusion of reference	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Iron metabolism disorder	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Iron binding capacity total decreased	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Iris hypopigmentation	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Iris discolouration	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Delayed ischaemic neurological deficit	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Yersinia infection	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Delayed delivery	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Airway remodelling	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Deformity thorax	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Wound closure	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Increased insulin requirement	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Streptobacillus infection	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
White blood cells urine	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
White blood cell count	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Aortic elongation	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Stroke volume increased	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Water intoxication	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Decreased vibratory sense	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Decreased gait velocity	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Vulval haemorrhage	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Von Willebrand's disease	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	3
Intestinal mucosal tear	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Volume blood	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Vitreous disorder	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Vitello-intestinal duct remnant	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Blood luteinising hormone increased	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Intestinal fistula infection	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Intestinal congestion	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Visual perseveration	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Visceral oedema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Visceral larva migrans	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Virilism	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Intervertebral disc annular tear	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Viral acanthoma	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Victim of child abuse	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Superinfection fungal	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Blood lactate dehydrogenase decreased	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Incision site abscess	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Supportive care	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Ventricular dyssynchrony	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Intensive care unit acquired weakness	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Cytology abnormal	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Vasectomy	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Vasculitic ulcer	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Instillation site reaction	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Vascular stent occlusion	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Vascular headache	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Vascular graft complication	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Vascular access site swelling	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Varicose vein ruptured	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Varicocele	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Injection site pallor	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Cystic fibrosis related diabetes	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Hypoglycaemia neonatal	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Vaginal fistula	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Vaginal cancer	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Vaccination site reaction	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Cyclothymic disorder	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Vaccination site cellulitis	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Blood growth hormone decreased	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Antiphospholipid antibodies positive	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Uterine haematoma	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Urticaria physical	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Cutaneous leishmaniasis	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Urticaria papular	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Urostomy	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Infusion site scab	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Urine output fluctuation	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Plagiocephaly	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Infusion site paraesthesia	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Abortion threatened	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Urinary occult blood positive	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Urethritis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Infrapatellar fat pad inflammation	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Ureteral disorder	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Pituitary gland operation	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Upper motor neurone lesion	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Upper airway resistance syndrome	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Unwanted pregnancy	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Abortion spontaneous incomplete	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Ulnar nerve injury	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Creatinine urine increased	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Creatinine urine decreased	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Type 1 lepra reaction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Antidepressant drug level above therapeutic	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Craniotomy	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Infantile spitting up	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Induced labour	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Craniofacial deformity	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Tuberculosis gastrointestinal	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Anticonvulsant drug level above therapeutic	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Trichotillomania	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Trichosporon infection	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Traumatic liver injury	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Transplant evaluation	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Inadvertent injection air bubble	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Inadequate peritoneal dialysis	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Inadequate aseptic technique in use of product	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Tracheomalacia	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Acromegaly	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Tracheal haemorrhage	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Tracheal deviation	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Anticoagulant therapy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Toxic anterior segment syndrome	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Implant site haemorrhage	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Tooth restoration	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Implant site erosion	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Tooth malformation	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Implant site discolouration	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Implant site cellulitis	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Tonsillar ulcer	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Impaired fasting glucose	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Immunisation	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Immune-mediated vasculitis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Corneal epithelial microcysts	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Tissue rupture	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Corneal infiltrates	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Corneal dystrophy	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blood bilirubin unconjugated increased	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Corneal degeneration	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Tonsillar haemorrhage	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	3
Thyroid gland injury	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Thyroid cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Immune-mediated cholestasis	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Cord blood transplant therapy	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Thymus enlargement	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Cor pulmonale acute	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Thymoma	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Thymectomy	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Anti-transglutaminase antibody increased	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Thrombocytopenia neonatal	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Throat lesion	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Convulsive threshold lowered	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Ilium fracture	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Iliac artery stenosis	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Gastric mucosal hypertrophy	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Ileectomy	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Contraindication to vaccination	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Blood chloride abnormal	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Contraindicated device used	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Ictal bradycardia syndrome	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Testicular abscess	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Illrd nerve disorder	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Tracheal compression	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Tenodesis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tendon operation	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Tendon calcification	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Conjunctivochalasis	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Tender joint count	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Temperature difference of extremities	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Tarsal tunnel syndrome	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Target skin lesion	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Implant site scar	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Tracheo-oesophageal fistula	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Tachyphylaxis	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Conjunctival retraction	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Blood 1,25-dihydroxycholecalciferol decreased	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Conjunctival pigmentation	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Systolic hypertension	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hypoprothrombinaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Systemic mastocytosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Synovial fluid analysis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Hyponatraemic encephalopathy	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Adrenal suppression	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Sweating fever	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Hypokinetic dysarthria	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Bacterial colitis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Corpus callosotomy	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Corrective lens user	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Hypocomplementaemia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Incision site erythema	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Corynebacterium bacteraemia	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Transvalvular pressure gradient increased	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hypocapnia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Superficial inflammatory dermatosis	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hypobarism	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Subdural hygroma	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Tricuspid valve disease	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Hypertrophy	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Anti factor X activity increased	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Subclavian vein stenosis	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Subclavian artery stenosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Coxsackie viral infection	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Congenital cytomegalovirus infection	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Streptococcal urinary tract infection	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Hypertelorism	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Strangury	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Anti factor V antibody positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Stomal hernia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Stoma site pruritus	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Stiff leg syndrome	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Concomitant drug effect decreased	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Status migrainosus	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Hyperinsulinaemia	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Staphylococcal abscess	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Squamous cell carcinoma of pharynx	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Hypergastrinaemia	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Spontaneous penile erection	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Bladder perforation	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hyperemesis gravidarum	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Spondylolysis	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Adrenal gland cancer	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Bladder outlet obstruction	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Splenic thrombosis	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Splenic injury	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Anterior chamber flare	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Splenic infection	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Splenic embolism	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Splenic artery thrombosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Bladder obstruction	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Hyperarousal	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Ultrasound scan abnormal	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Bladder mass	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Hyperactive pharyngeal reflex	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Antacid therapy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Spinal cord paralysis	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hydrometra	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Spider vein	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Sperm concentration decreased	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Speech sound disorder	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Infective spondylitis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Specific gravity urine decreased	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	3
Antimitochondrial antibody	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Human chorionic gonadotropin decreased	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Solitary fibrous tumour	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Soft tissue inflammation	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3



**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Soft tissue atrophy	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Coma acidotic	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Colour blindness acquired	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hormone receptor positive breast cancer	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Hormone receptor positive HER2 negative breast cancer	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Small intestine polyp	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	3
Influenza B virus test positive	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Sleep inertia	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Hippocampal sclerosis	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Hip deformity	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Sleep attacks	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
High-grade B-cell lymphoma	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
High risk sexual behaviour	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Skin test positive	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Infusion site abscess	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Skin lesion inflammation	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Infusion site coldness	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Anorectal swelling	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Colon cancer stage I	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Herpes simplex encephalitis	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Anorectal operation	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Colitis erosive	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Herpes oesophagitis	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Hernia hiatus repair	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Infusion site hypersensitivity	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Sickle cell disease	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Hereditary motor and sensory neuropathy	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Urinary casts present	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Hereditary angioedema with C1 esterase inhibitor defi	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Shunt infection	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Coinfection	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Biopsy prostate	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hepatopulmonary syndrome	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Sexually transmitted disease	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Abortion early	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Administration site wound	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Cochlea implant	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Sertoli-cell-only syndrome	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Blood gases abnormal	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Septic cardiomyopathy	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Hepatitis C RNA positive	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Sepsis syndrome	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Sensory processing sensitivity	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Hepatitis B virus test positive	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Urticaria pigmentosa	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Seminal vesicular disorder	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Hepatitis B antibody positive	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Infusion site thrombosis	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Selective IgG subclass deficiency	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Segmented hyalinising vasculitis	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Hepatic vein dilatation	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hepatic rupture	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Uterine inflammation	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Hepatic neuroendocrine tumour	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Administration site ulcer	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Scrotal operation	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Scleral oedema	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Scleral disorder	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Cleft lip and palate	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Binge drinking	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Hepatic artery thrombosis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Salpingo-oophorectomy unilateral	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Circumoral swelling	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Circumoral oedema	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Salivary gland cancer	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Salivary duct obstruction	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Sacroiliac joint dysfunction	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Sacroiliac fusion	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Helplessness	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Helminthic infection	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Heliotrope rash	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
SARS-CoV-2 test	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Ruptured ectopic pregnancy	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Chronic tonsillitis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Heart valve stenosis	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Right ventricular systolic pressure increased	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Right ventricular enlargement	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Rhodococcus infection	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Rhinoplasty	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Rheumatoid vasculitis	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Biliary ischaemia	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Rheumatoid arthritis-associated interstitial lung dis	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Vascular access site haemorrhage	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Administration site oedema	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Retroperitoneal cancer	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Chronic leukaemia	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Haptoglobin increased	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Retinopathy hypertensive	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Hangnail	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Hand-eye coordination impaired	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Retinal vein thrombosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Animal attack	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Retinal pigment epithelial tear	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Retinal neovascularisation	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Retinal migraine	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Retinal ischaemia	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Retinal drusen	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hairy cell leukaemia	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Retinal depigmentation	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Retinal aneurysm	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Reticulocytosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Reticulocyte count decreased	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Retained products of conception	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Haemostasis	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Chronic gastrointestinal bleeding	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Haemorrhagic ovarian cyst	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Antithrombin III decreased	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Chronic disease	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Respiratory moniliasis	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Respiratory gas exchange disorder	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Cytarabine syndrome	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Haemorrhagic cerebral infarction	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Chronic active Epstein-Barr virus infection	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Renin increased	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Instillation site pain	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Renal vascular thrombosis	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Renal stone removal	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Renal scan abnormal	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Renal phospholipidosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Renal oncocytoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Haemolytic transfusion reaction	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Renal artery occlusion	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Haematoma evacuation	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Removal of foreign body from eye	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Haematology test abnormal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Regressive behaviour	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Red cell distribution width decreased	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Chondritis	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Red cell distribution width abnormal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Red blood cells urine	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	3
Administration site inflammation	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Red blood cell sedimentation rate	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Angiomyolipoma	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Abscess bacterial	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
HRD gene mutation assay positive	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Rectosigmoid cancer	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Vertebral artery stenosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
HELLP syndrome	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
HCoV-HKU1 infection	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Gynaecological chlamydia infection	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Gut fermentation syndrome	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Growth hormone deficiency	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Growth accelerated	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Benign lung neoplasm	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Growing pains	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Radiation proctitis	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Vessel puncture site pain	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Radiation mucositis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Radiation associated pain	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Radial pulse abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Benign hepatic neoplasm	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Benign gastrointestinal neoplasm	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Internal hernia	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Angiocardiogram	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Pyramidal tract syndrome	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Administration site haemorrhage	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Pyometra	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Pyelonephritis chronic	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Putamen haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Viral myelitis	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Graft versus host disease in lung	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Dacryocanalculitis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Purine metabolism disorder	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Pupillary light reflex tests abnormal	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Child-Pugh-Turcotte score increased	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Graft loss	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Gradenigo's syndrome	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Gouty tophus	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Gonadotrophin deficiency	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Pulmonary tumour thrombotic microangiopathy	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Pulmonary pneumatocele	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Glutamate dehydrogenase increased	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Pulmonary malformation	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Pulmonary interstitial emphysema syndrome	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Glossopharyngeal nerve paralysis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Pulmonary capillary haemangiomatosis	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Chemotherapeutic drug level above therapeutic	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Chemokine increased	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Pulmonary artery occlusion	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Bauhin's valve syndrome	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Chemical poisoning	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Pulmonary artery aneurysm	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Chemical burns of eye	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Pulmonary air leakage	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Anembryonic gestation	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Intestinal gangrene	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Glioblastoma multiforme	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Pseudophakia	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Gingival pruritus	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Pseudoendophthalmitis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Intestinal mucosal atrophy	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Gingival injury	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Pseudarthrosis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Basilar artery stenosis	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Gingival graft	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Cervix operation	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Decorticate posture	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Protein S decreased	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Prosthetic cardiac valve thrombosis	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Prosthesis user	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Prostatic specific antigen decreased	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Prostatic obstruction	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Prostatic calcification	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Prostate examination abnormal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Prostate cancer stage I	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Genital infection male	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Intra-uterine contraceptive device insertion	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Blood osmolarity increased	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Bartholin's gland disorder	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Product sterility issue	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Cerumen impaction	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Genital discolouration	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Bartholin's cyst	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Cerebrovascular insufficiency	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Product intolerance	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Administration related reaction	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Product dosage form issue	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Product contamination with body fluid	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Product contamination chemical	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Gaucher's disease	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Bandaemia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Gastroesophageal sphincter insufficiency	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Gastrolithiasis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Gastrointestinal vascular malformation haemorrhagic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Procedural site reaction	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Gastrointestinal tract adenoma	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Adjustment disorder with mixed anxiety and depressed	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Primary hypoparathyroidism	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Cerebral congestion	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Gastrointestinal mucosal disorder	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Gastrointestinal lymphoma	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Intraocular lens implant	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Gastrointestinal erosion	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Cerebral arteriosclerosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Investigation noncompliance	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Bacterial pyelonephritis	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Anal ulcer haemorrhage	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Gastrointestinal arteriovenous malformation	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Gastrointestinal anastomotic stenosis	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Gastrointestinal amyloidosis	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Post-traumatic neuralgia	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Gastroenterostomy	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Wall motion score index abnormal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Post procedural pneumonia	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Bacterial gingivitis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Bacterial food poisoning	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Gastroenteritis clostridial	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Cephalhaematoma	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gastroenteritis bacterial	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Post procedural constipation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Central venous pressure increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Gastritis viral	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Positron emission tomogram	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Gastritis fungal	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Portal vein cavernous transformation	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Portal shunt procedure	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Porokeratosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Porcelain gallbladder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Central nervous system stimulation	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Poor dental condition	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Polyradiculoneuropathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Polyneuropathy in malignant disease	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Gastric neuroendocrine carcinoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Polyhydramnios	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Central nervous system leukaemia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Gastric mucosa erythema	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Polycystic liver disease	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Gastric infarction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Poikiloderma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pneumothorax traumatic	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pneumopericardium	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Gastric cancer stage IV	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pneumonitis chemical	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Central nervous system fungal infection	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Gastric banding	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Central nervous system function test abnormal	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gammopathy	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Pneumonia chlamydial	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pneumonia adenoviral	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pneumoconiosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Gallbladder obstruction	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Gallbladder neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pleural mesothelioma malignant	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pleural mass	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pleural calcification	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Cell-mediated immune deficiency	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Plethoric face	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cell marker increased	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Gallbladder cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Platelet aggregation abnormal	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Plastic surgery to the face	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Plastic surgery	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Catheterisation cardiac abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Gait deviation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Planning to become pregnant	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Catheter site warmth	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Fungating wound	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Fungal test positive	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Anal hypoaesthesia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Catheter site ulcer	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pityriasis rubra pilaris	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pityriasis rosea	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Fungal sepsis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Catheter site scab	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pituitary cyst	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Piriformis syndrome	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Anal fungal infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Phrenic nerve paralysis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Photorefractive keratectomy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Phospholipidosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Phonophobia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Phobia of driving	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Phobia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Phlebolith	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Fuchs' syndrome	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Fructose intolerance	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Phenylketonuria	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Frigophobia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Catheter site induration	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pharyngeal stenosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pharyngeal polyp	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Catheter site haematoma	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Fracture of penis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Fracture malunion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pharyngeal cyst	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Phantom limb syndrome	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Foveal reflex abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Perthes disease	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Foreskin oedema	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anal erythema	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Catheter site cellulitis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Periumbilical abscess	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Peritoneocutaneous fistula	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Peritoneal neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Peritoneal lesion	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Peritoneal haematoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Catheter removal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Peritoneal cyst	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Peritoneal adhesions	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Forced expiratory volume	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Forced expiratory flow decreased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Peripheral vascular haematoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Peripheral spondyloarthritis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Peripheral nerve palsy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Peripheral nerve operation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Food protein-induced enterocolitis syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cataract nuclear	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Abnormal cord insertion	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Follicular lymphoma recurrent	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Periorbital infection	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Periorbital disorder	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Periorbital discomfort	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Foetal monitoring abnormal	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Periorbital abscess	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Castleman's disease	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Foetal malposition	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Perineal ulceration	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Perineal infection	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Perineal fistula	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Perineal erythema	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Foetal heart rate deceleration abnormality	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Perineal cyst	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pericardial mesothelioma malignant	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Carotidynia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Focal nodular hyperplasia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Fluorosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Carotid bruit	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Autonomic failure syndrome	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Penile oedema	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Penile necrosis	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Penile haematoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Penile erosion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Automatism	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Penile discharge	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Penile burning sensation	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Flap surgery	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Penile abscess	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Carotid artery aneurysm	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Flail chest	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Carotid arterial embolus	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Fistula repair	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pelvic misalignment	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pelvic floor hernia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Peliosis hepatis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Fibrous cortical defect	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cardiothoracic ratio increased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Autoimmune pancytopenia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pathergy reaction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Paternal exposure before pregnancy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cardiopulmonary exercise test abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Parvovirus infection	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Cardiopulmonary bypass	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Parkinsonism hyperpyrexia syndrome	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Autoimmune nephritis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Parietal lobe stroke	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Paravenous drug administration	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Parathyroid tumour	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Parathyroid gland operation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Parasitic pneumonia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Parasitic encephalitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Achromobacter infection	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Cardiac valve vegetation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Paranasal sinus mucosal hypertrophy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cardiac valve thickening	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Paranasal sinus abscess	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Paralysis recurrent laryngeal nerve	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Paraganglion neoplasm	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Cardiac valve abscess	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Paradoxical embolism	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Papillitis	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Pancreatogenous diabetes	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Relapsing multiple sclerosis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Fasting	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pancreaticoduodenectomy	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pancreatic pseudocyst	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pancreatic leak	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Fascial infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pancreatic haemorrhage	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pancreatic enzymes decreased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pancreatic enzyme abnormality	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Familial periodic paralysis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pancreatic duct obstruction	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pancreatic cyst rupture	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Anaemia neonatal	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Fallopian tube obstruction	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Autoimmune anaemia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Fallopian tube abscess	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Palatal ulcer	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Failure to suspend medication	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pain assessment	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Paedophilia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Packaging design issue	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
PaO2/FiO2 ratio decreased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cardiac imaging procedure abnormal	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
PO2 increased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
PCO2 decreased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Factor XIII inhibition	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Factor VIII deficiency	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Overgrowth fungal	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Auditory nerve disorder	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Factor VII deficiency	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Ovarian operation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Faciobrachial dystonic seizure	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Ovarian fibroma	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Ovarian cancer stage III	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cardiac contractility decreased	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Cardiac cirrhosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Osteotomy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Abiotrophia defectiva endocarditis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cardiac asthma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Osteopetrosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Eyelid scar	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Cardiac aneurysm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Eyelid retraction	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Osteomyelitis bacterial	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Osteoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Osteochondroma	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Osmolar gap increased	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Eyelid haematoma	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Eyelid function disorder	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Oropharyngeal squamous cell carcinoma	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Carcinoid tumour in the large intestine	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Eyelid contusion	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Eyelid bleeding	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Eyelash discolouration	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Oropharyngeal gonococcal infection	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Carcinogenicity	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Orgasmic sensation decreased	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Adams-Stokes syndrome	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Organic erectile dysfunction	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Orchidectomy	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Orbital myositis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Eye naevus	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Oral viral infection	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Eye laser surgery	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Oral mucosal scar	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Oral mucosal roughening	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Oral hyperaesthesia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Oral dysaesthesia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Eye degenerative disorder	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Optic nerve sheath meningioma	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Optic nerve hypoplasia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Optic nerve cupping	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Optic nerve compression	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Optic disc haemorrhage	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Extubation	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Open reduction of fracture	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Open globe injury	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Capnogram abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Extrapulmonary tuberculosis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Extraocular muscle disorder	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Extramedullary haemopoiesis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Amputation stump pain	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Oligospermia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Oligodipsia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Oestrogen receptor assay positive	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Expulsion of medication	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Oestrogen deficiency	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Exposure via partner	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Oesophagobronchial fistula	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Exposure via ingestion	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Oesophageal variceal ligation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Acute right ventricular failure	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Exposure via body fluid	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Exposure to unspecified agent	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Candida endophthalmitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Oesophageal neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Atrial natriuretic peptide increased	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Exposure to radiation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Cancer screening	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Oesophageal compression	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Oesophageal atresia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Oedematous kidney	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Oedema due to renal disease	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Campylobacter sepsis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Oedema blister	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Oculomucocutaneous syndrome	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Oculocephalogyric reflex absent	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Ocular vasculitis	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Ocular sarcoidosis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Exercise tolerance increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Ocular retrobulbar haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Aberrant aortic arch	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Callus formation delayed	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Occipital lobe stroke	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Calculus urethral	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Calculus prostatic	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Obstructive nephropathy	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Atopic keratoconjunctivitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Ewing's sarcoma metastatic	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Eustachian tube obstruction	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Calcium ionised increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Amniotic cavity disorder	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Atlantoaxial subluxation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Normochromic anaemia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Nontherapeutic agent urine positive	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Calcineurin inhibitor induced pain syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Noninfective conjunctivitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Noninfective chorioretinitis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Calcification of muscle	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Amniorrhoea	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Atherectomy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Erythroid dysplasia	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
CSWS syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Non-Hodgkin's lymphoma refractory	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Erythema migrans	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Nodular regenerative hyperplasia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Erysipeloid	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
New onset refractory status epilepticus	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Astrocytoma	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Neutrophilic dermatosis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Epstein-Barr virus antibody positive	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
CSF HIV escape syndrome	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Epithelioid sarcoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neurone-specific enolase increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Epiphyses premature fusion	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Asthenospermia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
CHANTER syndrome	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Neurofibromatosis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Neuroendocrine tumour of the lung	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Amino acid level increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
CD8 lymphocytes decreased	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Neurodevelopmental disorder	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Saliva discolouration	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Neuritis cranial	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Amino acid level abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Nervous system injury	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Asplenia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Eosinophilic cystitis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Eosinophilia myalgia syndrome	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Neonatal tachypnoea	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Neonatal respiratory failure	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Neonatal respiratory distress	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Neonatal dyspnoea	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Enzyme level decreased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Neisseria infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neglect of personal appearance	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Abdominal wound dehiscence	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Negativism	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Aspergilloma	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Enteropathy-associated T-cell lymphoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Natural killer-cell lymphoblastic lymphoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Natural killer-cell leukaemia	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Natural killer cell activity abnormal	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Bursal fluid accumulation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Enterocolitis bacterial	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Nasopharyngeal cancer	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Nasal sinus cancer	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Nasal mucosal hypertrophy	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Nasal mucosal discolouration	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Burning feet syndrome	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Burn oral cavity	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Asbestosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Endovenous ablation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Burkitt's lymphoma	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Nail avulsion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Burkholderia pseudomallei infection	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Endoscopy abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Acute myopia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Endoscopic retrograde cholangiopancreatography	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
N-terminal prohormone brain natriuretic peptide abnor	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Myxomatous mitral valve degeneration	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Endometrial neoplasm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Alveolar lung disease	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Endometrial hyperplasia with cellular atypia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Myopathy toxic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Abdominal wall wound	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Bulimia nervosa	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Myocarditis infectious	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Endometrial cancer stage I	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Myocarditis bacterial	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Bulbospinal muscular atrophy congenital	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Endometrial cancer metastatic	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Myocardial depression	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Endocrine pancreatic disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Myeloma cast nephropathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Endocrine gland operation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Arthritis-dermatitis syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Myelodysplastic syndrome transformation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bronchoscopy	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Enamel anomaly	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Musculoskeletal injury	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Elephantiasis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Multiple system atrophy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Electroconvulsive therapy	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Electrocardiogram low voltage	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Electrocardiogram high voltage	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Multicentric reticulohistiocytosis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Mucous membrane pemphigoid	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mucosal pain	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Abdominal hernia repair	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Electrocardiogram T wave amplitude increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mucosal infection	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Alpha hydroxybutyrate dehydrogenase increased	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Electrocardiogram QT interval	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Mouth cyst	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Arteriovenous fistula thrombosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Bronchial irritation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bronchial injury	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Electrocardiogram J wave increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Mononucleosis syndrome	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Electrocardiogram J wave abnormal	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Monocyte morphology abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Elective surgery	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Bronchial aspiration procedure	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Arteriovenous fistula operation	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Molluscum contagiosum	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Model for end stage liver disease score increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Arteriovenous fistula aneurysm	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Eczema vesicular	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Misophonia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Breath sounds	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Migrainous infarction	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Arterioenteric fistula	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Middle cerebral artery stroke	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Microvillous inclusion disease	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Microscopic polyangiitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Micrographic skin surgery	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Echolalia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Micrococcus infection	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Echo virus infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Methylenetetrahydrofolate reductase gene mutation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Arterial stent insertion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Early retirement	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Ear, nose and throat examination abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Metastatic gastric cancer	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Breast necrosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Metastases to nasal sinuses	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Metastases to heart	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Metastases to fallopian tube	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Metastases to bladder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Acanthosis nigricans	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Breast engorgement	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Metaphyseal dysplasia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Arterial insufficiency	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Dystonic tremor	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Dyspraxia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Mesenteric neoplasm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Mephisto sign	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Menstrual discomfort	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Menopause delayed	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Meniscus removal	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Meniscus cyst	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Meniscopathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Acanthosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Penile contusion	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Meningitis meningococcal	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Meningitis enteroviral	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Meningism	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Melanosia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Meige's syndrome	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Meibomianitis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Megakaryocytes decreased	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Medulloblastoma	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Medication dilution	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Medical device site scar	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Medical device site odour	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Acanthamoeba infection	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Brain stem ischaemia	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Medical device site erythema	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Medical device site dryness	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Medical device site cellulitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Medical device site burn	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Medical device monitoring error	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Mediastinum neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mediastinal shift	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Mediastinal fibrosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mediastinal effusion	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Drug titration	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Mean platelet volume abnormal	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Brain malformation	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Mean arterial pressure increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Application site urticaria	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Application site ulcer	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Drug metabolising enzyme increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mastoid disorder	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Application site scar	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Marfan's syndrome	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Manufacturing materials issue	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Manufacturing issue	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Malignant transformation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Malignant splenic neoplasm	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Malignant palate neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bradycardia foetal	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Malignant neoplasm of thorax	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Allergic stomatitis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Drug delivery system removal	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Malignant neoplasm of conjunctiva	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Acute haemorrhagic ulcerative colitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Application site paraesthesia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Drug delivery device placement	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Malignant melanoma stage III	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Brachioradial pruritus	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Malignant glioma	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Malignant fibrous histiocytoma	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Brachial plexus injury	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Dreamy state	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Malaria recrudescence	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Malabsorption from administration site	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Magnetic resonance imaging	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Dopamine agonist withdrawal syndrome	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Lysozyme increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
5-hydroxyindolacetic acid increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Application site laceration	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Diverticular fistula	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Borderline ovarian tumour	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Bone tuberculosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Lymphocyte percentage abnormal	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Allergic fungal rhinosinusitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Lymphatic fistula	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Bone sequestrum	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bone prosthesis insertion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Disseminated gonococcal infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Lupus pneumonitis	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Lupus pleurisy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Lupus enteritis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bone metabolism disorder	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Lung squamous cell carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Lung diffusion disorder	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Lung carcinoma cell type unspecified stage II	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Application site folliculitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Lung carcinoma cell type unspecified stage I	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Bone marrow necrosis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Bone marrow myelogram abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Bone marrow haemorrhage	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bone marrow granuloma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Dilatation atrial	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Diffuse panbronchiolitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Diffuse mesangial sclerosis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Diffuse large B-cell lymphoma stage II	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Diffuse idiopathic skeletal hyperostosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Lividity	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Liver scan abnormal	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Dieulafoy's vascular malformation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Liver ablation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Liposarcoma metastatic	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Diastasis recti abdominis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Diaphragmatic spasm	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Lipids decreased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Diaphragmatic injury	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Lipase	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Dialysis hypotension	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Application site abscess	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Lip and/or oral cavity cancer	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Linitis plastica	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Diabetic retinal oedema	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Alcoholic liver disease	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Limb fracture	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Limb amputation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Ligneous conjunctivitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Light chain analysis decreased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Ligament laxity	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Diabetic foot infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Life support	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Life expectancy shortened	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Lid lag	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Appendicitis noninfective	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
DiGeorge's syndrome	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Leukoerythroblastic anaemia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Leukodystrophy	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Alcoholic	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Leptotrichia infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Leptospirosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Leprosy	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Axillary web syndrome	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Apparent mineralocorticoid excess	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Lennox-Gastaut syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Left ventricular end-diastolic pressure increased	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Left ventricular end-diastolic pressure decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Leclercia bacteraemia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Lateral medullary syndrome	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Latent autoimmune diabetes in adults	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Apolipoprotein B increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Device end of service	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Device effect incomplete	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Laryngeal injury	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Laryngeal dyspnoea	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Device computer issue	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Large intestine anastomosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Acute cutaneous lupus erythematosus	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Blood urea nitrogen/creatinine ratio decreased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Langerhans' cell histiocytosis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Blood triglycerides decreased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Lacrimal haemorrhage	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Laboratory test	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Labile hypertension	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blood testosterone free increased	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Labelled drug-disease interaction medication error	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Labelled drug-disease interaction issue	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Dermatitis papillaris capillitii	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Kniest dysplasia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Dermal absorption impaired	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Keratorhexis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Keratoplasty	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Keratoconus	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Keratitis fungal	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Keloid scar	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Kawasaki's disease	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Kaposi sarcoma inflammatory cytokine syndrome	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Acute cardiac event	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Joint stabilisation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Joint prosthesis user	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Joint microhaemorrhage	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Dental paraesthesia	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Dental fistula	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Dental cleaning	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Joint debridement	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Dental attrition	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Dengue virus test positive	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Jejunal stenosis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Jejunal perforation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Demodicidosis	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Demodex blepharitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Jaundice acholuric	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Jarisch-Herxheimer reaction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Delusional disorder, unspecified type	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Delusional disorder, somatic type	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Delusional disorder, persecutory type	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Aortic rupture	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Delirium tremens	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Iris transillumination defect	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Iris neovascularisation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
pH body fluid abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Delayed haemolytic transfusion reaction	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2



Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Xanthopsia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Xanthelasma	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
XIIth nerve injury	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
X-linked lymphoproliferative syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Dehydroepiandrosterone decreased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Wrong dosage form	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Intrauterine contraception	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Intrathecal pump insertion	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Wound infection pseudomonas	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Wound evisceration	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Wound cellulitis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Weight loss diet	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Wallerian degeneration	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Intestinal ulcer perforation	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Intestinal transit time decreased	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Vulvar dysplasia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Agraphia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Vocal cord thickening	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Decidual cast	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Debridement	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Intestinal malrotation	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Aortic bruit	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vitamin C decreased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Intestinal diaphragm disease	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Intestinal cyst	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Vitamin B1 increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Vitamin A decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Dandy-Walker syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Visual acuity tests abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Viruria	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Viral uveitis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Viral tonsillitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Blood lactic acid abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Dacryocystitis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Agonal rhythm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Viral pericarditis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Viral myocarditis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
DNA antibody positive	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Vipoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Internal injury	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Victim of abuse	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Internal fixation of fracture	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Vessel puncture site haemorrhage	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Vertebroplasty	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Vertebrobasilar insufficiency	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vertebral osteophyte	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Vertebral end plate impression	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vertebral column mass	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vertebral artery occlusion	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Intercapillary glomerulosclerosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Cytomegalovirus hepatitis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Ventricular enlargement	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Antiviral prophylaxis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Venous operation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Venous angioma of brain	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cytokine abnormal	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Vasculitis gastrointestinal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vascular procedure complication	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Inner ear inflammation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Injection site vasculitis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Vascular cauterisation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Vascular anastomotic haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Vascular access site extravasation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Injection site plaque	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Varicophlebitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cystine urine present	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vagus nerve disorder	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Vaginitis gardnerella	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Injection site muscle weakness	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Vaginal ulceration	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Blood immunoglobulin E	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Injection site muscle atrophy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vaginal polyp	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Vaginal lesion	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Injection site hyperaesthesia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vaccination site inflammation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
VIIIth nerve injury	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Uterine tachysystole	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cyanopsia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Injection site abscess sterile	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cutaneous tuberculosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Uterine hypotonus	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cutaneous lymphoma	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Uterine atony	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Uterine abscess	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Urine protein/creatinine ratio decreased	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cutaneous T-cell lymphoma recurrent	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Antinuclear antibody	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Urine glucose/creatinine ratio increased	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Infusion site mobility decreased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Infusion site laceration	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Urinary tract stoma complication	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blood folate increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Idiopathic angioedema	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Urinary occult blood	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Urinary hexose tetrasaccharide increased	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Urinary bladder rupture	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Urethritis noninfective	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Urethral injury	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Antineutrophil cytoplasmic antibody	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cryptococcal cutaneous infection	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Inflammatory carcinoma of the breast	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Urachal abnormality	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Upper respiratory fungal infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Infestation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Infertility female	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Unwanted awareness during anaesthesia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Infective thrombosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Unevaluable investigation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Infective scleritis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Unevaluable device issue	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Unemployment	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Undersensing	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Infective glossitis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Creutzfeldt-Jakob disease	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Ulnar neuritis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Ulcerative duodenitis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Antidepressant drug level increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Typical aura without headache	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Type 2 lepra reaction	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Blood creatinine	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Turbinectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Craniosynostosis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Tumour necrosis factor receptor-associated periodic s	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Infant irritability	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Craniectomy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cranial nerve injury	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Tryptase decreased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Trousseau's sign	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Troponin abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Trisomy 21	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cough variant asthma	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Tri-iodothyronine free abnormal	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Blood corticotrophin abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Traumatic shock	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Traumatic lumbar puncture	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anticoagulation drug level decreased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Transposition of the great vessels	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blood citric acid increased	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Transient tachypnoea of the newborn	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Transient psychosis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Transcatheter aortic valve implantation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Implantable cardiac monitor insertion	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Tracheal ulcer	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Coronary artery dilatation	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Toxic erythema of chemotherapy	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Implant site irritation	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Implant site injury	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Total cholesterol/HDL ratio increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Implant site hypoaesthesia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Torus fracture	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Tooth whitening	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Tooth resorption	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Implant site dehiscence	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Implant site bruising	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Tooth dislocation	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Abdominal compartment syndrome	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Corneal operation	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Tonsillolith	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Abortion of ectopic pregnancy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Impaired reasoning	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Blood cannabinoids increased	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tongue neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Tongue haematoma	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Tongue erosion	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Corneal exfoliation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Corneal erosion	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Tolosa-Hunt syndrome	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Blood calcitonin increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Tobacco interaction	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Immune-mediated oesophagitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Corneal endothelial cell loss	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Tinea cruris	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Tick-borne viral encephalitis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Thyroxine free abnormal	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Thyroid stimulating immunoglobulin increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Corneal decompensation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Corneal abscess	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Immune-mediated encephalopathy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Antibiotic associated colitis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Immune-mediated cytopenia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Thyroid adenoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Thymic cyst	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Copper deficiency	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Thrombosis mesenteric vessel	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Thrombophlebitis septic	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Threatened labour	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Imaging procedure abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Thoracotomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Anti-thyroid antibody positive	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Thoracic operation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cooling therapy	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Illiteracy	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Therapy responder	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Iliac artery occlusion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Iliac artery disease	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Therapeutic drug monitoring analysis not performed	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Thalassaemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blood alkaline phosphatase	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Tethered cord syndrome	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Testicular torsion	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anti-thyroid antibody	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Implant site mass	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Blood aldosterone decreased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Idiopathic generalised epilepsy	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Testicular haemorrhage	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Testicular failure	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Continuous haemodiafiltration	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anti-polyethylene glycol antibody present	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Ichthyosis acquired	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Illrd nerve paresis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Implant site pustules	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Adrenalitis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Hypozincaemia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Tendinous contracture	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Temporal lobe epilepsy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Abortion late	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Tangentiality	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Implantation complication	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Conjunctival staining	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Tachycardia foetal	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
T-lymphocyte count abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Systolic anterior motion of mitral valve	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Systemic viral infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Systemic toxicity	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Conjunctival irritation	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Syringomyelia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Synovial cyst removal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Syndesmophyte	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Conjunctival erosion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Symphysiolysis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hyponatriuria	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Conjunctival deposit	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Sweat gland tumour	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Sweat gland disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Suspiciousness	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Suspected suicide attempt	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hypoglycaemia unawareness	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Congenital tricuspid valve incompetence	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Surgical procedure repeated	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Congenital torticollis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Supraventricular tachyarrhythmia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hypoglossal nerve disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cortisol abnormal	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Transverse sinus thrombosis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Incision site cellulitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Supine hypertension	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hypocoagulable state	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Superinfection viral	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Incarcerated umbilical hernia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anti-Muellerian hormone level decreased	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Blepharoplasty	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Superficial vein prominence	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Superficial spreading melanoma stage unspecified	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Congenital musculoskeletal disorder of spine	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Blepharal pigmentation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Congenital musculoskeletal disorder	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Subretinal fibrosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Incision site ulcer	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Hypervitaminosis D	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Incision site vesicles	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Subglottic laryngitis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Tri-iodothyronine free increased	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hypertrophy of tongue papillae	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Subclavian artery thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Subchorionic haemorrhage	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Subarachnoid haematoma	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Congenital dyskeratosis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hypertensive nephropathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Stroke in evolution	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Stress ulcer	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Stress echocardiogram abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Anti factor VIII antibody increased	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Streptococcal bronchitis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Hypersplenism	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Blood creatine phosphokinase MB abnormal	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Stool pH decreased	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Congenital arterial malformation	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Stomal varices	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Stoma site ulcer	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blast cell crisis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Stoma site odour	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Stoma site cellulitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Anti factor IX antibody increased	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hyperoxia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Stitch abscess	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Condom catheter placement	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Adrenal gland operation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Stereotypy	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Stenotrophomonas test positive	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Anti A antibody positive	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Computerised tomogram liver abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Squamous cell carcinoma of the parotid gland	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Computerised tomogram heart abnormal	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Computerised tomogram head abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Squamous cell carcinoma antigen increased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Anterior chamber opacity	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bladder repair	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Compulsive sexual behaviour	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Spondylitic myelopathy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Hyperchromic anaemia	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Splenic marginal zone lymphoma	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Complications of transplanted liver	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Splenic granuloma	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Splenic calcification	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Complications of transplanted heart	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hyperbaric oxygen therapy	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Complications of transplant surgery	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Spirochaetal infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Spinocerebellar disorder	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Spindle cell sarcoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Complications of bone marrow transplant	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Spinal stroke	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Spinal nerve stimulator removal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hyper IgE syndrome	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Spinal cord injury cervical	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Spinal cord infarction	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Spinal cord haematoma	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Spinal claudication	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Complement factor C4 increased	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Spigelian hernia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Sphincter of Oddi dysfunction	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Complement factor C3 decreased	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Bladder diverticulum	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2

### Reaction Summary Table Derived Age Group

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Human herpesvirus 6 encephalitis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Combined pulmonary fibrosis and emphysema	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Human anaplasmosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Soft tissue neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Snapping hip syndrome	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Smooth muscle antibody positive	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Homicide	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Colostomy closure	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Small intestinal ulcer haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Ureteric cancer	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Small intestinal anastomosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Hodgkin's disease recurrent	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Small cell lung cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Histamine level increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Histamine abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Sleep study	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Colorectal adenocarcinoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Skull fractured base	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Skin ulcer haemorrhage	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Anorectal varices	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Birdshot chorioretinopathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Skin pressure mark	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Hiatus hernia strangulated	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Herpes zoster meningomyelitis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Skin indentation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Crystal urine	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Colon cancer recurrent	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Skin cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Herpes simplex oesophagitis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Skin angiosarcoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Biopsy thyroid gland abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Herpes simplex meningitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Infusion site dryness	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Herpes simplex hepatitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Herpes dermatitis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hernia obstructive	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Similar reaction on previous exposure to drug	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Silent myocardial infarction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Biopsy skin abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Sick relative	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Hereditary haemorrhagic telangiectasia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Adnexa uteri cyst	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Shunt thrombosis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Biopsy site unspecified abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Shoulder girdle pain	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Shoulder deformity	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Shortened cervix	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hepatosplenic abscess	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Hepatorenal failure	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Infusion site necrosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Severe acute respiratory syndrome	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Anonychia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cockroach allergy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Serum colour abnormal	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hepatitis chronic active	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Biopsy lymph gland	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Urine protein/creatinine ratio abnormal	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Septic rash	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Urobilinogen urine increased	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Septal panniculitis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Sepsis pasteurella	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Coagulation time abnormal	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Sensory processing disorder	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hepatitis B surface antibody positive	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Coagulation factor VIII level decreased	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Coagulation factor V level decreased	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hepatitis B DNA assay positive	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Uterine contractions abnormal	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Self-destructive behaviour	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Annular elastolytic giant cell granuloma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Selective mutism	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Selective IgA immunodeficiency	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Hepatic venous pressure gradient abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Hepatic vascular disorder	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Secondary cerebellar degeneration	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Scrotal ulcer	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hepatic ischaemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hepatic infection fungal	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Scrotal inflammation	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Scrotal discomfort	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Hepatic haemangioma rupture	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Scoliosis surgery	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Sclerotherapy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Scleromalacia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Cyanosis central	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Biochemical pregnancy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Clinical death	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Scleral thinning	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Cleft palate	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Scleral haemorrhage	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Sciatic nerve palsy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Schistocytosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Hepatic cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Vaccination site injury	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hepatic calcification	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Scalp haematoma	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Vaccination site haematoma	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Administration site reaction	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Vaccination site rash	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Sarcomatoid mesothelioma	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Sarcoma metastatic	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cirrhosis alcoholic	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Bilirubin urine present	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Salpingo-oophoritis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Salmonella test positive	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Salmonella sepsis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Salivary gland pain	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Salivary gland mass	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2



Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hemianopia heteronymous	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Saliva analysis abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bilirubin conjugated abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vaginal perforation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Ciliary hyperaemia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Heavy exposure to ultraviolet light	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Rubella	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Heavy chain disease	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Rickets	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Rib deformity	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Heart rate variability increased	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Rheumatoid meningitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Heart alternation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Rheumatoid factor negative	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Rhabdomyosarcoma	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Reversal of sedation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Rett syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Retroperitoneal neoplasm metastatic	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Hashimoto's encephalopathy	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Retrograde amnesia	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Cystitis klebsiella	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Retinoschisis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Retinopathy proliferative	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Retinopathy of prematurity	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hand repair operation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Retinal scar	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Retinal infarction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Retinal fovea disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Chronic graft versus host disease oral	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Reticulocytopenia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Reticulocyte count abnormal	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Chronic graft versus host disease in liver	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Chronic graft versus host disease in eye	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Respiratory syncytial virus test	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Administration site joint pain	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Haemorrhagic erosive gastritis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Chronic coronary syndrome	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Respiratory depth decreased	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Reproductive tract disorder	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Haemorrhagic ascites	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Chromosome analysis abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Administration site joint infection	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Angiotensin converting enzyme increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Renal replacement therapy	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Renal necrosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Haemoglobinaemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Renal dysplasia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Benzodiazepine drug level increased	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Renal cyst haemorrhage	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Benign uterine neoplasm	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Renal cell carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Renal cancer stage II	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Benign tumour excision	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Renal artery thrombosis	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Venous pressure jugular increased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Intention tremor	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Renal arteriosclerosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Removal of foreign body	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Chondrosarcoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Haematological neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Relapsing fever	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Refractory cancer	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Ventricular failure	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Haemangioma of bone	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Angiopathic neuropathy	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Red blood cell schistocytes present	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Red blood cell microcytes present	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Red blood cell hypochromic morphology present	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Habit cough	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cholesteatoma	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
HLA-B*27 positive	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
HIV-associated neurocognitive disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
HIV viraemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Benign neoplasm of spinal cord	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
HIV test positive	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Rectal spasm	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Cholelithotomy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Rectal injury	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Benign neoplasm of skin	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
HCoV-OC43 infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Rebound psychosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Rebound nasal congestion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
H1N1 influenza	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Reactive capillary endothelial proliferation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Reaction to sweetener	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Acquired cardiac septal defect	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Gun shot wound	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Rathke's cleft cyst	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Rasmussen encephalitis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Gross motor delay	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Vessel puncture site inflammation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Benign laryngeal neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Radiotherapy to brain	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Radiculotomy	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Internal carotid artery deformity	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Radical prostatectomy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Radiation retinopathy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Granulomatous rosacea	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Radial nerve palsy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
RET gene mutation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Quadrantanopia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Victim of chemical submission	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Granulocytosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Benign gastric neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Chitotriosidase increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Chillblains	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Graft versus host disease in eye	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Puncture site bruise	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Gorham's disease	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gonorrhoea	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gonococcal infection	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pulmonary vein occlusion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Aneurysm thrombosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pulmonary valve thickening	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pulmonary valve disease	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Chest tube insertion	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Bence Jones protein urine present	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Glycosylated haemoglobin	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Glycogen storage disease type II	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Glycated albumin increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pulmonary necrosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pulmonary microemboli	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Glossoptosis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pulmonary fistula	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Glomerulonephropathy	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pulmonary eosinophilia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pulmonary endarterectomy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Glomerulonephritis proliferative	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pulmonary artery therapeutic procedure	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Chemical cystitis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Pulmonary arterial wedge pressure increased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pulmonary arterial wedge pressure decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Pulmonary arterial pressure	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pubic pain	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Chemical burn of genitalia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Vitreous cyst	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Glioma	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Andropause	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Psychiatric care	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Glaucoma surgery	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pseudomyopia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Charles Bonnet syndrome	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pseudomonal skin infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pseudohypoadosteronism	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Cestode infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Prothrombin time ratio increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Gingival cancer	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Androgen deficiency	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Protein S deficiency	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Protein C deficiency	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Von Willebrand's factor inhibition	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Vulvar erosion	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Basal ganglia stroke	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Cervix carcinoma stage I	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Cervix carcinoma stage 0	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Geotrichum infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cervix cancer metastatic	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Genitourinary tract neoplasm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Genitourinary tract infection	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Prophylaxis against transplant rejection	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Prophylaxis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Genital neoplasm malignant female	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Prohormone brain natriuretic peptide increased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Genital injury	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Progressive familial intrahepatic cholestasis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Progressive external ophthalmoplegia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Bartonellosis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Genital infection female	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Genital infection bacterial	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Genital herpes zoster	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Cervical cyst	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Genital dysaesthesia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Product primary packaging issue	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Administration site abscess	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cerebrovascular stenosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Product label on wrong product	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Product impurity	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Generalised resistance to thyroid hormone	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Anaplastic thyroid cancer	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Product design confusion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cerebral ventricle dilatation	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
General anaesthesia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gender dysphoria	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Product compounding quality issue	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Product cleaning inadequate	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Gastrostomy failure	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Proctocolectomy	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Procrastination	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Procedural intestinal perforation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Withdrawal hypertension	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Intra-ocular injection	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Gastrointestinal tract mucosal discolouration	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Intranasal paraesthesia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Primary stabbing headache	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bacteroides bacteraemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Premenstrual pain	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Premenstrual dysphoric disorder	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gastrointestinal neuroendocrine carcinoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Gastrointestinal mucosal exfoliation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Bacterial tracheitis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pre-engraftment immune reaction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cerebral ataxia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Poverty of speech	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Posturing	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Postoperative respiratory failure	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Postoperative renal failure	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Gastrointestinal decompression	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Postoperative delirium	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Postmortem blood drug level increased	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Postmortem blood drug level	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gastrointestinal angiodysplasia	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Posterior tibial tendon dysfunction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cerebellar ischaemia	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
pH urine decreased	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Post-traumatic headache	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
11-beta-hydroxylase deficiency	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Post transfusion purpura	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Post procedural urine leak	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Cerebellar haematoma	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Gastroenteritis sapovirus	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Post procedural pruritus	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
5-hydroxyindolacetic acid in urine	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Post procedural hypoparathyroidism	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Gastroenteritis listeria	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Post procedural drainage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Post procedural cellulitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Post procedural cardiac valve avulsion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Post polio syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Post intensive care syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastroduodenal haemorrhage	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Post angioplasty restenosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Positive end-expiratory pressure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Portopulmonary hypertension	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bacterial diarrhoea	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastritis alcoholic	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Portal vein pressure increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Portal vein embolisation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastrinoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastrin-releasing peptide precursor increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Portal hypertensive colopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Portal fibrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Porphyria	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anal skin tags	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bacterial abscess central nervous system	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Poriomania	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Poor weight gain neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastric tube reconstruction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastric stent removal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastric prolapse	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Polyneuropathy chronic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastric pH increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Polyneuropathy alcoholic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Polyglandular autoimmune syndrome type II	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastric ischaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Central nervous system injury	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastric ileus	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adhesiolysis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pneumovirus test positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Central nervous system immune reconstitution inflamma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastric cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pneumonia serratia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Gastric atony	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bacillary angiomatosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pneumonia moraxella	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gardnerella infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ganglioneuroma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Central auditory processing disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adenovirus test positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cellulitis streptococcal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
BRCA2 gene mutation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pneumectomy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pneumocentesis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
BRCA1 gene mutation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cellulitis of male external genital organ	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gallbladder volvulus	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pneumaturia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pleuroparenchymal fibroelastosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pleural rub	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gallbladder necrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
BRAF gene mutation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cells in urine	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gallbladder mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pleural infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pleural cyst	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Plethysmography	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
BRAF V600E mutation positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gallbladder cholesterolosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Platypnoea-orthodeoxia syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Platelet toxicity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Platelet distribution width increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gallbladder abscess	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cavernous sinus syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Galactostasis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Platelet anisocytosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Platelet aggregation increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
BK polyomavirus test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Catheterisation venous	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Plasmodium falciparum infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acinetobacter bacteraemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fusobacterium infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Plantar fascial fibromatosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fungal test	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pityriasis lichenoides et varioliformis acuta	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pityriasis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fungal rhinitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pituitary tumour removal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pituitary infarction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Pituitary haemorrhage	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fungal myositis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Catheter site rash	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pineal gland cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Piercing associated complication	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Catheter site pustule	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Fungal cystitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pickwickian syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fundoscopy abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Physical fitness training	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Functional residual capacity increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
B-cell unclassifiable lymphoma high grade	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Catheter site phlebitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Physical abuse	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Functional residual capacity abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Phototherapeutic keratectomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Photosensitive seizure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Functional endoscopic sinus surgery	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fumbling	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Phosphaturic mesenchymal tumour	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Catheter site mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Phobic postural vertigo	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Phlyctenular keratoconjunctivitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Phlebitis superficial	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Phlebitis deep	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
B-cell lymphoma stage IV	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Phlebectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Adenoviral conjunctivitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
B-cell lymphoma stage II	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Philadelphia chromosome negative	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Catheter site hypoaesthesia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pharyngeal perforation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
B-cell lymphoma refractory	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fracture treatment	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pharyngeal neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pharyngeal exudate	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pharyngeal enanthema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fracture infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pharyngeal dystonia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pharyngeal contusion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pharyngeal chlamydia infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Catheter site exfoliation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fracture blisters	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pharyngeal cancer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pharmaceutical nomadism	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Catheter site erosion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fractional exhaled nitric oxide abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Persistent postural-perceptual dizziness	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Foreign body reaction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Catheter site dehiscence	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pernio-like erythema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Catheter site abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peritoneal mesothelial hyperplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Adenosquamous cell carcinoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peritoneal fibrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fordyce spots	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Peritoneal dialysis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Forced vital capacity increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Perisplenitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Catecholamines urine increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Periportal sinus dilatation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Periportal oedema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anal eczema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peripheral vein thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peripheral vein stenosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Foot and mouth disease	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Peripheral pulse decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peripheral oedema neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adenosquamous carcinoma of the cervix	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Peripheral nerve infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peripheral nerve decompression	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Peripheral artery stent insertion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peripheral artery stenosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peripheral artery aneurysm rupture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cataract cortical	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fontanelle bulging	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anal chlamydia infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Peripartum haemorrhage	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Folliculitis genital	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peripartum cardiomyopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Peripancreatic varices	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acid peptic disease	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Catamenial pneumothorax	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Periorbital injury	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Follicle centre lymphoma, follicular grade I, II, III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anal cancer stage I	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Avian influenza	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Foetal macrosomia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Perineal rash	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Perineal necrosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Foetal heart rate increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Perineal injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cartilage graft	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Perinatal stroke	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Perihepatic discomfort	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Perihepatic abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pericoronitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pericarditis tuberculous	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pericarditis lupus	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pericardial mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pericardial effusion malignant	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anal cancer recurrent	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Autonomic seizure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pericardial drainage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Carotid pulse abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Carotid intima-media thickness increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Performance fear	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Percutaneous coronary intervention	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Carotid endarterectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Peptic ulcer haemorrhage	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Penoscrotal fusion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fluid balance positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Penile prosthesis insertion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Floppy iris syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Penile odour	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Floppy infant	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Floating patella	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Penile gangrene	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Flight of ideas	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Penile exfoliation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Flat anterior chamber of eye	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Penetrating aortic ulcer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pemphigus disease area index	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Automatic bladder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Flagellate dermatitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pelvic pouch procedure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Autologous blood patching	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fixed bowel loop	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pelvic organ injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pelvic girdle pain	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
First degree chemical burn of skin	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pelvic floor muscle weakness	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anaesthetic complication neurological	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiovascular symptom	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Finger repair operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pelvic floor dysfunction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pelvic cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pelvic adhesions	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fine motor delay	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pedal pulse increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Filariasis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pedal pulse decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cardiovascular deconditioning	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fight in school	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pectus excavatum	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
ASXL1 gene mutation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Patient dissatisfaction with device	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Pathological tooth fracture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acid base balance abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fibrosarcoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pathological doubt	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pathologic myopia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Anaesthesia procedure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Paternal exposure timing unspecified	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fibroblast growth factor 23	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Paroxysmal perceptual alteration	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiomyopathy neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fibrin degradation products	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Paroxysmal atrioventricular block	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Fibrin D dimer decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cardiomyopathy acute	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fibrillary glomerulonephritis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fever neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Femoral nerve injury	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Femoral hernia incarcerated	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Paratonia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Femoral hernia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Femoral anteversion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Parathyroid hyperplasia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Parathyroid hormone-related protein increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cardioactive drug level decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Female reproductive tract disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardio-respiratory arrest neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Parathyroid gland abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anaemia vitamin B6 deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Female genital operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Parapharyngeal space infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiac ventricular scarring	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Paraneoplastic pleural effusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Paraneoplastic hypoglycaemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Paranasal sinus necrosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Paranasal sinus haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cardiac valve rupture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cardiac valve replacement complication	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Parakeratosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anaemia postoperative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Paradoxical skin reaction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Paracusis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Fear of weight gain	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Paracoccidioides infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fear of surgery	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Papilloma excision	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Papilloma conjunctival	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fear of eating	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Papilloma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adenocarcinoma of the cervix	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anaemia of pregnancy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Papillary cystadenoma lymphomatosum	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pantoea agglomerans infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Panophthalmitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Panniculitis lobular	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fat overload syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cardiac resynchronisation therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fat embolism syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cardiac rehabilitation therapy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fat embolism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pancreatitis bacterial	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fasciola test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pancreatic operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cardiac perfusion defect	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fascial rupture	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Achlorhydria	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fascial operation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiac perforation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pancreatic infarction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pancreatic enzymes abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Pancreatic duct stenosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Autoimmune cholangitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiac pacemaker evaluation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Familial cold autoinflammatory syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Familial amyloidosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
False positive tuberculosis test	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fallopian tube perforation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pancoast's syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fallopian tube operation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Palpatory finding abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cardiac myxoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fallopian tube cancer stage III	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Palliative sedation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cardiac monitoring abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Failure to anastomose	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Failure of child resistant product closure	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiac index abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pachydermoperiostosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
PRIDE syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
PO2 abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Achenbach syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
PCDH19 gene-related epilepsy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
PASH syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiac haemolytic anaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Oxygen saturation normal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aural polyp	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Faecal calprotectin decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Factor Xa activity increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oxidative stress	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ovulation pain	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ovulation disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Overwork	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Overgrowth syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Factor VIII activity increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Factor VIII activity decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Overchelation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Factor V deficiency	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Ovarian prolapse	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ovarian neoplasm surgery	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Factor IX deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ovarian haematoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Audiogram abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ovarian germ cell teratoma benign	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ovarian germ cell teratoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Ovarian cyst torsion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Facial operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ovarian cancer stage I	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ovarian adenoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Otorhinolaryngological surgery	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Otolithiasis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Otitis media staphylococcal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Face lift	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Otitis media haemophilus	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Otitis media chronic	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Face crushing	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Otitis externa bacterial	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
FLT3 gene mutation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Osteorrhagia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
FEV1/FVC ratio abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Osteoradionecrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Eyelid tumour	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Osteomyelitis drainage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Amyloidoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Atypical migraine	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Osteochondritis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Osteochondral fracture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Eyelid myoclonus	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Osteocalcin decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Atypical lymphocytes increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Carcinoma in situ of skin	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Osteitis deformans	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Ostectomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Osmophobia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Osmolar gap abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Osmolar gap	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Carcinoid tumour of the stomach	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Eyelid cyst removal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oropharyngitis fungal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oropharyngeal spasm	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Atypical fibroxanthoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oropharyngeal oedema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Eyelash thickening	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oropharyngeal neoplasm benign	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Accommodation disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oronasal fistula	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oroantral fistula	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Organ transplant	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Eye opacity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Orbital swelling	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Orbital infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oral pigmentation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Oral papilloma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Eye laser scar	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Oral neoplasm benign	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Atrophic glossitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Oral mucosa haematoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acute vestibular syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Carbon dioxide combining power decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Eye infection syphilitic	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oral mucosa atrophy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Carbohydrate metabolism disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oral dysplasia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Atrioventricular dissociation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Carbohydrate intolerance	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Eye haemangioma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Carbohydrate antigen 72-4	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Eye excision	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oral allergy syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aberrant motor behaviour	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Carbohydrate antigen 242 increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Optic nerve infarction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Optic glioma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Eye abrasion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Carbohydrate antigen 125	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ophthalmic vein thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Capsular contracture associated with breast implant	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ophthalmic fluid drainage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Extraskelatal ossification	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ophthalmic artery occlusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Amputee	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Capripox viral infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Extrarenal pelvis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oophoritis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oocyte harvest	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Capnocytophaga sepsis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Onychomalacia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Capillary permeability increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oncocytoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Atrial switch operation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
External ear pain	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
External ear neoplasm malignant	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
External ear inflammation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Olfactory dysfunction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
External ear disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oestrone increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oestrone decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exposure via unknown route	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oestradiol increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Atrial septal defect repair	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oesophagomediastinal fistula	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Oesophagogastroduodenoscopy abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oesophagogastric fundoplasty	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exposure via mucosa	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Exposure via inhalation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oesophagitis bacterial	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Atrial septal defect acquired	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oesophagectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Candida nappy rash	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oesophageal squamous cell carcinoma stage IV	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exposure to violent event	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oesophageal operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oesophageal oedema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Exposure to tobacco	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oesophageal mucosal tear	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oesophageal mucosal blister	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oesophageal motility test	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oesophageal mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oesophageal hypomotility	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Atrial natriuretic peptide	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cancer screening abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exposure to contaminated device	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Atrial hypertrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oesophageal dilation procedure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oesophageal atony	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exploding head syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oesophageal adenocarcinoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cancer cells present	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oedema due to hepatic disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Expanded disability status scale score decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ocular surface squamous neoplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exeresis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ocular surface disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ocular rosacea	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
ABO incompatibility	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Campylobacter bacteraemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ocular procedural complication	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exercise electrocardiogram abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ocular melanoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ocular implant exposure	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Amniotic fluid index decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Calyceal diverticulum	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ocular dysmetria	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ocular cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Excessive gingival display	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Occupational problem environmental	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Occupational exposure to dust	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Excessive dynamic airway collapse	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exanthema subitum	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Obstructive shock	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exaggerated startle response	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Obstetric procedure complication	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nutritional supplementation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nucleic acid test positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Calcium ionised decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nothing by mouth order	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Notalgia paraesthetica	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Nose deformity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Calcitonin secretion disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Amniotic band syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Normal tension glaucoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Escherichia pyelonephritis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nontherapeutic agent blood positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Erythrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Noninfectious myelitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Erythrospia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Non-small cell lung cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Acute pulmonary histoplasmosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Erythropoietin deficiency anaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Non-small cell lung cancer stage III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Non-small cell lung cancer stage I	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Caffeine allergy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Erythroid maturation arrest	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Non-obstructive cardiomyopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Non-Hodgkin's lymphoma stage II	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Amniocentesis abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Non-24-hour sleep-wake disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
CSF white blood cell count increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Erythema infectiosum	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nodular melanoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Erythema ab igne	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
CSF red blood cell count positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Erysipelothrix infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nocardia sepsis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Astrocytoma, low grade	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nipple inflammation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nipple exudate bloody	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nipple enlargement	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ergot poisoning	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
CSF protein	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nicotinic acid deficiency	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Erdheim-Chester disease	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
New daily persistent headache	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
CSF pressure decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Epulis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neutrophilic panniculitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neutrophil toxic granulation present	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
CSF lymphocyte count increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neutrophil percentage abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
CSF lactate decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neutrophil morphology abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neutrophil hypersegmented morphology present	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
CSF culture positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
CSF cell count decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Epithelioid sarcoma recurrent	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neurotransmitter level altered	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
COVID-19 treatment	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neuropathy vitamin B6 deficiency	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neuropathic pruritus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Epiphysiodesis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neuromyotonia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Epinephrine abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neuromuscular pain	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neuromuscular block prolonged	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Epileptic encephalopathy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acute postoperative sialadenitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
COPA syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neurological rehabilitation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neurological procedural complication	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Epilepsia partialis continua	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Epiglottic oedema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Neuroleptic-induced deficit syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Epiglottic cancer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neuroglycopenia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neurogenic cough	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
CD8 lymphocytes increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Epidural anaesthesia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neuroendocrine carcinoma of the bladder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neuroendocrine cancer of the prostate metastatic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
CD8 lymphocyte percentage increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Epididymal neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neurodevelopmental delay	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neurocysticercosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Epidermolysis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neurocryptococcosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Accidental device ingestion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neuroborreliosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Asteatosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neurectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Ependymoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Eosinophilic pustular folliculitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nervous system cyst	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Assisted suicide	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
CD4 lymphocytes abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nerve conduction studies abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
CD34 cell count decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
CD19 lymphocytes increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
CALR gene mutation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Neoplasm prostate	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neoplasm of appendix	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
C1q nephropathy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neonatal seizure	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Eosinophil count normal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
C-telopeptide increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neonatal pneumothorax	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neonatal pneumonia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neonatal leukaemia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
C-telopeptide decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neonatal intestinal perforation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neonatal epileptic seizure	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neonatal behavioural syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abdominal incarcerated hernia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Enzyme activity abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ameloblastoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Negative cardiac inotropic effect	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
C-kit gene mutation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Necrotising colitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Necrosis of artery	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Butanol-extractable iodine decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bursitis infective staphylococcal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Natural killer cell count	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nasopharyngeal reflux	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nasal septum ulceration	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nasal odour	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nasal necrosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Burns first degree	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nasal mucosal erosion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nasal flaring	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Enteric neuropathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nasal cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enophthalmos	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nasal aspiration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acute oesophageal mucosal lesion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enlarged clitoris	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enlarged cerebral perivascular spaces	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Narcissistic personality disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Engraft failure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nail necrosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Burn of internal organs	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enema administration	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Alveolar oxygen partial pressure decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nail cuticle fissure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endotoxic shock	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nail bed tenderness	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endoscopy upper gastrointestinal tract abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endoscopy gastrointestinal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nail atrophy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Naevus spilus	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Naevus haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
NYHA classification	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
NIH stroke scale score increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
NIH stroke scale abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1



Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
N-telopeptide abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Myxoid cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endometrial thinning	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Myxofibrosarcoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mysophobia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Myringotomy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bundle branch block bilateral	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endometrial stromal sarcoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Myringosclerosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endometrial sarcoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Myopic traction maculopathy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arthropod infestation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Endometrial hypoplasia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Myopic chorioretinal degeneration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endometrial dysplasia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Myoglobin urine present	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endometrial disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Endometrial cancer stage III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alveolar bone resorption	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Myocardial stunning	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Myocardial rupture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Myocardial necrosis marker	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Myocardial necrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endolymphatic hydrops	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Myocardial hypoxia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arthrofibrosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Endocrine toxicity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Myocardial haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Brunner's gland hyperplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endocrine test abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alveolar bone defect	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endocrine neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Myelomalacia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Brown tumour	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Myelodysplastic syndrome with multilineage dysplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endocarditis pseudomonal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Endocarditis noninfective	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Myeloblast percentage increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bronchus compression	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Endocarditis enterococcal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arthritis viral	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Myectomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mycotoxicosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
End-tidal CO2 increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bronchoscopy abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mycobacterium avium complex immune restoration diseases	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Encephalocele	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mycobacterial disease carrier	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bronchoscopic lung volume reduction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Encephalitis protozoal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arthritis gonococcal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mutagenic effect	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Musculoskeletal procedural complication	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arthritis fungal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Musculoskeletal complication associated with device	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Emphysematous cholecystitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Altered pitch perception	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Muscle relaxant therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Muscle relaxant drug level above therapeutic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bronchoplasty	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Muscle oedema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bronchogram abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Muscle neoplasm	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arthritis allergic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bronchoalveolar lavage abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bronchoalveolar lavage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Embolic pneumonia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Murphy's sign positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Multivisceral transplantation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bronchitis pneumococcal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Multisystem inflammatory syndrome in adults	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bronchitis haemophilus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Multiple pregnancy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Electroencephalogram	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Multiple endocrine neoplasia Type 1	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
AST/ALT ratio	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arteritis coronary	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Multiple congenital abnormalities	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abdominal wall operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Accelerated idioventricular rhythm	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mucositis management	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Mucosal roughness	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mucosal prolapse syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mucosal hyperaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Mucosal exfoliation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bronchial stent insertion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Electrocardiogram ST-T segment elevation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mucolipidosis type I	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mucoepidermoid carcinoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mucocutaneous rash	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arteriovenous graft site necrosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bronchial oedema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Mucocutaneous leishmaniasis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arteriovenous graft site infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Electrocardiogram RR interval prolonged	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bronchial mucosa hyperaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Motor developmental delay	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Electrocardiogram QRS complex	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Morose	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arteriovenous fistula site infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Moraxella test positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Mononucleosis heterophile test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arteriovenous fistula site haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bronchial dysplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mononeuropathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Monogenic diabetes	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Electrocardiogram	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Monocytopenia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Electrical burn	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Monocyte count abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Elective procedure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alpha 1 foetoprotein abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Monoclonal B-cell lymphocytosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bronchial artery hypertrophy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Molybdenum deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Elastofibroma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Modified radical mastectomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Modified Rodnan skin score abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Brief psychotic disorder, with postpartum onset	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Model for end stage liver disease score abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alpers disease	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mixed deafness	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Breech delivery	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mitral valve disease mixed	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Edentulous	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mitral commissurotomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mitochondrial myopathy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Breath sounds absent	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arteriosclerotic retinopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Misleading laboratory test result	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mineralocorticoid deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Milk soy protein intolerance	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ectropion of cervix	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Migraine-triggered seizure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ectopic gastric mucosa	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Abdominal wall oedema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Breast tumour excision	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Echovirus test positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Micrographia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Microglossia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Breast prosthesis user	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Microbiology test abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mevalonate kinase deficiency	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metastatic uterine cancer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Metastatic salivary gland cancer	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metastatic mesothelioma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ear, nose and throat disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metastatic carcinoid tumour	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Metastases to uterus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Metastases to rectum	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Breast induration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ear lobe infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arterial perforation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Metastases to muscle	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ear infection staphylococcal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metastases to diaphragm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Metastases to biliary tract	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ear deformity acquired	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metastases to abdominal wall	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Allogenic bone marrow transplantation therapy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arterial intramural haematoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metapneumovirus bronchiolitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
ECG signs of myocardial ischaemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metaphyseal corner fracture	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metabolic myopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dyssomnia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mesoblastic nephroma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Breast discolouration	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Breast discharge infected	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mesenteric haematoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mesenteric artery embolism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mesenteric arterial occlusion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Mesangioproliferative glomerulonephritis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Allergy to venom	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arterial graft	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Breast cyst rupture	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mental status changes postoperative	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arterial fibrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Menstruation normal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abdominal wall neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Meningococcal bacteraemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Allergy to synthetic fabric	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Meningitis trypanosomal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Meningitis streptococcal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Meningitis neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Breast cancer male	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Meningitis leptospiral	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Meningitis haemophilus	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arrested labour	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Meningitis chemical	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Meningeal thickening	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Meningeal repair	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Menarche	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dural arteriovenous fistula	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Melanaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arm amputation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Duodenostomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Megakaryocytes increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Megakaryocytes abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Megakaryocytes	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Duodenectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arginase deficiency	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Medium-chain acyl-coenzyme A dehydrogenase deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Medical observation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Brain tumour operation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Medical device site warmth	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Medical device site ulcer	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Duodenal obstruction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arboviral infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Brain stem stroke	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Medical device site reaction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Medical device site necrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Medical device site joint pain	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Medical device site irritation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Medical device site injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Medical device site inflammation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Medical device site hypertrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Medical device site extravasation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Medical device site eczema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Medical device site discharge	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Medical device site calcification	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Brain scan abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Drug-device interaction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aqueductal stenosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Drug-device incompatibility	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Medical device entrapment	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Brain radiation necrosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Drug withdrawal maintenance therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Drug withdrawal headache	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mediastinal lymphadenectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mediastinal haemorrhage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Mediastinal disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mediastinal abscess	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Meconium ileus	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mechanic's hand	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Drug therapeutic incompatibility	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Measles antibody positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Brain natriuretic peptide	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Abdominal wall mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Maxillofacial pain	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Drug rehabilitation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Maxillofacial operation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Brain lobectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Matrix metalloproteinase-3 increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Maternal hypertension affecting foetus	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Maternal exposure via partner during pregnancy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Maternal death	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Drug metabolite level	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mastoidectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mastoid effusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Drug metabolising enzyme decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mastitis bacterial	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Allergy test negative	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Brain dislocation syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mass excision	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Marginal zone lymphoma stage I	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Manufacturing materials contamination	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Allergy test	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Manual lymphatic drainage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mantle cell lymphoma refractory	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Manic symptom	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Drug half-life increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mammary duct ectasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malpositioned teeth	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Malignant urinary tract obstruction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Drug effect faster than expected	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Malignant syphilis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malignant pericardial neoplasm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Abscess sweat gland	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Malignant nervous system neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Malignant neoplasm of uterine adnexa	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Malignant neoplasm of lacrimal gland	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Malignant muscle neoplasm	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Drug clearance increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Malignant melanoma of sites other than skin	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malignant mediastinal neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Application site papules	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Drug chemical incompatibility	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malignant lymphoid neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malignant hypertensive heart disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malignant genitourinary tract neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malignant gastrointestinal obstruction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malignant biliary obstruction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malignant atrophic papulosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Brachial plexopathy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Male genital tract operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bowenoid papulosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Malaria relapse	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Drain removal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acute haemolytic transfusion reaction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Application site odour	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bowel preparation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Double outlet right ventricle	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Magnetic resonance imaging heart	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bowel obstruction surgery	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dosage not adjusted	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Application site nodule	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Magnetic resonance imaging abdominal abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Donor specific antibody present	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Macular telangiectasia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Application site necrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Botulinum toxin injection	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Macular fibrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Macular dystrophy congenital	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
22q11.2 deletion syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Botryomycosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Macroprolactinaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Macroamylasaemia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
ALK gene rearrangement positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Abscess soft tissue	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acute graft versus host disease oral	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
MAGIC syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lysosomal storage disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lymphorrhoea	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lymphoplasmacytoid lymphoma/immunocytoma recurrent	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Diversion proctitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lymphoid tissue hyperplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diversion colitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lymphoid hyperplasia of intestine	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Borderline mucinous tumour of ovary	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diuretic therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lymphodepletion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Allergic gastroenteritis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Application site injury	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Disturbance in sexual arousal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bone trimming	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Distal clavicle excision	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lymphatic system neoplasm	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lymphatic malformation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Lymphangiosarcoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lymphangi leiomyomatosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Application site induration	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bone scan	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Allergic eosinophilia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lymph node calcification	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lupus vasculitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Application site hypersensitivity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bone non-union	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lupus endocarditis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lupus encephalitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Application site hyperaesthesia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lung squamous cell carcinoma metastatic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dislocation of sternum	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lung induration	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bone marrow tumour cell infiltration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lung hypoinflation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Allergic bronchitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bone marrow transplant rejection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Disease susceptibility	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bone marrow oedema syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Disease prodromal stage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Lumbosacral radiculoplexus neuropathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lumbosacral plexopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lumbar spinal drainage complication	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bone marrow leukaemic cell infiltration	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Disability assessment scale score decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lower respiratory tract infection fungal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diminished ovarian reserve	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lower motor neurone lesion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dilated pores	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lower gastrointestinal perforation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Low density lipoprotein	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Low anterior resection syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Digital pulpitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Digestive enzyme abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Diffuse uveal melanocytic proliferation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acute graft versus host disease in eye	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Application site eczema	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Loss of bladder sensation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Loss of CAR T-cell persistence	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lordosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Long-chain acyl-coenzyme A dehydrogenase deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diffuse large B-cell lymphoma stage III	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Loefgren syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diffuse large B-cell lymphoma stage I	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Loeffler's syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alice in wonderland syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Localised lipodystrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bone graft removal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diffuse idiopathic pulmonary neuroendocrine cell hype	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Liver tenderness	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Liver sarcoidosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bone giant cell tumour malignant	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Liver iron concentration increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Alexithymia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bone giant cell tumour benign	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diet noncompliance	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dientamoeba infection	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diastolic hypotension	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Liposarcoma recurrent	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Liposarcoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diastema	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lipoprotein increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lipoprotein abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lipomatosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Application site cellulitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lipoma of breast	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lipoma excision	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lipogranuloma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abscess of salivary gland	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Alcoholic seizure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diaphragmatic operation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Lipase decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bone densitometry	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Diaphragm muscle weakness	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Lip neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alcoholic pancreatitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dialysis efficacy test abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dialysis device insertion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Diabetic wound	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lip and/or oral cavity cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bone cement implantation syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Limbal swelling	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Limbal stem cell deficiency	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diabetic microangiopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Limb prosthesis user	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Diabetic macroangiopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bone atrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diabetic hyperglycaemic coma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diabetic hepatopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Alcoholic ketoacidosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diabetic gastropathy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Light chain analysis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diabetic gangrene	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diabetic dermopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acute fatty liver of pregnancy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lichen myxoedematosus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diabetes mellitus management	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lice infestation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Leukotriene increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Leukoplakia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alcoholic coma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1



**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Body modification	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Device user interface issue	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Leukapheresis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Leukaemic retinopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Leukaemic lymphoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Appendiceal mucocoele	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Leukaemic infiltration renal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Leukaemia in remission	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Acute endocarditis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Leukaemia granulocytic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Leriche syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lens extraction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lens disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lens dislocation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Lens discolouration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Device optical issue	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lemmel's syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lemierre syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Legionella test positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Device material opacification	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Left atrial volume increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blue toe syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Device lead issue	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Left atrial volume abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Device intolerance	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Latent syphilis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Apolipoprotein E abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Bloodborne infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Laser brain ablation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lasegue's test negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Larynx irritation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Device extrusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Laryngoscopy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood volume expansion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Device environmental compatibility issue	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Laryngectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Device embolisation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Laryngeal ulceration	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Laryngeal squamous cell carcinoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Laryngeal repair	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Device effect decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Laryngeal operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alcohol septal ablation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Laryngeal leukoplakia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Laryngeal haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Laryngeal haematoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Laryngeal erythema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Laryngeal cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Device chemical property issue	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Large for dates baby	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Large cell lung cancer stage III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Developmental coordination disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lactation puerperal increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Detoxification	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Lactate pyruvate ratio increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Detachment of macular retinal pigment epithelium	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Lacrimonal structural disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lacrimonal disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lacrimonal atrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lack of application site rotation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Labour pain	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Apheresis related complication	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dermatophytosis of nail	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Labour complication	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
LDL/HDL ratio decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dermatitis herpetiformis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Knuckle pads	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood test normal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Kleefstra syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Kidney rupture	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Kidney malformation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood stem cell harvest	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Kidney duplex	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Kidney contusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Aorto-oesophageal fistula	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dermal absorption increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ketogenic diet	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Depressive delusion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Keratolysis exfoliativa acquired	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood selenium decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Deposit eye	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> (N=&AGEGRP1)	<i>Group2 (26-50)</i> (N=&AGEGRP2)	<i>Group3 (51-75)</i> (N=&AGEGRP3)	<i>Group4 (75+)</i> (N=&AGEGRP4)	<i>Total</i> (N=&AGEGRP5)
Juvenile spondyloarthritis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dependent personality disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Jugular vein haemorrhage	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Denture wearer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood pressure systolic inspiratory decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dental root perforation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Joint resurfacing surgery	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Joint neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Joint manipulation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Joint laxity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Joint irrigation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Joint impingement	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Joint dislocation reduction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blood pressure orthostatic	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acute biphenotypic leukaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dengue haemorrhagic fever	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood pressure management	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Jejunectomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Janus kinase 2 mutation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Jamestown Canyon encephalitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Isosporiasis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood pressure difference of extremities	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ischaemic skin ulcer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ischaemic pancreatitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acute aseptic arthritis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Delusional disorder, mixed type	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Delusion of theft	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Ischaemic demyelination	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Delusion of replacement	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Iron binding capacity unsaturated decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Iron binding capacity total increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Aortic root enlargement procedure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood pressure ambulatory abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Iron binding capacity total abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Iris haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Aortic pseudoaneurysm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Iris cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Iris bombe	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Yersinia test positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Delayed haematopoietic reconstitution	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Iodine overload	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Involuntary commitment	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Xeroderma pigmentosum	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Investigation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
X-ray gastrointestinal tract abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acute aortic syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Delayed dark adaptation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Wrong product stored	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aortic intramural haematoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intrinsic factor deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Wound infection fungal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aortic injury	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Degeneration of uterine leiomyoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intrapericardial thrombosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Wound haematoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intraocular pressure decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Wolfram syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Deficiency of bile secretion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intranasal hypoaesthesia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Withdrawal of life support	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Deficiency anaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Wiskott-Aldrich syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aortic embolus	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blood parathyroid hormone abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intraductal papillary-mucinous carcinoma of pancreas	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Winged scapula	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
White blood cells urine abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
White blood cells stool positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood pH increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
White blood cell morphology abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
White blood cell analysis abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intracranial germ cell tumour	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
West Nile virus test negative	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intracranial artery dissection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Wernicke-Korsakoff syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood pH abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Intracardiac pressure increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Weight control	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intra-uterine contraceptive device removal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Waxy flexibility	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Waterhouse-Friderichsen syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Warm autoimmune haemolytic anaemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Decreased nasolabial fold	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Walled-off pancreatic necrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Waist circumference decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Waist circumference	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intra-abdominal haemangioma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Wagner's disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intra-abdominal calcification	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intestinal tuberculosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vulvovaginal exfoliation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Decreased bronchial secretion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intestinal transit time increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intestinal strangulation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intestinal steatosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vulval neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vulval leukoplakia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vulval cancer stage III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intestinal prolapse	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vulval cancer stage 0	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vth nerve injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood methaemoglobin	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Decompressive craniectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Von Willebrand's factor activity abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aortic bypass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Von Hippel-Lindau disease	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Volvulus of small bowel	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vocal cord paresis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Decerebrate posture	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vocal cord operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acute HIV infection	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vocal cord atrophy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Intestinal intraepithelial lymphocytes increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vitreous fibrin	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Intestinal haematoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vitreous adhesions	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood magnesium	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vitreoretinal traction syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intestinal fistula repair	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vitamin K decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood luteinising hormone decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vitamin B12 absorption test normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Intestinal atony	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blood luteinising hormone abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intestinal anastomosis complication	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vitamin A abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intestinal adenocarcinoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Visual field tests abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Visceroptosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Visceral venous thrombosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Visceral pain	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intervertebral disc calcification	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Viral titre decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Interventricular septum rupture	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Viral sepsis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1



Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Dacryoadenitis acquired	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intersection syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood lactic acid	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Viral labyrinthitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Viral cardiomyopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
DNA antibody negative	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
International normalised ratio	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vibration syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vestibular migraine	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cytoreductive surgery	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vessel puncture site swelling	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cytophagic histiocytic panniculitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vessel puncture site injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vessel puncture site haematoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vessel puncture site discolouration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vessel puncture site bruise	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vessel perforation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Interleukin level decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vesicocutaneous fistula	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cytomegalovirus urinary tract infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intercostal neuralgia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Antral follicle count low	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vertebrobasilar dolichoectasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vertebral artery hypoplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vertebral artery aneurysm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Verbal abuse	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Ventriculo-peritoneal shunt	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Ventricular remodelling	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ventricular internal diameter abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Antiviral treatment	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intentional removal of drug delivery system by patien	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ventricular hypoplasia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ventricular flutter	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cytomegalovirus gastroenteritis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Intentional product misuse to child	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ventricular dyskinesia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ventricular cisternostomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ventricular assist device insertion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ventricle rupture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Venous stent insertion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Venous stenosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Venous repair	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intensive care unit delirium	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Venous oxygen saturation increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Venous intravasation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intelligence test abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Venous hypertension	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Antiviral drug level above therapeutic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Venomous sting	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Venogram abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vena cava injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vena cava embolism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Velo-cardio-facial syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Antithyroid arthritis syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Insulin-like growth factor	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Insulin C-peptide increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood immunoglobulin M abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vascular stent insertion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vascular rings and slings	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Instillation site erythema	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vascular resistance systemic increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Antithrombin III increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood immunoglobulin M	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cystoscopy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Instillation site complication	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vascular pseudoaneurysm thrombosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vascular graft infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vascular fragility	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vascular dissection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vascular cognitive impairment	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vascular catheterisation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vascular anastomosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vascular access site thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vascular access site rash	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vascular access site pruritus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood immunoglobulin G	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vascular access site occlusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vascular access site laceration	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vascular access site inflammation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vascular access site infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vascular access site erythema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Vascular access device culture negative	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Injection site phlebitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood immunoglobulin E decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Injection site panniculitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Varicella post vaccine	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood immunoglobulin E abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Varicella encephalitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vanishing twin syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vanillyl mandelic acid urine increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Activated partial thromboplastin time abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vaginitis chlamydial	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vaginal wall congestion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cystic fibrosis lung	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vaginal ring placement	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Injection site macule	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vaginal pH abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vaginal operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood immunoglobulin D increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vaginal necrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vaginal mucosal blistering	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cystatin C abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Injection site ischaemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cyst drainage	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vaccination site warmth	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vaccination site vesicles	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vaccination site pruritus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vaccination site paraesthesia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Aggregatibacter infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood homocysteine increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vaccination site oedema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vaccination site mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vaccination site haemorrhage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cyclitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vaccination site discomfort	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vaccination site discharge	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vaccination site bruising	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vaccination error	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cyclic neutropenia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
VIIth nerve injury	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
VACTERL syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Uvulitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Uveitic glaucoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Uveal melanoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood growth hormone abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Uterine stenosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Injection site deformation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Action tremor	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Uterine prolapse repair	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Uterine polypectomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cutibacterium acnes infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Injection site calcification	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Uterine operation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Uterine malposition	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Uterine injury	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Uterine fistula	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Inhibiting antibodies positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Uterine cervix ulcer	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Uterine cervix canal atresia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Inguinal hernia, obstructive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Uterine cervical laceration	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood glucose	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urticaria cholinergic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urostomy complication	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blood glucagon abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urogenital infection bacterial	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urogenital disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urobilinogen urine decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Urine viscosity increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urine viscosity abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cutaneous amyloidosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urine uric acid increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urine uric acid abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urine protein/creatinine ratio	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Infusion site pustule	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urine output	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cutaneous T-cell lymphoma stage I	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Infusion site phlebitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urine osmolarity increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urine magnesium increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urine ketone body	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Urine iodine increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Blood follicle stimulating hormone decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urine electrolytes increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urine calcium	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urine amphetamine positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood follicle stimulating hormone abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urine albumin/creatinine ratio decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urinary tract toxicity	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urinary tract procedural complication	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Culture throat positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Culture stool positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Infusion site hypoaesthesia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urinary straining	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Culture stool negative	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Infusion site hyperaesthesia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urinary sediment	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Antineutrophil cytoplasmic antibody negative	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urinary control neurostimulator implantation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Infusion site dysaesthesia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urinary bladder sarcoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urinary bladder herniation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urinary bladder haematoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urinary bladder adenoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Urinary bladder abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urinary ascites	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood fibrinogen abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urethritis chlamydial	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urethral repair	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Urethral polyp	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood fibrinogen	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urethral operation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Urethral intrinsic sphincter deficiency	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Actinomyces test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aerophagia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urethral fistula	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urethral discharge	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urethral dilation procedure	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Urethral abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ureteric injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ureteric fistula	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood erythropoietin decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Influenza A virus test	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ureteral stent removal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ureteral neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urea renal clearance decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blood erythropoietin abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urea cycle disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urate nephropathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aeromonas test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood electrolytes increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Inflammation scan	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Upper gastrointestinal perforation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Inferior vena caval occlusion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Inferior vena cava stenosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Unknown schedule of product administration	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Unhealthy lifestyle	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Unevaluable therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Crossmatch incompatible	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Umbilical cord compression	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Umbilical cord around neck	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Infective exacerbation of bronchiectasis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Umbilical cord abnormality	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ultrasound thyroid abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ultrasound ovary abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ultrasound liver	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ultrasound kidney abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Antidiuretic hormone abnormality	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Infectious thyroiditis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ultrasound foetal abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ultrasound antenatal screen abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ultrasound antenatal screen	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ulnar tunnel syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Creatinine renal clearance normal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Infected varicose vein	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Type IIa hyperlipidaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Infected lymphocele	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Type II hypersensitivity	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Type 3 diabetes mellitus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tympanosclerosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tympanomastoidectomy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tympanic membrane disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tumour response assessment	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tumour obstruction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Craniofacial injury	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Induced abortion failed	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Indolent systemic mastocytosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tumour fistulisation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Actinic elastosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tumour biopsy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cranial operation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Increased steroid activity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tuberous sclerosis complex	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Increased liver stiffness	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Increased intraperitoneal volume	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tuberculoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Trunk injury	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cranial nerve decompression	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Troponin decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Incorrect product dosage form administered	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tropical eosinophilia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Trigonitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Trigeminal palsy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Trigeminal neuropathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Trigeminal nerve disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Trifascicular block	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Tricuspid valve thickening	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Incomplete spinal fusion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Costochondral separation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Tri-iodothyronine increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tri-iodothyronine abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Corynebacterium test positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Treponema test false positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tremor neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Incision site inflammation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Trematode infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Acrophobia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Incision site hypoaesthesia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Traumatic ulcer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Traumatic torticollis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood corticotrophin	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Traumatic heart injury	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Traumatic delivery	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Traumatic arthropathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Traumatic amputation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Transverse presentation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood copper decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Incarcerated parastomal hernia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Transvalvular pressure gradient decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Transurethral bladder resection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Incarcerated hiatus hernia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Transsphenoidal surgery	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Inborn error of amino acid metabolism	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Transmission of an infectious agent via product	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Transitional cell carcinoma metastatic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Inappropriate release of product for distribution	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Transient lingual papillitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Transient aphasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood cholinesterase increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Coronary vein stenosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Transfusion related complication	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Coronary vascular graft occlusion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Inability to crawl	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Transferrin saturation abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Transferrin receptor increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Coronary artery surgery	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Transaminases decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anticoagulation drug level abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Transaminases	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Trance	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tracheostomy tube removal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Implantable defibrillator replacement	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tracheostomy closure	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Coronary artery perforation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Implantable cardiac monitor removal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tracheobronchitis bacterial	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Implant site warmth	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tracheal pain	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Implant site vesicles	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tracheal operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Implant site urticaria	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tracheal inflammation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Tracheal atresia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Implant site pruritus	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Toxoplasma serology positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Implant site paraesthesia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Implant site oedema	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anticipatory anxiety	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cornelia de Lange syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Implant site induration	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Total complement activity decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Corneal thickening	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Implant site dermatitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tooth hypoplasia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Corneal scar	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
5-hydroxyindolacetic acid in urine increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Implant site abscess	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood catecholamines abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tooth demineralisation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tooth agenesis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acrodynia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Adult T-cell lymphoma/leukaemia recurrent	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood carbon monoxide increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tonsillitis streptococcal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tonsillar exudate	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tonsillar erythema	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood carbon monoxide abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tonsillar cyst	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tongue tie operation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tongue thrust	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Corneal irritation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tongue operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Immunology test	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Tongue necrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Adult T-cell lymphoma/leukaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Corneal graft rejection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tongue dysplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tongue cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tongue cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Immune-mediated scleritis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tongue abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Toe walking	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Corneal epithelial downgrowth	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tobacco withdrawal symptoms	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Corneal endotheliitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood calcitonin decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tissue expansion procedure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acrochordon excision	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tidal volume abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Antibiotic level below therapeutic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tick-borne fever	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Immune-mediated myelitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Corneal defect	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroid tuberculosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroid stimulating immunoglobulin	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroid stimulating hormone deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroid pain	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroid dermatopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Adrenogenital syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroid cancer stage I	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroid atrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroglobulin decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thymoma malignant	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thrombosis with thrombocytopenia syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Immune effector cell encephalopathy score	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thrombosed varicose vein	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Coombs test positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Immobilisation bandage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Thrombolysis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blood bicarbonate abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thromboangiitis obliterans	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Immature granulocyte count	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Coombs indirect test negative	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Imaging procedure artifact	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood beta-D-glucan positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Threat of redundancy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thought insertion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Illogical thinking	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thoracic haemorrhage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Third degree chemical burn of skin	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood antidiuretic hormone decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thermohypoaesthesia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Iliac artery rupture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Iliac artery arteriosclerosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Therapeutic embolisation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Anti-thyroid antibody decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Theft	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thanatophobia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thalassaemia beta	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Contrast echocardiogram	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thalamic stroke	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Testicular yolk sac tumour	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acral overgrowth	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adrenergic syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood aldosterone increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Idiopathic pancreatitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Testicular rupture	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Testicular operation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Testicular oedema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Testicular microlithiasis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Testicular infarction	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Testicular hypertrophy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Testicular germ cell tumour mixed	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Testicular germ cell cancer metastatic	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Testicular embryonal carcinoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Continuous glucose monitoring	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Testicular cancer metastatic	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tertiary adrenal insufficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Contact stomatitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Iatrogenic infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tenonectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anti-platelet antibody	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1



Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Constricted affect	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hysterotomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tenon's capsule thickening	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hysterosalpingo-oophorectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tendon dislocation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hypoxanthine-guanine phosphoribosyl transferase defic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Temporomandibular joint surgery	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Temperature perception test abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypotony maculopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood 25-hydroxycholecalciferol increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tear discolouration	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hypotonic-hyporesponsive episode	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tattoo associated skin reaction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypotonic urinary bladder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Tarsal tunnel decompression	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acral lentiginous melanoma stage III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Adrenalectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anti-neuronal antibody positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Conjunctivalisation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tandem gait test abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Coronary artery restenosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Conjunctival ulcer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Taciturnity	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypothalamic hamartoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tachycardia paroxysmal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
TP53 gene mutation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anti-melanoma differentiation-associated protein 5 an	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hyposplenism	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
TET2 gene mutation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
T-cell prolymphocytic leukaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Block vertebra	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Conjunctival papillae	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
T-cell lymphoma refractory	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
T-cell lymphoma recurrent	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Adrenal thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bloch-Sulzberger syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Systemic sclerosis pulmonary	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hypopigmentation of eyelid	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Systemic bacterial infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Synovial fluid white blood cells positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anti-erythrocyte antibody positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Conjunctival follicles	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypopharyngeal cancer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Conjunctival filtering bleb leak	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acral lentiginous melanoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Sympathomimetic effect	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sympathetic posterior cervical syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sympathetic ophthalmia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sympathetic nerve destruction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Conjunctival discolouration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Swollen tear duct	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Conjunctival cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sweat test abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sweat gland excision	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Suture removal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Congenital uterine anomaly	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital urethral anomaly	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Transurethral prostatectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blindness cortical	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Congenital umbilical hernia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Susac's syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Surgical stapling	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anti-complement antibody	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Surgical skin tear	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypoglossal nerve paresis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Supplementation therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital thrombocyte disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Supernumerary teeth	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Superior vena cava occlusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital scoliosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Superior vena cava dilatation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Superior semicircular canal dehiscence	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital renal cyst	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Superior mesenteric artery syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Congenital pulmonary airway malformation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypochromasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Superimposed pre-eclampsia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital perforated nasal septum	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Superficial spreading melanoma stage I	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blepharitis allergic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital oral malformation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hypocalcaemic seizure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anti-JC virus antibody index	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital neurological disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sudden infant death syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital musculoskeletal disorder of limbs	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Substance-induced mood disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypnopompic hallucination	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Subretinal hyperreflective exudation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anti-HLA antibody test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Submaxillary gland enlargement	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital midline defect	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Submandibular abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypervitaminosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Subendocardial ischaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital megacolon	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Subendocardial haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital laryngeal stridor	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Subdural haematoma evacuation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital hypothyroidism	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Subcutaneous biopsy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adrenal insufficiency neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bleeding time abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Congenital hydronephrosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Subclavian vein occlusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Subclavian arteriosclerosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blau syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital genital malformation female	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hypertonia neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Subcapsular hepatic haematoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Subarachnoid abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital genital malformation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Subacute kidney injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Subacute hepatic failure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital eye disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Subacute combined cord degeneration	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Troponin	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Acquired syringomyelia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Struck by lightning	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Strongyloides test positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypertensive hydrocephalus	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital choroid plexus cyst	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypertensive cardiomyopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypertension neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Streptobacillary fever	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital brain damage	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Strangulated hernia repair	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Strangulated hernia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Congenital arterial occlusion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Stool analysis abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blast cells	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stomatococcus test positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Stomatococcal infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital aortic valve incompetence	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital aortic atresia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Stoma site paraesthesia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anti factor IX antibody positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Stoma site ischaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hyperplastic cholecystopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stoma site hypersensitivity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Confusional arousal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hyperpituitarism	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blast cell count decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Confusion postoperative	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Confabulation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cone-rod dystrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stoma hernia repair	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bladder transitional cell carcinoma stage IV	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypermutation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abdominal rebound tenderness	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abortion induced incomplete	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acquired right ventricle outflow obstruction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Steroid therapy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anti B antibody positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bladder transitional cell carcinoma recurrent	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Stereotactic electroencephalography	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Stent malfunction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stenotrophomonas maltophilia pneumonia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stenotrophomonas bacteraemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stauffer's syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hyperkeratosis follicularis et parafollicularis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bladder trabeculation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Status dystonicus	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Stasis syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hyperkaliuria	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hyperinsulinism	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Staphylococcal scalded skin syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Staphylococcal osteomyelitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Squamous cell carcinoma of the vulva	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hyperglycinaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Squamous cell carcinoma of the oral cavity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Computerised tomogram kidney abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hyperglycaemic unconsciousness	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Squamous cell carcinoma of the cervix	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hyperglycaemic seizure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hyperglycaemic crisis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypergeusia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Computerised tomogram head	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sputum decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Sputum culture	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Spur cell anaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hyperfibrinolysis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sporotrichosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spontaneous heparin-induced thrombocytopenia syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acquired protein S deficiency	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spontaneous ejaculation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spontaneous cerebrospinal fluid leak syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Compulsive handwashing	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Splinter haemorrhages	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Splenic vein occlusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypercatabolism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Splenic haematoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hyperbilirubinaemia neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spleen tuberculosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spleen contusion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Spleen atrophy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hyperandrogenism	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spinal subdural haematoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Spinal subarachnoid haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bladder neck obstruction	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hyperalbuminaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Spinal myelogram	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Spinal meningioma benign	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Spinal meningeal cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Complication of delivery	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spinal implantation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood cyanide increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Umbilical discharge	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spinal fusion fracture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Spinal epidural haematoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bladder leukoplakia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Complicated fracture	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hydrops foetalis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acquired plagiocephaly	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spinal corpectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hydromyelia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Spinal cord ischaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hydrocele operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bladder injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Complement factor increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spinal artery thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Spinal anaesthesia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spherocytic anaemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Human placental lactogen increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spermatozoa progressive motility decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spermatogenesis abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Crush injury	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Complement deficiency disease	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Speech rehabilitation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Adrenal cortex necrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anovulatory cycle	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Specific gravity urine increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Specialist consultation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Somatostatin receptor scan abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Somatic symptom disorder of pregnancy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Somatic dysfunction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Human chorionic gonadotropin abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Solid pseudopapillary tumour of the pancreas	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Solid organ transplant rejection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Combined immunodeficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acquired phimosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Adrenal atrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Huerthle cell carcinoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

# Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Social fear	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hormone-dependent prostate cancer	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Snake bite	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Smegma accumulation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urea urine abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Small intestine operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Colostomy infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hookworm infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bladder catheter permanent	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Small intestinal ulcer perforation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Home care	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hodgkin's disease stage IV	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bladder cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Colorectal cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Small cell lung cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cryptococcal meningoencephalitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Small cell carcinoma of the cervix	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Small airways disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anorexia nervosa	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Histiocytic necrotising lymphadenitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Slipping rib syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Histamine intolerance	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sleep study abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anorexia and bulimia syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bladder calculus removal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abortion incomplete	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bizarre personal appearance	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Skull base tumour	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
High frequency ablation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Skin squamous cell carcinoma metastatic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Heyde's syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Anorectal ulcer	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Heteroplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Skin maceration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Heterophoria	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Skin lesion removal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Heteronymous diplopia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Skin laxity	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Colon cancer stage III	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Skin hyperplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Herpes zoster immunisation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Skin graft infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Skin graft failure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urinary bladder atrophy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Biphasic mesothelioma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anorectal stenosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biopsy vulva abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Herpes simplex pneumonia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Herpes simplex meningoencephalitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Skin adhesion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Biopsy thyroid gland	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Herpes pharyngitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Herpangina	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sinuplasty	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Biopsy stomach abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hernia perforation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sinobronchitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Simple mastectomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Signet-ring cell carcinoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sigmoidoscopy abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sigmoid sinus thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hereditary retinal dystrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sideroblastic anaemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hereditary non-polyposis colorectal cancer syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Biopsy skin	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sickle cell anaemia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hereditary haemochromatosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sialic acid increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hereditary disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cold agglutinins positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Shoulder dystocia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biopsy rectum	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Shoshin beriberi	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Short-chain acyl-coenzyme A dehydrogenase deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Shigella infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Shift work disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Shagreen skin	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cogan's syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sexual transmission of infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sexual life impairment	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sexual abuse	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Biopsy pancreas abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatoblastoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sex hormone binding globulin decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Coeliac artery compression syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepato-lenticular degeneration	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biopsy mucosa abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Serum serotonin	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Serum procollagen type I N-terminal propeptide decrea	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hepatitis non-A non-B	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatitis infectious mononucleosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatitis immunisation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Serratia test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biopsy lymph gland abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Coccygectomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Serratia sepsis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Serology positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Serology abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Serial transverse enteroplasty	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Biopsy lung abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hepatitis D	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Septic endocarditis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Septic coagulopathy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cutaneous blastomycosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Infusion site streaking	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Coagulation time shortened	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatitis C antibody positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Septic arthritis streptococcal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Anogenital dysplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatitis C RNA increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatitis C RNA	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Separation anxiety disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sensory overload	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biopsy liver abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatitis B test negative	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sensory level abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatitis B surface antigen	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Sensation of blood flow	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Annuloplasty	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Biopsy liver	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatitis B core antigen positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Senile pruritus	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Coagulation factor XIII level decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Semen viscosity abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatitis B antibody abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biopsy kidney abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatitis B DNA increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Semen analysis abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Inhalation therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Self-induced vomiting	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Administration site urticaria	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatitis A antibody positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Self esteem inflated	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatitis A antibody abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Biopsy cornea	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Coagulation factor IX level decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatitis A antibody	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biopsy breast	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Secondary tic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatic vein occlusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Secondary thrombocytosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Secondary hyperthyroidism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sebaceous hyperplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sebaceous gland disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sebaceous carcinoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Scrub typhus	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Scrotum erosion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Scrotal pain	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatic infiltration eosinophilic	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biopsy bone abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Scrotal mass	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Scrotal irritation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Scrotal haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Scrotal haematoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Scrotal erythema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatic hypoperfusion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Scrotal disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biopsy bone	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatic hypertrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Scrotal dermatitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
ACTH-producing pituitary tumour	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Abdominal bruit	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

# Reaction Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hepatic haematoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Clitoris abscess	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Clinically isolated syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sclerema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Scleral pigmentation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatic embolisation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Scleral deposits	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatic dysplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cleft lip	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Schizotypal personality disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Schizophreniform disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Schimke immunosseous dysplasia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatic cancer stage III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Scar inflammation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Scar discomfort	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Injection site fibrosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Citrobacter test positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Scan myocardial perfusion abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Scalloped tongue	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anisomastia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bing-Neel syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Citrobacter sepsis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sarcopenic obesity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatic artery occlusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sarcomatoid carcinoma of the lung	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sarcoma uterus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatic artery flow decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Sarcoma of skin	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hepatic angiosarcoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biloma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatic amoebiasis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sarcoidosis of lymph node	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sapovirus infection	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Salt intoxication	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Salt craving	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Heparin-induced thrombocytopenia test positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Salpingo-oophorectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bilirubin urine	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Salpingitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acquired growth hormone resistance	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Salivary gland operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Salivary gland fistula	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hemidysaesthesia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Salivary gland cyst	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Injection site lymphadenopathy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cinchonism	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anisochromia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bilirubin conjugated	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ciliary body haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
SARS-CoV-2 test false positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
SARS-CoV-2 RNA	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biliary tract operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chvostek's sign	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
SARS-CoV-1 test positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Rubulavirus test positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chronic traumatic encephalopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Routine health maintenance	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rotavirus test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Heat oedema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Roseolovirus test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Rosai-Dorfman syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Heart-type fatty acid-binding protein increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Romberg test positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chronic rhinosinusitis without nasal polyps	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Right ventricular systolic pressure decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Right ventricular systolic pressure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Right ventricular hypertension	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Heart transplant failure	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Rickettsiosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rhythm idioventricular	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Abnormal withdrawal bleeding	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acquired generalised lipodystrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Heart rate variability decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anion gap abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Biliary neoplasm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Chronic pigmented purpura	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Rhinophyma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rheumatoid pleuritis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Rheumatoid factor	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rhesus antibodies	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Biliary dyskinesia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Reversible ischaemic neurological deficit	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chronic lymphocytic leukaemia stage 4	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Reverse tri-iodothyronine increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Head and neck cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Retroperitoneal mass	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Head and neck cancer	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Retroperitoneal infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vascular access site warmth	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Harlequin skin reaction	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Biliary catheter insertion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Retinopathy haemorrhagic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Administration site odour	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bile output increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anicteric leptospirosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chronic granulomatous disease	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hallucination, gustatory	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bile duct cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Chronic graft versus host disease in lung	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hair growth rate abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Administration site necrosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hair follicle tumour benign	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Retained placenta or membranes	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chronic graft versus host disease in intestine	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Restless leg augmentation syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Restenosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Haemosiderin stain	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Respirovirus test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Respiratory tract procedural complication	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Respiratory tract infection fungal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Haemorrhagic vasculitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Haemorrhagic urticaria	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chronic eosinophilic leukaemia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haemorrhagic pneumonia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Respiratory sinus arrhythmia magnitude	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Haemorrhagic fever	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Respiratory fatigue	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Instillation site infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chronic cheek biting	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haemorrhagic cholecystitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Haemorrhagic cerebellar infarction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Haemorrhagic arteriovenous malformation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renin decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Renal vein occlusion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bezold-Jarisch reflex	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chromophobe renal cell carcinoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renal vein compression	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haemophilic pseudotumour	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haemophilia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renal procedural complication	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Choroidal rupture	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Renal papillary necrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Angiotensin converting enzyme decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Beta 2 microglobulin urine increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Choroidal infarction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Renal hypoplasia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renal hypertrophy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haemoglobinuria	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renal hydrocele	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Haemoglobin urine	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Renal glycosuria	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Insulin-requiring type 2 diabetes mellitus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renal fusion anomaly	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acquired epidermolysis bullosa	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Angiosclerosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renal embolism	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Choroid neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renal disorder in pregnancy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renal cyst ruptured	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Haemodialysis complication	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renal cyst aspiration	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renal cell carcinoma stage IV	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chorioretinopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renal cell carcinoma stage I	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renal cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renal cancer stage I	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chorioretinal disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Renal artery stent placement	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chorioamniotic separation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haematosalpinx	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renal artery embolisation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Benign soft tissue neoplasm	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Renal artery dissection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haematopoietic neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renal arteritis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Administration site injury	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Renal aneurysm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Removal of internal fixation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Benign small intestinal neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chondrosarcoma metastatic	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Benign renal neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chondroporosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Refusal of treatment by relative	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Reflux nephropathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Haematuria	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Haematidrosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Red ear syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Benign pancreatic neoplasm	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Red cell distribution width	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Choluria	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Red blood cell spherocytes present	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Benign pancreatic hyperenzymaemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haemangioma embolisation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haemangioblastoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Habitual abortion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Red blood cell macrocytes present	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cholesterosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
HTLV-2 test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Red blood cell count	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
HTLV-1 test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Red blood cell burr cells present	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rectourethral fistula	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rectal obstruction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
HIV antibody positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Rectal neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
HER2 positive gastric cancer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rectal lesion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cholelithiasis obstructive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
HER2 mutant non-small cell lung cancer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rectal cancer stage III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cholelithiasis migration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Benign neoplasm of eye	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
HCoV-NL63 infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Benign neoplasm of bladder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cholecystostomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
H3N2 influenza	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Reaction to preservatives	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Reaction to food additive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Reaction to flavouring	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Grunting	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Rash scarlatiniform	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rash follicular	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Growing teratoma syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Rapidly progressive osteoarthritis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cholangitis chronic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rapid correction of hyponatraemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Radioisotope uptake increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Radioactive iodine therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Benign joint neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cholangiolitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Radiation thyroiditis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Radiation overdose	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Administration site indentation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Benign hydatidiform mole	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cholangiectasis acquired	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Radiation myelopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Radiation induced fatigue	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Radiation dysphagia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Radiation associated haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Radial head dislocation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Quarantine	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Granulocytes abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Granulocyte percentage increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pyopneumothorax	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acquired asplenia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chlamydia test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Granular cell tumour	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Grandiosity	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chimerism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Benign ethnic neutropenia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pus in stool	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Purple glove syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Purines abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Benign enlargement of the subarachnoid spaces	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Childhood asthma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Purging	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pure white cell aplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Graft overgrowth	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Puncture site reaction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Puncture site pruritus	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Puncture site oedema	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Administration site haematoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chikungunya virus infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Puncture site infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cheyne-Stokes respiration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Puncture site haematoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chest wall tumour	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulse volume decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulse pressure increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Benign bone neoplasm	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chest wall necrosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Good syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulse pressure decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Goniotomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Benign anorectal neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gonadal dysgenesis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bendopnoea	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chest scan abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary sensitisation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chest expansion decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Glucose-6-phosphate dehydrogenase deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Glucose tolerance impaired in pregnancy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulmonary hypoplasia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulmonary hypoperfusion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aneurysm repair	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chest crushing	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary hilum mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary hilar enlargement	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary haemorrhage neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulmonary function test	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chemotherapeutic drug level decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulmonary bullectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Glomerulonephritis chronic	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulmonary artery stenosis congenital	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anencephaly	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Glomerular vascular disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary artery atresia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulmonary arteriopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Glomerular filtration rate	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary ablation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Basosquamous carcinoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chemical burn of skin	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Globulin abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Pudendal canal syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chemical burn of oral cavity	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acquired ATTR amyloidosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Administration site dryness	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Basophilia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Global longitudinal strain abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Global longitudinal strain	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Psychological factor affecting medical condition	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Psychological abuse	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Psychogenic blindness	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cheilosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Psychiatric evaluation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Basophil percentage decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cheilitis granulomatosa	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Glaucomatous optic neuropathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Checkpoint kinase 2 gene mutation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Pseudomonas peritonitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pseudomonas bronchitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Administration site discomfort	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Androgens decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Charcot-Leyden crystals	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pseudohyponatraemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pseudogynaecomastia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Basophil count abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pseudocholinesterase deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gingival oedema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pseudocellulitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gingival hyperpigmentation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Proximal focal femoral deficiency	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gingival erosion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prothrombin time abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Basilar artery occlusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cervix scarring	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prothrombin level abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Gingival cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prothrombin index	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Base excess abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cervix inflammation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intestinal polypectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gingival atrophy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Protein total	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Protein intolerance	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Protein S increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Giant papillary conjunctivitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Protein C decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cervix carcinoma stage II	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Giant cell epulis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Prosthetic valve endocarditis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anastomotic ulcer haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prosthetic tracheal reconstruction	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gianotti-Crosti syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prosthetic cardiac valve failure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gestational trophoblastic detachment	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prostatism	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Decreased eye contact	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Basal ganglia infarction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cervix carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Germ cell neoplasm	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

**Reaction Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Administration site discharge	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Germ cell cancer	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prostatic cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prostatic adenoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cervicogenic headache	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Genitourinary operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Basal cell carcinoma metastatic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prostate cancer stage III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Genito-pelvic pain/penetration disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prostate cancer stage II	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prostaglandin analogue periorbitopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prosopagnosia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Propulsive gait	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prohormone brain natriuretic peptide abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Abnormal organ growth	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bartter's syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Genital labial adhesions	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Progressive supranuclear palsy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Progesterone receptor assay positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Progesterone increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Progesterone abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cervical discharge	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Genital hyperaesthesia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cervical dilatation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Genital herpes simplex	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Product substitution error	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bartholin's cyst removal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Genital disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ceruloplasmin decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Genital discharge	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Genital cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Product packaging counterfeit	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bartholin's abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cerebrovascular pseudoaneurysm	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Genetic polymorphism	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anastomotic complication	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cerebrovascular arteriovenous malformation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Product identification number issue	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Product gel formation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acne fulminans	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Barrel chest	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cerebrospinal fluid reservoir placement	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Barotrauma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Barotitis media	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastrostomy tube removal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Product barcode issue	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastrorrhaphy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastroparesis postoperative	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Adjuvant therapy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Product administered from unauthorised provider	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastroesophageal cancer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Proctitis gonococcal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cerebral revascularisation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Procoagulant therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

Reaction Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cerebral reperfusion injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anaphylactic transfusion reaction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Balanitis candida	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cerebral radiation injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastrointestinal tube removal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Procalcitonin decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Probiotic therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Primitive reflex test	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Primary pulmonary melanoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Primary progressive multiple sclerosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Primary progressive aphasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Primary mediastinal large B-cell lymphoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Primary hypogonadism	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Primary hyperthyroidism	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Primary familial brain calcification	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Primary effusion lymphoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Primary cough headache	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Primary breast lymphoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intrapulmonary lymphadenopathy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cerebral lobotomy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prevertebral soft tissue swelling of cervical space	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prescription form tampering	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prepuce redundant	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anamnestic reaction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastrointestinal organ contusion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Premature recovery from anaesthesia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Preictal state	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pregnancy with young maternal age	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastrointestinal mucosal necrosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pregnancy with contraceptive patch	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pregnancy related infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cerebral cavernous malformation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastrointestinal melanoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Gastrointestinal malformation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Preauricular cyst	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prealbumin decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prader-Willi syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Poverty of thought content	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bacterial toxemia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Potter's syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Postresuscitation encephalopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Postpartum uterine subinvolution	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Postpartum thrombosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Postpartum anxiety	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastrointestinal disorder therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Analgesic drug level above therapeutic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Postoperative thoracic procedure complication	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastrointestinal dilation procedure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Postoperative hypertension	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bacterial rhinitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Postnatal growth restriction	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adjusted calcium increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Postmenopause	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Postmastectomy lymphoedema syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1



### Reaction Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Posterior capsule rupture	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Post-tussive vomiting	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bacterial prostatitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastrointestinal anastomotic complication	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Post-depletion B-cell recovery	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
11-deoxycorticosterone increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bacterial pericarditis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastroenteritis yersinia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Post vaccination syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Post stroke seizure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
ACTH stimulation test abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Abdominal migraine	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastroenteritis shigella	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Post procedural stroke	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Post procedural hypothyroidism	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cerebellar calcification	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastroenteritis proteus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

**Outcome Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
DE	1042 ( 5.1%)	2967 ( 14.6%)	9734 ( 47.8%)	6618 ( 32.5%)	20361
LT	1260 ( 12.1%)	2777 ( 26.7%)	4783 ( 46.0%)	1579 ( 15.2%)	10399
HO	6292 ( 10.2%)	12992 ( 21.0%)	30802 ( 49.7%)	11828 ( 19.1%)	61914
DS	332 ( 8.1%)	1458 ( 35.5%)	1762 ( 42.9%)	552 ( 13.5%)	4104
CA	200 ( 49.0%)	127 ( 31.1%)	52 ( 12.7%)	29 ( 7.1%)	408
RI	103 ( 11.3%)	311 ( 34.0%)	397 ( 43.4%)	103 ( 11.3%)	914
OT	11393 ( 10.8%)	25993 ( 24.6%)	51032 ( 48.3%)	17321 ( 16.4%)	105739

### Report Source Summary Table

#### Derived Age Group

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
FGN	10 ( 12.0%)	37 ( 44.6%)	34 ( 41.0%)	2 ( 2.4%)	83
SDY	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0
LIT	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
CSM	243 ( 10.8%)	808 ( 35.9%)	1003 ( 44.6%)	196 ( 8.7%)	2250
HP	429 ( 6.3%)	1351 ( 19.8%)	3731 ( 54.8%)	1299 ( 19.1%)	6810
UF	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0
CR	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0
DT	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0
OTH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0

Therapy Summary Table  
Derived Age Group

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
N	39719	100087	228377	65139	433322
MEAN	434589.00	433377.19	421505.42	459862.73	431212.83
MEDIAN	1.00	1.00	1.00	1.00	1.00
GM	434589.00	433377.19	421505.42	459862.73	431212.83
MIN	1.00	0.00	0.00	0.00	0.00
MAX	20229195.0	20229191.0	20229207.0	20229197.0	20229207.0
STD	2918037.30	2911195.68	2874128.10	3001043.07	2906142.07
RANGE	1-20229195	0-20229191	0-20229207	0-20229197	0-20229207

**Indication Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Product used for unknown indication	15315 ( 6.1%)	60980 ( 24.2%)	125112 ( 49.7%)	50400 ( 20.0%)	251807
Rheumatoid arthritis	234 ( 0.8%)	15760 ( 53.8%)	10996 ( 37.6%)	2282 ( 7.8%)	29272
Plasma cell myeloma	6 ( 0.0%)	959 ( 6.2%)	10436 ( 67.3%)	4109 ( 26.5%)	15510
Hypertension	253 ( 2.4%)	1183 ( 11.1%)	5611 ( 52.7%)	3608 ( 33.9%)	10655
Prophylaxis	912 ( 9.2%)	1737 ( 17.5%)	5493 ( 55.4%)	1766 ( 17.8%)	9908
Dermatitis atopic	2931 ( 30.9%)	2568 ( 27.1%)	3320 ( 35.0%)	655 ( 6.9%)	9474
Asthma	746 ( 10.4%)	1692 ( 23.6%)	3560 ( 49.6%)	1183 ( 16.5%)	7181
Diffuse large B-cell lymphoma	168 ( 2.9%)	1381 ( 23.6%)	3523 ( 60.1%)	791 ( 13.5%)	5863
Type 2 diabetes mellitus	90 ( 1.5%)	856 ( 14.7%)	3790 ( 65.0%)	1094 ( 18.8%)	5830
Psoriasis	275 ( 4.7%)	1907 ( 32.9%)	3179 ( 54.9%)	432 ( 7.5%)	5793
Crohn's disease	948 ( 16.8%)	2151 ( 38.2%)	2208 ( 39.2%)	322 ( 5.7%)	5629
Pain	460 ( 8.2%)	1359 ( 24.3%)	2400 ( 42.9%)	1370 ( 24.5%)	5589
Colitis ulcerative	597 ( 12.3%)	1841 ( 38.0%)	2093 ( 43.2%)	318 ( 6.6%)	4849
Breast cancer	14 ( 0.3%)	1251 ( 28.5%)	2699 ( 61.4%)	430 ( 9.8%)	4394
Psoriatic arthropathy	72 ( 1.7%)	1925 ( 44.5%)	2068 ( 47.8%)	265 ( 6.1%)	4330
Depression	485 ( 11.4%)	1439 ( 33.8%)	1962 ( 46.1%)	369 ( 8.7%)	4255
Migraine	289 ( 7.2%)	1956 ( 48.7%)	1694 ( 42.2%)	75 ( 1.9%)	4014
Prostate cancer	5 ( 0.1%)	22 ( 0.6%)	2117 ( 53.1%)	1845 ( 46.3%)	3989
Diabetes mellitus	55 ( 1.4%)	525 ( 13.7%)	2395 ( 62.3%)	867 ( 22.6%)	3842
Multiple sclerosis	195 ( 5.2%)	1915 ( 50.8%)	1600 ( 42.4%)	60 ( 1.6%)	3770
HIV infection	175 ( 4.7%)	1808 ( 48.5%)	1709 ( 45.8%)	38 ( 1.0%)	3730
Short-bowel syndrome	905 ( 25.5%)	719 ( 20.3%)	1710 ( 48.3%)	209 ( 5.9%)	3543
Schizophrenia	732 ( 20.7%)	1557 ( 44.0%)	1200 ( 33.9%)	52 ( 1.5%)	3541
Breast cancer metastatic	2 ( 0.1%)	654 ( 19.0%)	2201 ( 64.0%)	584 ( 17.0%)	3441
Pulmonary arterial hypertension	181 ( 5.3%)	728 ( 21.4%)	1818 ( 53.4%)	678 ( 19.9%)	3405
Acute myeloid leukaemia	382 ( 11.8%)	392 ( 12.1%)	1448 ( 44.8%)	1013 ( 31.3%)	3235
Immunosuppressant drug therapy	721 ( 23.0%)	1027 ( 32.7%)	1302 ( 41.5%)	91 ( 2.9%)	3141

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
COVID-19 treatment	35 ( 1.2%)	599 ( 21.4%)	1677 ( 59.9%)	490 ( 17.5%)	2801
Constipation	145 ( 5.3%)	213 ( 7.8%)	814 ( 29.7%)	1570 ( 57.3%)	2742
Premedication	176 ( 6.7%)	733 ( 27.8%)	1404 ( 53.2%)	324 ( 12.3%)	2637
Non-small cell lung cancer	8 ( 0.3%)	216 ( 8.5%)	1830 ( 71.8%)	495 ( 19.4%)	2549
Ill-defined disorder	204 ( 8.2%)	540 ( 21.6%)	1272 ( 50.9%)	484 ( 19.4%)	2500
Parkinson's disease	0 ( 0.0%)	50 ( 2.0%)	1461 ( 59.8%)	934 ( 38.2%)	2445
Blood cholesterol increased	3 ( 0.1%)	138 ( 6.0%)	1538 ( 67.2%)	610 ( 26.6%)	2289
Atrial fibrillation	0 ( 0.0%)	62 ( 2.8%)	1004 ( 44.6%)	1187 ( 52.7%)	2253
Eczema	805 ( 37.4%)	548 ( 25.5%)	671 ( 31.2%)	128 ( 5.9%)	2152
Gastroesophageal reflux disease	83 ( 4.1%)	384 ( 18.9%)	1210 ( 59.6%)	352 ( 17.3%)	2029
Insomnia	77 ( 3.8%)	438 ( 21.6%)	808 ( 39.9%)	702 ( 34.7%)	2025
Relapsing-remitting multiple sclerosis	99 ( 4.9%)	1323 ( 65.7%)	586 ( 29.1%)	6 ( 0.3%)	2014
Anxiety	265 ( 13.4%)	692 ( 34.9%)	830 ( 41.9%)	193 ( 9.7%)	1980
Chronic lymphocytic leukaemia	1 ( 0.1%)	42 ( 2.1%)	1267 ( 64.4%)	658 ( 33.4%)	1968
Epilepsy	705 ( 37.3%)	606 ( 32.0%)	472 ( 24.9%)	109 ( 5.8%)	1892
HER2 positive breast cancer	1 ( 0.1%)	815 ( 43.7%)	911 ( 48.8%)	139 ( 7.4%)	1866
Hepatocellular carcinoma	6 ( 0.3%)	211 ( 12.0%)	1151 ( 65.2%)	397 ( 22.5%)	1765
Triple negative breast cancer	0 ( 0.0%)	651 ( 38.1%)	979 ( 57.4%)	77 ( 4.5%)	1707
Coronary artery disease	2 ( 0.1%)	68 ( 4.0%)	360 ( 21.2%)	1267 ( 74.7%)	1697
Blood cholesterol abnormal	5 ( 0.3%)	97 ( 5.7%)	1137 ( 67.4%)	448 ( 26.6%)	1687
Chemotherapy	372 ( 22.1%)	392 ( 23.3%)	788 ( 46.8%)	131 ( 7.8%)	1683
Acute lymphocytic leukaemia	1116 ( 66.7%)	345 ( 20.6%)	187 ( 11.2%)	25 ( 1.5%)	1673
Ankylosing spondylitis	71 ( 4.3%)	781 ( 46.9%)	749 ( 44.9%)	66 ( 4.0%)	1667
Follicular lymphoma	0 ( 0.0%)	204 ( 12.5%)	1166 ( 71.7%)	256 ( 15.7%)	1626
COVID-19	116 ( 7.2%)	386 ( 24.0%)	832 ( 51.7%)	275 ( 17.1%)	1609
Breast cancer female	1 ( 0.1%)	250 ( 15.7%)	971 ( 61.1%)	368 ( 23.1%)	1590
Seizure	661 ( 42.2%)	308 ( 19.6%)	320 ( 20.4%)	279 ( 17.8%)	1568

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Osteoporosis	14 ( 0.9%)	66 ( 4.3%)	910 ( 59.2%)	546 ( 35.5%)	1536
Renal cell carcinoma	6 ( 0.4%)	158 ( 10.5%)	1067 ( 70.9%)	274 ( 18.2%)	1505
Factor VIII deficiency	704 ( 49.1%)	521 ( 36.3%)	190 ( 13.2%)	19 ( 1.3%)	1434
Cardiac failure	24 ( 1.7%)	120 ( 8.6%)	649 ( 46.7%)	597 ( 42.9%)	1390
Chronic obstructive pulmonary disease	4 ( 0.3%)	60 ( 4.5%)	668 ( 50.2%)	600 ( 45.0%)	1332
Nausea	158 ( 12.3%)	284 ( 22.1%)	665 ( 51.8%)	178 ( 13.9%)	1285
Lung adenocarcinoma	14 ( 1.1%)	75 ( 5.9%)	1079 ( 84.5%)	109 ( 8.5%)	1277
Systemic lupus erythematosus	185 ( 14.9%)	666 ( 53.6%)	376 ( 30.3%)	15 ( 1.2%)	1242
Malignant melanoma	23 ( 1.9%)	213 ( 17.2%)	757 ( 61.2%)	244 ( 19.7%)	1237
Lung neoplasm malignant	4 ( 0.3%)	143 ( 11.7%)	809 ( 66.4%)	263 ( 21.6%)	1219
Chronic myeloid leukaemia	42 ( 3.5%)	281 ( 23.5%)	652 ( 54.4%)	223 ( 18.6%)	1198
Nasal polyps	52 ( 4.3%)	471 ( 39.3%)	597 ( 49.9%)	77 ( 6.4%)	1197
Hypothyroidism	84 ( 7.0%)	221 ( 18.5%)	662 ( 55.4%)	229 ( 19.1%)	1196
Contraception	351 ( 29.4%)	827 ( 69.2%)	17 ( 1.4%)	0 ( 0.0%)	1195
Hereditary angioedema	171 ( 14.4%)	610 ( 51.3%)	367 ( 30.8%)	42 ( 3.5%)	1190
Ovarian cancer	3 ( 0.3%)	136 ( 11.7%)	936 ( 80.3%)	91 ( 7.8%)	1166
Plasma cell myeloma refractory	1 ( 0.1%)	80 ( 6.9%)	897 ( 77.0%)	187 ( 16.1%)	1165
Angina pectoris	1 ( 0.1%)	17 ( 1.5%)	129 ( 11.1%)	1017 ( 87.4%)	1164
Prophylaxis against transplant rejection	207 ( 17.9%)	318 ( 27.5%)	625 ( 54.0%)	8 ( 0.7%)	1158
Bipolar disorder	186 ( 16.2%)	419 ( 36.6%)	521 ( 45.5%)	19 ( 1.7%)	1145
Off label use	153 ( 13.4%)	337 ( 29.6%)	194 ( 17.0%)	455 ( 39.9%)	1139
Pneumonia	123 ( 10.9%)	202 ( 17.9%)	613 ( 54.4%)	188 ( 16.7%)	1126
Immunosuppression	252 ( 22.5%)	343 ( 30.6%)	493 ( 43.9%)	34 ( 3.0%)	1122
Colon cancer	0 ( 0.0%)	122 ( 10.9%)	762 ( 68.2%)	234 ( 20.9%)	1118
Hypercholesterolaemia	11 ( 1.0%)	96 ( 8.7%)	706 ( 64.0%)	290 ( 26.3%)	1103
Mantle cell lymphoma	0 ( 0.0%)	70 ( 6.6%)	841 ( 79.3%)	149 ( 14.1%)	1060
Back pain	152 ( 15.1%)	209 ( 20.7%)	493 ( 48.9%)	155 ( 15.4%)	1009

### Indication Summary Table

#### Derived Age Group

	<i>Group1 (0-25)</i> (N=&AGEGRP1)	<i>Group2 (26-50)</i> (N=&AGEGRP2)	<i>Group3 (51-75)</i> (N=&AGEGRP3)	<i>Group4 (75+)</i> (N=&AGEGRP4)	<i>Total</i> (N=&AGEGRP5)
Supplementation therapy	81 ( 8.2%)	167 ( 16.8%)	492 ( 49.6%)	252 ( 25.4%)	992
Narcolepsy	119 ( 12.2%)	569 ( 58.2%)	262 ( 26.8%)	28 ( 2.9%)	978
Arthritis	17 ( 1.8%)	152 ( 15.8%)	420 ( 43.5%)	376 ( 39.0%)	965
Attention deficit hyperactivity disorder	575 ( 60.0%)	317 ( 33.1%)	66 ( 6.9%)	1 ( 0.1%)	959
Thrombosis prophylaxis	22 ( 2.3%)	156 ( 16.6%)	514 ( 54.7%)	248 ( 26.4%)	940
Anticoagulant therapy	44 ( 4.7%)	149 ( 15.9%)	424 ( 45.3%)	319 ( 34.1%)	936
COVID-19 immunisation	45 ( 4.8%)	183 ( 19.6%)	574 ( 61.4%)	133 ( 14.2%)	935
Hyperlipidaemia	8 ( 0.9%)	71 ( 7.6%)	639 ( 68.7%)	212 ( 22.8%)	930
Urinary tract infection	34 ( 3.7%)	190 ( 20.5%)	361 ( 38.9%)	343 ( 37.0%)	928
Infection prophylaxis	132 ( 14.3%)	161 ( 17.5%)	470 ( 51.1%)	157 ( 17.1%)	920
Chest pain	5 ( 0.5%)	30 ( 3.3%)	111 ( 12.2%)	767 ( 84.0%)	913
Colorectal cancer metastatic	0 ( 0.0%)	228 ( 25.4%)	509 ( 56.6%)	162 ( 18.0%)	899
Psychotic disorder	180 ( 20.2%)	367 ( 41.1%)	309 ( 34.6%)	37 ( 4.1%)	893
Neoplasm malignant	49 ( 5.5%)	141 ( 15.8%)	549 ( 61.5%)	154 ( 17.2%)	893
Headache	262 ( 29.4%)	303 ( 34.0%)	283 ( 31.8%)	42 ( 4.7%)	890
Gastric cancer	4 ( 0.5%)	80 ( 9.0%)	597 ( 67.5%)	204 ( 23.1%)	885
Endometrial cancer	5 ( 0.6%)	48 ( 5.5%)	698 ( 79.7%)	125 ( 14.3%)	876
Dyslipidaemia	5 ( 0.6%)	81 ( 9.3%)	579 ( 66.6%)	205 ( 23.6%)	870
Analgesic therapy	88 ( 10.1%)	238 ( 27.4%)	311 ( 35.8%)	232 ( 26.7%)	869
Infection	84 ( 9.7%)	211 ( 24.5%)	415 ( 48.1%)	152 ( 17.6%)	862
Relapsing multiple sclerosis	34 ( 4.0%)	502 ( 59.1%)	307 ( 36.2%)	6 ( 0.7%)	849
Vitamin supplementation	69 ( 8.4%)	89 ( 10.9%)	335 ( 41.0%)	325 ( 39.7%)	818
Immunodeficiency common variable	66 ( 8.1%)	166 ( 20.3%)	486 ( 59.6%)	98 ( 12.0%)	816
Chronic spontaneous urticaria	63 ( 7.8%)	433 ( 53.8%)	272 ( 33.8%)	37 ( 4.6%)	805
Eosinophilic oesophagitis	340 ( 42.4%)	330 ( 41.1%)	129 ( 16.1%)	3 ( 0.4%)	802
Major depression	168 ( 21.0%)	283 ( 35.4%)	304 ( 38.0%)	44 ( 5.5%)	799
Pyrexia	180 ( 22.8%)	194 ( 24.6%)	348 ( 44.1%)	68 ( 8.6%)	790



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Neuralgia	40 ( 5.1%)	285 ( 36.1%)	345 ( 43.7%)	120 ( 15.2%)	790
Arthralgia	26 ( 3.3%)	146 ( 18.6%)	507 ( 64.5%)	107 ( 13.6%)	786
Diarrhoea	66 ( 8.5%)	139 ( 17.8%)	433 ( 55.5%)	142 ( 18.2%)	780
Fibromyalgia	7 ( 0.9%)	117 ( 15.2%)	116 ( 15.1%)	530 ( 68.8%)	770
Antibiotic therapy	121 ( 15.7%)	229 ( 29.8%)	332 ( 43.2%)	87 ( 11.3%)	769
Hypersensitivity	116 ( 15.4%)	203 ( 27.0%)	331 ( 44.0%)	102 ( 13.6%)	752
Non-Hodgkin's lymphoma	60 ( 8.1%)	228 ( 30.6%)	409 ( 54.9%)	48 ( 6.4%)	745
Prophylaxis against graft versus host disease	275 ( 37.4%)	231 ( 31.4%)	222 ( 30.2%)	8 ( 1.1%)	736
Pancreatic carcinoma	2 ( 0.3%)	89 ( 12.1%)	516 ( 70.4%)	126 ( 17.2%)	733
Clear cell renal cell carcinoma	0 ( 0.0%)	92 ( 12.6%)	549 ( 75.0%)	91 ( 12.4%)	732
Renal transplant	94 ( 12.9%)	287 ( 39.4%)	320 ( 43.9%)	28 ( 3.8%)	729
Cataplexy	90 ( 12.6%)	400 ( 55.9%)	202 ( 28.3%)	23 ( 3.2%)	715
B-cell lymphoma	79 ( 11.4%)	141 ( 20.3%)	402 ( 57.8%)	74 ( 10.6%)	696
Non-small cell lung cancer metastatic	0 ( 0.0%)	57 ( 8.2%)	522 ( 75.1%)	116 ( 16.7%)	695
Sleep disorder	55 ( 7.9%)	237 ( 34.1%)	305 ( 43.9%)	97 ( 14.0%)	694
Bone marrow conditioning regimen	289 ( 42.4%)	198 ( 29.1%)	191 ( 28.0%)	3 ( 0.4%)	681
Nutritional supplementation	45 ( 6.7%)	48 ( 7.1%)	228 ( 33.7%)	355 ( 52.5%)	676
Myelodysplastic syndrome	17 ( 2.5%)	33 ( 4.9%)	319 ( 47.3%)	305 ( 45.3%)	674
Hodgkin's disease	94 ( 14.1%)	312 ( 46.8%)	219 ( 32.8%)	42 ( 6.3%)	667
Anaemia	65 ( 9.8%)	150 ( 22.6%)	295 ( 44.4%)	155 ( 23.3%)	665
Neurodermatitis	40 ( 6.0%)	147 ( 22.2%)	403 ( 60.8%)	73 ( 11.0%)	663
Pulmonary hypertension	73 ( 11.0%)	141 ( 21.3%)	295 ( 44.5%)	154 ( 23.2%)	663
Antiviral prophylaxis	160 ( 24.2%)	93 ( 14.1%)	345 ( 52.2%)	63 ( 9.5%)	661
Echocardiogram	13 ( 2.0%)	146 ( 22.2%)	423 ( 64.2%)	77 ( 11.7%)	659
Growth hormone deficiency	573 ( 87.9%)	32 ( 4.9%)	42 ( 6.4%)	5 ( 0.8%)	652
Invasive ductal breast carcinoma	24 ( 3.8%)	208 ( 32.6%)	319 ( 50.0%)	87 ( 13.6%)	638
Dyspnoea	22 ( 3.4%)	40 ( 6.3%)	172 ( 27.0%)	404 ( 63.3%)	638

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Oesophageal carcinoma	3 ( 0.5%)	35 ( 5.5%)	425 ( 66.7%)	174 ( 27.3%)	637
B-cell type acute leukaemia	426 ( 67.2%)	95 ( 15.0%)	112 ( 17.7%)	1 ( 0.2%)	634
IgA nephropathy	42 ( 6.7%)	321 ( 51.0%)	246 ( 39.1%)	20 ( 3.2%)	629
Prophylaxis of nausea and vomiting	41 ( 6.5%)	92 ( 14.7%)	390 ( 62.3%)	103 ( 16.5%)	626
Immune thrombocytopenia	140 ( 22.4%)	151 ( 24.2%)	229 ( 36.7%)	104 ( 16.7%)	624
Myasthenia gravis	12 ( 1.9%)	171 ( 27.4%)	343 ( 55.1%)	97 ( 15.6%)	623
Hidradenitis	123 ( 20.0%)	361 ( 58.6%)	129 ( 20.9%)	3 ( 0.5%)	616
Immune system disorder	52 ( 8.5%)	267 ( 43.5%)	260 ( 42.3%)	35 ( 5.7%)	614
Weight decreased	14 ( 2.3%)	332 ( 54.3%)	247 ( 40.4%)	18 ( 2.9%)	611
Colorectal cancer	0 ( 0.0%)	198 ( 32.4%)	353 ( 57.8%)	60 ( 9.8%)	611
Cardiac disorder	5 ( 0.8%)	30 ( 4.9%)	345 ( 56.6%)	230 ( 37.7%)	610
Cerebrovascular accident	3 ( 0.5%)	19 ( 3.1%)	121 ( 19.9%)	466 ( 76.5%)	609
Anaesthesia	98 ( 16.2%)	173 ( 28.5%)	309 ( 51.0%)	26 ( 4.3%)	606
Tuberculosis	96 ( 16.3%)	270 ( 45.9%)	197 ( 33.5%)	25 ( 4.3%)	588
Juvenile idiopathic arthritis	513 ( 88.4%)	39 ( 6.7%)	26 ( 4.5%)	2 ( 0.3%)	580
Cough	96 ( 16.6%)	121 ( 20.9%)	223 ( 38.6%)	138 ( 23.9%)	578
Oesophageal adenocarcinoma	1 ( 0.2%)	85 ( 14.7%)	430 ( 74.5%)	61 ( 10.6%)	577
COVID-19 pneumonia	9 ( 1.6%)	138 ( 24.4%)	382 ( 67.5%)	37 ( 6.5%)	566
Uterine cancer	0 ( 0.0%)	69 ( 12.2%)	391 ( 69.2%)	105 ( 18.6%)	565
Pruritus	55 ( 9.8%)	67 ( 11.9%)	334 ( 59.2%)	108 ( 19.1%)	564
Somnolence	56 ( 10.0%)	311 ( 55.7%)	168 ( 30.1%)	23 ( 4.1%)	558
Diffuse large B-cell lymphoma stage IV	28 ( 5.0%)	217 ( 39.1%)	191 ( 34.4%)	119 ( 21.4%)	555
Vomiting	70 ( 12.7%)	130 ( 23.6%)	273 ( 49.5%)	79 ( 14.3%)	552
Metastases to bone	24 ( 4.4%)	65 ( 11.9%)	378 ( 69.2%)	79 ( 14.5%)	546
Antifungal prophylaxis	136 ( 25.1%)	108 ( 20.0%)	254 ( 47.0%)	43 ( 7.9%)	541
Benign prostatic hyperplasia	3 ( 0.6%)	6 ( 1.1%)	271 ( 50.1%)	261 ( 48.2%)	541
Dermatitis	107 ( 19.9%)	174 ( 32.3%)	198 ( 36.8%)	59 ( 11.0%)	538

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Primary immunodeficiency syndrome	92 ( 17.3%)	111 ( 20.9%)	283 ( 53.3%)	45 ( 8.5%)	531
Metastatic malignant melanoma	5 ( 1.0%)	95 ( 18.1%)	351 ( 67.0%)	73 ( 13.9%)	524
Parkinson's disease psychosis	0 ( 0.0%)	2 ( 0.4%)	234 ( 45.8%)	275 ( 53.8%)	511
Haemorrhage	273 ( 53.6%)	145 ( 28.5%)	85 ( 16.7%)	6 ( 1.2%)	509
Rash	21 ( 4.2%)	116 ( 23.1%)	291 ( 57.9%)	75 ( 14.9%)	503
Immunisation	94 ( 18.7%)	75 ( 14.9%)	160 ( 31.9%)	173 ( 34.5%)	502
Granulomatosis with polyangiitis	41 ( 8.2%)	125 ( 24.9%)	261 ( 52.0%)	75 ( 14.9%)	502
Sepsis	58 ( 11.7%)	107 ( 21.7%)	232 ( 47.0%)	97 ( 19.6%)	494
Interstitial lung disease	29 ( 5.9%)	65 ( 13.2%)	291 ( 59.0%)	108 ( 21.9%)	493
Transitional cell carcinoma	0 ( 0.0%)	5 ( 1.0%)	306 ( 62.1%)	182 ( 36.9%)	493
Status epilepticus	97 ( 19.8%)	273 ( 55.6%)	105 ( 21.4%)	16 ( 3.3%)	491
Thyroid disorder	18 ( 3.7%)	50 ( 10.2%)	155 ( 31.7%)	266 ( 54.4%)	489
Small cell lung cancer extensive stage	0 ( 0.0%)	35 ( 7.2%)	379 ( 77.7%)	74 ( 15.2%)	488
Antibiotic prophylaxis	73 ( 15.3%)	80 ( 16.8%)	284 ( 59.5%)	40 ( 8.4%)	477
Deep vein thrombosis	16 ( 3.4%)	133 ( 27.9%)	267 ( 56.1%)	60 ( 12.6%)	476
Neutropenia	18 ( 3.8%)	96 ( 20.2%)	285 ( 59.9%)	77 ( 16.2%)	476
Blood cholesterol	1 ( 0.2%)	36 ( 7.6%)	301 ( 63.4%)	137 ( 28.8%)	475
Dyspepsia	15 ( 3.2%)	127 ( 26.7%)	248 ( 52.2%)	85 ( 17.9%)	475
Skin wrinkling	6 ( 1.3%)	290 ( 61.2%)	170 ( 35.9%)	8 ( 1.7%)	474
Type 1 diabetes mellitus	121 ( 25.6%)	159 ( 33.7%)	157 ( 33.3%)	35 ( 7.4%)	472
Small cell lung cancer	0 ( 0.0%)	29 ( 6.3%)	338 ( 73.0%)	96 ( 20.7%)	463
Bacterial infection	42 ( 9.2%)	96 ( 20.9%)	155 ( 33.8%)	166 ( 36.2%)	459
Idiopathic pulmonary fibrosis	1 ( 0.2%)	6 ( 1.3%)	233 ( 51.3%)	214 ( 47.1%)	454
Renal cancer	3 ( 0.7%)	50 ( 11.0%)	317 ( 69.8%)	84 ( 18.5%)	454
Suspected suicide	67 ( 14.9%)	137 ( 30.4%)	201 ( 44.7%)	45 ( 10.0%)	450
Evidence based treatment	70 ( 15.6%)	114 ( 25.4%)	219 ( 48.8%)	46 ( 10.2%)	449
Metastatic renal cell carcinoma	0 ( 0.0%)	36 ( 8.1%)	322 ( 72.2%)	88 ( 19.7%)	446

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blood pressure abnormal	3 ( 0.7%)	27 ( 6.2%)	293 ( 67.2%)	113 ( 25.9%)	436
Osteoarthritis	2 ( 0.5%)	68 ( 15.6%)	267 ( 61.4%)	98 ( 22.5%)	435
Thrombosis	20 ( 4.6%)	46 ( 10.6%)	161 ( 37.3%)	205 ( 47.5%)	432
Still's disease	277 ( 64.3%)	71 ( 16.5%)	59 ( 13.7%)	24 ( 5.6%)	431
Dermatitis allergic	182 ( 42.6%)	100 ( 23.4%)	112 ( 26.2%)	33 ( 7.7%)	427
Lymphoma	26 ( 6.1%)	102 ( 24.1%)	235 ( 55.6%)	60 ( 14.2%)	423
Rett syndrome	345 ( 81.9%)	71 ( 16.9%)	5 ( 1.2%)	0 ( 0.0%)	421
Prostate cancer metastatic	0 ( 0.0%)	2 ( 0.5%)	230 ( 55.0%)	186 ( 44.5%)	418
General anaesthesia	59 ( 14.1%)	109 ( 26.1%)	234 ( 56.0%)	16 ( 3.8%)	418
Adenocarcinoma of colon	0 ( 0.0%)	78 ( 18.7%)	275 ( 65.9%)	64 ( 15.3%)	417
Cystic fibrosis	244 ( 58.7%)	119 ( 28.6%)	42 ( 10.1%)	11 ( 2.6%)	416
Blood pressure measurement	3 ( 0.7%)	56 ( 13.6%)	248 ( 60.2%)	105 ( 25.5%)	412
Primary amyloidosis	0 ( 0.0%)	46 ( 11.2%)	264 ( 64.4%)	100 ( 24.4%)	410
Partial seizures	163 ( 39.9%)	87 ( 21.3%)	150 ( 36.7%)	9 ( 2.2%)	409
Infantile spasms	403 ( 99.5%)	2 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	405
Cardiac failure chronic	5 ( 1.2%)	46 ( 11.4%)	152 ( 37.5%)	202 ( 49.9%)	405
Glaucoma	32 ( 8.0%)	15 ( 3.8%)	195 ( 48.8%)	158 ( 39.5%)	400
Secondary progressive multiple sclerosis	3 ( 0.8%)	123 ( 31.0%)	269 ( 67.8%)	2 ( 0.5%)	397
Gout	0 ( 0.0%)	60 ( 15.1%)	234 ( 58.9%)	103 ( 25.9%)	397
Abdominal pain	74 ( 18.7%)	101 ( 25.5%)	179 ( 45.2%)	42 ( 10.6%)	396
Oedema	13 ( 3.3%)	48 ( 12.2%)	123 ( 31.2%)	210 ( 53.3%)	394
Intentional product misuse	1 ( 0.3%)	22 ( 5.6%)	57 ( 14.6%)	311 ( 79.5%)	391
Amyloidosis	0 ( 0.0%)	5 ( 1.3%)	156 ( 39.9%)	230 ( 58.8%)	391
Gastrointestinal stromal tumour	20 ( 5.1%)	37 ( 9.5%)	255 ( 65.4%)	78 ( 20.0%)	390
Cancer pain	9 ( 2.3%)	45 ( 11.6%)	292 ( 75.3%)	42 ( 10.8%)	388
Dermatomyositis	63 ( 16.2%)	100 ( 25.8%)	216 ( 55.7%)	9 ( 2.3%)	388
Cardiac amyloidosis	0 ( 0.0%)	1 ( 0.3%)	113 ( 29.4%)	271 ( 70.4%)	385

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Primary progressive multiple sclerosis	3 ( 0.8%)	115 ( 29.9%)	262 ( 68.1%)	5 ( 1.3%)	385
Pulmonary embolism	17 ( 4.4%)	78 ( 20.3%)	163 ( 42.4%)	126 ( 32.8%)	384
Adverse drug reaction	38 ( 9.9%)	106 ( 27.6%)	190 ( 49.5%)	50 ( 13.0%)	384
Petit mal epilepsy	379 ( 99.2%)	0 ( 0.0%)	3 ( 0.8%)	0 ( 0.0%)	382
Prophylaxis against gastrointestinal ulcer	25 ( 6.6%)	44 ( 11.6%)	193 ( 50.9%)	117 ( 30.9%)	379
Rectal cancer	0 ( 0.0%)	58 ( 15.4%)	257 ( 68.4%)	61 ( 16.2%)	376
Neoplasm	95 ( 25.4%)	103 ( 27.5%)	153 ( 40.9%)	23 ( 6.1%)	374
Seizure prophylaxis	23 ( 6.1%)	35 ( 9.4%)	55 ( 14.7%)	261 ( 69.8%)	374
Chronic kidney disease	14 ( 3.8%)	56 ( 15.0%)	185 ( 49.6%)	118 ( 31.6%)	373
Dementia	1 ( 0.3%)	0 ( 0.0%)	96 ( 25.8%)	275 ( 73.9%)	372
Adenocarcinoma gastric	0 ( 0.0%)	69 ( 18.6%)	264 ( 71.4%)	37 ( 10.0%)	370
Agitation	143 ( 39.5%)	112 ( 30.9%)	47 ( 13.0%)	60 ( 16.6%)	362
Burkitt's lymphoma	160 ( 44.2%)	166 ( 45.9%)	36 ( 9.9%)	0 ( 0.0%)	362
Alopecia	64 ( 17.9%)	143 ( 39.9%)	121 ( 33.8%)	30 ( 8.4%)	358
Hallucination	8 ( 2.3%)	8 ( 2.3%)	174 ( 49.0%)	165 ( 46.5%)	355
Hypokalaemia	25 ( 7.1%)	48 ( 13.6%)	202 ( 57.1%)	79 ( 22.3%)	354
Non-small cell lung cancer recurrent	0 ( 0.0%)	38 ( 10.8%)	252 ( 71.4%)	63 ( 17.8%)	353
Schizoaffective disorder	52 ( 14.8%)	200 ( 57.0%)	91 ( 25.9%)	8 ( 2.3%)	351
Muscle spasms	37 ( 10.6%)	66 ( 18.9%)	199 ( 56.9%)	48 ( 13.7%)	350
Lupus nephritis	85 ( 24.4%)	184 ( 52.7%)	80 ( 22.9%)	0 ( 0.0%)	349
Medication dilution	36 ( 10.4%)	110 ( 31.7%)	183 ( 52.7%)	18 ( 5.2%)	347
Sedation	53 ( 15.3%)	118 ( 34.1%)	146 ( 42.2%)	29 ( 8.4%)	346
Vitamin D deficiency	62 ( 18.2%)	86 ( 25.2%)	148 ( 43.4%)	45 ( 13.2%)	341
COVID-19 prophylaxis	14 ( 4.1%)	121 ( 35.7%)	153 ( 45.1%)	51 ( 15.0%)	339
Neuropathy peripheral	9 ( 2.7%)	48 ( 14.2%)	226 ( 66.9%)	55 ( 16.3%)	338
Mineral supplementation	16 ( 4.8%)	37 ( 11.0%)	229 ( 68.2%)	54 ( 16.1%)	336
Nephrotic syndrome	228 ( 68.1%)	43 ( 12.8%)	49 ( 14.6%)	15 ( 4.5%)	335

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Suicide attempt	143 ( 43.1%)	85 ( 25.6%)	60 ( 18.1%)	44 ( 13.3%)	332
Affective disorder	96 ( 29.0%)	153 ( 46.2%)	62 ( 18.7%)	20 ( 6.0%)	331
Spinal muscular atrophy	253 ( 77.6%)	54 ( 16.6%)	18 ( 5.5%)	1 ( 0.3%)	326
Allogenic stem cell transplantation	109 ( 33.7%)	112 ( 34.7%)	102 ( 31.6%)	0 ( 0.0%)	323
Migraine prophylaxis	24 ( 7.4%)	136 ( 42.1%)	145 ( 44.9%)	18 ( 5.6%)	323
Haemophagocytic lymphohistiocytosis	149 ( 46.1%)	88 ( 27.2%)	80 ( 24.8%)	6 ( 1.9%)	323
Glucose tolerance impaired	5 ( 1.5%)	160 ( 49.5%)	146 ( 45.2%)	12 ( 3.7%)	323
Lung adenocarcinoma stage IV	0 ( 0.0%)	18 ( 5.6%)	249 ( 77.3%)	55 ( 17.1%)	322
Cardiovascular event prophylaxis	2 ( 0.6%)	25 ( 7.8%)	176 ( 54.8%)	118 ( 36.8%)	321
Mycobacterium avium complex infection	29 ( 9.1%)	93 ( 29.2%)	160 ( 50.2%)	37 ( 11.6%)	319
Sickle cell disease	130 ( 40.8%)	131 ( 41.1%)	56 ( 17.6%)	2 ( 0.6%)	319
Urticaria	34 ( 10.7%)	112 ( 35.1%)	151 ( 47.3%)	22 ( 6.9%)	319
Hormone-refractory prostate cancer	0 ( 0.0%)	2 ( 0.6%)	180 ( 56.8%)	135 ( 42.6%)	317
Bile duct cancer	0 ( 0.0%)	7 ( 2.2%)	238 ( 75.8%)	69 ( 22.0%)	314
Non-small cell lung cancer stage IV	14 ( 4.5%)	42 ( 13.5%)	196 ( 63.0%)	59 ( 19.0%)	311
Myocardial infarction	6 ( 1.9%)	26 ( 8.4%)	220 ( 70.7%)	59 ( 19.0%)	311
Febrile neutropenia	55 ( 17.7%)	32 ( 10.3%)	202 ( 65.2%)	21 ( 6.8%)	310
Generalised tonic-clonic seizure	167 ( 54.2%)	85 ( 27.6%)	55 ( 17.9%)	1 ( 0.3%)	308
Neuromyelitis optica spectrum disorder	33 ( 10.7%)	77 ( 25.0%)	176 ( 57.1%)	22 ( 7.1%)	308
Metastases to liver	22 ( 7.1%)	65 ( 21.1%)	197 ( 64.0%)	24 ( 7.8%)	308
Induction of anaesthesia	58 ( 19.2%)	120 ( 39.7%)	94 ( 31.1%)	30 ( 9.9%)	302
Hyperuricaemia	5 ( 1.7%)	29 ( 9.6%)	160 ( 53.2%)	107 ( 35.5%)	301
Acne	156 ( 52.9%)	113 ( 38.3%)	23 ( 7.8%)	3 ( 1.0%)	295
Abdominal discomfort	6 ( 2.0%)	45 ( 15.3%)	222 ( 75.3%)	22 ( 7.5%)	295
Hormone receptor positive HER2 negative breast cance	0 ( 0.0%)	66 ( 22.4%)	154 ( 52.4%)	74 ( 25.2%)	294
Obesity	29 ( 9.9%)	159 ( 54.5%)	101 ( 34.6%)	3 ( 1.0%)	292
Inflammation	13 ( 4.5%)	146 ( 50.5%)	116 ( 40.1%)	14 ( 4.8%)	289

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Fungal infection	46 ( 16.0%)	74 ( 25.8%)	115 ( 40.1%)	52 ( 18.1%)	287
Cholangiocarcinoma	1 ( 0.3%)	55 ( 19.2%)	198 ( 69.2%)	32 ( 11.2%)	286
Acromegaly	8 ( 2.8%)	94 ( 33.2%)	165 ( 58.3%)	16 ( 5.7%)	283
Factor IX deficiency	149 ( 53.0%)	88 ( 31.3%)	43 ( 15.3%)	1 ( 0.4%)	281
Anti-infective therapy	70 ( 24.9%)	61 ( 21.7%)	116 ( 41.3%)	34 ( 12.1%)	281
Dementia Alzheimer's type	0 ( 0.0%)	5 ( 1.8%)	106 ( 38.3%)	166 ( 59.9%)	277
Gastrointestinal disorder	25 ( 9.0%)	41 ( 14.8%)	142 ( 51.3%)	69 ( 24.9%)	277
Renal cell carcinoma stage IV	2 ( 0.7%)	14 ( 5.1%)	159 ( 57.6%)	101 ( 36.6%)	276
Drug dependence	25 ( 9.1%)	212 ( 76.8%)	39 ( 14.1%)	0 ( 0.0%)	276
Chemotherapy side effect prophylaxis	4 ( 1.5%)	38 ( 13.8%)	167 ( 60.7%)	66 ( 24.0%)	275
Antiplatelet therapy	18 ( 6.6%)	53 ( 19.5%)	123 ( 45.2%)	78 ( 28.7%)	272
Dry eye	2 ( 0.7%)	35 ( 12.9%)	170 ( 62.5%)	65 ( 23.9%)	272
Herpes zoster	10 ( 3.7%)	70 ( 25.7%)	129 ( 47.4%)	63 ( 23.2%)	272
Complex regional pain syndrome	39 ( 14.3%)	212 ( 77.9%)	21 ( 7.7%)	0 ( 0.0%)	272
Hypoparathyroidism	5 ( 1.8%)	133 ( 48.9%)	121 ( 44.5%)	13 ( 4.8%)	272
Autism spectrum disorder	233 ( 86.9%)	19 ( 7.1%)	16 ( 6.0%)	0 ( 0.0%)	268
Adverse event	80 ( 30.0%)	43 ( 16.1%)	116 ( 43.4%)	28 ( 10.5%)	267
Hormone replacement therapy	8 ( 3.0%)	92 ( 34.6%)	147 ( 55.3%)	19 ( 7.1%)	266
Cellulitis	16 ( 6.0%)	127 ( 47.9%)	81 ( 30.6%)	41 ( 15.5%)	265
Transplant rejection	72 ( 27.2%)	111 ( 41.9%)	82 ( 30.9%)	0 ( 0.0%)	265
Weight control	8 ( 3.0%)	130 ( 49.2%)	121 ( 45.8%)	5 ( 1.9%)	264
Pain management	54 ( 20.5%)	98 ( 37.1%)	90 ( 34.1%)	22 ( 8.3%)	264
Myocardial ischaemia	3 ( 1.1%)	10 ( 3.8%)	164 ( 62.4%)	86 ( 32.7%)	263
Bladder cancer	0 ( 0.0%)	10 ( 3.8%)	158 ( 60.3%)	94 ( 35.9%)	262
Acute myocardial infarction	0 ( 0.0%)	39 ( 14.9%)	146 ( 55.9%)	76 ( 29.1%)	261
Mental disorder	32 ( 12.3%)	87 ( 33.3%)	136 ( 52.1%)	6 ( 2.3%)	261
Seasonal allergy	40 ( 15.3%)	73 ( 28.0%)	124 ( 47.5%)	24 ( 9.2%)	261

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Plasma cell myeloma in remission	0 ( 0.0%)	12 ( 4.6%)	192 ( 73.8%)	56 ( 21.5%)	260
Hypotension	64 ( 24.7%)	52 ( 20.1%)	108 ( 41.7%)	35 ( 13.5%)	259
Graft versus host disease	61 ( 23.6%)	56 ( 21.6%)	140 ( 54.1%)	2 ( 0.8%)	259
Nasopharyngitis	46 ( 17.8%)	52 ( 20.2%)	71 ( 27.5%)	89 ( 34.5%)	258
Staphylococcal infection	22 ( 8.6%)	33 ( 12.8%)	146 ( 56.8%)	56 ( 21.8%)	257
Pancreatic carcinoma metastatic	0 ( 0.0%)	43 ( 16.8%)	198 ( 77.3%)	15 ( 5.9%)	256
Pain in extremity	24 ( 9.4%)	68 ( 26.8%)	124 ( 48.8%)	38 ( 15.0%)	254
Muscle spasticity	21 ( 8.4%)	92 ( 36.7%)	120 ( 47.8%)	18 ( 7.2%)	251
Type IIa hyperlipidaemia	5 ( 2.0%)	58 ( 23.3%)	160 ( 64.3%)	26 ( 10.4%)	249
Iron deficiency	33 ( 13.3%)	60 ( 24.2%)	35 ( 14.1%)	120 ( 48.4%)	248
Sinusitis	29 ( 11.7%)	88 ( 35.5%)	113 ( 45.6%)	18 ( 7.3%)	248
Trigeminal neuralgia	3 ( 1.2%)	42 ( 17.1%)	138 ( 56.1%)	63 ( 25.6%)	246
Delusion	4 ( 1.6%)	6 ( 2.4%)	115 ( 46.9%)	120 ( 49.0%)	245
Adenocarcinoma pancreas	0 ( 0.0%)	53 ( 21.7%)	175 ( 71.7%)	16 ( 6.6%)	244
Hepatitis C	3 ( 1.2%)	114 ( 46.9%)	114 ( 46.9%)	12 ( 4.9%)	243
Ewing's sarcoma	180 ( 74.1%)	27 ( 11.1%)	35 ( 14.4%)	1 ( 0.4%)	243
Illness	44 ( 18.2%)	72 ( 29.8%)	101 ( 41.7%)	25 ( 10.3%)	242
Cytokine release syndrome	20 ( 8.3%)	32 ( 13.3%)	164 ( 68.0%)	25 ( 10.4%)	241
Amyotrophic lateral sclerosis	1 ( 0.4%)	18 ( 7.5%)	184 ( 76.7%)	37 ( 15.4%)	240
Neovascular age-related macular degeneration	0 ( 0.0%)	5 ( 2.1%)	90 ( 37.5%)	145 ( 60.4%)	240
Pemphigoid	1 ( 0.4%)	12 ( 5.0%)	120 ( 50.2%)	106 ( 44.4%)	239
Abdominal pain upper	12 ( 5.0%)	44 ( 18.5%)	143 ( 60.1%)	39 ( 16.4%)	238
Bronchitis	30 ( 12.7%)	44 ( 18.6%)	115 ( 48.5%)	48 ( 20.3%)	237
Vehicle solution use	37 ( 15.6%)	83 ( 35.0%)	102 ( 43.0%)	15 ( 6.3%)	237
Alpha-1 antitrypsin deficiency	1 ( 0.4%)	30 ( 12.8%)	172 ( 73.5%)	31 ( 13.2%)	234
Helicobacter infection	18 ( 7.7%)	92 ( 39.5%)	112 ( 48.1%)	11 ( 4.7%)	233
Squamous cell carcinoma of lung	0 ( 0.0%)	13 ( 5.6%)	195 ( 84.4%)	23 ( 10.0%)	231



**Indication Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Uveitis	27 ( 11.7%)	114 ( 49.4%)	73 ( 31.6%)	17 ( 7.4%)	231
Radioactive iodine therapy	0 ( 0.0%)	0 ( 0.0%)	3 ( 1.3%)	228 ( 98.7%)	231
Squamous cell carcinoma	2 ( 0.9%)	36 ( 15.7%)	111 ( 48.3%)	81 ( 35.2%)	230
Diffuse large B-cell lymphoma stage II	0 ( 0.0%)	88 ( 38.3%)	135 ( 58.7%)	7 ( 3.0%)	230
Bipolar I disorder	53 ( 23.1%)	98 ( 42.8%)	78 ( 34.1%)	0 ( 0.0%)	229
Metastases to lung	11 ( 4.8%)	48 ( 21.1%)	137 ( 60.1%)	32 ( 14.0%)	228
Lennox-Gastaut syndrome	169 ( 74.4%)	39 ( 17.2%)	18 ( 7.9%)	1 ( 0.4%)	227
End stage renal disease	8 ( 3.5%)	51 ( 22.6%)	116 ( 51.3%)	51 ( 22.6%)	226
Adenocarcinoma	1 ( 0.4%)	54 ( 24.0%)	147 ( 65.3%)	23 ( 10.2%)	225
Colitis	22 ( 9.8%)	40 ( 17.9%)	136 ( 60.7%)	26 ( 11.6%)	224
Tardive dyskinesia	31 ( 13.8%)	85 ( 37.9%)	95 ( 42.4%)	13 ( 5.8%)	224
Antipsychotic therapy	70 ( 31.4%)	87 ( 39.0%)	55 ( 24.7%)	11 ( 4.9%)	223
Sedative therapy	30 ( 13.6%)	91 ( 41.2%)	80 ( 36.2%)	20 ( 9.0%)	221
Mixed anxiety and depressive disorder	7 ( 3.2%)	54 ( 24.7%)	86 ( 39.3%)	72 ( 32.9%)	219
Prinzmetal angina	0 ( 0.0%)	0 ( 0.0%)	219 (100.0%)	0 ( 0.0%)	219
Severe myoclonic epilepsy of infancy	204 ( 93.2%)	15 ( 6.8%)	0 ( 0.0%)	0 ( 0.0%)	219
Cardiac failure congestive	2 ( 0.9%)	32 ( 14.6%)	75 ( 34.2%)	110 ( 50.2%)	219
Diffuse large B-cell lymphoma stage III	9 ( 4.1%)	45 ( 20.6%)	106 ( 48.6%)	58 ( 26.6%)	218
Anti-neutrophil cytoplasmic antibody positive vascul	33 ( 15.1%)	31 ( 14.2%)	112 ( 51.4%)	42 ( 19.3%)	218
Drug therapy	16 ( 7.4%)	29 ( 13.4%)	69 ( 31.8%)	103 ( 47.5%)	217
Neuroendocrine tumour	1 ( 0.5%)	31 ( 14.4%)	148 ( 68.5%)	36 ( 16.7%)	216
Pulmonary tuberculosis	22 ( 10.2%)	90 ( 41.7%)	55 ( 25.5%)	49 ( 22.7%)	216
Neuroblastoma	210 ( 97.2%)	6 ( 2.8%)	0 ( 0.0%)	0 ( 0.0%)	216
Gastritis	15 ( 7.0%)	35 ( 16.3%)	122 ( 56.7%)	43 ( 20.0%)	215
Cervix carcinoma	1 ( 0.5%)	95 ( 44.4%)	115 ( 53.7%)	3 ( 1.4%)	214
Bronchial carcinoma	0 ( 0.0%)	11 ( 5.1%)	186 ( 86.9%)	17 ( 7.9%)	214
Diffuse large B-cell lymphoma refractory	2 ( 0.9%)	67 ( 31.6%)	125 ( 59.0%)	18 ( 8.5%)	212

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hypertrophic cardiomyopathy	2 ( 1.0%)	28 ( 13.3%)	126 ( 60.0%)	54 ( 25.7%)	210
Liver transplant	47 ( 22.4%)	25 ( 11.9%)	125 ( 59.5%)	13 ( 6.2%)	210
Breast cancer stage IV	0 ( 0.0%)	30 ( 14.3%)	134 ( 63.8%)	46 ( 21.9%)	210
Bulbospinal muscular atrophy congenital	0 ( 0.0%)	35 ( 16.7%)	132 ( 63.2%)	42 ( 20.1%)	209
Hypertonic bladder	0 ( 0.0%)	29 ( 13.9%)	97 ( 46.4%)	83 ( 39.7%)	209
Cystitis interstitial	7 ( 3.4%)	78 ( 37.5%)	109 ( 52.4%)	14 ( 6.7%)	208
Giant cell arteritis	0 ( 0.0%)	1 ( 0.5%)	99 ( 47.6%)	108 ( 51.9%)	208
Osteomyelitis	20 ( 9.6%)	12 ( 5.8%)	146 ( 70.2%)	30 ( 14.4%)	208
Disseminated tuberculosis	140 ( 67.3%)	23 ( 11.1%)	45 ( 21.6%)	0 ( 0.0%)	208
Diuretic therapy	2 ( 1.0%)	24 ( 11.6%)	121 ( 58.5%)	60 ( 29.0%)	207
Iron deficiency anaemia	32 ( 15.5%)	84 ( 40.6%)	59 ( 28.5%)	32 ( 15.5%)	207
Aplastic anaemia	73 ( 35.3%)	44 ( 21.3%)	59 ( 28.5%)	31 ( 15.0%)	207
Carcinoid tumour	0 ( 0.0%)	23 ( 11.1%)	156 ( 75.4%)	28 ( 13.5%)	207
Rhinitis allergic	37 ( 18.0%)	67 ( 32.5%)	76 ( 36.9%)	26 ( 12.6%)	206
Short stature	204 ( 99.5%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	205
T-cell type acute leukaemia	192 ( 94.1%)	8 ( 3.9%)	4 ( 2.0%)	0 ( 0.0%)	204
Duodenal ulcer	9 ( 4.4%)	1 ( 0.5%)	20 ( 9.8%)	174 ( 85.3%)	204
Hepatic cancer	0 ( 0.0%)	41 ( 20.3%)	135 ( 66.8%)	26 ( 12.9%)	202
Restless legs syndrome	1 ( 0.5%)	39 ( 19.5%)	128 ( 64.0%)	32 ( 16.0%)	200
Arrhythmia	18 ( 9.0%)	18 ( 9.0%)	88 ( 44.0%)	76 ( 38.0%)	200
Foetal exposure during pregnancy	200 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	200
Computerised tomogram	6 ( 3.0%)	35 ( 17.7%)	120 ( 60.6%)	37 ( 18.7%)	198
Arteriosclerosis	0 ( 0.0%)	43 ( 21.9%)	104 ( 53.1%)	49 ( 25.0%)	196
Inflammatory bowel disease	70 ( 36.1%)	66 ( 34.0%)	56 ( 28.9%)	2 ( 1.0%)	194
Squamous cell carcinoma of head and neck	0 ( 0.0%)	38 ( 19.6%)	149 ( 76.8%)	7 ( 3.6%)	194
Hormone receptor positive breast cancer	0 ( 0.0%)	27 ( 14.1%)	140 ( 72.9%)	25 ( 13.0%)	192
Colon cancer metastatic	0 ( 0.0%)	50 ( 26.0%)	118 ( 61.5%)	24 ( 12.5%)	192

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Lymphodepletion	47 ( 24.5%)	40 ( 20.8%)	95 ( 49.5%)	10 ( 5.2%)	192
Polyarthritis	8 ( 4.2%)	31 ( 16.2%)	121 ( 63.4%)	31 ( 16.2%)	191
Cerebral infarction	0 ( 0.0%)	10 ( 5.3%)	115 ( 60.5%)	65 ( 34.2%)	190
Venoocclusive disease	63 ( 33.2%)	41 ( 21.6%)	85 ( 44.7%)	1 ( 0.5%)	190
Intentional overdose	75 ( 39.9%)	60 ( 31.9%)	46 ( 24.5%)	7 ( 3.7%)	188
Ventricular tachycardia	41 ( 21.9%)	34 ( 18.2%)	74 ( 39.6%)	38 ( 20.3%)	187
Cytomegalovirus infection	65 ( 34.8%)	38 ( 20.3%)	78 ( 41.7%)	6 ( 3.2%)	187
Lymphoma transformation	0 ( 0.0%)	18 ( 9.6%)	159 ( 85.0%)	10 ( 5.3%)	187
Atypical haemolytic uraemic syndrome	51 ( 27.3%)	103 ( 55.1%)	29 ( 15.5%)	4 ( 2.1%)	187
Microscopic polyangiitis	4 ( 2.2%)	22 ( 11.8%)	108 ( 58.1%)	52 ( 28.0%)	186
Polymyalgia rheumatica	0 ( 0.0%)	1 ( 0.5%)	101 ( 54.3%)	84 ( 45.2%)	186
Oedema peripheral	0 ( 0.0%)	21 ( 11.4%)	87 ( 47.0%)	77 ( 41.6%)	185
Heavy menstrual bleeding	38 ( 20.5%)	137 ( 74.1%)	10 ( 5.4%)	0 ( 0.0%)	185
Aspergillus infection	19 ( 10.3%)	62 ( 33.5%)	86 ( 46.5%)	18 ( 9.7%)	185
Renal failure	19 ( 10.3%)	36 ( 19.5%)	102 ( 55.1%)	28 ( 15.1%)	185
Pneumocystis jirovecii pneumonia	44 ( 23.9%)	29 ( 15.8%)	105 ( 57.1%)	6 ( 3.3%)	184
Post herpetic neuralgia	2 ( 1.1%)	1 ( 0.5%)	143 ( 77.7%)	38 ( 20.7%)	184
Waldenstrom's macroglobulinaemia	0 ( 0.0%)	1 ( 0.5%)	124 ( 67.8%)	58 ( 31.7%)	183
Parenteral nutrition	42 ( 23.1%)	15 ( 8.2%)	53 ( 29.1%)	72 ( 39.6%)	182
Condition aggravated	5 ( 2.8%)	124 ( 68.9%)	46 ( 25.6%)	5 ( 2.8%)	180
Post transplant lymphoproliferative disorder	135 ( 75.4%)	16 ( 8.9%)	23 ( 12.8%)	5 ( 2.8%)	179
Pemphigus	7 ( 3.9%)	81 ( 45.5%)	77 ( 43.3%)	13 ( 7.3%)	178
Essential hypertension	0 ( 0.0%)	13 ( 7.3%)	136 ( 76.8%)	28 ( 15.8%)	177
Surgery	14 ( 8.0%)	106 ( 60.6%)	30 ( 17.1%)	25 ( 14.3%)	175
Hepatitis B	1 ( 0.6%)	48 ( 27.6%)	107 ( 61.5%)	18 ( 10.3%)	174
Cardiovascular disorder	3 ( 1.7%)	19 ( 10.9%)	108 ( 62.1%)	44 ( 25.3%)	174
Gaucher's disease	39 ( 22.5%)	57 ( 32.9%)	64 ( 37.0%)	13 ( 7.5%)	173

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Post-traumatic stress disorder	33 ( 19.3%)	74 ( 43.3%)	55 ( 32.2%)	9 ( 5.3%)	171
Candida infection	29 ( 17.0%)	61 ( 35.7%)	73 ( 42.7%)	8 ( 4.7%)	171
Drug abuse	33 ( 19.3%)	83 ( 48.5%)	32 ( 18.7%)	23 ( 13.5%)	171
Paroxysmal nocturnal haemoglobinuria	18 ( 10.5%)	49 ( 28.7%)	73 ( 42.7%)	31 ( 18.1%)	171
Axial spondyloarthritis	7 ( 4.1%)	106 ( 62.4%)	57 ( 33.5%)	0 ( 0.0%)	170
Hypopituitarism	54 ( 32.0%)	40 ( 23.7%)	71 ( 42.0%)	4 ( 2.4%)	169
Thyroid cancer	2 ( 1.2%)	24 ( 14.2%)	103 ( 60.9%)	40 ( 23.7%)	169
Mycobacterium abscessus infection	38 ( 22.6%)	11 ( 6.5%)	106 ( 63.1%)	13 ( 7.7%)	168
Endometrial cancer recurrent	0 ( 0.0%)	12 ( 7.1%)	148 ( 88.1%)	8 ( 4.8%)	168
Hyperthyroidism	4 ( 2.4%)	56 ( 33.3%)	93 ( 55.4%)	15 ( 8.9%)	168
Hypercalcaemia	24 ( 14.4%)	25 ( 15.0%)	103 ( 61.7%)	15 ( 9.0%)	167
Heart transplant	56 ( 33.5%)	36 ( 21.6%)	74 ( 44.3%)	1 ( 0.6%)	167
Gastrointestinal disorder prophylaxis	6 ( 3.6%)	28 ( 16.8%)	109 ( 65.3%)	24 ( 14.4%)	167
Thrombotic thrombocytopenic purpura	38 ( 22.9%)	70 ( 42.2%)	47 ( 28.3%)	11 ( 6.6%)	166
Metastases to lymph nodes	16 ( 9.6%)	28 ( 16.9%)	111 ( 66.9%)	11 ( 6.6%)	166
Chronic hepatitis C	1 ( 0.6%)	98 ( 59.0%)	58 ( 34.9%)	9 ( 5.4%)	166
Bronchopulmonary aspergillosis	14 ( 8.4%)	20 ( 12.0%)	122 ( 73.5%)	10 ( 6.0%)	166
Chronic cutaneous lupus erythematosus	2 ( 1.2%)	83 ( 50.0%)	80 ( 48.2%)	1 ( 0.6%)	166
Precocious puberty	165 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	165
Hyperkalaemia	26 ( 15.8%)	19 ( 11.5%)	57 ( 34.5%)	63 ( 38.2%)	165
Rectal adenocarcinoma	0 ( 0.0%)	55 ( 33.3%)	97 ( 58.8%)	13 ( 7.9%)	165
Mucopolysaccharidosis II	150 ( 91.5%)	10 ( 6.1%)	4 ( 2.4%)	0 ( 0.0%)	164
Hypovitaminosis	37 ( 22.7%)	20 ( 12.3%)	74 ( 45.4%)	32 ( 19.6%)	163
Hormone-dependent prostate cancer	0 ( 0.0%)	1 ( 0.6%)	100 ( 61.7%)	61 ( 37.7%)	162
Cerebrovascular accident prophylaxis	0 ( 0.0%)	7 ( 4.3%)	81 ( 50.3%)	73 ( 45.3%)	161
Bladder disorder	3 ( 1.9%)	8 ( 5.0%)	34 ( 21.1%)	116 ( 72.0%)	161
Antidepressant therapy	21 ( 13.1%)	59 ( 36.9%)	73 ( 45.6%)	7 ( 4.4%)	160

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
B precursor type acute leukaemia	136 ( 85.0%)	9 ( 5.6%)	13 ( 8.1%)	2 ( 1.3%)	160
Lung cancer metastatic	0 ( 0.0%)	13 ( 8.1%)	131 ( 81.9%)	16 ( 10.0%)	160
Small intestine carcinoma	18 ( 11.3%)	30 ( 18.9%)	69 ( 43.4%)	42 ( 26.4%)	159
Gastric ulcer	5 ( 3.1%)	7 ( 4.4%)	82 ( 51.6%)	65 ( 40.9%)	159
Antiretroviral therapy	15 ( 9.5%)	100 ( 63.3%)	43 ( 27.2%)	0 ( 0.0%)	158
Lung disorder	12 ( 7.6%)	37 ( 23.4%)	67 ( 42.4%)	42 ( 26.6%)	158
Menopause	0 ( 0.0%)	34 ( 21.7%)	103 ( 65.6%)	20 ( 12.7%)	157
Chronic graft versus host disease	53 ( 33.8%)	29 ( 18.5%)	71 ( 45.2%)	4 ( 2.5%)	157
Hypersomnia	18 ( 11.5%)	90 ( 57.3%)	48 ( 30.6%)	1 ( 0.6%)	157
Hormone therapy	15 ( 9.6%)	42 ( 26.8%)	79 ( 50.3%)	21 ( 13.4%)	157
Stem cell transplant	59 ( 38.3%)	28 ( 18.2%)	66 ( 42.9%)	1 ( 0.6%)	154
Immunodeficiency	33 ( 21.4%)	24 ( 15.6%)	84 ( 54.5%)	13 ( 8.4%)	154
Pulmonary fibrosis	2 ( 1.3%)	14 ( 9.2%)	81 ( 52.9%)	56 ( 36.6%)	153
Hypogammaglobulinaemia	29 ( 19.0%)	30 ( 19.6%)	81 ( 52.9%)	13 ( 8.5%)	153
Gastritis prophylaxis	7 ( 4.6%)	24 ( 15.9%)	90 ( 59.6%)	30 ( 19.9%)	151
Thrombotic microangiopathy	53 ( 35.1%)	48 ( 31.8%)	46 ( 30.5%)	4 ( 2.6%)	151
Influenza	46 ( 30.5%)	41 ( 27.2%)	43 ( 28.5%)	21 ( 13.9%)	151
Eosinophilic granulomatosis with polyangiitis	5 ( 3.3%)	27 ( 17.9%)	111 ( 73.5%)	8 ( 5.3%)	151
Venoocclusive liver disease	43 ( 28.9%)	50 ( 33.6%)	56 ( 37.6%)	0 ( 0.0%)	149
Myalgia	7 ( 4.7%)	32 ( 21.5%)	71 ( 47.7%)	39 ( 26.2%)	149
Sleep disorder therapy	2 ( 1.4%)	7 ( 4.7%)	27 ( 18.2%)	112 ( 75.7%)	148
Systemic scleroderma	10 ( 6.8%)	38 ( 25.7%)	88 ( 59.5%)	12 ( 8.1%)	148
Blood pressure increased	1 ( 0.7%)	27 ( 18.2%)	104 ( 70.3%)	16 ( 10.8%)	148
Alopecia areata	39 ( 26.4%)	60 ( 40.5%)	46 ( 31.1%)	3 ( 2.0%)	148
Behaviour disorder	94 ( 63.9%)	13 ( 8.8%)	15 ( 10.2%)	25 ( 17.0%)	147
Erectile dysfunction	0 ( 0.0%)	28 ( 19.0%)	111 ( 75.5%)	8 ( 5.4%)	147
Central nervous system lymphoma	7 ( 4.8%)	52 ( 35.6%)	77 ( 52.7%)	10 ( 6.8%)	146

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Chronic rhinosinusitis with nasal polyps	7 ( 4.8%)	54 ( 37.2%)	74 ( 51.0%)	10 ( 6.9%)	145
Bacteraemia	14 ( 9.7%)	28 ( 19.3%)	93 ( 64.1%)	10 ( 6.9%)	145
Chronic inflammatory demyelinating polyradiculoneuro	14 ( 9.7%)	27 ( 18.8%)	89 ( 61.8%)	14 ( 9.7%)	144
Light chain disease	0 ( 0.0%)	4 ( 2.8%)	136 ( 94.4%)	4 ( 2.8%)	144
Premature baby	143 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	143
HER2 negative breast cancer	0 ( 0.0%)	32 ( 22.5%)	81 ( 57.0%)	29 ( 20.4%)	142
Hepatic encephalopathy	0 ( 0.0%)	13 ( 9.2%)	107 ( 75.4%)	22 ( 15.5%)	142
Osteoporosis postmenopausal	1 ( 0.7%)	0 ( 0.0%)	94 ( 66.2%)	47 ( 33.1%)	142
Assisted reproductive technology	0 ( 0.0%)	141 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	141
Metastases to central nervous system	8 ( 5.7%)	28 ( 19.9%)	98 ( 69.5%)	7 ( 5.0%)	141
Anxiety disorder	25 ( 17.9%)	47 ( 33.6%)	60 ( 42.9%)	8 ( 5.7%)	140
Device related infection	15 ( 10.7%)	22 ( 15.7%)	71 ( 50.7%)	32 ( 22.9%)	140
Mania	57 ( 40.7%)	64 ( 45.7%)	19 ( 13.6%)	0 ( 0.0%)	140
Decreased appetite	6 ( 4.3%)	14 ( 10.1%)	89 ( 64.0%)	30 ( 21.6%)	139
Intrauterine contraception	21 ( 15.2%)	116 ( 84.1%)	1 ( 0.7%)	0 ( 0.0%)	138
Hereditary angioedema with C1 esterase inhibitor def	9 ( 6.6%)	72 ( 52.6%)	49 ( 35.8%)	7 ( 5.1%)	137
Hypocalcaemia	24 ( 17.5%)	24 ( 17.5%)	73 ( 53.3%)	16 ( 11.7%)	137
Sarcoidosis	3 ( 2.2%)	41 ( 29.9%)	89 ( 65.0%)	4 ( 2.9%)	137
Fabry's disease	29 ( 21.2%)	52 ( 38.0%)	51 ( 37.2%)	5 ( 3.6%)	137
Haematuria	10 ( 7.4%)	65 ( 47.8%)	52 ( 38.2%)	9 ( 6.6%)	136
Groin abscess	0 ( 0.0%)	135 ( 99.3%)	1 ( 0.7%)	0 ( 0.0%)	136
Poisoning deliberate	20 ( 14.8%)	68 ( 50.4%)	31 ( 23.0%)	16 ( 11.9%)	135
Drug use disorder	20 ( 14.8%)	80 ( 59.3%)	33 ( 24.4%)	2 ( 1.5%)	135
Stress	2 ( 1.5%)	62 ( 45.9%)	23 ( 17.0%)	48 ( 35.6%)	135
Pancreatic neuroendocrine tumour	1 ( 0.7%)	24 ( 17.8%)	102 ( 75.6%)	8 ( 5.9%)	135
Hyperglycaemia	6 ( 4.5%)	16 ( 11.9%)	101 ( 75.4%)	11 ( 8.2%)	134
Obsessive-compulsive disorder	82 ( 61.2%)	36 ( 26.9%)	15 ( 11.2%)	1 ( 0.7%)	134

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Thrombocytopenia	36 ( 27.1%)	29 ( 21.8%)	51 ( 38.3%)	17 ( 12.8%)	133
Pain prophylaxis	1 ( 0.8%)	29 ( 21.8%)	86 ( 64.7%)	17 ( 12.8%)	133
Metastasis	7 ( 5.3%)	15 ( 11.4%)	100 ( 75.8%)	10 ( 7.6%)	132
Fluid replacement	12 ( 9.1%)	59 ( 44.7%)	57 ( 43.2%)	4 ( 3.0%)	132
Schizoaffective disorder bipolar type	64 ( 48.5%)	31 ( 23.5%)	37 ( 28.0%)	0 ( 0.0%)	132
Blood glucose increased	13 ( 9.8%)	18 ( 13.6%)	86 ( 65.2%)	15 ( 11.4%)	132
Hypoglycaemia	15 ( 11.4%)	24 ( 18.2%)	54 ( 40.9%)	39 ( 29.5%)	132
Nephrogenic anaemia	7 ( 5.3%)	19 ( 14.4%)	50 ( 37.9%)	56 ( 42.4%)	132
Diabetic retinal oedema	0 ( 0.0%)	11 ( 8.4%)	107 ( 81.7%)	13 ( 9.9%)	131
Psychotic symptom	39 ( 29.8%)	34 ( 26.0%)	28 ( 21.4%)	30 ( 22.9%)	131
Hypophosphatasia	63 ( 48.1%)	27 ( 20.6%)	39 ( 29.8%)	2 ( 1.5%)	131
Delirium	4 ( 3.1%)	49 ( 37.4%)	59 ( 45.0%)	19 ( 14.5%)	131
Acute myeloid leukaemia recurrent	21 ( 16.2%)	16 ( 12.3%)	61 ( 46.9%)	32 ( 24.6%)	130
Generalised anxiety disorder	5 ( 3.9%)	42 ( 32.6%)	78 ( 60.5%)	4 ( 3.1%)	129
Septic shock	25 ( 19.4%)	22 ( 17.1%)	68 ( 52.7%)	14 ( 10.9%)	129
Marginal zone lymphoma	0 ( 0.0%)	24 ( 18.6%)	90 ( 69.8%)	15 ( 11.6%)	129
Sjogren's syndrome	7 ( 5.4%)	41 ( 31.8%)	69 ( 53.5%)	12 ( 9.3%)	129
Osteitis	11 ( 8.5%)	36 ( 27.9%)	54 ( 41.9%)	28 ( 21.7%)	129
Local anaesthesia	18 ( 14.1%)	31 ( 24.2%)	56 ( 43.8%)	23 ( 18.0%)	128
Systemic mastocytosis	5 ( 3.9%)	24 ( 18.8%)	76 ( 59.4%)	23 ( 18.0%)	128
Blood pressure management	0 ( 0.0%)	28 ( 21.9%)	73 ( 57.0%)	27 ( 21.1%)	128
Plasma cell leukaemia	0 ( 0.0%)	23 ( 18.1%)	100 ( 78.7%)	4 ( 3.1%)	127
Ductal adenocarcinoma of pancreas	0 ( 0.0%)	7 ( 5.6%)	82 ( 65.1%)	37 ( 29.4%)	126
Fatigue	3 ( 2.4%)	36 ( 28.8%)	72 ( 57.6%)	14 ( 11.2%)	125
Haemophilia	59 ( 47.2%)	29 ( 23.2%)	23 ( 18.4%)	14 ( 11.2%)	125
Multiple allergies	26 ( 20.8%)	46 ( 36.8%)	48 ( 38.4%)	5 ( 4.0%)	125
Graves' disease	42 ( 33.6%)	45 ( 36.0%)	32 ( 25.6%)	6 ( 4.8%)	125

### Indication Summary Table

#### Derived Age Group

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Bone disorder	7 ( 5.7%)	10 ( 8.1%)	80 ( 65.0%)	26 ( 21.1%)	123
Irritable bowel syndrome	3 ( 2.4%)	34 ( 27.6%)	63 ( 51.2%)	23 ( 18.7%)	123
Sciatica	3 ( 2.4%)	28 ( 22.8%)	82 ( 66.7%)	10 ( 8.1%)	123
Breast neoplasm	0 ( 0.0%)	35 ( 28.5%)	77 ( 62.6%)	11 ( 8.9%)	123
Autoimmune thyroiditis	22 ( 18.0%)	38 ( 31.1%)	51 ( 41.8%)	11 ( 9.0%)	122
Fluid retention	2 ( 1.6%)	13 ( 10.7%)	61 ( 50.0%)	46 ( 37.7%)	122
Prophylaxis against HIV infection	27 ( 22.1%)	69 ( 56.6%)	26 ( 21.3%)	0 ( 0.0%)	122
Glioblastoma	10 ( 8.3%)	42 ( 34.7%)	59 ( 48.8%)	10 ( 8.3%)	121
Symptomatic treatment	9 ( 7.5%)	16 ( 13.3%)	75 ( 62.5%)	20 ( 16.7%)	120
Diffuse large B-cell lymphoma recurrent	1 ( 0.8%)	19 ( 15.8%)	91 ( 75.8%)	9 ( 7.5%)	120
Bone cancer	4 ( 3.3%)	7 ( 5.8%)	71 ( 59.2%)	38 ( 31.7%)	120
Supportive care	2 ( 1.7%)	57 ( 47.5%)	51 ( 42.5%)	10 ( 8.3%)	120
Procedural pain	11 ( 9.2%)	17 ( 14.3%)	83 ( 69.7%)	8 ( 6.7%)	119
Pseudomonas infection	19 ( 16.0%)	29 ( 24.4%)	52 ( 43.7%)	19 ( 16.0%)	119
Endocarditis	5 ( 4.2%)	15 ( 12.6%)	52 ( 43.7%)	47 ( 39.5%)	119
Adrenocortical carcinoma	8 ( 6.7%)	80 ( 67.2%)	31 ( 26.1%)	0 ( 0.0%)	119
Vascular device infection	31 ( 26.3%)	14 ( 11.9%)	53 ( 44.9%)	20 ( 16.9%)	118
Adrenal insufficiency	7 ( 5.9%)	53 ( 44.9%)	43 ( 36.4%)	15 ( 12.7%)	118
Upper respiratory tract infection	18 ( 15.3%)	39 ( 33.1%)	52 ( 44.1%)	9 ( 7.6%)	118
Behcet's syndrome	13 ( 11.0%)	70 ( 59.3%)	25 ( 21.2%)	10 ( 8.5%)	118
Secondary immunodeficiency	9 ( 7.7%)	11 ( 9.4%)	76 ( 65.0%)	21 ( 17.9%)	117
Ischaemic stroke	0 ( 0.0%)	12 ( 10.3%)	67 ( 57.3%)	38 ( 32.5%)	117
Enterococcal infection	29 ( 24.8%)	6 ( 5.1%)	70 ( 59.8%)	12 ( 10.3%)	117
Osteoporosis prophylaxis	3 ( 2.6%)	20 ( 17.1%)	76 ( 65.0%)	18 ( 15.4%)	117
Prostatitis	0 ( 0.0%)	49 ( 41.9%)	56 ( 47.9%)	12 ( 10.3%)	117
Peritoneal dialysis	0 ( 0.0%)	23 ( 19.7%)	61 ( 52.1%)	33 ( 28.2%)	117
Bone pain	1 ( 0.9%)	34 ( 29.3%)	62 ( 53.4%)	19 ( 16.4%)	116



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Respiratory tract infection	19 ( 16.5%)	22 ( 19.1%)	58 ( 50.4%)	16 ( 13.9%)	115
Antifungal treatment	20 ( 17.4%)	31 ( 27.0%)	57 ( 49.6%)	7 ( 6.1%)	115
Richter's syndrome	0 ( 0.0%)	5 ( 4.4%)	81 ( 71.1%)	28 ( 24.6%)	114
Productive cough	5 ( 4.4%)	14 ( 12.3%)	63 ( 55.3%)	32 ( 28.1%)	114
Product use in unapproved indication	16 ( 14.0%)	35 ( 30.7%)	46 ( 40.4%)	17 ( 14.9%)	114
Ovulation induction	1 ( 0.9%)	113 ( 99.1%)	0 ( 0.0%)	0 ( 0.0%)	114
Oesophageal squamous cell carcinoma	0 ( 0.0%)	9 ( 8.0%)	99 ( 87.6%)	5 ( 4.4%)	113
Smoking cessation therapy	0 ( 0.0%)	28 ( 24.8%)	74 ( 65.5%)	11 ( 9.7%)	113
Spondylitis	3 ( 2.7%)	75 ( 66.4%)	31 ( 27.4%)	4 ( 3.5%)	113
Stomatitis	1 ( 0.9%)	24 ( 21.4%)	72 ( 64.3%)	15 ( 13.4%)	112
Opportunistic infection prophylaxis	4 ( 3.6%)	10 ( 9.0%)	81 ( 73.0%)	16 ( 14.4%)	111
Congenital cystic kidney disease	3 ( 2.7%)	55 ( 49.5%)	52 ( 46.8%)	1 ( 0.9%)	111
Toxicity to various agents	54 ( 49.1%)	26 ( 23.6%)	28 ( 25.5%)	2 ( 1.8%)	110
Malignant peritoneal neoplasm	2 ( 1.8%)	13 ( 11.8%)	80 ( 72.7%)	15 ( 13.6%)	110
Constipation prophylaxis	2 ( 1.8%)	9 ( 8.2%)	85 ( 77.3%)	14 ( 12.7%)	110
Tachycardia	16 ( 14.7%)	26 ( 23.9%)	47 ( 43.1%)	20 ( 18.3%)	109
Swelling	6 ( 5.5%)	15 ( 13.8%)	30 ( 27.5%)	58 ( 53.2%)	109
Polyuria	15 ( 13.8%)	12 ( 11.0%)	59 ( 54.1%)	23 ( 21.1%)	109
Pyoderma gangrenosum	9 ( 8.3%)	55 ( 50.5%)	33 ( 30.3%)	12 ( 11.0%)	109
Anaphylactic reaction	42 ( 38.9%)	22 ( 20.4%)	43 ( 39.8%)	1 ( 0.9%)	108
Clostridium difficile infection	12 ( 11.1%)	29 ( 26.9%)	42 ( 38.9%)	25 ( 23.1%)	108
Intellectual disability	76 ( 70.4%)	20 ( 18.5%)	12 ( 11.1%)	0 ( 0.0%)	108
Menopausal symptoms	0 ( 0.0%)	15 ( 13.9%)	82 ( 75.9%)	11 ( 10.2%)	108
Neck pain	2 ( 1.9%)	46 ( 42.6%)	41 ( 38.0%)	19 ( 17.6%)	108
Leukaemia	37 ( 34.6%)	7 ( 6.5%)	43 ( 40.2%)	20 ( 18.7%)	107
Colonoscopy	4 ( 3.7%)	23 ( 21.5%)	65 ( 60.7%)	15 ( 14.0%)	107
Prostatomegaly	0 ( 0.0%)	3 ( 2.8%)	63 ( 58.9%)	41 ( 38.3%)	107

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Gastroenteropancreatic neuroendocrine tumour disease	1 ( 0.9%)	15 ( 14.0%)	72 ( 67.3%)	19 ( 17.8%)	107
Endometrial adenocarcinoma	0 ( 0.0%)	8 ( 7.5%)	93 ( 86.9%)	6 ( 5.6%)	107
Staphylococcal bacteraemia	17 ( 15.9%)	17 ( 15.9%)	48 ( 44.9%)	25 ( 23.4%)	107
Palliative care	80 ( 74.8%)	1 ( 0.9%)	23 ( 21.5%)	3 ( 2.8%)	107
Personality disorder	5 ( 4.7%)	34 ( 31.8%)	60 ( 56.1%)	8 ( 7.5%)	107
Insulin resistance	5 ( 4.7%)	75 ( 70.1%)	27 ( 25.2%)	0 ( 0.0%)	107
Diverticulitis	0 ( 0.0%)	35 ( 33.0%)	35 ( 33.0%)	36 ( 34.0%)	106
Oral herpes	5 ( 4.7%)	40 ( 37.7%)	54 ( 50.9%)	7 ( 6.6%)	106
Skin disorder	3 ( 2.8%)	27 ( 25.5%)	50 ( 47.2%)	26 ( 24.5%)	106
Pleural mesothelioma malignant	0 ( 0.0%)	2 ( 1.9%)	49 ( 46.7%)	54 ( 51.4%)	105
Hot flush	0 ( 0.0%)	10 ( 9.5%)	73 ( 69.5%)	22 ( 21.0%)	105
Oesophageal cancer metastatic	0 ( 0.0%)	8 ( 7.6%)	95 ( 90.5%)	2 ( 1.9%)	105
Coagulopathy	16 ( 15.2%)	4 ( 3.8%)	40 ( 38.1%)	45 ( 42.9%)	105
Polycythaemia vera	9 ( 8.7%)	12 ( 11.5%)	62 ( 59.6%)	21 ( 20.2%)	104
Rheumatic disorder	3 ( 2.9%)	21 ( 20.2%)	34 ( 32.7%)	46 ( 44.2%)	104
Medulloblastoma	94 ( 90.4%)	10 ( 9.6%)	0 ( 0.0%)	0 ( 0.0%)	104
Ventricular fibrillation	4 ( 3.8%)	2 ( 1.9%)	12 ( 11.5%)	86 ( 82.7%)	104
Skin infection	10 ( 9.6%)	16 ( 15.4%)	60 ( 57.7%)	18 ( 17.3%)	104
Low density lipoprotein increased	0 ( 0.0%)	7 ( 6.8%)	78 ( 75.7%)	18 ( 17.5%)	103
Acute myeloid leukaemia refractory	14 ( 13.7%)	14 ( 13.7%)	41 ( 40.2%)	33 ( 32.4%)	102
Vasculitis	7 ( 6.9%)	27 ( 26.7%)	54 ( 53.5%)	13 ( 12.9%)	101
Lung carcinoma cell type unspecified stage IV	1 ( 1.0%)	3 ( 3.0%)	91 ( 90.1%)	6 ( 5.9%)	101
Hypomagnesaemia	3 ( 3.0%)	6 ( 6.0%)	75 ( 75.0%)	16 ( 16.0%)	100
Antiinflammatory therapy	12 ( 12.0%)	24 ( 24.0%)	53 ( 53.0%)	11 ( 11.0%)	100
K-ras gene mutation	0 ( 0.0%)	4 ( 4.0%)	84 ( 84.0%)	12 ( 12.0%)	100
Atrial flutter	2 ( 2.0%)	5 ( 5.1%)	57 ( 57.6%)	35 ( 35.4%)	99
Allergy prophylaxis	2 ( 2.0%)	11 ( 11.1%)	83 ( 83.8%)	3 ( 3.0%)	99

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Antacid therapy	2 ( 2.0%)	5 ( 5.1%)	27 ( 27.6%)	64 ( 65.3%)	98
Suicidal ideation	23 ( 23.5%)	31 ( 31.6%)	44 ( 44.9%)	0 ( 0.0%)	98
Antiemetic supportive care	9 ( 9.2%)	36 ( 36.7%)	51 ( 52.0%)	2 ( 2.0%)	98
Acute promyelocytic leukaemia	10 ( 10.3%)	38 ( 39.2%)	32 ( 33.0%)	17 ( 17.5%)	97
Nervous system disorder	13 ( 13.4%)	47 ( 48.5%)	30 ( 30.9%)	7 ( 7.2%)	97
Glioma	26 ( 26.8%)	47 ( 48.5%)	24 ( 24.7%)	0 ( 0.0%)	97
Transplant	63 ( 65.6%)	10 ( 10.4%)	22 ( 22.9%)	1 ( 1.0%)	96
Wheezing	15 ( 15.6%)	13 ( 13.5%)	50 ( 52.1%)	18 ( 18.8%)	96
Antiallergic therapy	16 ( 16.7%)	14 ( 14.6%)	57 ( 59.4%)	9 ( 9.4%)	96
Dementia with Lewy bodies	0 ( 0.0%)	0 ( 0.0%)	62 ( 64.6%)	34 ( 35.4%)	96
Lung transplant	9 ( 9.5%)	14 ( 14.7%)	70 ( 73.7%)	2 ( 2.1%)	95
Haemorrhoids	22 ( 23.2%)	16 ( 16.8%)	52 ( 54.7%)	5 ( 5.3%)	95
Alcohol withdrawal syndrome	0 ( 0.0%)	67 ( 71.3%)	27 ( 28.7%)	0 ( 0.0%)	94
Computerised tomogram abdomen	3 ( 3.2%)	30 ( 31.9%)	43 ( 45.7%)	18 ( 19.1%)	94
Focal segmental glomerulosclerosis	65 ( 69.1%)	8 ( 8.5%)	16 ( 17.0%)	5 ( 5.3%)	94
Desmoplastic small round cell tumour	24 ( 25.5%)	70 ( 74.5%)	0 ( 0.0%)	0 ( 0.0%)	94
Atypical mycobacterial infection	5 ( 5.4%)	30 ( 32.3%)	54 ( 58.1%)	4 ( 4.3%)	93
Lung squamous cell carcinoma stage IV	0 ( 0.0%)	0 ( 0.0%)	83 ( 89.2%)	10 ( 10.8%)	93
Metastases to peritoneum	0 ( 0.0%)	21 ( 22.6%)	66 ( 71.0%)	6 ( 6.5%)	93
Angioedema	5 ( 5.4%)	45 ( 48.9%)	29 ( 31.5%)	13 ( 14.1%)	92
Familial mediterranean fever	51 ( 55.4%)	29 ( 31.5%)	10 ( 10.9%)	2 ( 2.2%)	92
Cardiogenic shock	0 ( 0.0%)	17 ( 18.5%)	31 ( 33.7%)	44 ( 47.8%)	92
Neutrophil count decreased	1 ( 1.1%)	19 ( 20.7%)	46 ( 50.0%)	26 ( 28.3%)	92
Hyperparathyroidism secondary	0 ( 0.0%)	18 ( 19.8%)	50 ( 54.9%)	23 ( 25.3%)	91
Phenylketonuria	57 ( 62.6%)	28 ( 30.8%)	6 ( 6.6%)	0 ( 0.0%)	91
Myelofibrosis	0 ( 0.0%)	1 ( 1.1%)	58 ( 63.7%)	32 ( 35.2%)	91
Osteopenia	7 ( 7.7%)	4 ( 4.4%)	55 ( 60.4%)	25 ( 27.5%)	91

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Mycobacterial infection	13 ( 14.3%)	40 ( 44.0%)	27 ( 29.7%)	11 ( 12.1%)	91
Aggression	54 ( 59.3%)	25 ( 27.5%)	5 ( 5.5%)	7 ( 7.7%)	91
Osteosarcoma	64 ( 71.1%)	18 ( 20.0%)	8 ( 8.9%)	0 ( 0.0%)	90
Chronic sinusitis	0 ( 0.0%)	35 ( 38.9%)	48 ( 53.3%)	7 ( 7.8%)	90
Myocarditis	22 ( 24.4%)	18 ( 20.0%)	45 ( 50.0%)	5 ( 5.6%)	90
Graft versus host disease in gastrointestinal tract	7 ( 7.8%)	35 ( 38.9%)	48 ( 53.3%)	0 ( 0.0%)	90
HER2 positive gastric cancer	9 ( 10.0%)	1 ( 1.1%)	67 ( 74.4%)	13 ( 14.4%)	90
Colon neoplasm	0 ( 0.0%)	0 ( 0.0%)	78 ( 86.7%)	12 ( 13.3%)	90
Rheumatoid factor positive	2 ( 2.2%)	14 ( 15.7%)	62 ( 69.7%)	11 ( 12.4%)	89
Growth disorder	86 ( 96.6%)	1 ( 1.1%)	2 ( 2.2%)	0 ( 0.0%)	89
Invasive breast carcinoma	0 ( 0.0%)	52 ( 58.4%)	36 ( 40.4%)	1 ( 1.1%)	89
Dental local anaesthesia	22 ( 25.0%)	35 ( 39.8%)	28 ( 31.8%)	3 ( 3.4%)	88
Acute coronary syndrome	0 ( 0.0%)	12 ( 13.6%)	64 ( 72.7%)	12 ( 13.6%)	88
Endometriosis	23 ( 26.1%)	63 ( 71.6%)	1 ( 1.1%)	1 ( 1.1%)	88
Migraine without aura	14 ( 15.9%)	38 ( 43.2%)	35 ( 39.8%)	1 ( 1.1%)	88
Bipolar II disorder	23 ( 26.1%)	46 ( 52.3%)	19 ( 21.6%)	0 ( 0.0%)	88
Muscle relaxant therapy	8 ( 9.1%)	27 ( 30.7%)	50 ( 56.8%)	3 ( 3.4%)	88
Emphysema	0 ( 0.0%)	0 ( 0.0%)	64 ( 73.6%)	23 ( 26.4%)	87
Arthritis bacterial	5 ( 5.8%)	15 ( 17.4%)	31 ( 36.0%)	35 ( 40.7%)	86
Encephalitis autoimmune	35 ( 40.7%)	40 ( 46.5%)	11 ( 12.8%)	0 ( 0.0%)	86
Lower respiratory tract infection	15 ( 17.4%)	16 ( 18.6%)	51 ( 59.3%)	4 ( 4.7%)	86
Refractory cancer	85 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	85
Malabsorption	21 ( 24.7%)	22 ( 25.9%)	34 ( 40.0%)	8 ( 9.4%)	85
Combined immunodeficiency	34 ( 40.0%)	35 ( 41.2%)	13 ( 15.3%)	3 ( 3.5%)	85
Proteinuria	20 ( 23.5%)	24 ( 28.2%)	29 ( 34.1%)	12 ( 14.1%)	85
Acute leukaemia	7 ( 8.2%)	16 ( 18.8%)	57 ( 67.1%)	5 ( 5.9%)	85
Rhinitis	20 ( 23.5%)	12 ( 14.1%)	38 ( 44.7%)	15 ( 17.6%)	85

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Haemorrhage prophylaxis	29 ( 34.1%)	10 ( 11.8%)	43 ( 50.6%)	3 ( 3.5%)	85
Spinal pain	5 ( 5.9%)	31 ( 36.5%)	37 ( 43.5%)	12 ( 14.1%)	85
Monoclonal gammopathy	0 ( 0.0%)	12 ( 14.1%)	44 ( 51.8%)	29 ( 34.1%)	85
Pneumonia aspiration	1 ( 1.2%)	5 ( 5.9%)	52 ( 61.2%)	27 ( 31.8%)	85
Senile osteoporosis	0 ( 0.0%)	4 ( 4.8%)	55 ( 65.5%)	25 ( 29.8%)	84
Glycogen storage disease type II	40 ( 47.6%)	21 ( 25.0%)	21 ( 25.0%)	2 ( 2.4%)	84
Magnetic resonance imaging	8 ( 9.5%)	29 ( 34.5%)	36 ( 42.9%)	11 ( 13.1%)	84
Renal cancer metastatic	0 ( 0.0%)	2 ( 2.4%)	72 ( 85.7%)	10 ( 11.9%)	84
Philadelphia chromosome positive	1 ( 1.2%)	44 ( 53.0%)	33 ( 39.8%)	5 ( 6.0%)	83
Spinal anaesthesia	26 ( 31.3%)	28 ( 33.7%)	24 ( 28.9%)	5 ( 6.0%)	83
Glomerulonephritis membranous	5 ( 6.0%)	38 ( 45.8%)	38 ( 45.8%)	2 ( 2.4%)	83
Lung carcinoma cell type unspecified stage 0	0 ( 0.0%)	4 ( 4.9%)	50 ( 61.0%)	28 ( 34.1%)	82
Secretion discharge	4 ( 4.9%)	1 ( 1.2%)	4 ( 4.9%)	73 ( 89.0%)	82
Polyneuropathy	6 ( 7.3%)	47 ( 57.3%)	19 ( 23.2%)	10 ( 12.2%)	82
Idiopathic urticaria	7 ( 8.6%)	42 ( 51.9%)	28 ( 34.6%)	4 ( 4.9%)	81
Left ventricular failure	0 ( 0.0%)	9 ( 11.1%)	48 ( 59.3%)	24 ( 29.6%)	81
Atypical teratoid/rhabdoid tumour of CNS	77 ( 95.1%)	0 ( 0.0%)	4 ( 4.9%)	0 ( 0.0%)	81
Acute graft versus host disease	51 ( 63.0%)	10 ( 12.3%)	19 ( 23.5%)	1 ( 1.2%)	81
Langerhans' cell histiocytosis	52 ( 64.2%)	12 ( 14.8%)	3 ( 3.7%)	14 ( 17.3%)	81
Thyrotoxic crisis	6 ( 7.5%)	64 ( 80.0%)	10 ( 12.5%)	0 ( 0.0%)	80
Head and neck cancer	0 ( 0.0%)	4 ( 5.0%)	54 ( 67.5%)	22 ( 27.5%)	80
Bone marrow transplant	25 ( 31.3%)	5 ( 6.3%)	49 ( 61.3%)	1 ( 1.3%)	80
Transient ischaemic attack	0 ( 0.0%)	1 ( 1.3%)	39 ( 48.8%)	40 ( 50.0%)	80
Ovarian epithelial cancer	0 ( 0.0%)	42 ( 52.5%)	27 ( 33.8%)	11 ( 13.8%)	80
Multiple sclerosis relapse	3 ( 3.8%)	58 ( 72.5%)	19 ( 23.8%)	0 ( 0.0%)	80
Skin ulcer	2 ( 2.5%)	17 ( 21.3%)	52 ( 65.0%)	9 ( 11.3%)	80
Anal cancer	0 ( 0.0%)	17 ( 21.3%)	54 ( 67.5%)	9 ( 11.3%)	80

Indication Summary Table  
Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Alcoholism	2 ( 2.5%)	49 ( 62.0%)	27 ( 34.2%)	1 ( 1.3%)	79
Metastatic neoplasm	5 ( 6.3%)	21 ( 26.6%)	46 ( 58.2%)	7 ( 8.9%)	79
Parkinsonism	0 ( 0.0%)	10 ( 12.7%)	55 ( 69.6%)	14 ( 17.7%)	79
Cystitis	3 ( 3.8%)	8 ( 10.1%)	43 ( 54.4%)	25 ( 31.6%)	79
Panic disorder	10 ( 12.7%)	39 ( 49.4%)	25 ( 31.6%)	5 ( 6.3%)	79
Astrocytoma	17 ( 21.5%)	44 ( 55.7%)	18 ( 22.8%)	0 ( 0.0%)	79
Maintenance of anaesthesia	26 ( 32.9%)	23 ( 29.1%)	21 ( 26.6%)	9 ( 11.4%)	79
Nasal congestion	16 ( 20.3%)	15 ( 19.0%)	41 ( 51.9%)	7 ( 8.9%)	79
Tremor	7 ( 8.9%)	4 ( 5.1%)	54 ( 68.4%)	14 ( 17.7%)	79
Intervertebral discitis	0 ( 0.0%)	17 ( 21.5%)	38 ( 48.1%)	24 ( 30.4%)	79
Arthritis infective	11 ( 14.1%)	6 ( 7.7%)	59 ( 75.6%)	2 ( 2.6%)	78
Spondyloarthropathy	2 ( 2.6%)	33 ( 42.3%)	40 ( 51.3%)	3 ( 3.8%)	78
Dyskinesia	7 ( 9.0%)	9 ( 11.5%)	44 ( 56.4%)	18 ( 23.1%)	78
B-cell small lymphocytic lymphoma	0 ( 0.0%)	2 ( 2.6%)	55 ( 70.5%)	21 ( 26.9%)	78
B-cell lymphoma refractory	0 ( 0.0%)	7 ( 9.0%)	71 ( 91.0%)	0 ( 0.0%)	78
Hiatus hernia	1 ( 1.3%)	4 ( 5.1%)	60 ( 76.9%)	13 ( 16.7%)	78
Pneumonia bacterial	2 ( 2.6%)	3 ( 3.9%)	48 ( 62.3%)	24 ( 31.2%)	77
Open angle glaucoma	0 ( 0.0%)	18 ( 23.4%)	33 ( 42.9%)	26 ( 33.8%)	77
Proctalgia	63 ( 81.8%)	7 ( 9.1%)	6 ( 7.8%)	1 ( 1.3%)	77
Bronchospasm	11 ( 14.3%)	14 ( 18.2%)	37 ( 48.1%)	15 ( 19.5%)	77
Peritonitis	21 ( 27.3%)	13 ( 16.9%)	24 ( 31.2%)	19 ( 24.7%)	77
General physical condition	13 ( 16.9%)	11 ( 14.3%)	46 ( 59.7%)	7 ( 9.1%)	77
Gestational diabetes	19 ( 24.7%)	58 ( 75.3%)	0 ( 0.0%)	0 ( 0.0%)	77
Dehydration	23 ( 29.9%)	8 ( 10.4%)	35 ( 45.5%)	11 ( 14.3%)	77
Breast cancer recurrent	0 ( 0.0%)	13 ( 16.9%)	49 ( 63.6%)	15 ( 19.5%)	77
Bladder transitional cell carcinoma	0 ( 0.0%)	1 ( 1.3%)	59 ( 77.6%)	16 ( 21.1%)	76
Follicular lymphoma stage IV	0 ( 0.0%)	13 ( 17.1%)	38 ( 50.0%)	25 ( 32.9%)	76

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Drug reaction with eosinophilia and systemic symptom	36 ( 47.4%)	6 ( 7.9%)	30 ( 39.5%)	4 ( 5.3%)	76
Myositis	4 ( 5.3%)	34 ( 44.7%)	32 ( 42.1%)	6 ( 7.9%)	76
Macular degeneration	0 ( 0.0%)	3 ( 3.9%)	26 ( 34.2%)	47 ( 61.8%)	76
Psychiatric symptom	12 ( 15.8%)	39 ( 51.3%)	25 ( 32.9%)	0 ( 0.0%)	76
Antiviral treatment	15 ( 20.0%)	21 ( 28.0%)	32 ( 42.7%)	7 ( 9.3%)	75
Overweight	1 ( 1.3%)	30 ( 40.0%)	43 ( 57.3%)	1 ( 1.3%)	75
Cluster headache	3 ( 4.0%)	53 ( 70.7%)	19 ( 25.3%)	0 ( 0.0%)	75
Bowel movement irregularity	0 ( 0.0%)	1 ( 1.3%)	44 ( 58.7%)	30 ( 40.0%)	75
Dizziness	10 ( 13.3%)	10 ( 13.3%)	45 ( 60.0%)	10 ( 13.3%)	75
Pneumothorax	1 ( 1.3%)	4 ( 5.3%)	4 ( 5.3%)	66 ( 88.0%)	75
Pustular psoriasis	13 ( 17.3%)	17 ( 22.7%)	35 ( 46.7%)	10 ( 13.3%)	75
Chronic gastritis	2 ( 2.7%)	15 ( 20.0%)	41 ( 54.7%)	17 ( 22.7%)	75
Dry skin	8 ( 10.7%)	11 ( 14.7%)	43 ( 57.3%)	13 ( 17.3%)	75
Liver disorder	8 ( 10.8%)	19 ( 25.7%)	42 ( 56.8%)	5 ( 6.8%)	74
Peripheral arterial occlusive disease	1 ( 1.4%)	0 ( 0.0%)	44 ( 59.5%)	29 ( 39.2%)	74
Pancreatic failure	5 ( 6.8%)	18 ( 24.3%)	35 ( 47.3%)	16 ( 21.6%)	74
Blood triglycerides increased	1 ( 1.4%)	6 ( 8.1%)	52 ( 70.3%)	15 ( 20.3%)	74
Cushing's syndrome	4 ( 5.4%)	23 ( 31.1%)	35 ( 47.3%)	12 ( 16.2%)	74
Ovarian cancer stage III	0 ( 0.0%)	7 ( 9.5%)	67 ( 90.5%)	0 ( 0.0%)	74
Cervix carcinoma stage IV	0 ( 0.0%)	29 ( 39.7%)	44 ( 60.3%)	0 ( 0.0%)	73
Pericarditis	4 ( 5.5%)	44 ( 60.3%)	17 ( 23.3%)	8 ( 11.0%)	73
Clinically isolated syndrome	2 ( 2.7%)	27 ( 37.0%)	43 ( 58.9%)	1 ( 1.4%)	73
Stiff person syndrome	14 ( 19.2%)	51 ( 69.9%)	8 ( 11.0%)	0 ( 0.0%)	73
Conjunctivitis	12 ( 16.4%)	9 ( 12.3%)	36 ( 49.3%)	16 ( 21.9%)	73
Duchenne muscular dystrophy	69 ( 94.5%)	4 ( 5.5%)	0 ( 0.0%)	0 ( 0.0%)	73
Ovarian cancer recurrent	0 ( 0.0%)	9 ( 12.3%)	60 ( 82.2%)	4 ( 5.5%)	73
Dermatitis contact	7 ( 9.6%)	24 ( 32.9%)	30 ( 41.1%)	12 ( 16.4%)	73

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tumour lysis syndrome	7 ( 9.6%)	14 ( 19.2%)	23 ( 31.5%)	29 ( 39.7%)	73
Primary mediastinal large B-cell lymphoma	56 ( 76.7%)	17 ( 23.3%)	0 ( 0.0%)	0 ( 0.0%)	73
Vitamin B12 deficiency	13 ( 17.8%)	16 ( 21.9%)	33 ( 45.2%)	11 ( 15.1%)	73
Selective IgG subclass deficiency	0 ( 0.0%)	15 ( 20.5%)	48 ( 65.8%)	10 ( 13.7%)	73
Autoimmune haemolytic anaemia	17 ( 23.6%)	3 ( 4.2%)	50 ( 69.4%)	2 ( 2.8%)	72
Meningitis tuberculous	24 ( 33.3%)	9 ( 12.5%)	35 ( 48.6%)	4 ( 5.6%)	72
Erythema	14 ( 19.4%)	12 ( 16.7%)	31 ( 43.1%)	15 ( 20.8%)	72
In vitro fertilisation	0 ( 0.0%)	72 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	72
Burkitt's lymphoma stage IV	0 ( 0.0%)	42 ( 58.3%)	30 ( 41.7%)	0 ( 0.0%)	72
Primary biliary cholangitis	0 ( 0.0%)	12 ( 16.7%)	48 ( 66.7%)	12 ( 16.7%)	72
Adjuvant therapy	1 ( 1.4%)	32 ( 45.1%)	30 ( 42.3%)	8 ( 11.3%)	71
Scleroderma	10 ( 14.1%)	12 ( 16.9%)	44 ( 62.0%)	5 ( 7.0%)	71
Insulin-requiring type 2 diabetes mellitus	1 ( 1.4%)	1 ( 1.4%)	46 ( 64.8%)	23 ( 32.4%)	71
Blood uric acid increased	1 ( 1.4%)	9 ( 12.7%)	17 ( 23.9%)	44 ( 62.0%)	71
Hypertriglyceridaemia	10 ( 14.1%)	26 ( 36.6%)	33 ( 46.5%)	2 ( 2.8%)	71
Dyshidrotic eczema	5 ( 7.0%)	31 ( 43.7%)	34 ( 47.9%)	1 ( 1.4%)	71
Ulcer	6 ( 8.5%)	18 ( 25.4%)	28 ( 39.4%)	19 ( 26.8%)	71
Plasmacytoma	0 ( 0.0%)	13 ( 18.3%)	45 ( 63.4%)	13 ( 18.3%)	71
Toothache	24 ( 34.3%)	37 ( 52.9%)	7 ( 10.0%)	2 ( 2.9%)	70
Blood glucose abnormal	0 ( 0.0%)	12 ( 17.1%)	44 ( 62.9%)	14 ( 20.0%)	70
Carcinoid syndrome	0 ( 0.0%)	5 ( 7.1%)	50 ( 71.4%)	15 ( 21.4%)	70
Colon cancer stage IV	0 ( 0.0%)	9 ( 12.9%)	37 ( 52.9%)	24 ( 34.3%)	70
Vulvovaginal dryness	0 ( 0.0%)	3 ( 4.3%)	57 ( 81.4%)	10 ( 14.3%)	70
Acquired ATTR amyloidosis	0 ( 0.0%)	1 ( 1.4%)	21 ( 30.0%)	48 ( 68.6%)	70
Age-related macular degeneration	0 ( 0.0%)	0 ( 0.0%)	24 ( 34.3%)	46 ( 65.7%)	70
Chronic hepatitis B	1 ( 1.4%)	18 ( 25.7%)	48 ( 68.6%)	3 ( 4.3%)	70
Pelvic pain	13 ( 18.6%)	29 ( 41.4%)	26 ( 37.1%)	2 ( 2.9%)	70



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Depressed mood	12 ( 17.4%)	12 ( 17.4%)	38 ( 55.1%)	7 ( 10.1%)	69
Urinary incontinence	3 ( 4.3%)	5 ( 7.2%)	34 ( 49.3%)	27 ( 39.1%)	69
Gastrointestinal haemorrhage	10 ( 14.5%)	9 ( 13.0%)	28 ( 40.6%)	22 ( 31.9%)	69
Hepatic cirrhosis	3 ( 4.3%)	6 ( 8.7%)	47 ( 68.1%)	13 ( 18.8%)	69
Osteolysis	0 ( 0.0%)	3 ( 4.3%)	50 ( 72.5%)	16 ( 23.2%)	69
Hallucination, auditory	39 ( 56.5%)	20 ( 29.0%)	8 ( 11.6%)	2 ( 2.9%)	69
Chronic myelomonocytic leukaemia	0 ( 0.0%)	7 ( 10.3%)	39 ( 57.4%)	22 ( 32.4%)	68
Diagnostic procedure	9 ( 13.2%)	20 ( 29.4%)	37 ( 54.4%)	2 ( 2.9%)	68
Metastatic gastric cancer	0 ( 0.0%)	6 ( 8.8%)	32 ( 47.1%)	30 ( 44.1%)	68
Respiratory failure	5 ( 7.4%)	10 ( 14.7%)	42 ( 61.8%)	11 ( 16.2%)	68
Bronchiectasis	4 ( 5.9%)	4 ( 5.9%)	44 ( 64.7%)	16 ( 23.5%)	68
Hodgkin's disease stage IV	59 ( 86.8%)	1 ( 1.5%)	8 ( 11.8%)	0 ( 0.0%)	68
Squamous cell carcinoma of skin	0 ( 0.0%)	4 ( 5.9%)	44 ( 64.7%)	20 ( 29.4%)	68
Breast cancer stage II	0 ( 0.0%)	27 ( 39.7%)	36 ( 52.9%)	5 ( 7.4%)	68
Acute kidney injury	7 ( 10.4%)	9 ( 13.4%)	37 ( 55.2%)	14 ( 20.9%)	67
Pyelonephritis	5 ( 7.5%)	12 ( 17.9%)	43 ( 64.2%)	7 ( 10.4%)	67
Hyperemesis gravidarum	3 ( 4.5%)	64 ( 95.5%)	0 ( 0.0%)	0 ( 0.0%)	67
Arthropathy	0 ( 0.0%)	15 ( 22.4%)	45 ( 67.2%)	7 ( 10.4%)	67
Acquired immunodeficiency syndrome	5 ( 7.5%)	47 ( 70.1%)	15 ( 22.4%)	0 ( 0.0%)	67
Oesophagitis	9 ( 13.4%)	9 ( 13.4%)	44 ( 65.7%)	5 ( 7.5%)	67
Meningitis cryptococcal	0 ( 0.0%)	5 ( 7.5%)	59 ( 88.1%)	3 ( 4.5%)	67
Renal disorder	4 ( 6.0%)	12 ( 17.9%)	30 ( 44.8%)	21 ( 31.3%)	67
Drug hypersensitivity	4 ( 6.0%)	4 ( 6.0%)	40 ( 59.7%)	19 ( 28.4%)	67
Hyponatraemia	2 ( 3.0%)	13 ( 19.7%)	27 ( 40.9%)	24 ( 36.4%)	66
Post procedural infection	10 ( 15.2%)	1 ( 1.5%)	15 ( 22.7%)	40 ( 60.6%)	66
Hepatic function abnormal	0 ( 0.0%)	19 ( 28.8%)	35 ( 53.0%)	12 ( 18.2%)	66
Pneumonia pseudomonal	0 ( 0.0%)	29 ( 43.9%)	35 ( 53.0%)	2 ( 3.0%)	66

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Acute respiratory distress syndrome	11 ( 16.7%)	30 ( 45.5%)	22 ( 33.3%)	3 ( 4.5%)	66
Colorectal cancer stage IV	0 ( 0.0%)	6 ( 9.1%)	60 ( 90.9%)	0 ( 0.0%)	66
Plasma cell myeloma recurrent	0 ( 0.0%)	6 ( 9.1%)	45 ( 68.2%)	15 ( 22.7%)	66
Pollakiuria	0 ( 0.0%)	35 ( 53.0%)	18 ( 27.3%)	13 ( 19.7%)	66
Epidural anaesthesia	3 ( 4.5%)	63 ( 95.5%)	0 ( 0.0%)	0 ( 0.0%)	66
Enterobacter infection	18 ( 27.3%)	36 ( 54.5%)	9 ( 13.6%)	3 ( 4.5%)	66
Hyperphosphataemia	0 ( 0.0%)	8 ( 12.3%)	23 ( 35.4%)	34 ( 52.3%)	65
Colorectal adenocarcinoma	3 ( 4.6%)	17 ( 26.2%)	38 ( 58.5%)	7 ( 10.8%)	65
Prader-Willi syndrome	60 ( 92.3%)	5 ( 7.7%)	0 ( 0.0%)	0 ( 0.0%)	65
Bursitis	0 ( 0.0%)	38 ( 58.5%)	12 ( 18.5%)	15 ( 23.1%)	65
Idiopathic generalised epilepsy	19 ( 29.2%)	46 ( 70.8%)	0 ( 0.0%)	0 ( 0.0%)	65
Angioimmunoblastic T-cell lymphoma	0 ( 0.0%)	2 ( 3.1%)	51 ( 78.5%)	12 ( 18.5%)	65
Atrophic vulvovaginitis	0 ( 0.0%)	1 ( 1.6%)	44 ( 68.8%)	19 ( 29.7%)	64
Immune-mediated myositis	0 ( 0.0%)	32 ( 50.0%)	28 ( 43.8%)	4 ( 6.3%)	64
Cardiac arrest	41 ( 64.1%)	13 ( 20.3%)	8 ( 12.5%)	2 ( 3.1%)	64
Mucosal inflammation	1 ( 1.6%)	4 ( 6.3%)	24 ( 37.5%)	35 ( 54.7%)	64
Supraventricular tachycardia	17 ( 26.6%)	24 ( 37.5%)	15 ( 23.4%)	8 ( 12.5%)	64
Dysuria	2 ( 3.2%)	13 ( 20.6%)	26 ( 41.3%)	22 ( 34.9%)	63
Sarcoma	19 ( 30.2%)	11 ( 17.5%)	24 ( 38.1%)	9 ( 14.3%)	63
Platelet count decreased	4 ( 6.3%)	14 ( 22.2%)	38 ( 60.3%)	7 ( 11.1%)	63
Nerve block	22 ( 34.9%)	10 ( 15.9%)	30 ( 47.6%)	1 ( 1.6%)	63
Scan with contrast	6 ( 9.5%)	19 ( 30.2%)	31 ( 49.2%)	7 ( 11.1%)	63
Hypereosinophilic syndrome	1 ( 1.6%)	26 ( 41.3%)	29 ( 46.0%)	7 ( 11.1%)	63
Tooth infection	13 ( 21.0%)	15 ( 24.2%)	30 ( 48.4%)	4 ( 6.5%)	62
Prostatic specific antigen	0 ( 0.0%)	58 ( 93.5%)	4 ( 6.5%)	0 ( 0.0%)	62
Soft tissue sarcoma	11 ( 17.7%)	17 ( 27.4%)	30 ( 48.4%)	4 ( 6.5%)	62
Basal cell carcinoma	0 ( 0.0%)	5 ( 8.1%)	30 ( 48.4%)	27 ( 43.5%)	62

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Skin cosmetic procedure	2 ( 3.2%)	36 ( 58.1%)	20 ( 32.3%)	4 ( 6.5%)	62
High-grade B-cell lymphoma	0 ( 0.0%)	11 ( 17.7%)	51 ( 82.3%)	0 ( 0.0%)	62
Acquired haemophilia	0 ( 0.0%)	2 ( 3.2%)	27 ( 43.5%)	33 ( 53.2%)	62
Polycystic ovaries	3 ( 4.9%)	53 ( 86.9%)	5 ( 8.2%)	0 ( 0.0%)	61
Angiogram	1 ( 1.6%)	13 ( 21.3%)	35 ( 57.4%)	12 ( 19.7%)	61
Glomerulonephritis minimal lesion	57 ( 93.4%)	3 ( 4.9%)	1 ( 1.6%)	0 ( 0.0%)	61
Recurrent cancer	47 ( 77.0%)	14 ( 23.0%)	0 ( 0.0%)	0 ( 0.0%)	61
Androgenetic alopecia	11 ( 18.0%)	39 ( 63.9%)	11 ( 18.0%)	0 ( 0.0%)	61
Viral infection	15 ( 24.6%)	13 ( 21.3%)	26 ( 42.6%)	7 ( 11.5%)	61
Prostatic disorder	0 ( 0.0%)	1 ( 1.6%)	42 ( 68.9%)	18 ( 29.5%)	61
Endophthalmitis	0 ( 0.0%)	13 ( 21.3%)	37 ( 60.7%)	11 ( 18.0%)	61
Spinal osteoarthritis	4 ( 6.6%)	27 ( 44.3%)	26 ( 42.6%)	4 ( 6.6%)	61
Paronychia	2 ( 3.3%)	4 ( 6.6%)	49 ( 80.3%)	6 ( 9.8%)	61
Brain neoplasm malignant	20 ( 32.8%)	11 ( 18.0%)	25 ( 41.0%)	5 ( 8.2%)	61
Herpes simplex	12 ( 19.7%)	13 ( 21.3%)	15 ( 24.6%)	21 ( 34.4%)	61
Glomerulonephritis	10 ( 16.4%)	8 ( 13.1%)	25 ( 41.0%)	18 ( 29.5%)	61
Electrolyte substitution therapy	2 ( 3.3%)	10 ( 16.7%)	46 ( 76.7%)	2 ( 3.3%)	60
Von Willebrand's disease	20 ( 33.3%)	20 ( 33.3%)	13 ( 21.7%)	7 ( 11.7%)	60
Angiocardiogram	0 ( 0.0%)	15 ( 25.0%)	32 ( 53.3%)	13 ( 21.7%)	60
Gait disturbance	0 ( 0.0%)	20 ( 33.3%)	30 ( 50.0%)	10 ( 16.7%)	60
Uterine leiomyoma	0 ( 0.0%)	53 ( 88.3%)	7 ( 11.7%)	0 ( 0.0%)	60
Drug eruption	4 ( 6.7%)	8 ( 13.3%)	31 ( 51.7%)	17 ( 28.3%)	60
Medical device site joint infection	0 ( 0.0%)	0 ( 0.0%)	59 ( 98.3%)	1 ( 1.7%)	60
Anxiolytic therapy	0 ( 0.0%)	15 ( 25.4%)	38 ( 64.4%)	6 ( 10.2%)	59
Essential thrombocythaemia	0 ( 0.0%)	9 ( 15.3%)	25 ( 42.4%)	25 ( 42.4%)	59
Encephalitis	11 ( 18.6%)	16 ( 27.1%)	27 ( 45.8%)	5 ( 8.5%)	59
Steroid therapy	12 ( 20.3%)	11 ( 18.6%)	30 ( 50.8%)	6 ( 10.2%)	59

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Acute lymphocytic leukaemia recurrent	29 ( 49.2%)	6 ( 10.2%)	23 ( 39.0%)	1 ( 1.7%)	59
Pleural mesothelioma	0 ( 0.0%)	12 ( 20.3%)	35 ( 59.3%)	12 ( 20.3%)	59
Philadelphia positive chronic myeloid leukaemia	2 ( 3.4%)	21 ( 35.6%)	28 ( 47.5%)	8 ( 13.6%)	59
Polyarteritis nodosa	3 ( 5.1%)	19 ( 32.2%)	37 ( 62.7%)	0 ( 0.0%)	59
Prolactin-producing pituitary tumour	0 ( 0.0%)	48 ( 81.4%)	9 ( 15.3%)	2 ( 3.4%)	59
Overlap syndrome	2 ( 3.4%)	42 ( 71.2%)	10 ( 16.9%)	5 ( 8.5%)	59
Meningitis	8 ( 13.6%)	15 ( 25.4%)	35 ( 59.3%)	1 ( 1.7%)	59
Disease progression	0 ( 0.0%)	10 ( 16.9%)	46 ( 78.0%)	3 ( 5.1%)	59
Synovitis	5 ( 8.6%)	42 ( 72.4%)	10 ( 17.2%)	1 ( 1.7%)	58
Dysmenorrhoea	32 ( 55.2%)	25 ( 43.1%)	1 ( 1.7%)	0 ( 0.0%)	58
Rosacea	3 ( 5.2%)	20 ( 34.5%)	27 ( 46.6%)	8 ( 13.8%)	58
Localised infection	4 ( 6.9%)	2 ( 3.4%)	36 ( 62.1%)	16 ( 27.6%)	58
Cardiomyopathy	1 ( 1.7%)	3 ( 5.2%)	40 ( 69.0%)	14 ( 24.1%)	58
Diabetic ketoacidosis	13 ( 22.4%)	20 ( 34.5%)	23 ( 39.7%)	2 ( 3.4%)	58
Pre-eclampsia	7 ( 12.1%)	51 ( 87.9%)	0 ( 0.0%)	0 ( 0.0%)	58
Mood swings	37 ( 63.8%)	14 ( 24.1%)	7 ( 12.1%)	0 ( 0.0%)	58
Gastroenteritis	21 ( 36.2%)	12 ( 20.7%)	18 ( 31.0%)	7 ( 12.1%)	58
Oropharyngeal pain	13 ( 22.4%)	21 ( 36.2%)	19 ( 32.8%)	5 ( 8.6%)	58
Pneumonitis	1 ( 1.7%)	4 ( 6.9%)	38 ( 65.5%)	15 ( 25.9%)	58
Small cell lung cancer metastatic	0 ( 0.0%)	6 ( 10.5%)	42 ( 73.7%)	9 ( 15.8%)	57
White blood cell count decreased	1 ( 1.8%)	7 ( 12.3%)	39 ( 68.4%)	10 ( 17.5%)	57
Dilated cardiomyopathy	27 ( 47.4%)	17 ( 29.8%)	13 ( 22.8%)	0 ( 0.0%)	57
Infusion related reaction	6 ( 10.5%)	22 ( 38.6%)	16 ( 28.1%)	13 ( 22.8%)	57
Castleman's disease	12 ( 21.1%)	10 ( 17.5%)	26 ( 45.6%)	9 ( 15.8%)	57
Thyroidectomy	2 ( 3.5%)	14 ( 24.6%)	34 ( 59.6%)	7 ( 12.3%)	57
Dysphonia	0 ( 0.0%)	0 ( 0.0%)	4 ( 7.0%)	53 ( 93.0%)	57
Withdrawal syndrome	1 ( 1.8%)	54 ( 94.7%)	2 ( 3.5%)	0 ( 0.0%)	57

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Glycosylated haemoglobin increased	0 ( 0.0%)	23 ( 40.4%)	27 ( 47.4%)	7 ( 12.3%)	57
T-cell lymphoma	2 ( 3.5%)	15 ( 26.3%)	35 ( 61.4%)	5 ( 8.8%)	57
Rhinorrhoea	5 ( 8.9%)	7 ( 12.5%)	24 ( 42.9%)	20 ( 35.7%)	56
Iridocyclitis	13 ( 23.2%)	19 ( 33.9%)	24 ( 42.9%)	0 ( 0.0%)	56
Blood phosphorus increased	0 ( 0.0%)	1 ( 1.8%)	2 ( 3.6%)	53 ( 94.6%)	56
Therapeutic procedure	3 ( 5.4%)	23 ( 41.1%)	29 ( 51.8%)	1 ( 1.8%)	56
Stress echocardiogram	0 ( 0.0%)	9 ( 16.1%)	43 ( 76.8%)	4 ( 7.1%)	56
Gastrooesophageal reflux prophylaxis	0 ( 0.0%)	8 ( 14.3%)	37 ( 66.1%)	11 ( 19.6%)	56
Positron emission tomogram	0 ( 0.0%)	1 ( 1.8%)	32 ( 57.1%)	23 ( 41.1%)	56
Gastrointestinal disorder therapy	0 ( 0.0%)	9 ( 16.1%)	38 ( 67.9%)	9 ( 16.1%)	56
Immunoglobulin G4 related disease	0 ( 0.0%)	3 ( 5.4%)	45 ( 80.4%)	8 ( 14.3%)	56
Renal impairment	1 ( 1.8%)	5 ( 8.9%)	38 ( 67.9%)	12 ( 21.4%)	56
Haematopoietic stem cell mobilisation	13 ( 23.2%)	15 ( 26.8%)	28 ( 50.0%)	0 ( 0.0%)	56
Nocardiosis	0 ( 0.0%)	15 ( 26.8%)	37 ( 66.1%)	4 ( 7.1%)	56
Embolism	0 ( 0.0%)	5 ( 8.9%)	43 ( 76.8%)	8 ( 14.3%)	56
Transgender hormonal therapy	23 ( 41.8%)	24 ( 43.6%)	8 ( 14.5%)	0 ( 0.0%)	55
Oesophageal carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	35 ( 63.6%)	20 ( 36.4%)	55
Systemic candida	25 ( 45.5%)	6 ( 10.9%)	14 ( 25.5%)	10 ( 18.2%)	55
Invasive lobular breast carcinoma	0 ( 0.0%)	8 ( 14.5%)	24 ( 43.6%)	23 ( 41.8%)	55
Philadelphia positive acute lymphocytic leukaemia	14 ( 25.5%)	15 ( 27.3%)	24 ( 43.6%)	2 ( 3.6%)	55
Blood growth hormone abnormal	49 ( 89.1%)	1 ( 1.8%)	4 ( 7.3%)	1 ( 1.8%)	55
Nephroblastoma	55 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	55
Angina unstable	0 ( 0.0%)	3 ( 5.5%)	14 ( 25.5%)	38 ( 69.1%)	55
Neurotrophic keratopathy	1 ( 1.8%)	9 ( 16.4%)	27 ( 49.1%)	18 ( 32.7%)	55
Alopecia scarring	0 ( 0.0%)	44 ( 80.0%)	10 ( 18.2%)	1 ( 1.8%)	55
Morning sickness	17 ( 31.5%)	37 ( 68.5%)	0 ( 0.0%)	0 ( 0.0%)	54
Postoperative wound infection	1 ( 1.9%)	14 ( 25.9%)	25 ( 46.3%)	14 ( 25.9%)	54

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Analgesic intervention supportive therapy	3 ( 5.6%)	15 ( 27.8%)	21 ( 38.9%)	15 ( 27.8%)	54
Glioblastoma multiforme	10 ( 18.5%)	11 ( 20.4%)	33 ( 61.1%)	0 ( 0.0%)	54
Cognitive disorder	0 ( 0.0%)	1 ( 1.9%)	29 ( 53.7%)	24 ( 44.4%)	54
Musculoskeletal pain	0 ( 0.0%)	11 ( 20.4%)	20 ( 37.0%)	23 ( 42.6%)	54
Squamous cell carcinoma of the cervix	0 ( 0.0%)	8 ( 14.8%)	45 ( 83.3%)	1 ( 1.9%)	54
Temporal lobe epilepsy	21 ( 38.9%)	20 ( 37.0%)	2 ( 3.7%)	11 ( 20.4%)	54
Colitis microscopic	0 ( 0.0%)	15 ( 27.8%)	34 ( 63.0%)	5 ( 9.3%)	54
Klebsiella infection	8 ( 14.8%)	12 ( 22.2%)	26 ( 48.1%)	8 ( 14.8%)	54
Myoclonus	12 ( 22.6%)	19 ( 35.8%)	18 ( 34.0%)	4 ( 7.5%)	53
Hypoalbuminaemia	2 ( 3.8%)	6 ( 11.3%)	43 ( 81.1%)	2 ( 3.8%)	53
Chronic leukaemia	0 ( 0.0%)	0 ( 0.0%)	52 ( 98.1%)	1 ( 1.9%)	53
Onychomycosis	3 ( 5.7%)	7 ( 13.2%)	37 ( 69.8%)	6 ( 11.3%)	53
Focal dyscognitive seizures	40 ( 75.5%)	5 ( 9.4%)	7 ( 13.2%)	1 ( 1.9%)	53
Polymyositis	0 ( 0.0%)	7 ( 13.2%)	41 ( 77.4%)	5 ( 9.4%)	53
Neurofibromatosis	39 ( 73.6%)	11 ( 20.8%)	3 ( 5.7%)	0 ( 0.0%)	53
Palmar-plantar erythrodysesthesia syndrome	0 ( 0.0%)	6 ( 11.3%)	43 ( 81.1%)	4 ( 7.5%)	53
Rectal cancer metastatic	0 ( 0.0%)	20 ( 37.7%)	28 ( 52.8%)	5 ( 9.4%)	53
Oral contraception	11 ( 21.2%)	39 ( 75.0%)	2 ( 3.8%)	0 ( 0.0%)	52
Ear infection	17 ( 32.7%)	18 ( 34.6%)	15 ( 28.8%)	2 ( 3.8%)	52
Pituitary tumour	5 ( 9.6%)	6 ( 11.5%)	40 ( 76.9%)	1 ( 1.9%)	52
Panic attack	4 ( 7.7%)	16 ( 30.8%)	25 ( 48.1%)	7 ( 13.5%)	52
Choroidal neovascularisation	3 ( 5.8%)	11 ( 21.2%)	28 ( 53.8%)	10 ( 19.2%)	52
Osteonecrosis of jaw	0 ( 0.0%)	0 ( 0.0%)	13 ( 25.0%)	39 ( 75.0%)	52
Hyperhidrosis	16 ( 30.8%)	18 ( 34.6%)	18 ( 34.6%)	0 ( 0.0%)	52
Toxic epidermal necrolysis	16 ( 30.8%)	17 ( 32.7%)	16 ( 30.8%)	3 ( 5.8%)	52
Rhabdomyosarcoma	43 ( 82.7%)	7 ( 13.5%)	2 ( 3.8%)	0 ( 0.0%)	52
Chronic lymphocytic leukaemia refractory	0 ( 0.0%)	40 ( 78.4%)	5 ( 9.8%)	6 ( 11.8%)	51

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Routine health maintenance	0 ( 0.0%)	5 ( 9.8%)	25 ( 49.0%)	21 ( 41.2%)	51
Cutaneous T-cell lymphoma	3 ( 5.9%)	7 ( 13.7%)	26 ( 51.0%)	15 ( 29.4%)	51
Graft versus host disease in lung	0 ( 0.0%)	2 ( 3.9%)	49 ( 96.1%)	0 ( 0.0%)	51
Polycystic ovarian syndrome	7 ( 13.7%)	37 ( 72.5%)	7 ( 13.7%)	0 ( 0.0%)	51
Eosinophilic fasciitis	3 ( 5.9%)	15 ( 29.4%)	23 ( 45.1%)	10 ( 19.6%)	51
Immune effector cell-associated neurotoxicity syndro	1 ( 2.0%)	6 ( 11.8%)	41 ( 80.4%)	3 ( 5.9%)	51
Neuroendocrine carcinoma	0 ( 0.0%)	1 ( 2.0%)	28 ( 54.9%)	22 ( 43.1%)	51
Lichen planopilaris	0 ( 0.0%)	5 ( 10.0%)	34 ( 68.0%)	11 ( 22.0%)	50
Wrong patient	0 ( 0.0%)	6 ( 12.0%)	28 ( 56.0%)	16 ( 32.0%)	50
Child abuse	50 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	50
Malignant neoplasm of renal pelvis	0 ( 0.0%)	1 ( 2.0%)	34 ( 68.0%)	15 ( 30.0%)	50
Fallopian tube cancer	0 ( 0.0%)	10 ( 20.0%)	40 ( 80.0%)	0 ( 0.0%)	50
Cervix carcinoma recurrent	0 ( 0.0%)	41 ( 82.0%)	9 ( 18.0%)	0 ( 0.0%)	50
Iron overload	13 ( 26.0%)	4 ( 8.0%)	29 ( 58.0%)	4 ( 8.0%)	50
Ascites	1 ( 2.0%)	5 ( 10.0%)	36 ( 72.0%)	8 ( 16.0%)	50
Chronic graft versus host disease in skin	46 ( 92.0%)	2 ( 4.0%)	2 ( 4.0%)	0 ( 0.0%)	50
Postoperative care	3 ( 6.0%)	12 ( 24.0%)	26 ( 52.0%)	9 ( 18.0%)	50
Controlled ovarian stimulation	3 ( 6.0%)	47 ( 94.0%)	0 ( 0.0%)	0 ( 0.0%)	50
Metabolic surgery	0 ( 0.0%)	5 ( 10.2%)	44 ( 89.8%)	0 ( 0.0%)	49
Depressive symptom	16 ( 32.7%)	8 ( 16.3%)	7 ( 14.3%)	18 ( 36.7%)	49
Choriocarcinoma	8 ( 16.3%)	33 ( 67.3%)	8 ( 16.3%)	0 ( 0.0%)	49
Cytomegalovirus viraemia	17 ( 34.7%)	12 ( 24.5%)	15 ( 30.6%)	5 ( 10.2%)	49
Hypopharyngeal cancer	0 ( 0.0%)	1 ( 2.0%)	44 ( 89.8%)	4 ( 8.2%)	49
Metastases to meninges	14 ( 28.6%)	8 ( 16.3%)	27 ( 55.1%)	0 ( 0.0%)	49
Hypoxia	4 ( 8.2%)	12 ( 24.5%)	23 ( 46.9%)	10 ( 20.4%)	49
Dry age-related macular degeneration	0 ( 0.0%)	2 ( 4.1%)	11 ( 22.4%)	36 ( 73.5%)	49
Vertigo	1 ( 2.0%)	6 ( 12.2%)	39 ( 79.6%)	3 ( 6.1%)	49

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blood potassium decreased	0 ( 0.0%)	9 ( 18.4%)	21 ( 42.9%)	19 ( 38.8%)	49
Breast cancer male	0 ( 0.0%)	3 ( 6.1%)	37 ( 75.5%)	9 ( 18.4%)	49
Hypervolaemia	3 ( 6.3%)	4 ( 8.3%)	26 ( 54.2%)	15 ( 31.3%)	48
Mood altered	21 ( 43.8%)	11 ( 22.9%)	13 ( 27.1%)	3 ( 6.3%)	48
Sinus polyp	2 ( 4.2%)	23 ( 47.9%)	22 ( 45.8%)	1 ( 2.1%)	48
Dermatitis acneiform	4 ( 8.3%)	11 ( 22.9%)	28 ( 58.3%)	5 ( 10.4%)	48
Stent placement	0 ( 0.0%)	1 ( 2.1%)	34 ( 70.8%)	13 ( 27.1%)	48
Papillary thyroid cancer	0 ( 0.0%)	7 ( 14.6%)	33 ( 68.8%)	8 ( 16.7%)	48
Hypertensive heart disease	0 ( 0.0%)	2 ( 4.2%)	20 ( 41.7%)	26 ( 54.2%)	48
Mycobacterium chelonae infection	12 ( 25.0%)	8 ( 16.7%)	23 ( 47.9%)	5 ( 10.4%)	48
Catatonia	20 ( 41.7%)	22 ( 45.8%)	5 ( 10.4%)	1 ( 2.1%)	48
Febrile bone marrow aplasia	23 ( 47.9%)	2 ( 4.2%)	2 ( 4.2%)	21 ( 43.8%)	48
Macular oedema	1 ( 2.1%)	7 ( 14.6%)	27 ( 56.3%)	13 ( 27.1%)	48
Cytomegalovirus infection reactivation	9 ( 18.8%)	17 ( 35.4%)	22 ( 45.8%)	0 ( 0.0%)	48
Intraocular pressure increased	6 ( 12.5%)	5 ( 10.4%)	26 ( 54.2%)	11 ( 22.9%)	48
Autoimmune disorder	4 ( 8.3%)	23 ( 47.9%)	18 ( 37.5%)	3 ( 6.3%)	48
Oral candidiasis	0 ( 0.0%)	6 ( 12.5%)	33 ( 68.8%)	9 ( 18.8%)	48
Adenocarcinoma metastatic	0 ( 0.0%)	7 ( 14.9%)	34 ( 72.3%)	6 ( 12.8%)	47
Guillain-Barre syndrome	2 ( 4.3%)	25 ( 53.2%)	10 ( 21.3%)	10 ( 21.3%)	47
Diabetic neuropathy	17 ( 36.2%)	5 ( 10.6%)	23 ( 48.9%)	2 ( 4.3%)	47
Arteriosclerosis coronary artery	0 ( 0.0%)	5 ( 10.6%)	27 ( 57.4%)	15 ( 31.9%)	47
Endometrial cancer metastatic	0 ( 0.0%)	1 ( 2.1%)	40 ( 85.1%)	6 ( 12.8%)	47
Stenotrophomonas infection	0 ( 0.0%)	24 ( 51.1%)	20 ( 42.6%)	3 ( 6.4%)	47
Sinus tachycardia	0 ( 0.0%)	18 ( 38.3%)	27 ( 57.4%)	2 ( 4.3%)	47
Restlessness	6 ( 12.8%)	12 ( 25.5%)	25 ( 53.2%)	4 ( 8.5%)	47
Intraductal proliferative breast lesion	1 ( 2.1%)	14 ( 29.8%)	21 ( 44.7%)	11 ( 23.4%)	47
Myeloid leukaemia	1 ( 2.1%)	16 ( 34.0%)	21 ( 44.7%)	9 ( 19.1%)	47



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tumour pain	2 ( 4.3%)	10 ( 21.7%)	23 ( 50.0%)	11 ( 23.9%)	46
Erysipelas	0 ( 0.0%)	9 ( 19.6%)	9 ( 19.6%)	28 ( 60.9%)	46
Chest discomfort	0 ( 0.0%)	6 ( 13.0%)	18 ( 39.1%)	22 ( 47.8%)	46
Folate deficiency	2 ( 4.3%)	12 ( 26.1%)	20 ( 43.5%)	12 ( 26.1%)	46
Peripheral swelling	0 ( 0.0%)	5 ( 10.9%)	21 ( 45.7%)	20 ( 43.5%)	46
Blood pressure decreased	1 ( 2.2%)	21 ( 45.7%)	21 ( 45.7%)	3 ( 6.5%)	46
Psychomotor hyperactivity	21 ( 45.7%)	1 ( 2.2%)	19 ( 41.3%)	5 ( 10.9%)	46
Intentional self-injury	14 ( 30.4%)	14 ( 30.4%)	18 ( 39.1%)	0 ( 0.0%)	46
Helicobacter gastritis	4 ( 8.7%)	21 ( 45.7%)	16 ( 34.8%)	5 ( 10.9%)	46
Dystonia	31 ( 67.4%)	7 ( 15.2%)	4 ( 8.7%)	4 ( 8.7%)	46
Tonsillitis	9 ( 19.6%)	14 ( 30.4%)	23 ( 50.0%)	0 ( 0.0%)	46
Testis cancer	3 ( 6.5%)	37 ( 80.4%)	6 ( 13.0%)	0 ( 0.0%)	46
Haemarthrosis	13 ( 28.9%)	30 ( 66.7%)	2 ( 4.4%)	0 ( 0.0%)	45
Neonatal seizure	45 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	45
Pancreatic neuroendocrine tumour metastatic	2 ( 4.4%)	22 ( 48.9%)	20 ( 44.4%)	1 ( 2.2%)	45
Retinal vein occlusion	1 ( 2.2%)	3 ( 6.7%)	26 ( 57.8%)	15 ( 33.3%)	45
Antiphospholipid syndrome	10 ( 22.2%)	24 ( 53.3%)	11 ( 24.4%)	0 ( 0.0%)	45
Irritability	39 ( 86.7%)	5 ( 11.1%)	1 ( 2.2%)	0 ( 0.0%)	45
Lung neoplasm	0 ( 0.0%)	4 ( 8.9%)	20 ( 44.4%)	21 ( 46.7%)	45
Advanced systemic mastocytosis	0 ( 0.0%)	5 ( 11.1%)	29 ( 64.4%)	11 ( 24.4%)	45
Fusarium infection	25 ( 55.6%)	6 ( 13.3%)	14 ( 31.1%)	0 ( 0.0%)	45
Disseminated mycobacterium avium complex infection	3 ( 6.7%)	42 ( 93.3%)	0 ( 0.0%)	0 ( 0.0%)	45
Anaplastic large cell lymphoma T- and null-cell type	3 ( 6.7%)	24 ( 53.3%)	14 ( 31.1%)	4 ( 8.9%)	45
Turner's syndrome	40 ( 88.9%)	5 ( 11.1%)	0 ( 0.0%)	0 ( 0.0%)	45
Leiomyosarcoma	0 ( 0.0%)	12 ( 27.3%)	28 ( 63.6%)	4 ( 9.1%)	44
Wrong patient received product	0 ( 0.0%)	0 ( 0.0%)	8 ( 18.2%)	36 ( 81.8%)	44
Metastatic bronchial carcinoma	0 ( 0.0%)	1 ( 2.3%)	43 ( 97.7%)	0 ( 0.0%)	44

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Reflux gastritis	4 ( 9.1%)	12 ( 27.3%)	26 ( 59.1%)	2 ( 4.5%)	44
Hereditary angioedema with normal C1 esterase inhibi	4 ( 9.1%)	28 ( 63.6%)	12 ( 27.3%)	0 ( 0.0%)	44
HIV test positive	0 ( 0.0%)	2 ( 4.5%)	42 ( 95.5%)	0 ( 0.0%)	44
Kawasaki's disease	42 ( 95.5%)	2 ( 4.5%)	0 ( 0.0%)	0 ( 0.0%)	44
Eye disorder	2 ( 4.5%)	5 ( 11.4%)	22 ( 50.0%)	15 ( 34.1%)	44
Lung squamous cell carcinoma stage III	0 ( 0.0%)	0 ( 0.0%)	40 ( 90.9%)	4 ( 9.1%)	44
Hypophosphataemia	10 ( 22.7%)	2 ( 4.5%)	20 ( 45.5%)	12 ( 27.3%)	44
Intra-uterine contraceptive device insertion	8 ( 18.2%)	32 ( 72.7%)	4 ( 9.1%)	0 ( 0.0%)	44
Vitamin D decreased	3 ( 6.8%)	11 ( 25.0%)	24 ( 54.5%)	6 ( 13.6%)	44
New onset refractory status epilepticus	6 ( 13.6%)	35 ( 79.5%)	3 ( 6.8%)	0 ( 0.0%)	44
Cholangitis	0 ( 0.0%)	2 ( 4.5%)	33 ( 75.0%)	9 ( 20.5%)	44
Brain neoplasm	12 ( 27.3%)	12 ( 27.3%)	15 ( 34.1%)	5 ( 11.4%)	44
Immunomodulatory therapy	3 ( 6.8%)	25 ( 56.8%)	15 ( 34.1%)	1 ( 2.3%)	44
Escherichia infection	12 ( 27.9%)	17 ( 39.5%)	7 ( 16.3%)	7 ( 16.3%)	43
Head titubation	0 ( 0.0%)	0 ( 0.0%)	13 ( 30.2%)	30 ( 69.8%)	43
Borderline personality disorder	20 ( 46.5%)	22 ( 51.2%)	1 ( 2.3%)	0 ( 0.0%)	43
Vulvovaginal pain	36 ( 83.7%)	2 ( 4.7%)	3 ( 7.0%)	2 ( 4.7%)	43
Hypomania	0 ( 0.0%)	12 ( 27.9%)	29 ( 67.4%)	2 ( 4.7%)	43
Malnutrition	7 ( 16.3%)	3 ( 7.0%)	30 ( 69.8%)	3 ( 7.0%)	43
Burkitt's lymphoma stage III	42 ( 97.7%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 2.3%)	43
Ischaemic heart disease prophylaxis	0 ( 0.0%)	4 ( 9.3%)	31 ( 72.1%)	8 ( 18.6%)	43
Targeted cancer therapy	1 ( 2.3%)	6 ( 14.0%)	30 ( 69.8%)	6 ( 14.0%)	43
Tuberculosis of central nervous system	43 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	43
Nasopharyngeal cancer	1 ( 2.3%)	18 ( 41.9%)	21 ( 48.8%)	3 ( 7.0%)	43
Pneumonia klebsiella	3 ( 7.0%)	8 ( 18.6%)	21 ( 48.8%)	11 ( 25.6%)	43
Stevens-Johnson syndrome	15 ( 34.9%)	15 ( 34.9%)	8 ( 18.6%)	5 ( 11.6%)	43
Joint stiffness	1 ( 2.3%)	3 ( 7.0%)	4 ( 9.3%)	35 ( 81.4%)	43

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Venous thrombosis	2 ( 4.7%)	13 ( 30.2%)	22 ( 51.2%)	6 ( 14.0%)	43
Encephalopathy	16 ( 38.1%)	10 ( 23.8%)	10 ( 23.8%)	6 ( 14.3%)	42
Malaise	3 ( 7.1%)	12 ( 28.6%)	26 ( 61.9%)	1 ( 2.4%)	42
Electrolyte imbalance	6 ( 14.3%)	10 ( 23.8%)	23 ( 54.8%)	3 ( 7.1%)	42
Resting tremor	0 ( 0.0%)	0 ( 0.0%)	14 ( 33.3%)	28 ( 66.7%)	42
Mixed hepatocellular cholangiocarcinoma	2 ( 4.8%)	9 ( 21.4%)	23 ( 54.8%)	8 ( 19.0%)	42
Intervertebral disc protrusion	0 ( 0.0%)	10 ( 23.8%)	26 ( 61.9%)	6 ( 14.3%)	42
Breast cancer stage III	0 ( 0.0%)	18 ( 42.9%)	19 ( 45.2%)	5 ( 11.9%)	42
Gastric disorder	7 ( 16.7%)	8 ( 19.0%)	22 ( 52.4%)	5 ( 11.9%)	42
Leukopenia	7 ( 16.7%)	5 ( 11.9%)	29 ( 69.0%)	1 ( 2.4%)	42
Alcohol use disorder	0 ( 0.0%)	7 ( 16.7%)	35 ( 83.3%)	0 ( 0.0%)	42
Embolism venous	0 ( 0.0%)	10 ( 24.4%)	22 ( 53.7%)	9 ( 22.0%)	41
Minimal residual disease	1 ( 2.4%)	4 ( 9.8%)	36 ( 87.8%)	0 ( 0.0%)	41
Type V hyperlipidaemia	0 ( 0.0%)	1 ( 2.4%)	25 ( 61.0%)	15 ( 36.6%)	41
Memory impairment	0 ( 0.0%)	1 ( 2.4%)	18 ( 43.9%)	22 ( 53.7%)	41
Overdose	12 ( 29.3%)	13 ( 31.7%)	15 ( 36.6%)	1 ( 2.4%)	41
Congenital hypogammaglobulinaemia	7 ( 17.1%)	11 ( 26.8%)	18 ( 43.9%)	5 ( 12.2%)	41
Human epidermal growth factor receptor negative	0 ( 0.0%)	4 ( 9.8%)	35 ( 85.4%)	2 ( 4.9%)	41
Peyronie's disease	0 ( 0.0%)	8 ( 19.5%)	31 ( 75.6%)	2 ( 4.9%)	41
Injury	16 ( 39.0%)	7 ( 17.1%)	14 ( 34.1%)	4 ( 9.8%)	41
Endotracheal intubation	5 ( 12.2%)	11 ( 26.8%)	21 ( 51.2%)	4 ( 9.8%)	41
Diabetic retinopathy	3 ( 7.3%)	6 ( 14.6%)	28 ( 68.3%)	4 ( 9.8%)	41
Adult T-cell lymphoma/leukaemia	0 ( 0.0%)	14 ( 34.1%)	9 ( 22.0%)	18 ( 43.9%)	41
Urinary retention	1 ( 2.4%)	3 ( 7.3%)	23 ( 56.1%)	14 ( 34.1%)	41
Blood glucose	0 ( 0.0%)	11 ( 26.8%)	20 ( 48.8%)	10 ( 24.4%)	41
Gouty arthritis	2 ( 4.9%)	2 ( 4.9%)	28 ( 68.3%)	9 ( 22.0%)	41
Oppositional defiant disorder	41 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	41

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Computerised tomogram thorax	1 ( 2.5%)	10 ( 25.0%)	20 ( 50.0%)	9 ( 22.5%)	40
Wound infection	0 ( 0.0%)	16 ( 40.0%)	20 ( 50.0%)	4 ( 10.0%)	40
Paraesthesia	3 ( 7.5%)	8 ( 20.0%)	24 ( 60.0%)	5 ( 12.5%)	40
Peripheral T-cell lymphoma unspecified	0 ( 0.0%)	0 ( 0.0%)	30 ( 75.0%)	10 ( 25.0%)	40
Cholelithiasis	2 ( 5.0%)	13 ( 32.5%)	23 ( 57.5%)	2 ( 5.0%)	40
Rhabdomyolysis	7 ( 17.5%)	0 ( 0.0%)	33 ( 82.5%)	0 ( 0.0%)	40
Respiratory syncytial virus infection	30 ( 75.0%)	1 ( 2.5%)	3 ( 7.5%)	6 ( 15.0%)	40
Nephrolithiasis	3 ( 7.5%)	7 ( 17.5%)	29 ( 72.5%)	1 ( 2.5%)	40
Night sweats	0 ( 0.0%)	4 ( 10.0%)	24 ( 60.0%)	12 ( 30.0%)	40
Blood growth hormone	36 ( 92.3%)	0 ( 0.0%)	3 ( 7.7%)	0 ( 0.0%)	39
Anti-melanoma differentiation-associated protein 5 a	16 ( 41.0%)	9 ( 23.1%)	14 ( 35.9%)	0 ( 0.0%)	39
Muscular weakness	4 ( 10.3%)	11 ( 28.2%)	17 ( 43.6%)	7 ( 17.9%)	39
Lipids abnormal	0 ( 0.0%)	3 ( 7.7%)	29 ( 74.4%)	7 ( 17.9%)	39
Alveolar rhabdomyosarcoma	37 ( 94.9%)	0 ( 0.0%)	2 ( 5.1%)	0 ( 0.0%)	39
Skin cancer	1 ( 2.6%)	2 ( 5.1%)	29 ( 74.4%)	7 ( 17.9%)	39
Hepatitis	1 ( 2.6%)	13 ( 33.3%)	24 ( 61.5%)	1 ( 2.6%)	39
Sickle cell anaemia with crisis	20 ( 51.3%)	17 ( 43.6%)	2 ( 5.1%)	0 ( 0.0%)	39
Musculoskeletal stiffness	0 ( 0.0%)	6 ( 15.4%)	32 ( 82.1%)	1 ( 2.6%)	39
Hyperchlorhydria	3 ( 7.7%)	5 ( 12.8%)	23 ( 59.0%)	8 ( 20.5%)	39
Hypergammaglobulinaemia	7 ( 17.9%)	9 ( 23.1%)	22 ( 56.4%)	1 ( 2.6%)	39
Functional gastrointestinal disorder	6 ( 15.4%)	4 ( 10.3%)	26 ( 66.7%)	3 ( 7.7%)	39
Malignant fibrous histiocytoma	2 ( 5.1%)	28 ( 71.8%)	9 ( 23.1%)	0 ( 0.0%)	39
Parkinsonian rest tremor	0 ( 0.0%)	0 ( 0.0%)	9 ( 23.1%)	30 ( 76.9%)	39
Pleural effusion	4 ( 10.3%)	4 ( 10.3%)	16 ( 41.0%)	15 ( 38.5%)	39
Asthenia	2 ( 5.1%)	7 ( 17.9%)	20 ( 51.3%)	10 ( 25.6%)	39
Epstein-Barr virus infection	15 ( 38.5%)	13 ( 33.3%)	11 ( 28.2%)	0 ( 0.0%)	39
Psychiatric decompensation	18 ( 46.2%)	0 ( 0.0%)	21 ( 53.8%)	0 ( 0.0%)	39

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Skin lesion	20 ( 51.3%)	5 ( 12.8%)	13 ( 33.3%)	1 ( 2.6%)	39
Anaemia prophylaxis	2 ( 5.3%)	13 ( 34.2%)	14 ( 36.8%)	9 ( 23.7%)	38
Blood triglycerides abnormal	0 ( 0.0%)	7 ( 18.4%)	24 ( 63.2%)	7 ( 18.4%)	38
Cardiac failure acute	2 ( 5.3%)	4 ( 10.5%)	13 ( 34.2%)	19 ( 50.0%)	38
Breakthrough pain	0 ( 0.0%)	15 ( 39.5%)	10 ( 26.3%)	13 ( 34.2%)	38
Salivary gland cancer	0 ( 0.0%)	5 ( 13.2%)	28 ( 73.7%)	5 ( 13.2%)	38
Pharyngitis	22 ( 57.9%)	8 ( 21.1%)	7 ( 18.4%)	1 ( 2.6%)	38
Musculoskeletal chest pain	0 ( 0.0%)	4 ( 10.5%)	25 ( 65.8%)	9 ( 23.7%)	38
Peptic ulcer	2 ( 5.3%)	6 ( 15.8%)	28 ( 73.7%)	2 ( 5.3%)	38
Medication error	1 ( 2.6%)	10 ( 26.3%)	10 ( 26.3%)	17 ( 44.7%)	38
Chronic graft versus host disease in lung	38 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	38
Somatic symptom disorder	0 ( 0.0%)	0 ( 0.0%)	37 ( 97.4%)	1 ( 2.6%)	38
Migraine with aura	1 ( 2.6%)	21 ( 55.3%)	16 ( 42.1%)	0 ( 0.0%)	38
Acute monocytic leukaemia	26 ( 68.4%)	7 ( 18.4%)	5 ( 13.2%)	0 ( 0.0%)	38
Pulmonary sarcoidosis	0 ( 0.0%)	13 ( 34.2%)	24 ( 63.2%)	1 ( 2.6%)	38
Lung adenocarcinoma stage III	0 ( 0.0%)	11 ( 28.9%)	26 ( 68.4%)	1 ( 2.6%)	38
Influenza immunisation	4 ( 10.5%)	6 ( 15.8%)	20 ( 52.6%)	8 ( 21.1%)	38
Angiosarcoma	7 ( 18.9%)	23 ( 62.2%)	5 ( 13.5%)	2 ( 5.4%)	37
Cystic fibrosis lung	10 ( 27.0%)	18 ( 48.6%)	8 ( 21.6%)	1 ( 2.7%)	37
Autoimmune hepatitis	11 ( 29.7%)	13 ( 35.1%)	13 ( 35.1%)	0 ( 0.0%)	37
Laxative supportive care	3 ( 8.1%)	4 ( 10.8%)	15 ( 40.5%)	15 ( 40.5%)	37
BRAF gene mutation	0 ( 0.0%)	6 ( 16.2%)	27 ( 73.0%)	4 ( 10.8%)	37
Mobility decreased	0 ( 0.0%)	0 ( 0.0%)	2 ( 5.4%)	35 ( 94.6%)	37
Mantle cell lymphoma stage IV	0 ( 0.0%)	7 ( 18.9%)	30 ( 81.1%)	0 ( 0.0%)	37
Bronchitis chronic	0 ( 0.0%)	2 ( 5.4%)	31 ( 83.8%)	4 ( 10.8%)	37
Chills	1 ( 2.7%)	5 ( 13.5%)	26 ( 70.3%)	5 ( 13.5%)	37
Micturition urgency	0 ( 0.0%)	2 ( 5.4%)	26 ( 70.3%)	9 ( 24.3%)	37

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Rectosigmoid cancer	0 ( 0.0%)	2 ( 5.4%)	34 ( 91.9%)	1 ( 2.7%)	37
Chorioretinitis	26 ( 70.3%)	1 ( 2.7%)	8 ( 21.6%)	2 ( 5.4%)	37
Perichondritis	2 ( 5.6%)	1 ( 2.8%)	31 ( 86.1%)	2 ( 5.6%)	36
Ventricular extrasystoles	8 ( 22.2%)	3 ( 8.3%)	13 ( 36.1%)	12 ( 33.3%)	36
Kidney transplant rejection	6 ( 16.7%)	2 ( 5.6%)	25 ( 69.4%)	3 ( 8.3%)	36
Brain abscess	0 ( 0.0%)	13 ( 36.1%)	15 ( 41.7%)	8 ( 22.2%)	36
Haemostasis	13 ( 36.1%)	5 ( 13.9%)	14 ( 38.9%)	4 ( 11.1%)	36
Shock	2 ( 5.6%)	20 ( 55.6%)	10 ( 27.8%)	4 ( 11.1%)	36
Diabetes mellitus management	0 ( 0.0%)	8 ( 22.2%)	25 ( 69.4%)	3 ( 8.3%)	36
Aortic dissection	0 ( 0.0%)	3 ( 8.3%)	20 ( 55.6%)	13 ( 36.1%)	36
Leukaemia recurrent	7 ( 19.4%)	0 ( 0.0%)	29 ( 80.6%)	0 ( 0.0%)	36
Raynaud's phenomenon	1 ( 2.8%)	18 ( 50.0%)	15 ( 41.7%)	2 ( 5.6%)	36
Diabetes prophylaxis	9 ( 25.0%)	19 ( 52.8%)	8 ( 22.2%)	0 ( 0.0%)	36
Pancreatitis	3 ( 8.3%)	8 ( 22.2%)	17 ( 47.2%)	8 ( 22.2%)	36
Papillary renal cell carcinoma	0 ( 0.0%)	4 ( 11.1%)	24 ( 66.7%)	8 ( 22.2%)	36
Infusion site pain	0 ( 0.0%)	16 ( 44.4%)	19 ( 52.8%)	1 ( 2.8%)	36
Coronavirus infection	1 ( 2.8%)	0 ( 0.0%)	22 ( 61.1%)	13 ( 36.1%)	36
Ovarian cancer stage IV	0 ( 0.0%)	16 ( 44.4%)	18 ( 50.0%)	2 ( 5.6%)	36
Bowel preparation	1 ( 2.8%)	7 ( 19.4%)	19 ( 52.8%)	9 ( 25.0%)	36
VEXAS syndrome	0 ( 0.0%)	0 ( 0.0%)	35 ( 97.2%)	1 ( 2.8%)	36
Post-traumatic headache	34 ( 94.4%)	0 ( 0.0%)	2 ( 5.6%)	0 ( 0.0%)	36
Imaging procedure	1 ( 2.8%)	11 ( 30.6%)	20 ( 55.6%)	4 ( 11.1%)	36
Psychotherapy	1 ( 2.8%)	14 ( 38.9%)	20 ( 55.6%)	1 ( 2.8%)	36
Herpes virus infection	3 ( 8.3%)	8 ( 22.2%)	22 ( 61.1%)	3 ( 8.3%)	36
Disruptive mood dysregulation disorder	35 ( 97.2%)	1 ( 2.8%)	0 ( 0.0%)	0 ( 0.0%)	36
Salivary hypersecretion	3 ( 8.6%)	10 ( 28.6%)	20 ( 57.1%)	2 ( 5.7%)	35
Abscess	14 ( 40.0%)	10 ( 28.6%)	7 ( 20.0%)	4 ( 11.4%)	35

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Nephropathy	0 ( 0.0%)	12 ( 34.3%)	22 ( 62.9%)	1 ( 2.9%)	35
Wrong drug	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	35 (100.0%)	35
Electrolyte depletion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	35 (100.0%)	35
Aspartate aminotransferase increased	0 ( 0.0%)	8 ( 22.9%)	24 ( 68.6%)	3 ( 8.6%)	35
Anaesthesia procedure	4 ( 11.4%)	2 ( 5.7%)	19 ( 54.3%)	10 ( 28.6%)	35
Liver abscess	0 ( 0.0%)	3 ( 8.6%)	23 ( 65.7%)	9 ( 25.7%)	35
Pulmonary oedema	4 ( 11.4%)	22 ( 62.9%)	5 ( 14.3%)	4 ( 11.4%)	35
PIK3CA related overgrowth spectrum	21 ( 60.0%)	10 ( 28.6%)	4 ( 11.4%)	0 ( 0.0%)	35
Connective tissue disorder	0 ( 0.0%)	9 ( 25.7%)	23 ( 65.7%)	3 ( 8.6%)	35
Takayasu's arteritis	27 ( 77.1%)	8 ( 22.9%)	0 ( 0.0%)	0 ( 0.0%)	35
Myeloproliferative neoplasm	0 ( 0.0%)	3 ( 8.6%)	25 ( 71.4%)	7 ( 20.0%)	35
Oesophageal squamous cell carcinoma stage IV	0 ( 0.0%)	6 ( 17.1%)	15 ( 42.9%)	14 ( 40.0%)	35
Indolent systemic mastocytosis	1 ( 2.9%)	11 ( 31.4%)	18 ( 51.4%)	5 ( 14.3%)	35
Prophylaxis against diarrhoea	0 ( 0.0%)	1 ( 2.9%)	33 ( 94.3%)	1 ( 2.9%)	35
Anaplastic large-cell lymphoma	5 ( 14.3%)	1 ( 2.9%)	19 ( 54.3%)	10 ( 28.6%)	35
Uterine hypotonus	13 ( 37.1%)	22 ( 62.9%)	0 ( 0.0%)	0 ( 0.0%)	35
Anaplastic thyroid cancer	0 ( 0.0%)	9 ( 25.7%)	17 ( 48.6%)	9 ( 25.7%)	35
Follicular lymphoma stage III	0 ( 0.0%)	6 ( 17.1%)	21 ( 60.0%)	8 ( 22.9%)	35
Sickle cell anaemia	8 ( 22.9%)	6 ( 17.1%)	21 ( 60.0%)	0 ( 0.0%)	35
Oral pain	2 ( 5.9%)	13 ( 38.2%)	18 ( 52.9%)	1 ( 2.9%)	34
Actinic keratosis	0 ( 0.0%)	1 ( 2.9%)	27 ( 79.4%)	6 ( 17.6%)	34
Extrapyramidal disorder	2 ( 5.9%)	10 ( 29.4%)	19 ( 55.9%)	3 ( 8.8%)	34
Pulmonary nocardiosis	0 ( 0.0%)	0 ( 0.0%)	33 ( 97.1%)	1 ( 2.9%)	34
Oropharyngeal cancer	0 ( 0.0%)	1 ( 2.9%)	27 ( 79.4%)	6 ( 17.6%)	34
Alopecia universalis	10 ( 29.4%)	13 ( 38.2%)	11 ( 32.4%)	0 ( 0.0%)	34
Diabetes insipidus	14 ( 41.2%)	10 ( 29.4%)	6 ( 17.6%)	4 ( 11.8%)	34
Bile acid malabsorption	2 ( 5.9%)	23 ( 67.6%)	9 ( 26.5%)	0 ( 0.0%)	34

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Chronic recurrent multifocal osteomyelitis	34 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	34
Latent tuberculosis	14 ( 41.2%)	4 ( 11.8%)	15 ( 44.1%)	1 ( 2.9%)	34
Lymphadenopathy	4 ( 11.8%)	13 ( 38.2%)	11 ( 32.4%)	6 ( 17.6%)	34
Blastic plasmacytoid dendritic cell neoplasia	3 ( 8.8%)	0 ( 0.0%)	25 ( 73.5%)	6 ( 17.6%)	34
Lymphocytic leukaemia	15 ( 44.1%)	6 ( 17.6%)	10 ( 29.4%)	3 ( 8.8%)	34
Scoliosis	1 ( 2.9%)	28 ( 82.4%)	1 ( 2.9%)	4 ( 11.8%)	34
Maternal therapy to enhance foetal lung maturity	8 ( 23.5%)	26 ( 76.5%)	0 ( 0.0%)	0 ( 0.0%)	34
Peritonitis bacterial	4 ( 11.8%)	4 ( 11.8%)	24 ( 70.6%)	2 ( 5.9%)	34
Eosinophilia	1 ( 2.9%)	10 ( 29.4%)	22 ( 64.7%)	1 ( 2.9%)	34
Neutropenic sepsis	14 ( 41.2%)	16 ( 47.1%)	4 ( 11.8%)	0 ( 0.0%)	34
Mesothelioma	0 ( 0.0%)	1 ( 3.0%)	18 ( 54.5%)	14 ( 42.4%)	33
Amyloidosis senile	0 ( 0.0%)	0 ( 0.0%)	7 ( 21.2%)	26 ( 78.8%)	33
EGFR gene mutation	0 ( 0.0%)	3 ( 9.1%)	17 ( 51.5%)	13 ( 39.4%)	33
Ejection fraction decreased	0 ( 0.0%)	9 ( 27.3%)	18 ( 54.5%)	6 ( 18.2%)	33
Middle insomnia	24 ( 72.7%)	2 ( 6.1%)	4 ( 12.1%)	3 ( 9.1%)	33
Respiratory disorder	5 ( 15.2%)	8 ( 24.2%)	11 ( 33.3%)	9 ( 27.3%)	33
Rheumatoid factor negative	0 ( 0.0%)	6 ( 18.2%)	21 ( 63.6%)	6 ( 18.2%)	33
Heart rate increased	0 ( 0.0%)	7 ( 21.2%)	24 ( 72.7%)	2 ( 6.1%)	33
Seborrhoeic dermatitis	11 ( 33.3%)	9 ( 27.3%)	12 ( 36.4%)	1 ( 3.0%)	33
Muscle building therapy	1 ( 3.0%)	32 ( 97.0%)	0 ( 0.0%)	0 ( 0.0%)	33
Acute psychosis	16 ( 48.5%)	14 ( 42.4%)	3 ( 9.1%)	0 ( 0.0%)	33
Retinoblastoma	33 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	33
Respiratory distress	6 ( 18.2%)	7 ( 21.2%)	18 ( 54.5%)	2 ( 6.1%)	33
Salvage therapy	20 ( 60.6%)	3 ( 9.1%)	9 ( 27.3%)	1 ( 3.0%)	33
Pneumonia mycoplasmal	15 ( 45.5%)	13 ( 39.4%)	3 ( 9.1%)	2 ( 6.1%)	33
Ectopic pregnancy	3 ( 9.1%)	30 ( 90.9%)	0 ( 0.0%)	0 ( 0.0%)	33
Gastrointestinal carcinoma	0 ( 0.0%)	1 ( 3.0%)	31 ( 93.9%)	1 ( 3.0%)	33



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Ocular hyperaemia	2 ( 6.1%)	5 ( 15.2%)	22 ( 66.7%)	4 ( 12.1%)	33
Haemochromatosis	10 ( 30.3%)	7 ( 21.2%)	11 ( 33.3%)	5 ( 15.2%)	33
Cataract	0 ( 0.0%)	10 ( 30.3%)	16 ( 48.5%)	7 ( 21.2%)	33
Orthostatic hypotension	0 ( 0.0%)	4 ( 12.5%)	17 ( 53.1%)	11 ( 34.4%)	32
Haemoglobin decreased	2 ( 6.3%)	5 ( 15.6%)	19 ( 59.4%)	6 ( 18.8%)	32
Postoperative analgesia	3 ( 9.4%)	2 ( 6.3%)	26 ( 81.3%)	1 ( 3.1%)	32
Tonic convulsion	26 ( 81.3%)	6 ( 18.8%)	0 ( 0.0%)	0 ( 0.0%)	32
Optic neuritis	12 ( 37.5%)	7 ( 21.9%)	13 ( 40.6%)	0 ( 0.0%)	32
Arteritis	2 ( 6.3%)	3 ( 9.4%)	20 ( 62.5%)	7 ( 21.9%)	32
Sinus disorder	3 ( 9.4%)	3 ( 9.4%)	15 ( 46.9%)	11 ( 34.4%)	32
Cervix carcinoma stage III	0 ( 0.0%)	11 ( 34.4%)	20 ( 62.5%)	1 ( 3.1%)	32
Hypoproteinaemia	1 ( 3.1%)	4 ( 12.5%)	18 ( 56.3%)	9 ( 28.1%)	32
Neoadjuvant therapy	0 ( 0.0%)	11 ( 34.4%)	20 ( 62.5%)	1 ( 3.1%)	32
Mantle cell lymphoma recurrent	0 ( 0.0%)	10 ( 31.3%)	11 ( 34.4%)	11 ( 34.4%)	32
Nasal sinus cancer	0 ( 0.0%)	3 ( 9.7%)	25 ( 80.6%)	3 ( 9.7%)	31
Alpha haemolytic streptococcal infection	2 ( 6.5%)	0 ( 0.0%)	2 ( 6.5%)	27 ( 87.1%)	31
Pulmonary sepsis	0 ( 0.0%)	12 ( 38.7%)	19 ( 61.3%)	0 ( 0.0%)	31
Extranodal marginal zone B-cell lymphoma (MALT type)	2 ( 6.5%)	0 ( 0.0%)	25 ( 80.6%)	4 ( 12.9%)	31
Cholecystitis	0 ( 0.0%)	3 ( 9.7%)	12 ( 38.7%)	16 ( 51.6%)	31
Follicular lymphoma stage II	0 ( 0.0%)	0 ( 0.0%)	12 ( 38.7%)	19 ( 61.3%)	31
Dysphagia	3 ( 9.7%)	13 ( 41.9%)	12 ( 38.7%)	3 ( 9.7%)	31
Disease risk factor	1 ( 3.2%)	2 ( 6.5%)	22 ( 71.0%)	6 ( 19.4%)	31
Diabetic nephropathy	0 ( 0.0%)	0 ( 0.0%)	24 ( 77.4%)	7 ( 22.6%)	31
Syncope	4 ( 12.9%)	12 ( 38.7%)	10 ( 32.3%)	5 ( 16.1%)	31
C3 glomerulopathy	16 ( 51.6%)	12 ( 38.7%)	3 ( 9.7%)	0 ( 0.0%)	31
Alanine aminotransferase increased	1 ( 3.2%)	7 ( 22.6%)	17 ( 54.8%)	6 ( 19.4%)	31
Bronchopulmonary dysplasia	31 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	31

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hypertransaminaemia	22 ( 71.0%)	8 ( 25.8%)	1 ( 3.2%)	0 ( 0.0%)	31
Otitis media acute	30 ( 96.8%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 3.2%)	31
Oestrogen therapy	17 ( 54.8%)	2 ( 6.5%)	9 ( 29.0%)	3 ( 9.7%)	31
Urticaria chronic	4 ( 12.9%)	20 ( 64.5%)	6 ( 19.4%)	1 ( 3.2%)	31
Colorectal cancer stage III	0 ( 0.0%)	4 ( 12.9%)	26 ( 83.9%)	1 ( 3.2%)	31
Hypercalcaemia of malignancy	1 ( 3.2%)	10 ( 32.3%)	18 ( 58.1%)	2 ( 6.5%)	31
Upper gastrointestinal haemorrhage	14 ( 45.2%)	0 ( 0.0%)	15 ( 48.4%)	2 ( 6.5%)	31
Autologous haematopoietic stem cell transplant	1 ( 3.2%)	14 ( 45.2%)	15 ( 48.4%)	1 ( 3.2%)	31
Glomerulonephritis rapidly progressive	1 ( 3.2%)	3 ( 9.7%)	26 ( 83.9%)	1 ( 3.2%)	31
Hysterectomy	0 ( 0.0%)	1 ( 3.2%)	25 ( 80.6%)	5 ( 16.1%)	31
Otitis media	11 ( 35.5%)	13 ( 41.9%)	6 ( 19.4%)	1 ( 3.2%)	31
Post procedural complication	1 ( 3.2%)	9 ( 29.0%)	21 ( 67.7%)	0 ( 0.0%)	31
Cerebral palsy	26 ( 83.9%)	3 ( 9.7%)	2 ( 6.5%)	0 ( 0.0%)	31
Pityriasis rubra pilaris	12 ( 38.7%)	3 ( 9.7%)	16 ( 51.6%)	0 ( 0.0%)	31
Familial haemophagocytic lymphohistiocytosis	12 ( 38.7%)	12 ( 38.7%)	7 ( 22.6%)	0 ( 0.0%)	31
Blood iron decreased	1 ( 3.2%)	6 ( 19.4%)	15 ( 48.4%)	9 ( 29.0%)	31
Ocular hypertension	0 ( 0.0%)	1 ( 3.3%)	25 ( 83.3%)	4 ( 13.3%)	30
Nocturia	0 ( 0.0%)	5 ( 16.7%)	15 ( 50.0%)	10 ( 33.3%)	30
Ileus paralytic	0 ( 0.0%)	0 ( 0.0%)	30 (100.0%)	0 ( 0.0%)	30
Right ventricular failure	0 ( 0.0%)	1 ( 3.3%)	27 ( 90.0%)	2 ( 6.7%)	30
Angiocentric lymphoma	0 ( 0.0%)	20 ( 66.7%)	10 ( 33.3%)	0 ( 0.0%)	30
Transplant dysfunction	26 ( 86.7%)	0 ( 0.0%)	4 ( 13.3%)	0 ( 0.0%)	30
Shock haemorrhagic	0 ( 0.0%)	0 ( 0.0%)	30 (100.0%)	0 ( 0.0%)	30
Juvenile myoclonic epilepsy	22 ( 73.3%)	8 ( 26.7%)	0 ( 0.0%)	0 ( 0.0%)	30
Colony stimulating factor therapy	0 ( 0.0%)	7 ( 23.3%)	17 ( 56.7%)	6 ( 20.0%)	30
Immune reconstitution inflammatory syndrome	3 ( 10.0%)	18 ( 60.0%)	9 ( 30.0%)	0 ( 0.0%)	30
Completed suicide	0 ( 0.0%)	8 ( 26.7%)	14 ( 46.7%)	8 ( 26.7%)	30

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Immune tolerance induction	12 ( 40.0%)	7 ( 23.3%)	9 ( 30.0%)	2 ( 6.7%)	30
Neuromuscular blockade reversal	6 ( 20.0%)	9 ( 30.0%)	12 ( 40.0%)	3 ( 10.0%)	30
Malignant melanoma stage IV	0 ( 0.0%)	4 ( 13.3%)	18 ( 60.0%)	8 ( 26.7%)	30
Brain oedema	6 ( 20.0%)	8 ( 26.7%)	14 ( 46.7%)	2 ( 6.7%)	30
Bradycardia	1 ( 3.3%)	6 ( 20.0%)	12 ( 40.0%)	11 ( 36.7%)	30
Anal squamous cell carcinoma	0 ( 0.0%)	11 ( 36.7%)	19 ( 63.3%)	0 ( 0.0%)	30
Isocitrate dehydrogenase gene mutation	3 ( 10.0%)	27 ( 90.0%)	0 ( 0.0%)	0 ( 0.0%)	30
Hypersensitivity pneumonitis	0 ( 0.0%)	3 ( 10.0%)	18 ( 60.0%)	9 ( 30.0%)	30
Abdominal distension	4 ( 13.3%)	5 ( 16.7%)	19 ( 63.3%)	2 ( 6.7%)	30
Ureteric cancer	0 ( 0.0%)	0 ( 0.0%)	15 ( 50.0%)	15 ( 50.0%)	30
Non-small cell lung cancer stage III	0 ( 0.0%)	0 ( 0.0%)	26 ( 89.7%)	3 ( 10.3%)	29
Nightmare	3 ( 10.3%)	5 ( 17.2%)	4 ( 13.8%)	17 ( 58.6%)	29
Mucormycosis	3 ( 10.3%)	8 ( 27.6%)	18 ( 62.1%)	0 ( 0.0%)	29
Monkeypox	1 ( 3.4%)	28 ( 96.6%)	0 ( 0.0%)	0 ( 0.0%)	29
Malignant melanoma stage III	0 ( 0.0%)	11 ( 37.9%)	15 ( 51.7%)	3 ( 10.3%)	29
Ovarian cancer metastatic	0 ( 0.0%)	5 ( 17.2%)	23 ( 79.3%)	1 ( 3.4%)	29
Magnesium deficiency	1 ( 3.4%)	9 ( 31.0%)	17 ( 58.6%)	2 ( 6.9%)	29
Kaposi's sarcoma	0 ( 0.0%)	12 ( 41.4%)	6 ( 20.7%)	11 ( 37.9%)	29
Biliary neoplasm	0 ( 0.0%)	5 ( 17.2%)	23 ( 79.3%)	1 ( 3.4%)	29
Appendicitis	4 ( 13.8%)	6 ( 20.7%)	16 ( 55.2%)	3 ( 10.3%)	29
Urinary tract disorder	0 ( 0.0%)	2 ( 6.9%)	19 ( 65.5%)	8 ( 27.6%)	29
Intracranial pressure increased	2 ( 6.9%)	10 ( 34.5%)	12 ( 41.4%)	5 ( 17.2%)	29
Gestational trophoblastic tumour	0 ( 0.0%)	24 ( 82.8%)	5 ( 17.2%)	0 ( 0.0%)	29
Preoperative care	0 ( 0.0%)	14 ( 48.3%)	10 ( 34.5%)	5 ( 17.2%)	29
Magnetic resonance imaging head	5 ( 17.2%)	16 ( 55.2%)	6 ( 20.7%)	2 ( 6.9%)	29
Haemophilia A without inhibitors	11 ( 37.9%)	7 ( 24.1%)	9 ( 31.0%)	2 ( 6.9%)	29
Impaired gastric emptying	5 ( 17.2%)	9 ( 31.0%)	14 ( 48.3%)	1 ( 3.4%)	29

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Osteoporotic fracture	0 ( 0.0%)	0 ( 0.0%)	17 ( 58.6%)	12 ( 41.4%)	29
On and off phenomenon	0 ( 0.0%)	0 ( 0.0%)	11 ( 37.9%)	18 ( 62.1%)	29
Grey zone lymphoma	0 ( 0.0%)	28 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	28
Prophylaxis against dehydration	3 ( 10.7%)	5 ( 17.9%)	11 ( 39.3%)	9 ( 32.1%)	28
Mixed connective tissue disease	6 ( 21.4%)	6 ( 21.4%)	16 ( 57.1%)	0 ( 0.0%)	28
Drug withdrawal syndrome	1 ( 3.6%)	26 ( 92.9%)	1 ( 3.6%)	0 ( 0.0%)	28
Lipids increased	0 ( 0.0%)	3 ( 10.7%)	18 ( 64.3%)	7 ( 25.0%)	28
Malignant neoplasm progression	0 ( 0.0%)	4 ( 14.3%)	24 ( 85.7%)	0 ( 0.0%)	28
Prophylactic chemotherapy	4 ( 14.3%)	3 ( 10.7%)	10 ( 35.7%)	11 ( 39.3%)	28
Metabolic acidosis	8 ( 28.6%)	5 ( 17.9%)	14 ( 50.0%)	1 ( 3.6%)	28
Acute lymphocytic leukaemia refractory	19 ( 67.9%)	0 ( 0.0%)	5 ( 17.9%)	4 ( 14.3%)	28
Diabetes mellitus inadequate control	1 ( 3.6%)	3 ( 10.7%)	20 ( 71.4%)	4 ( 14.3%)	28
Influenza like illness	1 ( 3.6%)	5 ( 17.9%)	17 ( 60.7%)	5 ( 17.9%)	28
Myelin oligodendrocyte glycoprotein antibody-associa	15 ( 53.6%)	9 ( 32.1%)	4 ( 14.3%)	0 ( 0.0%)	28
Folliculitis	1 ( 3.6%)	13 ( 46.4%)	14 ( 50.0%)	0 ( 0.0%)	28
Intestinal transplant	27 ( 96.4%)	1 ( 3.6%)	0 ( 0.0%)	0 ( 0.0%)	28
Kidney infection	1 ( 3.6%)	18 ( 64.3%)	8 ( 28.6%)	1 ( 3.6%)	28
Philadelphia chromosome negative	4 ( 14.3%)	5 ( 17.9%)	19 ( 67.9%)	0 ( 0.0%)	28
Foetal growth restriction	27 ( 96.4%)	1 ( 3.6%)	0 ( 0.0%)	0 ( 0.0%)	28
Dwarfism	26 ( 92.9%)	0 ( 0.0%)	2 ( 7.1%)	0 ( 0.0%)	28
Subacute cutaneous lupus erythematosus	0 ( 0.0%)	9 ( 32.1%)	18 ( 64.3%)	1 ( 3.6%)	28
Hypertonia	2 ( 7.4%)	3 ( 11.1%)	18 ( 66.7%)	4 ( 14.8%)	27
Escherichia bacteraemia	1 ( 3.7%)	0 ( 0.0%)	21 ( 77.8%)	5 ( 18.5%)	27
Essential tremor	1 ( 3.7%)	0 ( 0.0%)	21 ( 77.8%)	5 ( 18.5%)	27
Epstein-Barr viraemia	9 ( 33.3%)	12 ( 44.4%)	6 ( 22.2%)	0 ( 0.0%)	27
Thymic carcinoma	2 ( 7.4%)	7 ( 25.9%)	17 ( 63.0%)	1 ( 3.7%)	27
Neuroendocrine carcinoma of the skin	0 ( 0.0%)	4 ( 14.8%)	12 ( 44.4%)	11 ( 40.7%)	27

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pyelonephritis acute	0 ( 0.0%)	0 ( 0.0%)	21 ( 77.8%)	6 ( 22.2%)	27
Organ transplant	5 ( 18.5%)	9 ( 33.3%)	11 ( 40.7%)	2 ( 7.4%)	27
Mycobacterium haemophilum infection	0 ( 0.0%)	0 ( 0.0%)	15 ( 55.6%)	12 ( 44.4%)	27
Metabolic disorder	6 ( 22.2%)	16 ( 59.3%)	4 ( 14.8%)	1 ( 3.7%)	27
Thrombocytopenic purpura	3 ( 11.1%)	1 ( 3.7%)	23 ( 85.2%)	0 ( 0.0%)	27
Seronegative arthritis	2 ( 7.4%)	7 ( 25.9%)	13 ( 48.1%)	5 ( 18.5%)	27
Demyelination	6 ( 22.2%)	18 ( 66.7%)	3 ( 11.1%)	0 ( 0.0%)	27
Henoch-Schonlein purpura	19 ( 70.4%)	5 ( 18.5%)	3 ( 11.1%)	0 ( 0.0%)	27
Antipyresis	8 ( 29.6%)	3 ( 11.1%)	10 ( 37.0%)	6 ( 22.2%)	27
Joint swelling	1 ( 3.7%)	2 ( 7.4%)	20 ( 74.1%)	4 ( 14.8%)	27
Thalassaemia beta	19 ( 70.4%)	5 ( 18.5%)	2 ( 7.4%)	1 ( 3.7%)	27
Haemolytic anaemia	5 ( 18.5%)	5 ( 18.5%)	17 ( 63.0%)	0 ( 0.0%)	27
Hepatoblastoma	27 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	27
Vitamin D	0 ( 0.0%)	1 ( 3.7%)	4 ( 14.8%)	22 ( 81.5%)	27
Visual impairment	0 ( 0.0%)	3 ( 11.1%)	9 ( 33.3%)	15 ( 55.6%)	27
Food allergy	8 ( 29.6%)	14 ( 51.9%)	3 ( 11.1%)	2 ( 7.4%)	27
Pregnancy	8 ( 29.6%)	19 ( 70.4%)	0 ( 0.0%)	0 ( 0.0%)	27
BRAF V600E mutation positive	0 ( 0.0%)	8 ( 29.6%)	19 ( 70.4%)	0 ( 0.0%)	27
HIV infection CDC Group III	0 ( 0.0%)	12 ( 44.4%)	15 ( 55.6%)	0 ( 0.0%)	27
Procoagulant therapy	1 ( 3.7%)	1 ( 3.7%)	15 ( 55.6%)	10 ( 37.0%)	27
Bacillus infection	27 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	27
Urosepsis	1 ( 3.7%)	6 ( 22.2%)	10 ( 37.0%)	10 ( 37.0%)	27
Antisynthetase syndrome	0 ( 0.0%)	8 ( 29.6%)	19 ( 70.4%)	0 ( 0.0%)	27
Epilepsy with myoclonic-atonic seizures	27 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	27
Precursor T-lymphoblastic lymphoma/leukaemia	23 ( 85.2%)	0 ( 0.0%)	4 ( 14.8%)	0 ( 0.0%)	27
Gigantism	0 ( 0.0%)	10 ( 37.0%)	14 ( 51.9%)	3 ( 11.1%)	27
Chloroma	12 ( 44.4%)	7 ( 25.9%)	6 ( 22.2%)	2 ( 7.4%)	27

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cryopyrin associated periodic syndrome	14 ( 53.8%)	6 ( 23.1%)	5 ( 19.2%)	1 ( 3.8%)	26
Goitre	8 ( 30.8%)	1 ( 3.8%)	8 ( 30.8%)	9 ( 34.6%)	26
HER2 low breast cancer	0 ( 0.0%)	4 ( 15.4%)	19 ( 73.1%)	3 ( 11.5%)	26
Blood disorder	0 ( 0.0%)	2 ( 7.7%)	13 ( 50.0%)	11 ( 42.3%)	26
Metabolic syndrome	0 ( 0.0%)	15 ( 57.7%)	5 ( 19.2%)	6 ( 23.1%)	26
Heart rate irregular	2 ( 7.7%)	0 ( 0.0%)	9 ( 34.6%)	15 ( 57.7%)	26
Laryngeal cancer	0 ( 0.0%)	1 ( 3.8%)	18 ( 69.2%)	7 ( 26.9%)	26
Cord blood transplant therapy	3 ( 11.5%)	6 ( 23.1%)	17 ( 65.4%)	0 ( 0.0%)	26
Sleep related hypermotor epilepsy	22 ( 84.6%)	4 ( 15.4%)	0 ( 0.0%)	0 ( 0.0%)	26
Encephalitis cytomegalovirus	0 ( 0.0%)	26 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	26
Impulse-control disorder	24 ( 92.3%)	2 ( 7.7%)	0 ( 0.0%)	0 ( 0.0%)	26
Cold type haemolytic anaemia	0 ( 0.0%)	6 ( 23.1%)	13 ( 50.0%)	7 ( 26.9%)	26
Hypothalamo-pituitary disorder	10 ( 38.5%)	9 ( 34.6%)	7 ( 26.9%)	0 ( 0.0%)	26
Endocarditis bacterial	4 ( 15.4%)	0 ( 0.0%)	15 ( 57.7%)	7 ( 26.9%)	26
Peripheral sensory neuropathy	0 ( 0.0%)	1 ( 3.8%)	15 ( 57.7%)	10 ( 38.5%)	26
T-cell lymphoma stage IV	0 ( 0.0%)	0 ( 0.0%)	26 (100.0%)	0 ( 0.0%)	26
Vasopressive therapy	0 ( 0.0%)	10 ( 38.5%)	16 ( 61.5%)	0 ( 0.0%)	26
Blood glucose decreased	1 ( 3.8%)	4 ( 15.4%)	13 ( 50.0%)	8 ( 30.8%)	26
Acidosis	4 ( 15.4%)	11 ( 42.3%)	8 ( 30.8%)	3 ( 11.5%)	26
Necrotising fasciitis	1 ( 3.8%)	15 ( 57.7%)	10 ( 38.5%)	0 ( 0.0%)	26
Gastric cancer stage IV	0 ( 0.0%)	3 ( 11.5%)	19 ( 73.1%)	4 ( 15.4%)	26
Venous thrombosis limb	0 ( 0.0%)	1 ( 3.8%)	24 ( 92.3%)	1 ( 3.8%)	26
Neurogenic bladder	1 ( 3.8%)	7 ( 26.9%)	16 ( 61.5%)	2 ( 7.7%)	26
Epidural analgesia	4 ( 15.4%)	21 ( 80.8%)	1 ( 3.8%)	0 ( 0.0%)	26
Central hypothyroidism	16 ( 61.5%)	7 ( 26.9%)	3 ( 11.5%)	0 ( 0.0%)	26
Infective pulmonary exacerbation of cystic fibrosis	6 ( 23.1%)	18 ( 69.2%)	2 ( 7.7%)	0 ( 0.0%)	26
Flatulence	2 ( 7.7%)	7 ( 26.9%)	14 ( 53.8%)	3 ( 11.5%)	26

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Oxygen therapy	3 ( 11.5%)	6 ( 23.1%)	11 ( 42.3%)	6 ( 23.1%)	26
Metastatic carcinoma of the bladder	0 ( 0.0%)	2 ( 8.0%)	14 ( 56.0%)	9 ( 36.0%)	25
Neuromuscular blocking therapy	2 ( 8.0%)	3 ( 12.0%)	20 ( 80.0%)	0 ( 0.0%)	25
Endometrial cancer stage IV	0 ( 0.0%)	4 ( 16.0%)	19 ( 76.0%)	2 ( 8.0%)	25
Eye infection	6 ( 24.0%)	6 ( 24.0%)	11 ( 44.0%)	2 ( 8.0%)	25
Neoplasm prophylaxis	4 ( 16.0%)	3 ( 12.0%)	18 ( 72.0%)	0 ( 0.0%)	25
Acarodermatitis	4 ( 16.0%)	10 ( 40.0%)	7 ( 28.0%)	4 ( 16.0%)	25
Acinetobacter infection	9 ( 36.0%)	5 ( 20.0%)	11 ( 44.0%)	0 ( 0.0%)	25
Metastases to adrenals	0 ( 0.0%)	0 ( 0.0%)	24 ( 96.0%)	1 ( 4.0%)	25
Progressive multiple sclerosis	11 ( 44.0%)	5 ( 20.0%)	9 ( 36.0%)	0 ( 0.0%)	25
Chronic graft versus host disease in liver	25 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	25
HIV infection CDC category C	0 ( 0.0%)	25 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	25
Diffuse large B-cell lymphoma stage I	0 ( 0.0%)	0 ( 0.0%)	19 ( 76.0%)	6 ( 24.0%)	25
Affect lability	5 ( 20.0%)	3 ( 12.0%)	9 ( 36.0%)	8 ( 32.0%)	25
Thrombolysis	0 ( 0.0%)	2 ( 8.0%)	19 ( 76.0%)	4 ( 16.0%)	25
Bone density abnormal	1 ( 4.0%)	1 ( 4.0%)	16 ( 64.0%)	7 ( 28.0%)	25
Breast cancer stage I	0 ( 0.0%)	11 ( 44.0%)	14 ( 56.0%)	0 ( 0.0%)	25
Abdominal pain lower	0 ( 0.0%)	19 ( 76.0%)	6 ( 24.0%)	0 ( 0.0%)	25
Decompensated hypothyroidism	0 ( 0.0%)	17 ( 68.0%)	8 ( 32.0%)	0 ( 0.0%)	25
Renovascular hypertension	24 ( 96.0%)	1 ( 4.0%)	0 ( 0.0%)	0 ( 0.0%)	25
Palpitations	0 ( 0.0%)	7 ( 28.0%)	13 ( 52.0%)	5 ( 20.0%)	25
Micturition disorder	2 ( 8.0%)	2 ( 8.0%)	15 ( 60.0%)	6 ( 24.0%)	25
Hypoaesthesia	0 ( 0.0%)	4 ( 16.0%)	16 ( 64.0%)	5 ( 20.0%)	25
Social anxiety disorder	5 ( 20.0%)	20 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	25
Infarction	0 ( 0.0%)	0 ( 0.0%)	23 ( 92.0%)	2 ( 8.0%)	25
Palliative sedation	25 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	25
Infertility female	0 ( 0.0%)	25 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	25

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Substance-induced psychotic disorder	6 ( 24.0%)	1 ( 4.0%)	18 ( 72.0%)	0 ( 0.0%)	25
Lymphoproliferative disorder	14 ( 56.0%)	0 ( 0.0%)	9 ( 36.0%)	2 ( 8.0%)	25
Ischaemia	7 ( 28.0%)	2 ( 8.0%)	14 ( 56.0%)	2 ( 8.0%)	25
Cryoglobulinaemia	0 ( 0.0%)	12 ( 48.0%)	12 ( 48.0%)	1 ( 4.0%)	25
Juvenile chronic myelomonocytic leukaemia	25 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	25
Adrenal gland cancer	12 ( 48.0%)	3 ( 12.0%)	6 ( 24.0%)	4 ( 16.0%)	25
Evans syndrome	13 ( 52.0%)	4 ( 16.0%)	8 ( 32.0%)	0 ( 0.0%)	25
Plasma cell disorder	0 ( 0.0%)	0 ( 0.0%)	25 (100.0%)	0 ( 0.0%)	25
Epstein-Barr virus associated lymphoma	0 ( 0.0%)	3 ( 12.0%)	5 ( 20.0%)	17 ( 68.0%)	25
Product use issue	1 ( 4.0%)	1 ( 4.0%)	5 ( 20.0%)	18 ( 72.0%)	25
FLT3 gene mutation	4 ( 16.0%)	6 ( 24.0%)	13 ( 52.0%)	2 ( 8.0%)	25
Ex-tobacco user	6 ( 25.0%)	4 ( 16.7%)	7 ( 29.2%)	7 ( 29.2%)	24
Endometrial cancer stage I	0 ( 0.0%)	4 ( 16.7%)	20 ( 83.3%)	0 ( 0.0%)	24
Dermatitis bullous	0 ( 0.0%)	2 ( 8.3%)	10 ( 41.7%)	12 ( 50.0%)	24
Drug toxicity prophylaxis	11 ( 45.8%)	1 ( 4.2%)	11 ( 45.8%)	1 ( 4.2%)	24
Maternal drugs affecting foetus	24 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	24
Facial pain	0 ( 0.0%)	10 ( 41.7%)	13 ( 54.2%)	1 ( 4.2%)	24
Haemorrhage intracranial	2 ( 8.3%)	13 ( 54.2%)	8 ( 33.3%)	1 ( 4.2%)	24
Pituitary tumour benign	2 ( 8.3%)	13 ( 54.2%)	9 ( 37.5%)	0 ( 0.0%)	24
SARS-CoV-2 test positive	0 ( 0.0%)	5 ( 20.8%)	16 ( 66.7%)	3 ( 12.5%)	24
Small cell carcinoma	0 ( 0.0%)	1 ( 4.2%)	15 ( 62.5%)	8 ( 33.3%)	24
Tumour invasion	0 ( 0.0%)	24 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	24
Cystinuria	6 ( 25.0%)	8 ( 33.3%)	10 ( 41.7%)	0 ( 0.0%)	24
Superovulation	0 ( 0.0%)	24 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	24
Peripheral spondyloarthritis	6 ( 25.0%)	10 ( 41.7%)	8 ( 33.3%)	0 ( 0.0%)	24
Spinal fracture	0 ( 0.0%)	0 ( 0.0%)	18 ( 75.0%)	6 ( 25.0%)	24
Hepatotoxicity	1 ( 4.2%)	2 ( 8.3%)	21 ( 87.5%)	0 ( 0.0%)	24



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Ganglioneuroblastoma	15 ( 62.5%)	9 ( 37.5%)	0 ( 0.0%)	0 ( 0.0%)	24
Thyroid cancer metastatic	1 ( 4.2%)	4 ( 16.7%)	13 ( 54.2%)	6 ( 25.0%)	24
Disseminated aspergillosis	7 ( 29.2%)	1 ( 4.2%)	16 ( 66.7%)	0 ( 0.0%)	24
Hallucination, visual	1 ( 4.2%)	0 ( 0.0%)	8 ( 33.3%)	15 ( 62.5%)	24
Tongue neoplasm malignant stage unspecified	0 ( 0.0%)	4 ( 16.7%)	18 ( 75.0%)	2 ( 8.3%)	24
Palmoplantar pustulosis	0 ( 0.0%)	8 ( 33.3%)	15 ( 62.5%)	1 ( 4.2%)	24
Porphyria acute	23 ( 95.8%)	1 ( 4.2%)	0 ( 0.0%)	0 ( 0.0%)	24
Neuroblastoma recurrent	24 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	24
Anaplastic lymphoma kinase gene mutation	7 ( 29.2%)	13 ( 54.2%)	3 ( 12.5%)	1 ( 4.2%)	24
Mast cell activation syndrome	6 ( 25.0%)	12 ( 50.0%)	6 ( 25.0%)	0 ( 0.0%)	24
Torticollis	2 ( 8.3%)	6 ( 25.0%)	15 ( 62.5%)	1 ( 4.2%)	24
Labour induction	12 ( 50.0%)	12 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	24
Drug resistance	0 ( 0.0%)	12 ( 50.0%)	11 ( 45.8%)	1 ( 4.2%)	24
Calcium deficiency	1 ( 4.2%)	8 ( 33.3%)	10 ( 41.7%)	5 ( 20.8%)	24
Vulvovaginal mycotic infection	3 ( 12.5%)	10 ( 41.7%)	9 ( 37.5%)	2 ( 8.3%)	24
Abdominal infection	3 ( 12.5%)	2 ( 8.3%)	18 ( 75.0%)	1 ( 4.2%)	24
Adenocarcinoma of the cervix	0 ( 0.0%)	7 ( 29.2%)	16 ( 66.7%)	1 ( 4.2%)	24
Arrhythmia prophylaxis	0 ( 0.0%)	4 ( 16.7%)	8 ( 33.3%)	12 ( 50.0%)	24
Normochromic normocytic anaemia	23 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	23
Cholangitis sclerosing	2 ( 8.7%)	4 ( 17.4%)	17 ( 73.9%)	0 ( 0.0%)	23
Pulmonary alveolar haemorrhage	0 ( 0.0%)	0 ( 0.0%)	21 ( 91.3%)	2 ( 8.7%)	23
Lichen myxoedematosus	0 ( 0.0%)	10 ( 43.5%)	13 ( 56.5%)	0 ( 0.0%)	23
Lichen planus	1 ( 4.3%)	5 ( 21.7%)	12 ( 52.2%)	5 ( 21.7%)	23
Ear pain	13 ( 56.5%)	4 ( 17.4%)	5 ( 21.7%)	1 ( 4.3%)	23
Metastases to pleura	0 ( 0.0%)	7 ( 30.4%)	15 ( 65.2%)	1 ( 4.3%)	23
Metastases to bone marrow	14 ( 60.9%)	7 ( 30.4%)	2 ( 8.7%)	0 ( 0.0%)	23
Alopecia totalis	7 ( 30.4%)	7 ( 30.4%)	9 ( 39.1%)	0 ( 0.0%)	23

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Mediastinitis	0 ( 0.0%)	3 ( 13.0%)	6 ( 26.1%)	14 ( 60.9%)	23
Detoxification	10 ( 43.5%)	8 ( 34.8%)	4 ( 17.4%)	1 ( 4.3%)	23
Clostridium difficile colitis	0 ( 0.0%)	4 ( 17.4%)	14 ( 60.9%)	5 ( 21.7%)	23
Prostate cancer stage IV	0 ( 0.0%)	2 ( 8.7%)	16 ( 69.6%)	5 ( 21.7%)	23
Blood magnesium decreased	2 ( 8.7%)	5 ( 21.7%)	12 ( 52.2%)	4 ( 17.4%)	23
Hiccups	0 ( 0.0%)	11 ( 47.8%)	10 ( 43.5%)	2 ( 8.7%)	23
Catheter management	0 ( 0.0%)	15 ( 65.2%)	7 ( 30.4%)	1 ( 4.3%)	23
Platelet aggregation inhibition	1 ( 4.3%)	0 ( 0.0%)	16 ( 69.6%)	6 ( 26.1%)	23
Anger	17 ( 73.9%)	1 ( 4.3%)	5 ( 21.7%)	0 ( 0.0%)	23
Hepatic steatosis	4 ( 17.4%)	4 ( 17.4%)	9 ( 39.1%)	6 ( 26.1%)	23
Myoclonic epilepsy	14 ( 60.9%)	1 ( 4.3%)	8 ( 34.8%)	0 ( 0.0%)	23
Ischaemic cardiomyopathy	0 ( 0.0%)	2 ( 8.7%)	8 ( 34.8%)	13 ( 56.5%)	23
Hyperparathyroidism	2 ( 8.7%)	6 ( 26.1%)	14 ( 60.9%)	1 ( 4.3%)	23
Post-acute COVID-19 syndrome	2 ( 8.7%)	19 ( 82.6%)	0 ( 0.0%)	2 ( 8.7%)	23
Scedosporium infection	5 ( 21.7%)	2 ( 8.7%)	16 ( 69.6%)	0 ( 0.0%)	23
Malignant connective tissue neoplasm	7 ( 30.4%)	8 ( 34.8%)	6 ( 26.1%)	2 ( 8.7%)	23
Pneumonia staphylococcal	2 ( 8.7%)	0 ( 0.0%)	21 ( 91.3%)	0 ( 0.0%)	23
Double hit lymphoma	0 ( 0.0%)	0 ( 0.0%)	14 ( 60.9%)	9 ( 39.1%)	23
Coronary arterial stent insertion	0 ( 0.0%)	0 ( 0.0%)	14 ( 60.9%)	9 ( 39.1%)	23
Central pain syndrome	2 ( 8.7%)	1 ( 4.3%)	20 ( 87.0%)	0 ( 0.0%)	23
Scleritis	1 ( 4.3%)	3 ( 13.0%)	18 ( 78.3%)	1 ( 4.3%)	23
Central nervous system leukaemia	20 ( 87.0%)	3 ( 13.0%)	0 ( 0.0%)	0 ( 0.0%)	23
Vitamin B complex deficiency	2 ( 8.7%)	6 ( 26.1%)	14 ( 60.9%)	1 ( 4.3%)	23
Non-Hodgkin's lymphoma metastatic	14 ( 60.9%)	0 ( 0.0%)	6 ( 26.1%)	3 ( 13.0%)	23
Caesarean section	4 ( 18.2%)	18 ( 81.8%)	0 ( 0.0%)	0 ( 0.0%)	22
Neuroendocrine carcinoma metastatic	0 ( 0.0%)	5 ( 22.7%)	15 ( 68.2%)	2 ( 9.1%)	22
Nervous system disorder prophylaxis	3 ( 13.6%)	10 ( 45.5%)	8 ( 36.4%)	1 ( 4.5%)	22

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Reduction of increased intracranial pressure	4 ( 18.2%)	6 ( 27.3%)	8 ( 36.4%)	4 ( 18.2%)	22
Bacterial endophthalmitis	0 ( 0.0%)	0 ( 0.0%)	15 ( 68.2%)	7 ( 31.8%)	22
Metastatic squamous cell carcinoma	0 ( 0.0%)	2 ( 9.1%)	16 ( 72.7%)	4 ( 18.2%)	22
Lung squamous cell carcinoma metastatic	0 ( 0.0%)	1 ( 4.5%)	16 ( 72.7%)	5 ( 22.7%)	22
Libido decreased	0 ( 0.0%)	15 ( 68.2%)	7 ( 31.8%)	0 ( 0.0%)	22
Keratitis	10 ( 45.5%)	2 ( 9.1%)	7 ( 31.8%)	3 ( 13.6%)	22
Intestinal obstruction	0 ( 0.0%)	1 ( 4.5%)	17 ( 77.3%)	4 ( 18.2%)	22
Skin exfoliation	0 ( 0.0%)	2 ( 9.1%)	15 ( 68.2%)	5 ( 22.7%)	22
Corneal infection	22 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	22
Myasthenic syndrome	0 ( 0.0%)	3 ( 13.6%)	18 ( 81.8%)	1 ( 4.5%)	22
Computerised tomogram heart	0 ( 0.0%)	4 ( 18.2%)	16 ( 72.7%)	2 ( 9.1%)	22
Premenstrual syndrome	0 ( 0.0%)	8 ( 36.4%)	3 ( 13.6%)	11 ( 50.0%)	22
Hyperparathyroidism primary	4 ( 18.2%)	4 ( 18.2%)	10 ( 45.5%)	4 ( 18.2%)	22
Varicella zoster virus infection	2 ( 9.1%)	4 ( 18.2%)	16 ( 72.7%)	0 ( 0.0%)	22
Pleurisy	0 ( 0.0%)	2 ( 9.1%)	20 ( 90.9%)	0 ( 0.0%)	22
Necrotising myositis	0 ( 0.0%)	7 ( 31.8%)	13 ( 59.1%)	2 ( 9.1%)	22
Pneumonia fungal	1 ( 4.5%)	1 ( 4.5%)	15 ( 68.2%)	5 ( 22.7%)	22
Portal hypertension	4 ( 18.2%)	8 ( 36.4%)	8 ( 36.4%)	2 ( 9.1%)	22
Gastrointestinal bacterial overgrowth	9 ( 40.9%)	5 ( 22.7%)	5 ( 22.7%)	3 ( 13.6%)	22
Agranulocytosis	2 ( 9.1%)	2 ( 9.1%)	17 ( 77.3%)	1 ( 4.5%)	22
Cataract operation	0 ( 0.0%)	2 ( 9.1%)	18 ( 81.8%)	2 ( 9.1%)	22
Nicotine dependence	0 ( 0.0%)	4 ( 18.2%)	17 ( 77.3%)	1 ( 4.5%)	22
Palisaded neutrophilic granulomatous dermatitis	0 ( 0.0%)	0 ( 0.0%)	22 (100.0%)	0 ( 0.0%)	22
Barrett's oesophagus	0 ( 0.0%)	5 ( 22.7%)	12 ( 54.5%)	5 ( 22.7%)	22
Eye pruritus	0 ( 0.0%)	3 ( 13.6%)	18 ( 81.8%)	1 ( 4.5%)	22
Insulinoma	1 ( 4.5%)	0 ( 0.0%)	2 ( 9.1%)	19 ( 86.4%)	22
Mouth ulceration	6 ( 28.6%)	2 ( 9.5%)	12 ( 57.1%)	1 ( 4.8%)	21

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Coronary artery dilatation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	21 (100.0%)	21
Tuberous sclerosis complex	12 ( 57.1%)	9 ( 42.9%)	0 ( 0.0%)	0 ( 0.0%)	21
Artificial menopause	0 ( 0.0%)	9 ( 42.9%)	12 ( 57.1%)	0 ( 0.0%)	21
Empty sella syndrome	0 ( 0.0%)	0 ( 0.0%)	21 (100.0%)	0 ( 0.0%)	21
Morphoea	10 ( 47.6%)	6 ( 28.6%)	5 ( 23.8%)	0 ( 0.0%)	21
Rectosigmoid cancer stage IV	0 ( 0.0%)	3 ( 14.3%)	18 ( 85.7%)	0 ( 0.0%)	21
Metastases to spine	0 ( 0.0%)	3 ( 14.3%)	15 ( 71.4%)	3 ( 14.3%)	21
HIV test	1 ( 4.8%)	19 ( 90.5%)	1 ( 4.8%)	0 ( 0.0%)	21
Acute myelomonocytic leukaemia	2 ( 9.5%)	4 ( 19.0%)	10 ( 47.6%)	5 ( 23.8%)	21
Renal cancer stage IV	0 ( 0.0%)	5 ( 23.8%)	15 ( 71.4%)	1 ( 4.8%)	21
Dry mouth	0 ( 0.0%)	3 ( 14.3%)	16 ( 76.2%)	2 ( 9.5%)	21
Rectal cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	11 ( 52.4%)	10 ( 47.6%)	21
Chronic graft versus host disease in eye	19 ( 90.5%)	0 ( 0.0%)	2 ( 9.5%)	0 ( 0.0%)	21
Malignant neoplasm of ampulla of Vater	0 ( 0.0%)	0 ( 0.0%)	21 (100.0%)	0 ( 0.0%)	21
Lymphoplasmacytoid lymphoma/immunocytoma	0 ( 0.0%)	0 ( 0.0%)	3 ( 14.3%)	18 ( 85.7%)	21
Lung carcinoma cell type unspecified recurrent	0 ( 0.0%)	5 ( 23.8%)	11 ( 52.4%)	5 ( 23.8%)	21
Ludwig angina	0 ( 0.0%)	21 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	21
Blood testosterone decreased	2 ( 9.5%)	6 ( 28.6%)	13 ( 61.9%)	0 ( 0.0%)	21
Cystoid macular oedema	1 ( 4.8%)	5 ( 23.8%)	15 ( 71.4%)	0 ( 0.0%)	21
Skin papilloma	3 ( 14.3%)	12 ( 57.1%)	3 ( 14.3%)	3 ( 14.3%)	21
Flushing	2 ( 9.5%)	5 ( 23.8%)	12 ( 57.1%)	2 ( 9.5%)	21
Spinal stenosis	0 ( 0.0%)	0 ( 0.0%)	18 ( 85.7%)	3 ( 14.3%)	21
Histoplasmosis	0 ( 0.0%)	12 ( 57.1%)	8 ( 38.1%)	1 ( 4.8%)	21
Hormone level abnormal	4 ( 19.0%)	5 ( 23.8%)	11 ( 52.4%)	1 ( 4.8%)	21
Hyperbilirubinaemia	21 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	21
Hodgkin's disease nodular sclerosis stage IV	0 ( 0.0%)	21 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	21
High grade B-cell lymphoma Burkitt-like lymphoma	21 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	21

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Aplasia pure red cell	0 ( 0.0%)	0 ( 0.0%)	14 ( 66.7%)	7 ( 33.3%)	21
Anaphylactic shock	4 ( 19.0%)	3 ( 14.3%)	14 ( 66.7%)	0 ( 0.0%)	21
Disseminated intravascular coagulation	2 ( 9.5%)	7 ( 33.3%)	9 ( 42.9%)	3 ( 14.3%)	21
Tourette's disorder	17 ( 81.0%)	4 ( 19.0%)	0 ( 0.0%)	0 ( 0.0%)	21
Tooth abscess	2 ( 9.5%)	6 ( 28.6%)	9 ( 42.9%)	4 ( 19.0%)	21
Cerebral haemorrhage	4 ( 19.0%)	1 ( 4.8%)	10 ( 47.6%)	6 ( 28.6%)	21
Tubulointerstitial nephritis	3 ( 14.3%)	8 ( 38.1%)	7 ( 33.3%)	3 ( 14.3%)	21
Undifferentiated sarcoma	3 ( 14.3%)	3 ( 14.3%)	15 ( 71.4%)	0 ( 0.0%)	21
Poor quality sleep	1 ( 4.8%)	9 ( 42.9%)	11 ( 52.4%)	0 ( 0.0%)	21
Post lumbar puncture syndrome	0 ( 0.0%)	20 ( 95.2%)	1 ( 4.8%)	0 ( 0.0%)	21
Drug intolerance	1 ( 4.8%)	1 ( 4.8%)	14 ( 66.7%)	5 ( 23.8%)	21
Cachexia	0 ( 0.0%)	2 ( 9.5%)	13 ( 61.9%)	6 ( 28.6%)	21
Gallbladder cancer	0 ( 0.0%)	1 ( 4.8%)	18 ( 85.7%)	2 ( 9.5%)	21
Blood cholesterol decreased	0 ( 0.0%)	3 ( 14.3%)	13 ( 61.9%)	5 ( 23.8%)	21
Asthmatic crisis	1 ( 4.8%)	15 ( 71.4%)	5 ( 23.8%)	0 ( 0.0%)	21
Mastocytosis	0 ( 0.0%)	8 ( 38.1%)	13 ( 61.9%)	0 ( 0.0%)	21
Wound treatment	6 ( 28.6%)	7 ( 33.3%)	0 ( 0.0%)	8 ( 38.1%)	21
White blood cell count increased	1 ( 4.8%)	4 ( 19.0%)	16 ( 76.2%)	0 ( 0.0%)	21
Prophylaxis urinary tract infection	3 ( 14.3%)	0 ( 0.0%)	8 ( 38.1%)	10 ( 47.6%)	21
5q minus syndrome	0 ( 0.0%)	0 ( 0.0%)	7 ( 33.3%)	14 ( 66.7%)	21
Carcinoid tumour of the small bowel	0 ( 0.0%)	1 ( 4.8%)	15 ( 71.4%)	5 ( 23.8%)	21
Prurigo	2 ( 10.0%)	3 ( 15.0%)	4 ( 20.0%)	11 ( 55.0%)	20
Epistaxis	3 ( 15.0%)	10 ( 50.0%)	4 ( 20.0%)	3 ( 15.0%)	20
Epilepsy congenital	20 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	20
Neuromuscular blockade	10 ( 50.0%)	0 ( 0.0%)	9 ( 45.0%)	1 ( 5.0%)	20
Pulmonary mass	0 ( 0.0%)	5 ( 25.0%)	13 ( 65.0%)	2 ( 10.0%)	20
Natural killer-cell leukaemia	0 ( 0.0%)	0 ( 0.0%)	10 ( 50.0%)	10 ( 50.0%)	20

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Enterocolitis	0 ( 0.0%)	3 ( 15.0%)	12 ( 60.0%)	5 ( 25.0%)	20
Transitional cell carcinoma metastatic	0 ( 0.0%)	0 ( 0.0%)	15 ( 75.0%)	5 ( 25.0%)	20
Renal neoplasm	0 ( 0.0%)	0 ( 0.0%)	18 ( 90.0%)	2 ( 10.0%)	20
Bronchopulmonary aspergillosis allergic	0 ( 0.0%)	15 ( 75.0%)	5 ( 25.0%)	0 ( 0.0%)	20
Eczema nummular	3 ( 15.0%)	2 ( 10.0%)	13 ( 65.0%)	2 ( 10.0%)	20
Heart disease congenital	16 ( 80.0%)	0 ( 0.0%)	2 ( 10.0%)	2 ( 10.0%)	20
Chest scan	0 ( 0.0%)	1 ( 5.0%)	19 ( 95.0%)	0 ( 0.0%)	20
Dysbiosis	3 ( 15.0%)	7 ( 35.0%)	8 ( 40.0%)	2 ( 10.0%)	20
Dry skin prophylaxis	3 ( 15.0%)	4 ( 20.0%)	10 ( 50.0%)	3 ( 15.0%)	20
Maternal exposure timing unspecified	20 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	20
Mineral deficiency	6 ( 30.0%)	2 ( 10.0%)	11 ( 55.0%)	1 ( 5.0%)	20
Abnormal behaviour	13 ( 65.0%)	5 ( 25.0%)	1 ( 5.0%)	1 ( 5.0%)	20
Bone tuberculosis	0 ( 0.0%)	16 ( 80.0%)	4 ( 20.0%)	0 ( 0.0%)	20
Eye irritation	1 ( 5.0%)	4 ( 20.0%)	12 ( 60.0%)	3 ( 15.0%)	20
Bone giant cell tumour	10 ( 50.0%)	7 ( 35.0%)	3 ( 15.0%)	0 ( 0.0%)	20
Lip and/or oral cavity cancer	0 ( 0.0%)	0 ( 0.0%)	13 ( 65.0%)	7 ( 35.0%)	20
Legionella infection	0 ( 0.0%)	4 ( 20.0%)	4 ( 20.0%)	12 ( 60.0%)	20
Rash maculo-papular	0 ( 0.0%)	3 ( 15.0%)	16 ( 80.0%)	1 ( 5.0%)	20
Cytogenetic abnormality	20 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	20
Pancytopenia	1 ( 5.0%)	3 ( 15.0%)	15 ( 75.0%)	1 ( 5.0%)	20
Thoracic vertebral fracture	0 ( 0.0%)	11 ( 55.0%)	9 ( 45.0%)	0 ( 0.0%)	20
Hereditary haemorrhagic telangiectasia	0 ( 0.0%)	2 ( 10.0%)	18 ( 90.0%)	0 ( 0.0%)	20
Proctitis	1 ( 5.0%)	5 ( 25.0%)	14 ( 70.0%)	0 ( 0.0%)	20
Small for dates baby	20 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	20
Idiopathic interstitial pneumonia	0 ( 0.0%)	6 ( 30.0%)	9 ( 45.0%)	5 ( 25.0%)	20
Spinal disorder	0 ( 0.0%)	5 ( 25.0%)	13 ( 65.0%)	2 ( 10.0%)	20
Cystitis noninfective	0 ( 0.0%)	0 ( 0.0%)	20 (100.0%)	0 ( 0.0%)	20

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Autoinflammatory disease	19 ( 95.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 5.0%)	20
Abortion induced	3 ( 15.0%)	17 ( 85.0%)	0 ( 0.0%)	0 ( 0.0%)	20
Respiratory syncytial virus immunisation	18 ( 90.0%)	0 ( 0.0%)	2 ( 10.0%)	0 ( 0.0%)	20
Tobacco user	0 ( 0.0%)	4 ( 20.0%)	14 ( 70.0%)	2 ( 10.0%)	20
Varices oesophageal	2 ( 10.0%)	5 ( 25.0%)	12 ( 60.0%)	1 ( 5.0%)	20
Nerve injury	0 ( 0.0%)	4 ( 20.0%)	14 ( 70.0%)	2 ( 10.0%)	20
Gingival cancer	0 ( 0.0%)	0 ( 0.0%)	18 ( 90.0%)	2 ( 10.0%)	20
Gastrointestinal motility disorder	6 ( 30.0%)	5 ( 25.0%)	9 ( 45.0%)	0 ( 0.0%)	20
Immune-mediated enterocolitis	2 ( 10.0%)	1 ( 5.0%)	13 ( 65.0%)	4 ( 20.0%)	20
Gastric pH decreased	2 ( 10.0%)	1 ( 5.0%)	16 ( 80.0%)	1 ( 5.0%)	20
Central nervous system infection	2 ( 10.0%)	6 ( 30.0%)	2 ( 10.0%)	10 ( 50.0%)	20
Oropharyngeal squamous cell carcinoma	0 ( 0.0%)	6 ( 30.0%)	8 ( 40.0%)	6 ( 30.0%)	20
Bacterial disease carrier	4 ( 20.0%)	6 ( 30.0%)	10 ( 50.0%)	0 ( 0.0%)	20
Organising pneumonia	1 ( 5.0%)	4 ( 20.0%)	13 ( 65.0%)	2 ( 10.0%)	20
Neuropsychiatric lupus	19 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	19
Trisomy 21	19 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	19
Rectal haemorrhage	2 ( 10.5%)	6 ( 31.6%)	9 ( 47.4%)	2 ( 10.5%)	19
Renal and pancreas transplant	0 ( 0.0%)	8 ( 42.1%)	11 ( 57.9%)	0 ( 0.0%)	19
Lipidosis	2 ( 10.5%)	7 ( 36.8%)	8 ( 42.1%)	2 ( 10.5%)	19
Discomfort	4 ( 21.1%)	0 ( 0.0%)	15 ( 78.9%)	0 ( 0.0%)	19
Dialysis	1 ( 5.3%)	1 ( 5.3%)	13 ( 68.4%)	4 ( 21.1%)	19
Low density lipoprotein abnormal	0 ( 0.0%)	1 ( 5.3%)	14 ( 73.7%)	4 ( 21.1%)	19
Transitional cell cancer of the renal pelvis and ure	0 ( 0.0%)	0 ( 0.0%)	11 ( 57.9%)	8 ( 42.1%)	19
Desmoid tumour	4 ( 21.1%)	12 ( 63.2%)	3 ( 15.8%)	0 ( 0.0%)	19
Rhabdoid tumour	19 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	19
Lacunar infarction	0 ( 0.0%)	0 ( 0.0%)	16 ( 84.2%)	3 ( 15.8%)	19
Post procedural hypothyroidism	0 ( 0.0%)	3 ( 15.8%)	13 ( 68.4%)	3 ( 15.8%)	19

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Isodicentric chromosome 15 syndrome	16 ( 84.2%)	3 ( 15.8%)	0 ( 0.0%)	0 ( 0.0%)	19
Hepatic failure	1 ( 5.3%)	2 ( 10.5%)	12 ( 63.2%)	4 ( 21.1%)	19
Non-renal cell carcinoma of kidney	0 ( 0.0%)	19 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	19
Vision blurred	0 ( 0.0%)	0 ( 0.0%)	17 ( 89.5%)	2 ( 10.5%)	19
Volvulus	0 ( 0.0%)	1 ( 5.3%)	18 ( 94.7%)	0 ( 0.0%)	19
Radiculopathy	4 ( 21.1%)	5 ( 26.3%)	10 ( 52.6%)	0 ( 0.0%)	19
Anal incontinence	0 ( 0.0%)	2 ( 10.5%)	2 ( 10.5%)	15 ( 78.9%)	19
Soft tissue infection	2 ( 10.5%)	4 ( 21.1%)	10 ( 52.6%)	3 ( 15.8%)	19
Spinal fusion surgery	1 ( 5.3%)	14 ( 73.7%)	4 ( 21.1%)	0 ( 0.0%)	19
Complement deficiency disease	2 ( 10.5%)	7 ( 36.8%)	10 ( 52.6%)	0 ( 0.0%)	19
Perinatal depression	8 ( 42.1%)	11 ( 57.9%)	0 ( 0.0%)	0 ( 0.0%)	19
Sleep deficit	10 ( 52.6%)	0 ( 0.0%)	3 ( 15.8%)	6 ( 31.6%)	19
Tic	19 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	19
Autonomic neuropathy	2 ( 10.5%)	10 ( 52.6%)	6 ( 31.6%)	1 ( 5.3%)	19
Neoplasm prostate	0 ( 0.0%)	0 ( 0.0%)	12 ( 63.2%)	7 ( 36.8%)	19
Coronary artery bypass	0 ( 0.0%)	1 ( 5.3%)	16 ( 84.2%)	2 ( 10.5%)	19
Ileus	1 ( 5.3%)	2 ( 10.5%)	9 ( 47.4%)	7 ( 36.8%)	19
Cervix cancer metastatic	0 ( 0.0%)	8 ( 42.1%)	8 ( 42.1%)	3 ( 15.8%)	19
Graft infection	14 ( 73.7%)	0 ( 0.0%)	3 ( 15.8%)	2 ( 10.5%)	19
Pre-existing disease	0 ( 0.0%)	0 ( 0.0%)	9 ( 47.4%)	10 ( 52.6%)	19
Wisdom teeth removal	9 ( 47.4%)	9 ( 47.4%)	1 ( 5.3%)	0 ( 0.0%)	19
Appendix cancer	0 ( 0.0%)	3 ( 15.8%)	15 ( 78.9%)	1 ( 5.3%)	19
Neuroendocrine tumour of the rectum	0 ( 0.0%)	3 ( 15.8%)	16 ( 84.2%)	0 ( 0.0%)	19
Pneumocystis jirovecii infection	4 ( 21.1%)	7 ( 36.8%)	7 ( 36.8%)	1 ( 5.3%)	19
Ocular icterus	19 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	19
Cryptococcosis	0 ( 0.0%)	1 ( 5.3%)	16 ( 84.2%)	2 ( 10.5%)	19
Fungaemia	3 ( 15.8%)	2 ( 10.5%)	11 ( 57.9%)	3 ( 15.8%)	19



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Primary hypothyroidism	0 ( 0.0%)	2 ( 10.5%)	15 ( 78.9%)	2 ( 10.5%)	19
Performance enhancing product use	0 ( 0.0%)	18 ( 94.7%)	1 ( 5.3%)	0 ( 0.0%)	19
Partial seizures with secondary generalisation	18 ( 94.7%)	0 ( 0.0%)	1 ( 5.3%)	0 ( 0.0%)	19
Paraganglion neoplasm	15 ( 78.9%)	3 ( 15.8%)	1 ( 5.3%)	0 ( 0.0%)	19
Renal cell carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	15 ( 78.9%)	4 ( 21.1%)	19
Factor VII deficiency	13 ( 68.4%)	4 ( 21.1%)	2 ( 10.5%)	0 ( 0.0%)	19
Blood thyroid stimulating hormone increased	4 ( 21.1%)	6 ( 31.6%)	6 ( 31.6%)	3 ( 15.8%)	19
Pancreatitis acute	0 ( 0.0%)	11 ( 57.9%)	6 ( 31.6%)	2 ( 10.5%)	19
Accidental exposure to product by child	19 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	19
Dental care	3 ( 15.8%)	6 ( 31.6%)	10 ( 52.6%)	0 ( 0.0%)	19
Erythema multiforme	1 ( 5.3%)	1 ( 5.3%)	16 ( 84.2%)	1 ( 5.3%)	19
Tumour necrosis factor receptor-associated periodic	3 ( 16.7%)	9 ( 50.0%)	5 ( 27.8%)	1 ( 5.6%)	18
Obstructive airways disorder	0 ( 0.0%)	6 ( 33.3%)	12 ( 66.7%)	0 ( 0.0%)	18
Neuropsychological symptoms	16 ( 88.9%)	0 ( 0.0%)	2 ( 11.1%)	0 ( 0.0%)	18
Microalbuminuria	0 ( 0.0%)	0 ( 0.0%)	18 (100.0%)	0 ( 0.0%)	18
Pulmonary congestion	1 ( 5.6%)	3 ( 16.7%)	6 ( 33.3%)	8 ( 44.4%)	18
Neoplasm progression	4 ( 22.2%)	1 ( 5.6%)	7 ( 38.9%)	6 ( 33.3%)	18
Acute respiratory failure	4 ( 22.2%)	6 ( 33.3%)	7 ( 38.9%)	1 ( 5.6%)	18
Myopathy	0 ( 0.0%)	4 ( 22.2%)	8 ( 44.4%)	6 ( 33.3%)	18
Myelosuppression	1 ( 5.6%)	4 ( 22.2%)	9 ( 50.0%)	4 ( 22.2%)	18
Chordoma	0 ( 0.0%)	0 ( 0.0%)	18 (100.0%)	0 ( 0.0%)	18
Emotional disorder	9 ( 50.0%)	6 ( 33.3%)	2 ( 11.1%)	1 ( 5.6%)	18
Chronic actinic dermatitis	0 ( 0.0%)	0 ( 0.0%)	17 ( 94.4%)	1 ( 5.6%)	18
Arterial disorder	0 ( 0.0%)	3 ( 16.7%)	9 ( 50.0%)	6 ( 33.3%)	18
Metaplastic breast carcinoma	0 ( 0.0%)	0 ( 0.0%)	18 (100.0%)	0 ( 0.0%)	18
Meningococcal sepsis	18 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	18
Acinar cell carcinoma of pancreas	0 ( 0.0%)	18 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	18

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Weight increased	3 ( 16.7%)	6 ( 33.3%)	7 ( 38.9%)	2 ( 11.1%)	18
Retroperitoneal fibrosis	0 ( 0.0%)	1 ( 5.6%)	15 ( 83.3%)	2 ( 11.1%)	18
Body mass index decreased	18 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	18
Heart rate	0 ( 0.0%)	2 ( 11.1%)	14 ( 77.8%)	2 ( 11.1%)	18
Immune-mediated lung disease	0 ( 0.0%)	12 ( 66.7%)	5 ( 27.8%)	1 ( 5.6%)	18
Pathogen resistance	0 ( 0.0%)	12 ( 66.7%)	3 ( 16.7%)	3 ( 16.7%)	18
Squamous cell carcinoma of the tongue	0 ( 0.0%)	1 ( 5.6%)	13 ( 72.2%)	4 ( 22.2%)	18
Percutaneous coronary intervention	0 ( 0.0%)	4 ( 22.2%)	5 ( 27.8%)	9 ( 50.0%)	18
Huntington's disease	0 ( 0.0%)	4 ( 22.2%)	12 ( 66.7%)	2 ( 11.1%)	18
Myopericarditis	4 ( 22.2%)	7 ( 38.9%)	7 ( 38.9%)	0 ( 0.0%)	18
Soft tissue neoplasm	2 ( 11.1%)	6 ( 33.3%)	9 ( 50.0%)	1 ( 5.6%)	18
Persistent depressive disorder	2 ( 11.1%)	2 ( 11.1%)	14 ( 77.8%)	0 ( 0.0%)	18
Burning sensation	3 ( 16.7%)	6 ( 33.3%)	8 ( 44.4%)	1 ( 5.6%)	18
Otitis externa	1 ( 5.6%)	7 ( 38.9%)	0 ( 0.0%)	10 ( 55.6%)	18
Postmenopause	1 ( 5.6%)	2 ( 11.1%)	14 ( 77.8%)	1 ( 5.6%)	18
Keratopathy	0 ( 0.0%)	0 ( 0.0%)	15 ( 83.3%)	3 ( 16.7%)	18
Gingivitis	5 ( 27.8%)	8 ( 44.4%)	5 ( 27.8%)	0 ( 0.0%)	18
Conjunctivitis allergic	3 ( 16.7%)	7 ( 38.9%)	6 ( 33.3%)	2 ( 11.1%)	18
Carpal tunnel syndrome	3 ( 16.7%)	1 ( 5.6%)	12 ( 66.7%)	2 ( 11.1%)	18
Cheilitis	18 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	18
Atypical pneumonia	0 ( 0.0%)	5 ( 27.8%)	13 ( 72.2%)	0 ( 0.0%)	18
Campylobacter infection	0 ( 0.0%)	11 ( 61.1%)	2 ( 11.1%)	5 ( 27.8%)	18
Hypovolaemia	0 ( 0.0%)	1 ( 5.6%)	12 ( 66.7%)	5 ( 27.8%)	18
Intermenstrual bleeding	5 ( 27.8%)	12 ( 66.7%)	1 ( 5.6%)	0 ( 0.0%)	18
Pseudomonal bacteraemia	0 ( 0.0%)	0 ( 0.0%)	7 ( 38.9%)	11 ( 61.1%)	18
Carcinoid tumour pulmonary	0 ( 0.0%)	0 ( 0.0%)	18 (100.0%)	0 ( 0.0%)	18
Asthma prophylaxis	3 ( 17.6%)	2 ( 11.8%)	5 ( 29.4%)	7 ( 41.2%)	17

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Euphoric mood	8 ( 47.1%)	9 ( 52.9%)	0 ( 0.0%)	0 ( 0.0%)	17
Addison's disease	2 ( 11.8%)	8 ( 47.1%)	7 ( 41.2%)	0 ( 0.0%)	17
Neuroendocrine tumour of the lung	0 ( 0.0%)	0 ( 0.0%)	14 ( 82.4%)	3 ( 17.6%)	17
Astrocytoma, low grade	11 ( 64.7%)	5 ( 29.4%)	1 ( 5.9%)	0 ( 0.0%)	17
Adjustment disorder with depressed mood	0 ( 0.0%)	10 ( 58.8%)	4 ( 23.5%)	3 ( 17.6%)	17
Trichophytosis	0 ( 0.0%)	17 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	17
Menstrual disorder	9 ( 52.9%)	7 ( 41.2%)	1 ( 5.9%)	0 ( 0.0%)	17
Menstrual cycle management	9 ( 52.9%)	6 ( 35.3%)	2 ( 11.8%)	0 ( 0.0%)	17
Duodenitis	5 ( 29.4%)	6 ( 35.3%)	6 ( 35.3%)	0 ( 0.0%)	17
Dermo-hypodermatitis	0 ( 0.0%)	3 ( 17.6%)	12 ( 70.6%)	2 ( 11.8%)	17
Lymph node tuberculosis	0 ( 0.0%)	8 ( 47.1%)	5 ( 29.4%)	4 ( 23.5%)	17
Warm autoimmune haemolytic anaemia	6 ( 35.3%)	2 ( 11.8%)	4 ( 23.5%)	5 ( 29.4%)	17
Listeriosis	0 ( 0.0%)	0 ( 0.0%)	5 ( 29.4%)	12 ( 70.6%)	17
Allergic respiratory symptom	2 ( 11.8%)	1 ( 5.9%)	8 ( 47.1%)	6 ( 35.3%)	17
Blood triglycerides	0 ( 0.0%)	3 ( 17.6%)	13 ( 76.5%)	1 ( 5.9%)	17
Keratoconus	5 ( 29.4%)	10 ( 58.8%)	2 ( 11.8%)	0 ( 0.0%)	17
Sarcomatoid carcinoma of the lung	0 ( 0.0%)	0 ( 0.0%)	17 (100.0%)	0 ( 0.0%)	17
Self-medication	0 ( 0.0%)	0 ( 0.0%)	15 ( 88.2%)	2 ( 11.8%)	17
Akathisia	1 ( 5.9%)	11 ( 64.7%)	2 ( 11.8%)	3 ( 17.6%)	17
Paranoia	8 ( 47.1%)	3 ( 17.6%)	1 ( 5.9%)	5 ( 29.4%)	17
Incontinence	0 ( 0.0%)	1 ( 5.9%)	11 ( 64.7%)	5 ( 29.4%)	17
Confusional state	1 ( 5.9%)	0 ( 0.0%)	11 ( 64.7%)	5 ( 29.4%)	17
Colon cancer stage III	0 ( 0.0%)	9 ( 52.9%)	3 ( 17.6%)	5 ( 29.4%)	17
Computerised tomogram head	0 ( 0.0%)	6 ( 35.3%)	10 ( 58.8%)	1 ( 5.9%)	17
Spinal compression fracture	0 ( 0.0%)	0 ( 0.0%)	7 ( 41.2%)	10 ( 58.8%)	17
Bladder dysfunction	0 ( 0.0%)	3 ( 17.6%)	12 ( 70.6%)	2 ( 11.8%)	17
Thrombocytosis	2 ( 11.8%)	4 ( 23.5%)	6 ( 35.3%)	5 ( 29.4%)	17

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Infertility	1 ( 5.9%)	16 ( 94.1%)	0 ( 0.0%)	0 ( 0.0%)	17
Thalassaemia	10 ( 58.8%)	2 ( 11.8%)	5 ( 29.4%)	0 ( 0.0%)	17
Necrotising scleritis	0 ( 0.0%)	2 ( 11.8%)	0 ( 0.0%)	15 ( 88.2%)	17
Contusion	0 ( 0.0%)	7 ( 41.2%)	10 ( 58.8%)	0 ( 0.0%)	17
Product substitution	0 ( 0.0%)	1 ( 5.9%)	15 ( 88.2%)	1 ( 5.9%)	17
Poisoning	4 ( 23.5%)	1 ( 5.9%)	11 ( 64.7%)	1 ( 5.9%)	17
B-cell lymphoma recurrent	0 ( 0.0%)	0 ( 0.0%)	17 (100.0%)	0 ( 0.0%)	17
Primitive neuroectodermal tumour	3 ( 17.6%)	0 ( 0.0%)	14 ( 82.4%)	0 ( 0.0%)	17
B-cell lymphoma stage IV	0 ( 0.0%)	10 ( 58.8%)	7 ( 41.2%)	0 ( 0.0%)	17
B-cell lymphoma stage II	0 ( 0.0%)	17 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	17
Gastrointestinal lymphoma	0 ( 0.0%)	13 ( 76.5%)	4 ( 23.5%)	0 ( 0.0%)	17
Gastric cancer recurrent	0 ( 0.0%)	2 ( 11.8%)	11 ( 64.7%)	4 ( 23.5%)	17
Lung adenocarcinoma stage II	0 ( 0.0%)	1 ( 5.9%)	16 ( 94.1%)	0 ( 0.0%)	17
Paroxysmal sympathetic hyperactivity	4 ( 23.5%)	5 ( 29.4%)	8 ( 47.1%)	0 ( 0.0%)	17
Flank pain	3 ( 17.6%)	5 ( 29.4%)	8 ( 47.1%)	1 ( 5.9%)	17
Progressive familial intrahepatic cholestasis	17 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	17
Neurosarcoidosis	3 ( 18.8%)	5 ( 31.3%)	8 ( 50.0%)	0 ( 0.0%)	16
Enthesopathy	9 ( 56.3%)	6 ( 37.5%)	1 ( 6.3%)	0 ( 0.0%)	16
Engraftment syndrome	2 ( 12.5%)	8 ( 50.0%)	6 ( 37.5%)	0 ( 0.0%)	16
Acinetobacter test positive	0 ( 0.0%)	0 ( 0.0%)	16 (100.0%)	0 ( 0.0%)	16
Metastases to skin	0 ( 0.0%)	9 ( 56.3%)	1 ( 6.3%)	6 ( 37.5%)	16
Metastases to breast	0 ( 0.0%)	8 ( 50.0%)	3 ( 18.8%)	5 ( 31.3%)	16
Transfusion	6 ( 37.5%)	3 ( 18.8%)	5 ( 31.3%)	2 ( 12.5%)	16
Menstruation irregular	6 ( 37.5%)	9 ( 56.3%)	1 ( 6.3%)	0 ( 0.0%)	16
Haemodynamic instability	7 ( 43.8%)	1 ( 6.3%)	7 ( 43.8%)	1 ( 6.3%)	16
Transcatheter arterial chemoembolisation	0 ( 0.0%)	0 ( 0.0%)	13 ( 81.3%)	3 ( 18.8%)	16
Lymphoedema	0 ( 0.0%)	3 ( 18.8%)	9 ( 56.3%)	4 ( 25.0%)	16

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Lymphocytic lymphoma	0 ( 0.0%)	0 ( 0.0%)	12 ( 75.0%)	4 ( 25.0%)	16
Lung opacity	0 ( 0.0%)	5 ( 31.3%)	7 ( 43.8%)	4 ( 25.0%)	16
Lung adenocarcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	9 ( 56.3%)	7 ( 43.8%)	16
Low density lipoprotein	0 ( 0.0%)	0 ( 0.0%)	11 ( 68.8%)	5 ( 31.3%)	16
Liver transplant rejection	1 ( 6.3%)	5 ( 31.3%)	10 ( 62.5%)	0 ( 0.0%)	16
Lipid metabolism disorder	6 ( 37.5%)	0 ( 0.0%)	6 ( 37.5%)	4 ( 25.0%)	16
Linear IgA disease	5 ( 31.3%)	0 ( 0.0%)	11 ( 68.8%)	0 ( 0.0%)	16
Chronic myeloid leukaemia (in remission)	0 ( 0.0%)	1 ( 6.3%)	11 ( 68.8%)	4 ( 25.0%)	16
Dependence	1 ( 6.3%)	10 ( 62.5%)	5 ( 31.3%)	0 ( 0.0%)	16
Chronic lymphocytic leukaemia recurrent	0 ( 0.0%)	0 ( 0.0%)	10 ( 62.5%)	6 ( 37.5%)	16
Multifocal motor neuropathy	0 ( 0.0%)	6 ( 37.5%)	10 ( 62.5%)	0 ( 0.0%)	16
Serotonin syndrome	5 ( 31.3%)	9 ( 56.3%)	2 ( 12.5%)	0 ( 0.0%)	16
Thrombophlebitis	0 ( 0.0%)	2 ( 12.5%)	8 ( 50.0%)	6 ( 37.5%)	16
Germ cell neoplasm	6 ( 37.5%)	0 ( 0.0%)	10 ( 62.5%)	0 ( 0.0%)	16
Hepatobiliary disorder prophylaxis	2 ( 12.5%)	7 ( 43.8%)	5 ( 31.3%)	2 ( 12.5%)	16
Giant cell tumour of tendon sheath	5 ( 31.3%)	4 ( 25.0%)	5 ( 31.3%)	2 ( 12.5%)	16
Thalamus haemorrhage	0 ( 0.0%)	0 ( 0.0%)	10 ( 62.5%)	6 ( 37.5%)	16
Hypertensive crisis	0 ( 0.0%)	7 ( 43.8%)	9 ( 56.3%)	0 ( 0.0%)	16
Sleep apnoea syndrome	1 ( 6.3%)	3 ( 18.8%)	12 ( 75.0%)	0 ( 0.0%)	16
Arthritis enteropathic	0 ( 0.0%)	10 ( 62.5%)	6 ( 37.5%)	0 ( 0.0%)	16
Hyperprolactinaemia	3 ( 18.8%)	11 ( 68.8%)	2 ( 12.5%)	0 ( 0.0%)	16
Oligodendroglioma	0 ( 0.0%)	12 ( 75.0%)	4 ( 25.0%)	0 ( 0.0%)	16
Primary myelofibrosis	0 ( 0.0%)	3 ( 18.8%)	8 ( 50.0%)	5 ( 31.3%)	16
Humoral immune defect	3 ( 18.8%)	2 ( 12.5%)	11 ( 68.8%)	0 ( 0.0%)	16
Swelling face	0 ( 0.0%)	5 ( 31.3%)	10 ( 62.5%)	1 ( 6.3%)	16
Hyperaldosteronism	1 ( 6.3%)	1 ( 6.3%)	14 ( 87.5%)	0 ( 0.0%)	16
Substance abuse	0 ( 0.0%)	14 ( 87.5%)	2 ( 12.5%)	0 ( 0.0%)	16

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Subdural haematoma	1 ( 6.3%)	0 ( 0.0%)	1 ( 6.3%)	14 ( 87.5%)	16
Babesiosis	0 ( 0.0%)	9 ( 56.3%)	1 ( 6.3%)	6 ( 37.5%)	16
Streptococcal bacteraemia	1 ( 6.3%)	0 ( 0.0%)	11 ( 68.8%)	4 ( 25.0%)	16
Hyperphenylalaninaemia	11 ( 68.8%)	4 ( 25.0%)	1 ( 6.3%)	0 ( 0.0%)	16
Frontal lobe epilepsy	1 ( 6.3%)	6 ( 37.5%)	9 ( 56.3%)	0 ( 0.0%)	16
Hodgkin's disease refractory	0 ( 0.0%)	16 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	16
Sneezing	1 ( 6.3%)	2 ( 12.5%)	11 ( 68.8%)	2 ( 12.5%)	16
Herpes zoster oticus	0 ( 0.0%)	16 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	16
Animal bite	0 ( 0.0%)	13 ( 81.3%)	3 ( 18.8%)	0 ( 0.0%)	16
Groin pain	0 ( 0.0%)	0 ( 0.0%)	15 ( 93.8%)	1 ( 6.3%)	16
Chronic respiratory disease	14 ( 87.5%)	1 ( 6.3%)	1 ( 6.3%)	0 ( 0.0%)	16
Cholestasis	10 ( 62.5%)	0 ( 0.0%)	6 ( 37.5%)	0 ( 0.0%)	16
Acute sinusitis	0 ( 0.0%)	2 ( 12.5%)	14 ( 87.5%)	0 ( 0.0%)	16
Cerebrovascular disorder	1 ( 6.3%)	6 ( 37.5%)	4 ( 25.0%)	5 ( 31.3%)	16
Uveal melanoma	0 ( 0.0%)	1 ( 6.3%)	14 ( 87.5%)	1 ( 6.3%)	16
Primary adrenal insufficiency	2 ( 12.5%)	9 ( 56.3%)	5 ( 31.3%)	0 ( 0.0%)	16
Antitussive therapy	2 ( 12.5%)	8 ( 50.0%)	5 ( 31.3%)	1 ( 6.3%)	16
Inflammatory carcinoma of the breast	0 ( 0.0%)	2 ( 12.5%)	12 ( 75.0%)	2 ( 12.5%)	16
Muckle-Wells syndrome	9 ( 56.3%)	3 ( 18.8%)	4 ( 25.0%)	0 ( 0.0%)	16
Inhalation therapy	1 ( 6.3%)	0 ( 0.0%)	14 ( 87.5%)	1 ( 6.3%)	16
Glycosylated haemoglobin	0 ( 0.0%)	10 ( 62.5%)	5 ( 31.3%)	1 ( 6.3%)	16
Antidiarrhoeal supportive care	2 ( 12.5%)	2 ( 12.5%)	9 ( 56.3%)	3 ( 18.8%)	16
Weight loss diet	0 ( 0.0%)	11 ( 68.8%)	5 ( 31.3%)	0 ( 0.0%)	16
X-linked lymphoproliferative syndrome	16 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	16
Oesophageal squamous cell carcinoma metastatic	0 ( 0.0%)	0 ( 0.0%)	12 ( 80.0%)	3 ( 20.0%)	15
Oesophageal pain	0 ( 0.0%)	8 ( 53.3%)	7 ( 46.7%)	0 ( 0.0%)	15
Vitiligo	2 ( 13.3%)	5 ( 33.3%)	8 ( 53.3%)	0 ( 0.0%)	15

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Oesophageal candidiasis	2 ( 13.3%)	2 ( 13.3%)	9 ( 60.0%)	2 ( 13.3%)	15
Enteritis	2 ( 13.3%)	8 ( 53.3%)	5 ( 33.3%)	0 ( 0.0%)	15
Guttate psoriasis	4 ( 26.7%)	4 ( 26.7%)	6 ( 40.0%)	1 ( 6.7%)	15
Multivisceral transplantation	15 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	15
Multisystem inflammatory syndrome in children	15 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	15
Prophylaxis of neural tube defect	14 ( 93.3%)	1 ( 6.7%)	0 ( 0.0%)	0 ( 0.0%)	15
Choroidal detachment	0 ( 0.0%)	0 ( 0.0%)	15 (100.0%)	0 ( 0.0%)	15
Tracheobronchitis	0 ( 0.0%)	6 ( 40.0%)	8 ( 53.3%)	1 ( 6.7%)	15
Wiskott-Aldrich syndrome	15 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	15
Brain cancer metastatic	5 ( 33.3%)	6 ( 40.0%)	3 ( 20.0%)	1 ( 6.7%)	15
Malignant neoplasm of unknown primary site	0 ( 0.0%)	2 ( 13.3%)	5 ( 33.3%)	8 ( 53.3%)	15
Disseminated cryptococcosis	1 ( 6.7%)	5 ( 33.3%)	7 ( 46.7%)	2 ( 13.3%)	15
Osteosarcoma metastatic	10 ( 66.7%)	3 ( 20.0%)	2 ( 13.3%)	0 ( 0.0%)	15
Bone neoplasm	0 ( 0.0%)	0 ( 0.0%)	13 ( 86.7%)	2 ( 13.3%)	15
Bone loss	0 ( 0.0%)	4 ( 26.7%)	11 ( 73.3%)	0 ( 0.0%)	15
Faeces hard	0 ( 0.0%)	0 ( 0.0%)	10 ( 66.7%)	5 ( 33.3%)	15
Tonsil cancer	0 ( 0.0%)	0 ( 0.0%)	15 (100.0%)	0 ( 0.0%)	15
Eczema infantile	14 ( 93.3%)	0 ( 0.0%)	1 ( 6.7%)	0 ( 0.0%)	15
Bone density decreased	2 ( 13.3%)	7 ( 46.7%)	4 ( 26.7%)	2 ( 13.3%)	15
Heart rate decreased	0 ( 0.0%)	1 ( 6.7%)	7 ( 46.7%)	7 ( 46.7%)	15
Intestinal fistula	0 ( 0.0%)	1 ( 6.7%)	14 ( 93.3%)	0 ( 0.0%)	15
Vulval cancer	0 ( 0.0%)	5 ( 33.3%)	10 ( 66.7%)	0 ( 0.0%)	15
Anti-SRP antibody positive	0 ( 0.0%)	6 ( 40.0%)	9 ( 60.0%)	0 ( 0.0%)	15
Varicose vein	1 ( 6.7%)	4 ( 26.7%)	10 ( 66.7%)	0 ( 0.0%)	15
Carotid artery stenosis	0 ( 0.0%)	0 ( 0.0%)	13 ( 86.7%)	2 ( 13.3%)	15
Small intestine neuroendocrine tumour	0 ( 0.0%)	2 ( 13.3%)	12 ( 80.0%)	1 ( 6.7%)	15
Splenic marginal zone lymphoma	0 ( 0.0%)	0 ( 0.0%)	3 ( 20.0%)	12 ( 80.0%)	15

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Differentiation syndrome	0 ( 0.0%)	4 ( 26.7%)	0 ( 0.0%)	11 ( 73.3%)	15
Inflammatory myofibroblastic tumour	6 ( 40.0%)	9 ( 60.0%)	0 ( 0.0%)	0 ( 0.0%)	15
Bladder transitional cell carcinoma stage IV	0 ( 0.0%)	0 ( 0.0%)	6 ( 40.0%)	9 ( 60.0%)	15
Hypercoagulation	0 ( 0.0%)	10 ( 66.7%)	5 ( 33.3%)	0 ( 0.0%)	15
General physical health deterioration	1 ( 6.7%)	7 ( 46.7%)	5 ( 33.3%)	2 ( 13.3%)	15
Primary hypogonadism	0 ( 0.0%)	2 ( 13.3%)	13 ( 86.7%)	0 ( 0.0%)	15
Arthropod bite	1 ( 6.7%)	2 ( 13.3%)	11 ( 73.3%)	1 ( 6.7%)	15
Heritable pulmonary arterial hypertension	2 ( 13.3%)	2 ( 13.3%)	10 ( 66.7%)	1 ( 6.7%)	15
Cutibacterium acnes infection	6 ( 40.0%)	0 ( 0.0%)	9 ( 60.0%)	0 ( 0.0%)	15
Cytomegalovirus chorioretinitis	4 ( 26.7%)	9 ( 60.0%)	0 ( 0.0%)	2 ( 13.3%)	15
Fungal skin infection	2 ( 13.3%)	2 ( 13.3%)	11 ( 73.3%)	0 ( 0.0%)	15
Phlebitis	0 ( 0.0%)	1 ( 6.7%)	12 ( 80.0%)	2 ( 13.3%)	15
Thymoma	0 ( 0.0%)	5 ( 33.3%)	10 ( 66.7%)	0 ( 0.0%)	15
Rheumatoid vasculitis	0 ( 0.0%)	3 ( 20.0%)	5 ( 33.3%)	7 ( 46.7%)	15
Autonomic nervous system imbalance	1 ( 6.7%)	5 ( 33.3%)	5 ( 33.3%)	4 ( 26.7%)	15
Haemoptysis	0 ( 0.0%)	2 ( 13.3%)	12 ( 80.0%)	1 ( 6.7%)	15
Rectosigmoid cancer metastatic	0 ( 0.0%)	7 ( 46.7%)	8 ( 53.3%)	0 ( 0.0%)	15
Growth retardation	15 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	15
Pustule	0 ( 0.0%)	4 ( 26.7%)	11 ( 73.3%)	0 ( 0.0%)	15
Tuberculosis of genitourinary system	0 ( 0.0%)	15 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	15
Graft versus host disease in skin	9 ( 60.0%)	2 ( 13.3%)	4 ( 26.7%)	0 ( 0.0%)	15
Corneal epithelial downgrowth	0 ( 0.0%)	6 ( 40.0%)	2 ( 13.3%)	7 ( 46.7%)	15
Glossodynia	0 ( 0.0%)	4 ( 26.7%)	11 ( 73.3%)	0 ( 0.0%)	15
Portal vein thrombosis	2 ( 13.3%)	3 ( 20.0%)	9 ( 60.0%)	1 ( 6.7%)	15
Sacroiliitis	7 ( 46.7%)	7 ( 46.7%)	1 ( 6.7%)	0 ( 0.0%)	15
Gender dysphoria	6 ( 40.0%)	3 ( 20.0%)	6 ( 40.0%)	0 ( 0.0%)	15
Gaucher's disease type I	1 ( 6.7%)	4 ( 26.7%)	9 ( 60.0%)	1 ( 6.7%)	15



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pathological fracture	0 ( 0.0%)	5 ( 33.3%)	7 ( 46.7%)	3 ( 20.0%)	15
Meningococcal immunisation	1 ( 6.7%)	10 ( 66.7%)	0 ( 0.0%)	4 ( 26.7%)	15
Cardiac sarcoidosis	0 ( 0.0%)	2 ( 13.3%)	13 ( 86.7%)	0 ( 0.0%)	15
Wrong product administered	2 ( 13.3%)	1 ( 6.7%)	0 ( 0.0%)	12 ( 80.0%)	15
Eosinophilic pneumonia acute	0 ( 0.0%)	4 ( 28.6%)	10 ( 71.4%)	0 ( 0.0%)	14
Oesophageal spasm	0 ( 0.0%)	3 ( 21.4%)	10 ( 71.4%)	1 ( 7.1%)	14
Myelodysplastic syndrome with excess blasts	0 ( 0.0%)	1 ( 7.1%)	6 ( 42.9%)	7 ( 50.0%)	14
Musculoskeletal disorder	0 ( 0.0%)	4 ( 28.6%)	9 ( 64.3%)	1 ( 7.1%)	14
Rectal cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	14 (100.0%)	0 ( 0.0%)	14
Cardiac dysfunction	8 ( 57.1%)	0 ( 0.0%)	5 ( 35.7%)	1 ( 7.1%)	14
Metastatic ocular melanoma	0 ( 0.0%)	12 ( 85.7%)	1 ( 7.1%)	1 ( 7.1%)	14
Streptococcal sepsis	0 ( 0.0%)	10 ( 71.4%)	4 ( 28.6%)	0 ( 0.0%)	14
Drug-induced liver injury	0 ( 0.0%)	1 ( 7.1%)	13 ( 92.9%)	0 ( 0.0%)	14
Ovarian neoplasm	0 ( 0.0%)	0 ( 0.0%)	13 ( 92.9%)	1 ( 7.1%)	14
Lyme disease	0 ( 0.0%)	5 ( 35.7%)	9 ( 64.3%)	0 ( 0.0%)	14
Head and neck cancer stage IV	0 ( 0.0%)	7 ( 50.0%)	5 ( 35.7%)	2 ( 14.3%)	14
Thyroid therapy	2 ( 14.3%)	5 ( 35.7%)	7 ( 50.0%)	0 ( 0.0%)	14
Lactic acidosis	3 ( 21.4%)	4 ( 28.6%)	0 ( 0.0%)	7 ( 50.0%)	14
Schizotypal personality disorder	0 ( 0.0%)	12 ( 85.7%)	0 ( 0.0%)	2 ( 14.3%)	14
Keratosis follicular	1 ( 7.1%)	12 ( 85.7%)	1 ( 7.1%)	0 ( 0.0%)	14
Intraocular pressure test abnormal	3 ( 21.4%)	1 ( 7.1%)	4 ( 28.6%)	6 ( 42.9%)	14
Intraocular pressure test	1 ( 7.1%)	3 ( 21.4%)	3 ( 21.4%)	7 ( 50.0%)	14
Cystocele	0 ( 0.0%)	0 ( 0.0%)	5 ( 35.7%)	9 ( 64.3%)	14
Adrenocortical insufficiency acute	5 ( 35.7%)	3 ( 21.4%)	6 ( 42.9%)	0 ( 0.0%)	14
Blood calcium decreased	1 ( 7.1%)	4 ( 28.6%)	5 ( 35.7%)	4 ( 28.6%)	14
Panniculitis	6 ( 42.9%)	2 ( 14.3%)	6 ( 42.9%)	0 ( 0.0%)	14
Ureaplasma infection	13 ( 92.9%)	1 ( 7.1%)	0 ( 0.0%)	0 ( 0.0%)	14

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Vogt-Koyanagi-Harada disease	0 ( 0.0%)	6 ( 42.9%)	6 ( 42.9%)	2 ( 14.3%)	14
Sinus congestion	1 ( 7.1%)	1 ( 7.1%)	6 ( 42.9%)	6 ( 42.9%)	14
Paralysis	1 ( 7.1%)	11 ( 78.6%)	2 ( 14.3%)	0 ( 0.0%)	14
Blood immunoglobulin G decreased	5 ( 35.7%)	0 ( 0.0%)	8 ( 57.1%)	1 ( 7.1%)	14
HER2 positive colorectal cancer	0 ( 0.0%)	5 ( 35.7%)	9 ( 64.3%)	0 ( 0.0%)	14
Vitamin K deficiency	5 ( 35.7%)	5 ( 35.7%)	4 ( 28.6%)	0 ( 0.0%)	14
Tension headache	4 ( 28.6%)	7 ( 50.0%)	3 ( 21.4%)	0 ( 0.0%)	14
Somatic dysfunction	0 ( 0.0%)	0 ( 0.0%)	14 (100.0%)	0 ( 0.0%)	14
Torsade de pointes	8 ( 57.1%)	4 ( 28.6%)	2 ( 14.3%)	0 ( 0.0%)	14
Mycobacterium fortuitum infection	10 ( 71.4%)	0 ( 0.0%)	4 ( 28.6%)	0 ( 0.0%)	14
Autoimmune colitis	0 ( 0.0%)	0 ( 0.0%)	14 (100.0%)	0 ( 0.0%)	14
Mycoplasma infection	11 ( 78.6%)	1 ( 7.1%)	1 ( 7.1%)	1 ( 7.1%)	14
Hyperammonaemia	5 ( 35.7%)	5 ( 35.7%)	4 ( 28.6%)	0 ( 0.0%)	14
Substance use	3 ( 21.4%)	8 ( 57.1%)	3 ( 21.4%)	0 ( 0.0%)	14
Subarachnoid haemorrhage	0 ( 0.0%)	2 ( 14.3%)	3 ( 21.4%)	9 ( 64.3%)	14
Peripheral ischaemia	0 ( 0.0%)	0 ( 0.0%)	13 ( 92.9%)	1 ( 7.1%)	14
Fear	0 ( 0.0%)	0 ( 0.0%)	9 ( 64.3%)	5 ( 35.7%)	14
Peripheral venous disease	0 ( 0.0%)	0 ( 0.0%)	6 ( 42.9%)	8 ( 57.1%)	14
Colon cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	8 ( 57.1%)	6 ( 42.9%)	14
Clear cell endometrial carcinoma	0 ( 0.0%)	0 ( 0.0%)	14 (100.0%)	0 ( 0.0%)	14
Sacral pain	0 ( 0.0%)	9 ( 64.3%)	5 ( 35.7%)	0 ( 0.0%)	14
Head injury	8 ( 57.1%)	3 ( 21.4%)	3 ( 21.4%)	0 ( 0.0%)	14
Respiratory tract congestion	1 ( 7.1%)	4 ( 28.6%)	5 ( 35.7%)	4 ( 28.6%)	14
Haemolytic uraemic syndrome	3 ( 21.4%)	2 ( 14.3%)	3 ( 21.4%)	6 ( 42.9%)	14
Pulmonary mucormycosis	4 ( 28.6%)	1 ( 7.1%)	9 ( 64.3%)	0 ( 0.0%)	14
Chondrosarcoma	0 ( 0.0%)	10 ( 71.4%)	4 ( 28.6%)	0 ( 0.0%)	14
Glomerulonephritis proliferative	0 ( 0.0%)	5 ( 35.7%)	0 ( 0.0%)	9 ( 64.3%)	14

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Urogram	1 ( 7.1%)	1 ( 7.1%)	11 ( 78.6%)	1 ( 7.1%)	14
Cerebral toxoplasmosis	0 ( 0.0%)	8 ( 57.1%)	6 ( 42.9%)	0 ( 0.0%)	14
Gastrointestinal stoma complication	2 ( 14.3%)	0 ( 0.0%)	4 ( 28.6%)	8 ( 57.1%)	14
Gastrointestinal inflammation	2 ( 14.3%)	0 ( 0.0%)	12 ( 85.7%)	0 ( 0.0%)	14
Blood culture positive	5 ( 35.7%)	0 ( 0.0%)	7 ( 50.0%)	2 ( 14.3%)	14
B-lymphocyte abnormalities	1 ( 7.1%)	5 ( 35.7%)	5 ( 35.7%)	3 ( 21.4%)	14
Pericardial effusion	2 ( 14.3%)	3 ( 21.4%)	7 ( 50.0%)	2 ( 14.3%)	14
Pancreatic disorder	6 ( 42.9%)	0 ( 0.0%)	7 ( 50.0%)	1 ( 7.1%)	14
Gestational hypertension	8 ( 57.1%)	6 ( 42.9%)	0 ( 0.0%)	0 ( 0.0%)	14
Pancreatic neoplasm	0 ( 0.0%)	2 ( 14.3%)	12 ( 85.7%)	0 ( 0.0%)	14
Vulvovaginal candidiasis	8 ( 57.1%)	5 ( 35.7%)	1 ( 7.1%)	0 ( 0.0%)	14
Oxygen saturation decreased	1 ( 7.1%)	0 ( 0.0%)	12 ( 85.7%)	1 ( 7.1%)	14
Nodular melanoma	0 ( 0.0%)	0 ( 0.0%)	13 ( 92.9%)	1 ( 7.1%)	14
Ovarian Sertoli-Leydig cell tumour	14 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	14
Yao syndrome	0 ( 0.0%)	14 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	14
Non-small cell lung cancer stage IIIB	0 ( 0.0%)	2 ( 15.4%)	4 ( 30.8%)	7 ( 53.8%)	13
Ocular discomfort	0 ( 0.0%)	1 ( 7.7%)	5 ( 38.5%)	7 ( 53.8%)	13
Epstein-Barr virus associated lymphoproliferative di	4 ( 30.8%)	1 ( 7.7%)	8 ( 61.5%)	0 ( 0.0%)	13
Epithelioid mesothelioma	0 ( 0.0%)	1 ( 7.7%)	9 ( 69.2%)	3 ( 23.1%)	13
Neurotoxicity	6 ( 46.2%)	0 ( 0.0%)	2 ( 15.4%)	5 ( 38.5%)	13
Dyspnoea exertional	0 ( 0.0%)	1 ( 7.7%)	12 ( 92.3%)	0 ( 0.0%)	13
Rash pruritic	5 ( 38.5%)	0 ( 0.0%)	6 ( 46.2%)	2 ( 15.4%)	13
Muscle hypertrophy	0 ( 0.0%)	13 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	13
HER2 mutant non-small cell lung cancer	0 ( 0.0%)	5 ( 38.5%)	8 ( 61.5%)	0 ( 0.0%)	13
Eye abscess	13 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	13
Radiotherapy	0 ( 0.0%)	1 ( 7.7%)	9 ( 69.2%)	3 ( 23.1%)	13
Bronchial disorder	0 ( 0.0%)	0 ( 0.0%)	2 ( 15.4%)	11 ( 84.6%)	13

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Metastatic choriocarcinoma	0 ( 0.0%)	11 ( 84.6%)	2 ( 15.4%)	0 ( 0.0%)	13
Metastases to spleen	7 ( 53.8%)	3 ( 23.1%)	3 ( 23.1%)	0 ( 0.0%)	13
Dysgeusia	0 ( 0.0%)	0 ( 0.0%)	8 ( 61.5%)	5 ( 38.5%)	13
Acute myeloid leukaemia (in remission)	1 ( 7.7%)	6 ( 46.2%)	5 ( 38.5%)	1 ( 7.7%)	13
Brain sarcoma	12 ( 92.3%)	1 ( 7.7%)	0 ( 0.0%)	0 ( 0.0%)	13
Mechanical ventilation	0 ( 0.0%)	3 ( 23.1%)	10 ( 76.9%)	0 ( 0.0%)	13
Magnetic resonance imaging abdominal	1 ( 7.7%)	6 ( 46.2%)	5 ( 38.5%)	1 ( 7.7%)	13
Ovarian clear cell carcinoma	0 ( 0.0%)	5 ( 38.5%)	8 ( 61.5%)	0 ( 0.0%)	13
Rheumatoid arthritis-associated interstitial lung di	5 ( 38.5%)	0 ( 0.0%)	8 ( 61.5%)	0 ( 0.0%)	13
Bone cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	9 ( 69.2%)	4 ( 30.8%)	13
Limb discomfort	2 ( 15.4%)	5 ( 38.5%)	5 ( 38.5%)	1 ( 7.7%)	13
Ligament pain	13 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	13
Lichenoid keratosis	0 ( 0.0%)	0 ( 0.0%)	12 ( 92.3%)	1 ( 7.7%)	13
Leptospirosis	0 ( 0.0%)	13 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	13
Cardiac stress test	0 ( 0.0%)	0 ( 0.0%)	10 ( 76.9%)	3 ( 23.1%)	13
Left ventricular dysfunction	2 ( 15.4%)	4 ( 30.8%)	7 ( 53.8%)	0 ( 0.0%)	13
Overgrowth bacterial	8 ( 61.5%)	0 ( 0.0%)	4 ( 30.8%)	1 ( 7.7%)	13
Scan myocardial perfusion	2 ( 15.4%)	4 ( 30.8%)	6 ( 46.2%)	1 ( 7.7%)	13
Klebsiella bacteraemia	0 ( 0.0%)	11 ( 84.6%)	2 ( 15.4%)	0 ( 0.0%)	13
Embolism arterial	0 ( 0.0%)	0 ( 0.0%)	9 ( 69.2%)	4 ( 30.8%)	13
Joint injection	0 ( 0.0%)	0 ( 0.0%)	4 ( 30.8%)	9 ( 69.2%)	13
Adjustment disorder	6 ( 46.2%)	3 ( 23.1%)	3 ( 23.1%)	1 ( 7.7%)	13
Thyroid mass	0 ( 0.0%)	4 ( 30.8%)	9 ( 69.2%)	0 ( 0.0%)	13
Hepatic pain	0 ( 0.0%)	0 ( 0.0%)	13 (100.0%)	0 ( 0.0%)	13
Hepatitis viral	0 ( 0.0%)	4 ( 30.8%)	8 ( 61.5%)	1 ( 7.7%)	13
Proctitis ulcerative	0 ( 0.0%)	6 ( 46.2%)	7 ( 53.8%)	0 ( 0.0%)	13
Injection site pain	2 ( 15.4%)	7 ( 53.8%)	4 ( 30.8%)	0 ( 0.0%)	13

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Intervertebral disc disorder	2 ( 15.4%)	4 ( 30.8%)	3 ( 23.1%)	4 ( 30.8%)	13
Coccidioidomycosis	3 ( 23.1%)	4 ( 30.8%)	6 ( 46.2%)	0 ( 0.0%)	13
Intestinal adenocarcinoma	0 ( 0.0%)	0 ( 0.0%)	13 (100.0%)	0 ( 0.0%)	13
Smith-Lemli-Opitz syndrome	10 ( 76.9%)	3 ( 23.1%)	0 ( 0.0%)	0 ( 0.0%)	13
Anogenital warts	11 ( 84.6%)	1 ( 7.7%)	1 ( 7.7%)	0 ( 0.0%)	13
T-cell prolymphocytic leukaemia	0 ( 0.0%)	0 ( 0.0%)	10 ( 76.9%)	3 ( 23.1%)	13
Staphylococcal sepsis	2 ( 15.4%)	4 ( 30.8%)	1 ( 7.7%)	6 ( 46.2%)	13
Streptococcal infection	7 ( 53.8%)	4 ( 30.8%)	1 ( 7.7%)	1 ( 7.7%)	13
Cervix carcinoma stage I	0 ( 0.0%)	4 ( 30.8%)	9 ( 69.2%)	0 ( 0.0%)	13
Hormone suppression therapy	2 ( 15.4%)	6 ( 46.2%)	5 ( 38.5%)	0 ( 0.0%)	13
Blepharitis	0 ( 0.0%)	1 ( 7.7%)	10 ( 76.9%)	2 ( 15.4%)	13
Adrenocortical steroid therapy	0 ( 0.0%)	4 ( 30.8%)	8 ( 61.5%)	1 ( 7.7%)	13
Clostridial infection	0 ( 0.0%)	0 ( 0.0%)	11 ( 84.6%)	2 ( 15.4%)	13
Aplasia	6 ( 46.2%)	0 ( 0.0%)	1 ( 7.7%)	6 ( 46.2%)	13
Heart transplant rejection	4 ( 30.8%)	0 ( 0.0%)	9 ( 69.2%)	0 ( 0.0%)	13
Hairy cell leukaemia	0 ( 0.0%)	2 ( 15.4%)	7 ( 53.8%)	4 ( 30.8%)	13
Induction and maintenance of anaesthesia	2 ( 15.4%)	5 ( 38.5%)	4 ( 30.8%)	2 ( 15.4%)	13
Toxic skin eruption	0 ( 0.0%)	0 ( 0.0%)	10 ( 76.9%)	3 ( 23.1%)	13
Gastroenteritis Escherichia coli	0 ( 0.0%)	0 ( 0.0%)	5 ( 38.5%)	8 ( 61.5%)	13
Radicular pain	0 ( 0.0%)	4 ( 30.8%)	9 ( 69.2%)	0 ( 0.0%)	13
Triple positive breast cancer	0 ( 0.0%)	6 ( 46.2%)	6 ( 46.2%)	1 ( 7.7%)	13
Pituitary tumour removal	0 ( 0.0%)	0 ( 0.0%)	13 (100.0%)	0 ( 0.0%)	13
Polychondritis	2 ( 15.4%)	0 ( 0.0%)	10 ( 76.9%)	1 ( 7.7%)	13
Psychomotor retardation	2 ( 15.4%)	0 ( 0.0%)	11 ( 84.6%)	0 ( 0.0%)	13
Prostate infection	0 ( 0.0%)	0 ( 0.0%)	12 ( 92.3%)	1 ( 7.7%)	13
Gastroenteritis radiation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	13 (100.0%)	13
Progressive multifocal leukoencephalopathy	0 ( 0.0%)	1 ( 7.7%)	12 ( 92.3%)	0 ( 0.0%)	13

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Gastrointestinal infection	0 ( 0.0%)	4 ( 30.8%)	5 ( 38.5%)	4 ( 30.8%)	13
Gender reassignment therapy	8 ( 61.5%)	5 ( 38.5%)	0 ( 0.0%)	0 ( 0.0%)	13
Toxoplasmosis	0 ( 0.0%)	10 ( 76.9%)	3 ( 23.1%)	0 ( 0.0%)	13
Impulsive behaviour	7 ( 53.8%)	2 ( 15.4%)	4 ( 30.8%)	0 ( 0.0%)	13
Corynebacterium infection	0 ( 0.0%)	0 ( 0.0%)	13 (100.0%)	0 ( 0.0%)	13
Gastrointestinal cancer metastatic	2 ( 15.4%)	0 ( 0.0%)	11 ( 84.6%)	0 ( 0.0%)	13
Cranio-cerebral injury	9 ( 69.2%)	1 ( 7.7%)	3 ( 23.1%)	0 ( 0.0%)	13
Postural orthostatic tachycardia syndrome	4 ( 30.8%)	3 ( 23.1%)	6 ( 46.2%)	0 ( 0.0%)	13
Periarthritis	0 ( 0.0%)	1 ( 7.7%)	10 ( 76.9%)	2 ( 15.4%)	13
Fluid imbalance	0 ( 0.0%)	7 ( 53.8%)	3 ( 23.1%)	3 ( 23.1%)	13
Injection site reaction	0 ( 0.0%)	1 ( 7.7%)	11 ( 84.6%)	1 ( 7.7%)	13
Osteitis deformans	0 ( 0.0%)	1 ( 7.7%)	5 ( 38.5%)	7 ( 53.8%)	13
Onycholysis	0 ( 0.0%)	0 ( 0.0%)	13 (100.0%)	0 ( 0.0%)	13
Non-Hodgkin's lymphoma unspecified histology indolen	0 ( 0.0%)	2 ( 16.7%)	8 ( 66.7%)	2 ( 16.7%)	12
Neurofibroma	10 ( 83.3%)	2 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	12
Neuralgic amyotrophy	0 ( 0.0%)	10 ( 83.3%)	2 ( 16.7%)	0 ( 0.0%)	12
Nephropathy toxic	0 ( 0.0%)	3 ( 25.0%)	9 ( 75.0%)	0 ( 0.0%)	12
Cholecystectomy	1 ( 8.3%)	6 ( 50.0%)	0 ( 0.0%)	5 ( 41.7%)	12
Blood HIV RNA below assay limit	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	0 ( 0.0%)	12
Myelitis transverse	3 ( 25.0%)	5 ( 41.7%)	4 ( 33.3%)	0 ( 0.0%)	12
Endocrine ophthalmopathy	0 ( 0.0%)	0 ( 0.0%)	6 ( 50.0%)	6 ( 50.0%)	12
Endocrine disorder	5 ( 41.7%)	1 ( 8.3%)	5 ( 41.7%)	1 ( 8.3%)	12
Muscle strain	1 ( 8.3%)	6 ( 50.0%)	5 ( 41.7%)	0 ( 0.0%)	12
Hysteroscopy	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	0 ( 0.0%)	12
Xanthoma	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	0 ( 0.0%)	12
Embolic stroke	0 ( 0.0%)	1 ( 8.3%)	6 ( 50.0%)	5 ( 41.7%)	12
Mixed dementia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	12

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Eye inflammation	0 ( 0.0%)	3 ( 25.0%)	8 ( 66.7%)	1 ( 8.3%)	12
Middle cerebral artery stroke	0 ( 0.0%)	2 ( 16.7%)	10 ( 83.3%)	0 ( 0.0%)	12
Metastatic lymphoma	3 ( 25.0%)	5 ( 41.7%)	2 ( 16.7%)	2 ( 16.7%)	12
Metastatic carcinoid tumour	1 ( 8.3%)	0 ( 0.0%)	11 ( 91.7%)	0 ( 0.0%)	12
Breast mass	0 ( 0.0%)	1 ( 8.3%)	11 ( 91.7%)	0 ( 0.0%)	12
Glomerulonephritis chronic	0 ( 0.0%)	2 ( 16.7%)	10 ( 83.3%)	0 ( 0.0%)	12
Wound	3 ( 25.0%)	5 ( 41.7%)	4 ( 33.3%)	0 ( 0.0%)	12
Meningococcal infection	8 ( 66.7%)	1 ( 8.3%)	0 ( 0.0%)	3 ( 25.0%)	12
Hypotony maculopathy	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	0 ( 0.0%)	12
Malignant central nervous system neoplasm	12 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	12
Disease recurrence	0 ( 0.0%)	5 ( 41.7%)	5 ( 41.7%)	2 ( 16.7%)	12
Connective tissue neoplasm	1 ( 8.3%)	6 ( 50.0%)	5 ( 41.7%)	0 ( 0.0%)	12
Lysosomal acid lipase deficiency	11 ( 91.7%)	0 ( 0.0%)	1 ( 8.3%)	0 ( 0.0%)	12
Bone marrow failure	1 ( 8.3%)	3 ( 25.0%)	8 ( 66.7%)	0 ( 0.0%)	12
Insulin-like growth factor increased	0 ( 0.0%)	10 ( 83.3%)	1 ( 8.3%)	1 ( 8.3%)	12
Device related thrombosis	1 ( 8.3%)	0 ( 0.0%)	10 ( 83.3%)	1 ( 8.3%)	12
Bronchiolitis obliterans syndrome	6 ( 50.0%)	3 ( 25.0%)	3 ( 25.0%)	0 ( 0.0%)	12
Aortic stenosis	0 ( 0.0%)	2 ( 16.7%)	8 ( 66.7%)	2 ( 16.7%)	12
Lip disorder	0 ( 0.0%)	10 ( 83.3%)	1 ( 8.3%)	1 ( 8.3%)	12
Lichen sclerosus	0 ( 0.0%)	6 ( 50.0%)	1 ( 8.3%)	5 ( 41.7%)	12
Thyroid hormone replacement therapy	0 ( 0.0%)	7 ( 58.3%)	2 ( 16.7%)	3 ( 25.0%)	12
Laryngitis	3 ( 25.0%)	6 ( 50.0%)	3 ( 25.0%)	0 ( 0.0%)	12
Chronic respiratory failure	2 ( 16.7%)	1 ( 8.3%)	4 ( 33.3%)	5 ( 41.7%)	12
Blood test	0 ( 0.0%)	1 ( 8.3%)	9 ( 75.0%)	2 ( 16.7%)	12
Knee arthroplasty	0 ( 0.0%)	0 ( 0.0%)	11 ( 91.7%)	1 ( 8.3%)	12
Mucopolysaccharidosis	9 ( 75.0%)	1 ( 8.3%)	2 ( 16.7%)	0 ( 0.0%)	12
Accidental exposure to product	8 ( 66.7%)	1 ( 8.3%)	2 ( 16.7%)	1 ( 8.3%)	12

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Alcohol abuse	1 ( 8.3%)	3 ( 25.0%)	8 ( 66.7%)	0 ( 0.0%)	12
Cytopenia	8 ( 66.7%)	0 ( 0.0%)	3 ( 25.0%)	1 ( 8.3%)	12
Investigation	6 ( 50.0%)	1 ( 8.3%)	5 ( 41.7%)	0 ( 0.0%)	12
Cytomegalovirus colitis	0 ( 0.0%)	5 ( 41.7%)	7 ( 58.3%)	0 ( 0.0%)	12
Hepatic neoplasm	2 ( 16.7%)	1 ( 8.3%)	8 ( 66.7%)	1 ( 8.3%)	12
Intervertebral disc operation	0 ( 0.0%)	3 ( 25.0%)	8 ( 66.7%)	1 ( 8.3%)	12
Initial insomnia	3 ( 25.0%)	2 ( 16.7%)	5 ( 41.7%)	2 ( 16.7%)	12
Sinus polyp degeneration	0 ( 0.0%)	3 ( 25.0%)	8 ( 66.7%)	1 ( 8.3%)	12
Small intestine adenocarcinoma	2 ( 16.7%)	0 ( 0.0%)	8 ( 66.7%)	2 ( 16.7%)	12
Back disorder	0 ( 0.0%)	2 ( 16.7%)	8 ( 66.7%)	2 ( 16.7%)	12
Blood folate decreased	0 ( 0.0%)	1 ( 8.3%)	4 ( 33.3%)	7 ( 58.3%)	12
Small intestine carcinoma metastatic	0 ( 0.0%)	0 ( 0.0%)	10 ( 83.3%)	2 ( 16.7%)	12
Transient acantholytic dermatosis	0 ( 0.0%)	1 ( 8.3%)	7 ( 58.3%)	4 ( 33.3%)	12
Acute febrile neutrophilic dermatosis	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	0 ( 0.0%)	12
Congenital cytomegalovirus infection	12 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	12
Superinfection bacterial	0 ( 0.0%)	9 ( 75.0%)	2 ( 16.7%)	1 ( 8.3%)	12
Bladder spasm	1 ( 8.3%)	2 ( 16.7%)	8 ( 66.7%)	1 ( 8.3%)	12
Steroid diabetes	1 ( 8.3%)	0 ( 0.0%)	9 ( 75.0%)	2 ( 16.7%)	12
Histoplasmosis disseminated	2 ( 16.7%)	2 ( 16.7%)	3 ( 25.0%)	5 ( 41.7%)	12
Presenile dementia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	12
Cold urticaria	3 ( 25.0%)	3 ( 25.0%)	3 ( 25.0%)	3 ( 25.0%)	12
Selective IgA immunodeficiency	1 ( 8.3%)	4 ( 33.3%)	7 ( 58.3%)	0 ( 0.0%)	12
Gamma-glutamyltransferase increased	0 ( 0.0%)	7 ( 58.3%)	5 ( 41.7%)	0 ( 0.0%)	12
Heart valve replacement	0 ( 0.0%)	3 ( 25.0%)	8 ( 66.7%)	1 ( 8.3%)	12
Angiopathy	1 ( 8.3%)	2 ( 16.7%)	9 ( 75.0%)	0 ( 0.0%)	12
Plasmablastic lymphoma	0 ( 0.0%)	2 ( 16.7%)	10 ( 83.3%)	0 ( 0.0%)	12
Renal vasculitis	0 ( 0.0%)	0 ( 0.0%)	9 ( 75.0%)	3 ( 25.0%)	12



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Crying	6 ( 50.0%)	1 ( 8.3%)	3 ( 25.0%)	2 ( 16.7%)	12
Haematotoxicity	0 ( 0.0%)	1 ( 8.3%)	11 ( 91.7%)	0 ( 0.0%)	12
Hypouricaemia	0 ( 0.0%)	0 ( 0.0%)	8 ( 66.7%)	4 ( 33.3%)	12
Chorioretinal folds	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	0 ( 0.0%)	12
Rash erythematous	0 ( 0.0%)	2 ( 16.7%)	7 ( 58.3%)	3 ( 25.0%)	12
Rapid eye movement sleep behaviour disorder	0 ( 0.0%)	0 ( 0.0%)	3 ( 25.0%)	9 ( 75.0%)	12
Tracheitis	0 ( 0.0%)	8 ( 66.7%)	3 ( 25.0%)	1 ( 8.3%)	12
Granuloma annulare	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	0 ( 0.0%)	12
Contraceptive implant	6 ( 50.0%)	6 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	12
Coronary artery occlusion	0 ( 0.0%)	2 ( 16.7%)	10 ( 83.3%)	0 ( 0.0%)	12
Immunotherapy	0 ( 0.0%)	1 ( 8.3%)	11 ( 91.7%)	0 ( 0.0%)	12
Pouchitis	0 ( 0.0%)	2 ( 16.7%)	10 ( 83.3%)	0 ( 0.0%)	12
Post procedural hypoparathyroidism	0 ( 0.0%)	10 ( 83.3%)	1 ( 8.3%)	1 ( 8.3%)	12
Post coital contraception	3 ( 25.0%)	9 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	12
Gallbladder cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	11 ( 91.7%)	1 ( 8.3%)	12
Follicular lymphoma stage I	0 ( 0.0%)	0 ( 0.0%)	10 ( 83.3%)	2 ( 16.7%)	12
Autoimmune heparin-induced thrombocytopenia	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	0 ( 0.0%)	12
Paracoccidioides infection	2 ( 16.7%)	9 ( 75.0%)	1 ( 8.3%)	0 ( 0.0%)	12
Cardiac neoplasm malignant	0 ( 0.0%)	6 ( 50.0%)	6 ( 50.0%)	0 ( 0.0%)	12
Orchitis	4 ( 33.3%)	6 ( 50.0%)	2 ( 16.7%)	0 ( 0.0%)	12
Adenocarcinoma of appendix	0 ( 0.0%)	0 ( 0.0%)	12 (100.0%)	0 ( 0.0%)	12
Ocular lymphoma	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	0 ( 0.0%)	11
Non-small cell lung cancer stage IIIA	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Niemann-Pick disease	9 ( 81.8%)	2 ( 18.2%)	0 ( 0.0%)	0 ( 0.0%)	11
Ewing's sarcoma metastatic	8 ( 72.7%)	0 ( 0.0%)	3 ( 27.3%)	0 ( 0.0%)	11
Nephritic syndrome	4 ( 36.4%)	3 ( 27.3%)	4 ( 36.4%)	0 ( 0.0%)	11
Balance disorder	1 ( 9.1%)	1 ( 9.1%)	5 ( 45.5%)	4 ( 36.4%)	11

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Neoplasm recurrence	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Oesophageal adenocarcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	11
Enterococcal bacteraemia	0 ( 0.0%)	2 ( 18.2%)	7 ( 63.6%)	2 ( 18.2%)	11
Burkitt's leukaemia	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Myocardial injury	0 ( 0.0%)	0 ( 0.0%)	6 ( 54.5%)	5 ( 45.5%)	11
Endometrial neoplasm	0 ( 0.0%)	1 ( 9.1%)	10 ( 90.9%)	0 ( 0.0%)	11
Embryonal rhabdomyosarcoma	5 ( 45.5%)	6 ( 54.5%)	0 ( 0.0%)	0 ( 0.0%)	11
Mitral valve incompetence	6 ( 54.5%)	0 ( 0.0%)	2 ( 18.2%)	3 ( 27.3%)	11
Bronchial hyperreactivity	5 ( 45.5%)	2 ( 18.2%)	3 ( 27.3%)	1 ( 9.1%)	11
Haemangioma	10 ( 90.9%)	1 ( 9.1%)	0 ( 0.0%)	0 ( 0.0%)	11
Dermatitis papillaris capillitii	0 ( 0.0%)	10 ( 90.9%)	1 ( 9.1%)	0 ( 0.0%)	11
Renal colic	0 ( 0.0%)	3 ( 27.3%)	8 ( 72.7%)	0 ( 0.0%)	11
Atrial tachycardia	1 ( 9.1%)	0 ( 0.0%)	1 ( 9.1%)	9 ( 81.8%)	11
Disturbance in social behaviour	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Malignant glioma	3 ( 27.3%)	4 ( 36.4%)	4 ( 36.4%)	0 ( 0.0%)	11
Anaesthetic premedication	7 ( 63.6%)	1 ( 9.1%)	3 ( 27.3%)	0 ( 0.0%)	11
Magnetic resonance imaging pelvic	1 ( 9.1%)	7 ( 63.6%)	3 ( 27.3%)	0 ( 0.0%)	11
Haemorrhagic diathesis	6 ( 54.5%)	3 ( 27.3%)	1 ( 9.1%)	1 ( 9.1%)	11
Retinopathy of prematurity	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Low birth weight baby	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Device related sepsis	3 ( 27.3%)	6 ( 54.5%)	2 ( 18.2%)	0 ( 0.0%)	11
Fall	2 ( 18.2%)	6 ( 54.5%)	3 ( 27.3%)	0 ( 0.0%)	11
Chronic myeloid leukaemia recurrent	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Blood uric acid	0 ( 0.0%)	3 ( 27.3%)	4 ( 36.4%)	4 ( 36.4%)	11
Large granular lymphocytosis	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Schizophreniform disorder	4 ( 36.4%)	4 ( 36.4%)	3 ( 27.3%)	0 ( 0.0%)	11
Angiosarcoma metastatic	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	11

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hepatic cancer metastatic	0 ( 0.0%)	3 ( 27.3%)	8 ( 72.7%)	0 ( 0.0%)	11
Decubitus ulcer	0 ( 0.0%)	1 ( 9.1%)	4 ( 36.4%)	6 ( 54.5%)	11
Juvenile psoriatic arthritis	6 ( 54.5%)	1 ( 9.1%)	4 ( 36.4%)	0 ( 0.0%)	11
Mucositis management	1 ( 9.1%)	0 ( 0.0%)	10 ( 90.9%)	0 ( 0.0%)	11
Intermittent explosive disorder	9 ( 81.8%)	2 ( 18.2%)	0 ( 0.0%)	0 ( 0.0%)	11
Intestinal metastasis	0 ( 0.0%)	0 ( 0.0%)	7 ( 63.6%)	4 ( 36.4%)	11
Cystinosis	5 ( 45.5%)	6 ( 54.5%)	0 ( 0.0%)	0 ( 0.0%)	11
Intervertebral disc degeneration	2 ( 18.2%)	5 ( 45.5%)	4 ( 36.4%)	0 ( 0.0%)	11
Acquired epileptic aphasia	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Septic arthritis staphylococcal	10 ( 90.9%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 9.1%)	11
Clostridium bacteraemia	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Pancreatitis chronic	0 ( 0.0%)	5 ( 45.5%)	4 ( 36.4%)	2 ( 18.2%)	11
Cutaneous lupus erythematosus	1 ( 9.1%)	4 ( 36.4%)	4 ( 36.4%)	2 ( 18.2%)	11
Hepatobiliary cancer	0 ( 0.0%)	2 ( 18.2%)	9 ( 81.8%)	0 ( 0.0%)	11
Simple partial seizures	0 ( 0.0%)	3 ( 27.3%)	8 ( 72.7%)	0 ( 0.0%)	11
Hereditary ataxia	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Skin bacterial infection	1 ( 9.1%)	1 ( 9.1%)	8 ( 72.7%)	1 ( 9.1%)	11
Hereditary neuropathic amyloidosis	0 ( 0.0%)	0 ( 0.0%)	6 ( 54.5%)	5 ( 45.5%)	11
Skin fissures	0 ( 0.0%)	0 ( 0.0%)	10 ( 90.9%)	1 ( 9.1%)	11
Skin laceration	0 ( 0.0%)	1 ( 9.1%)	9 ( 81.8%)	1 ( 9.1%)	11
Taste disorder	0 ( 0.0%)	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	11
HLA-B*1502 assay negative	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Toxic shock syndrome streptococcal	3 ( 27.3%)	0 ( 0.0%)	8 ( 72.7%)	0 ( 0.0%)	11
Hormone receptor negative HER2 positive breast cance	0 ( 0.0%)	10 ( 90.9%)	1 ( 9.1%)	0 ( 0.0%)	11
Hypogonadism	1 ( 9.1%)	3 ( 27.3%)	7 ( 63.6%)	0 ( 0.0%)	11
Hyperthermia	6 ( 54.5%)	2 ( 18.2%)	3 ( 27.3%)	0 ( 0.0%)	11
Superficial vein thrombosis	0 ( 0.0%)	1 ( 9.1%)	6 ( 54.5%)	4 ( 36.4%)	11

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hypergammaglobulinaemia benign monoclonal	0 ( 0.0%)	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	11
Q fever	0 ( 0.0%)	4 ( 36.4%)	3 ( 27.3%)	4 ( 36.4%)	11
Substance dependence	5 ( 45.5%)	1 ( 9.1%)	5 ( 45.5%)	0 ( 0.0%)	11
Hydronephrosis	0 ( 0.0%)	0 ( 0.0%)	5 ( 45.5%)	6 ( 54.5%)	11
Fracture pain	2 ( 18.2%)	0 ( 0.0%)	3 ( 27.3%)	6 ( 54.5%)	11
Squamous cell carcinoma of the hypopharynx	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Holmes tremor	0 ( 0.0%)	1 ( 9.1%)	10 ( 90.9%)	0 ( 0.0%)	11
Genital herpes	0 ( 0.0%)	2 ( 18.2%)	8 ( 72.7%)	1 ( 9.1%)	11
Hodgkin's disease mixed cellularity stage unspecifie	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Snake bite	1 ( 9.1%)	7 ( 63.6%)	2 ( 18.2%)	1 ( 9.1%)	11
Gallbladder adenocarcinoma	0 ( 0.0%)	6 ( 54.5%)	5 ( 45.5%)	0 ( 0.0%)	11
Generalised oedema	0 ( 0.0%)	3 ( 27.3%)	6 ( 54.5%)	2 ( 18.2%)	11
Postpartum haemorrhage	2 ( 18.2%)	9 ( 81.8%)	0 ( 0.0%)	0 ( 0.0%)	11
Road traffic accident	9 ( 81.8%)	2 ( 18.2%)	0 ( 0.0%)	0 ( 0.0%)	11
Hypopharyngeal cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	6 ( 54.5%)	5 ( 45.5%)	11
Retroperitoneal cancer	3 ( 27.3%)	2 ( 18.2%)	6 ( 54.5%)	0 ( 0.0%)	11
Hypophysitis	0 ( 0.0%)	2 ( 18.2%)	5 ( 45.5%)	4 ( 36.4%)	11
Retinal haemorrhage	0 ( 0.0%)	1 ( 9.1%)	8 ( 72.7%)	2 ( 18.2%)	11
Plasmodium vivax infection	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Renal disorder prophylaxis	0 ( 0.0%)	3 ( 27.3%)	7 ( 63.6%)	1 ( 9.1%)	11
Haematological malignancy	0 ( 0.0%)	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	11
Vaginal disorder	0 ( 0.0%)	1 ( 9.1%)	5 ( 45.5%)	5 ( 45.5%)	11
Pneumonia cytomegaloviral	4 ( 36.4%)	3 ( 27.3%)	4 ( 36.4%)	0 ( 0.0%)	11
HIV infection CDC Group IV subgroup C2	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	0 ( 0.0%)	11
Bacterial vaginosis	3 ( 27.3%)	5 ( 45.5%)	3 ( 27.3%)	0 ( 0.0%)	11
Prostatic adenoma	0 ( 0.0%)	0 ( 0.0%)	7 ( 63.6%)	4 ( 36.4%)	11
Uraemic pruritus	0 ( 0.0%)	0 ( 0.0%)	8 ( 72.7%)	3 ( 27.3%)	11

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Coronary artery thrombosis	0 ( 0.0%)	9 ( 81.8%)	2 ( 18.2%)	0 ( 0.0%)	11
Chalazion	0 ( 0.0%)	6 ( 54.5%)	4 ( 36.4%)	1 ( 9.1%)	11
Germ cell cancer	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Cerebrohepatorenal syndrome	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Thyroiditis	1 ( 9.1%)	1 ( 9.1%)	9 ( 81.8%)	0 ( 0.0%)	11
Portopulmonary hypertension	7 ( 63.6%)	0 ( 0.0%)	4 ( 36.4%)	0 ( 0.0%)	11
Maternal exposure during pregnancy	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Cerebral haematoma	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Gastroenteritis astroviral	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Vascular dementia	0 ( 0.0%)	0 ( 0.0%)	7 ( 63.6%)	4 ( 36.4%)	11
Mastoiditis	10 ( 90.9%)	0 ( 0.0%)	1 ( 9.1%)	0 ( 0.0%)	11
Phaeochromocytoma	1 ( 9.1%)	2 ( 18.2%)	8 ( 72.7%)	0 ( 0.0%)	11
Vena cava thrombosis	0 ( 0.0%)	4 ( 36.4%)	7 ( 63.6%)	0 ( 0.0%)	11
Catheterisation cardiac	0 ( 0.0%)	2 ( 18.2%)	9 ( 81.8%)	0 ( 0.0%)	11
Perinatal HIV infection	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	11
Viral hepatitis carrier	1 ( 9.1%)	0 ( 0.0%)	5 ( 45.5%)	5 ( 45.5%)	11
Inflammatory pain	0 ( 0.0%)	0 ( 0.0%)	11 (100.0%)	0 ( 0.0%)	11
Glomerulonephritis membranoproliferative	2 ( 18.2%)	4 ( 36.4%)	1 ( 9.1%)	4 ( 36.4%)	11
Osteomyelitis chronic	8 ( 72.7%)	0 ( 0.0%)	3 ( 27.3%)	0 ( 0.0%)	11
Cardiac fibrillation	0 ( 0.0%)	0 ( 0.0%)	7 ( 63.6%)	4 ( 36.4%)	11
Eye pain	0 ( 0.0%)	2 ( 18.2%)	9 ( 81.8%)	0 ( 0.0%)	11
Oestrogen replacement therapy	0 ( 0.0%)	0 ( 0.0%)	10 ( 90.9%)	1 ( 9.1%)	11
Oesophageal squamous cell carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	7 ( 70.0%)	3 ( 30.0%)	10
Exposure to communicable disease	2 ( 20.0%)	8 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Noonan syndrome	9 ( 90.0%)	1 ( 10.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Asthma-chronic obstructive pulmonary disease overlap	0 ( 0.0%)	1 ( 10.0%)	7 ( 70.0%)	2 ( 20.0%)	10
Erythrodermic psoriasis	0 ( 0.0%)	4 ( 40.0%)	5 ( 50.0%)	1 ( 10.0%)	10

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Non-compact cardiomyopathy	1 ( 10.0%)	9 ( 90.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Epithelioid sarcoma	0 ( 0.0%)	4 ( 40.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Neuropathy vitamin B12 deficiency	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Epididymitis	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Nervousness	3 ( 30.0%)	1 ( 10.0%)	3 ( 30.0%)	3 ( 30.0%)	10
Eosinophilic cellulitis	0 ( 0.0%)	0 ( 0.0%)	1 ( 10.0%)	9 ( 90.0%)	10
Nephritis	2 ( 20.0%)	5 ( 50.0%)	2 ( 20.0%)	1 ( 10.0%)	10
Necrotising colitis	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	10
Necrobiosis lipoidica diabetorum	0 ( 0.0%)	2 ( 20.0%)	8 ( 80.0%)	0 ( 0.0%)	10
Ammonia increased	6 ( 60.0%)	0 ( 0.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Burkholderia cepacia complex infection	0 ( 0.0%)	2 ( 20.0%)	8 ( 80.0%)	0 ( 0.0%)	10
Idiopathic intracranial hypertension	0 ( 0.0%)	6 ( 60.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Brucellosis	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Motion sickness	0 ( 0.0%)	3 ( 30.0%)	6 ( 60.0%)	1 ( 10.0%)	10
Arterial thrombosis	2 ( 20.0%)	4 ( 40.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Mevalonate kinase deficiency	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Metastases to the mediastinum	0 ( 0.0%)	7 ( 70.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Red blood cell transfusion	4 ( 40.0%)	4 ( 40.0%)	2 ( 20.0%)	0 ( 0.0%)	10
Metastases to gastrointestinal tract	0 ( 0.0%)	2 ( 20.0%)	3 ( 30.0%)	5 ( 50.0%)	10
Meningitis bacterial	2 ( 20.0%)	5 ( 50.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Medullary thyroid cancer	1 ( 10.0%)	1 ( 10.0%)	5 ( 50.0%)	3 ( 30.0%)	10
Medical diet	1 ( 10.0%)	4 ( 40.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Angiogram cerebral	1 ( 10.0%)	3 ( 30.0%)	4 ( 40.0%)	2 ( 20.0%)	10
Medical device site abscess	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)	10
Dopamine agonist withdrawal syndrome	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Brain contusion	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	10
Haemolytic transfusion reaction	0 ( 0.0%)	3 ( 30.0%)	7 ( 70.0%)	0 ( 0.0%)	10

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Disturbance in attention	6 ( 60.0%)	2 ( 20.0%)	1 ( 10.0%)	1 ( 10.0%)	10
Malaria prophylaxis	0 ( 0.0%)	4 ( 40.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Aphthous ulcer	5 ( 50.0%)	0 ( 0.0%)	4 ( 40.0%)	1 ( 10.0%)	10
Hair disorder	0 ( 0.0%)	5 ( 50.0%)	3 ( 30.0%)	2 ( 20.0%)	10
Lumbar spinal stenosis	0 ( 0.0%)	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	10
Lower urinary tract symptoms	0 ( 0.0%)	0 ( 0.0%)	4 ( 40.0%)	6 ( 60.0%)	10
Body temperature increased	2 ( 20.0%)	4 ( 40.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Dermatophytosis of nail	0 ( 0.0%)	3 ( 30.0%)	6 ( 60.0%)	1 ( 10.0%)	10
Limb injury	1 ( 10.0%)	3 ( 30.0%)	4 ( 40.0%)	2 ( 20.0%)	10
Leiomyosarcoma metastatic	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Latent autoimmune diabetes in adults	0 ( 0.0%)	4 ( 40.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Hemiplegic migraine	0 ( 0.0%)	2 ( 20.0%)	8 ( 80.0%)	0 ( 0.0%)	10
Defaecation disorder	0 ( 0.0%)	1 ( 10.0%)	8 ( 80.0%)	1 ( 10.0%)	10
Cytomegalovirus enterocolitis	0 ( 0.0%)	3 ( 30.0%)	3 ( 30.0%)	4 ( 40.0%)	10
Xerosis	1 ( 10.0%)	0 ( 0.0%)	6 ( 60.0%)	3 ( 30.0%)	10
Hepatitis E	1 ( 10.0%)	2 ( 20.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Urticaria pressure	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Cutaneous T-cell lymphoma stage IV	0 ( 0.0%)	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	10
Tubular breast carcinoma	0 ( 0.0%)	8 ( 80.0%)	1 ( 10.0%)	1 ( 10.0%)	10
Skin reaction	1 ( 10.0%)	7 ( 70.0%)	1 ( 10.0%)	1 ( 10.0%)	10
Tachypnoea	1 ( 10.0%)	1 ( 10.0%)	7 ( 70.0%)	1 ( 10.0%)	10
Tooth extraction	1 ( 10.0%)	1 ( 10.0%)	5 ( 50.0%)	3 ( 30.0%)	10
Anti-glomerular basement membrane disease	0 ( 0.0%)	2 ( 20.0%)	6 ( 60.0%)	2 ( 20.0%)	10
Thromboangiitis obliterans	0 ( 0.0%)	9 ( 90.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Testicular germ cell tumour mixed	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Subclavian vein thrombosis	2 ( 20.0%)	5 ( 50.0%)	3 ( 30.0%)	0 ( 0.0%)	10
Substance use disorder	0 ( 0.0%)	6 ( 60.0%)	1 ( 10.0%)	3 ( 30.0%)	10

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Squamous cell carcinoma of pharynx	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	10
Genital neoplasm malignant female	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Hordeolum	1 ( 10.0%)	1 ( 10.0%)	8 ( 80.0%)	0 ( 0.0%)	10
Myelodysplastic syndrome with ringed sideroblasts	0 ( 0.0%)	0 ( 0.0%)	2 ( 20.0%)	8 ( 80.0%)	10
Acute generalised exanthematous pustulosis	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Phantom limb syndrome	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	10
Scar	1 ( 10.0%)	2 ( 20.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Sarcoma metastatic	4 ( 40.0%)	1 ( 10.0%)	3 ( 30.0%)	2 ( 20.0%)	10
Cor pulmonale	3 ( 30.0%)	0 ( 0.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Antiandrogen therapy	0 ( 0.0%)	3 ( 30.0%)	1 ( 10.0%)	6 ( 60.0%)	10
Pulmonary pain	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	0 ( 0.0%)	10
Prostatic specific antigen increased	0 ( 0.0%)	0 ( 0.0%)	6 ( 60.0%)	4 ( 40.0%)	10
Coronary angioplasty	0 ( 0.0%)	0 ( 0.0%)	4 ( 40.0%)	6 ( 60.0%)	10
Product administration error	5 ( 50.0%)	1 ( 10.0%)	3 ( 30.0%)	1 ( 10.0%)	10
Procedural haemorrhage	0 ( 0.0%)	8 ( 80.0%)	2 ( 20.0%)	0 ( 0.0%)	10
Gastrointestinal adenocarcinoma	0 ( 0.0%)	0 ( 0.0%)	7 ( 70.0%)	3 ( 30.0%)	10
Anaplastic astrocytoma	5 ( 50.0%)	4 ( 40.0%)	1 ( 10.0%)	0 ( 0.0%)	10
Anaphylaxis prophylaxis	0 ( 0.0%)	2 ( 20.0%)	8 ( 80.0%)	0 ( 0.0%)	10
Central nervous system vasculitis	0 ( 0.0%)	2 ( 20.0%)	3 ( 30.0%)	5 ( 50.0%)	10
Peritoneal carcinoma metastatic	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Peripheral vascular disorder	0 ( 0.0%)	1 ( 10.0%)	4 ( 40.0%)	5 ( 50.0%)	10
Fracture	4 ( 40.0%)	2 ( 20.0%)	3 ( 30.0%)	1 ( 10.0%)	10
Peripheral T-cell lymphoma unspecified recurrent	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	10
Autoimmune hypothyroidism	0 ( 0.0%)	4 ( 40.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Pericarditis constrictive	4 ( 40.0%)	5 ( 50.0%)	0 ( 0.0%)	1 ( 10.0%)	10
Pelvic neoplasm	0 ( 0.0%)	6 ( 60.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Procedural headache	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	10



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cutaneous calcification	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Paraneoplastic pemphigus	0 ( 0.0%)	6 ( 60.0%)	4 ( 40.0%)	0 ( 0.0%)	10
Upper respiratory tract inflammation	0 ( 0.0%)	0 ( 0.0%)	5 ( 50.0%)	5 ( 50.0%)	10
Renal cell carcinoma stage III	0 ( 0.0%)	0 ( 0.0%)	8 ( 80.0%)	2 ( 20.0%)	10
Cutaneous vasculitis	0 ( 0.0%)	3 ( 30.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Eructation	0 ( 0.0%)	9 ( 90.0%)	0 ( 0.0%)	1 ( 10.0%)	10
Familial amyloidosis	3 ( 30.0%)	0 ( 0.0%)	5 ( 50.0%)	2 ( 20.0%)	10
Ovarian germ cell endodermal sinus tumour	0 ( 0.0%)	10 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	10
Weight abnormal	0 ( 0.0%)	3 ( 30.0%)	7 ( 70.0%)	0 ( 0.0%)	10
Anaesthesia eye	0 ( 0.0%)	4 ( 40.0%)	6 ( 60.0%)	0 ( 0.0%)	10
Ophthalmic herpes zoster	0 ( 0.0%)	0 ( 0.0%)	8 ( 80.0%)	2 ( 20.0%)	10
Interventional procedure	0 ( 0.0%)	1 ( 10.0%)	8 ( 80.0%)	1 ( 10.0%)	10
Odynophagia	4 ( 44.4%)	3 ( 33.3%)	2 ( 22.2%)	0 ( 0.0%)	9
Obsessive thoughts	4 ( 44.4%)	3 ( 33.3%)	2 ( 22.2%)	0 ( 0.0%)	9
Non-Hodgkin's lymphoma refractory	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Neutrophilia	1 ( 11.1%)	0 ( 0.0%)	8 ( 88.9%)	0 ( 0.0%)	9
Prosthetic valve endocarditis	0 ( 0.0%)	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	9
Acne cystic	7 ( 77.8%)	2 ( 22.2%)	0 ( 0.0%)	0 ( 0.0%)	9
C-reactive protein increased	0 ( 0.0%)	1 ( 11.1%)	3 ( 33.3%)	5 ( 55.6%)	9
Nasal septum deviation	1 ( 11.1%)	5 ( 55.6%)	3 ( 33.3%)	0 ( 0.0%)	9
NSAID exacerbated respiratory disease	0 ( 0.0%)	4 ( 44.4%)	4 ( 44.4%)	1 ( 11.1%)	9
Myelopathy	2 ( 22.2%)	2 ( 22.2%)	5 ( 55.6%)	0 ( 0.0%)	9
Gynaecomastia	8 ( 88.9%)	1 ( 11.1%)	0 ( 0.0%)	0 ( 0.0%)	9
Transitional cell carcinoma urethra	0 ( 0.0%)	0 ( 0.0%)	2 ( 22.2%)	7 ( 77.8%)	9
Multiple organ dysfunction syndrome	2 ( 22.2%)	0 ( 0.0%)	4 ( 44.4%)	3 ( 33.3%)	9
Rash macular	2 ( 22.2%)	1 ( 11.1%)	4 ( 44.4%)	2 ( 22.2%)	9
Mucous membrane pemphigoid	0 ( 0.0%)	0 ( 0.0%)	7 ( 77.8%)	2 ( 22.2%)	9

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Mucopolysaccharidosis I	7 ( 77.8%)	2 ( 22.2%)	0 ( 0.0%)	0 ( 0.0%)	9
Mucoepidermoid carcinoma	0 ( 0.0%)	8 ( 88.9%)	1 ( 11.1%)	0 ( 0.0%)	9
Ehlers-Danlos syndrome	1 ( 11.1%)	6 ( 66.7%)	2 ( 22.2%)	0 ( 0.0%)	9
Oral fungal infection	0 ( 0.0%)	4 ( 44.4%)	1 ( 11.1%)	4 ( 44.4%)	9
Ectopic ACTH syndrome	0 ( 0.0%)	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	9
Eating disorder	2 ( 22.2%)	5 ( 55.6%)	2 ( 22.2%)	0 ( 0.0%)	9
Brief psychotic disorder, with postpartum onset	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Adrenal disorder	3 ( 33.3%)	0 ( 0.0%)	6 ( 66.7%)	0 ( 0.0%)	9
Ear, nose and throat infection	4 ( 44.4%)	2 ( 22.2%)	3 ( 33.3%)	0 ( 0.0%)	9
Metastases to retroperitoneum	0 ( 0.0%)	4 ( 44.4%)	2 ( 22.2%)	3 ( 33.3%)	9
Metastases to muscle	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Metastases to abdominal cavity	2 ( 22.2%)	0 ( 0.0%)	7 ( 77.8%)	0 ( 0.0%)	9
Arrhythmic storm	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Meningioma	0 ( 0.0%)	3 ( 33.3%)	4 ( 44.4%)	2 ( 22.2%)	9
Appetite disorder	4 ( 44.4%)	0 ( 0.0%)	2 ( 22.2%)	3 ( 33.3%)	9
Brain injury	3 ( 33.3%)	1 ( 11.1%)	2 ( 22.2%)	3 ( 33.3%)	9
Respiration abnormal	1 ( 11.1%)	0 ( 0.0%)	5 ( 55.6%)	3 ( 33.3%)	9
Body mass index increased	1 ( 11.1%)	4 ( 44.4%)	2 ( 22.2%)	2 ( 22.2%)	9
Malignant melanoma of sites other than skin	0 ( 0.0%)	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	9
Malignant catatonia	4 ( 44.4%)	3 ( 33.3%)	2 ( 22.2%)	0 ( 0.0%)	9
Diffuse alveolar damage	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	9
Hair growth abnormal	1 ( 11.1%)	2 ( 22.2%)	6 ( 66.7%)	0 ( 0.0%)	9
Lung transplant rejection	0 ( 0.0%)	5 ( 55.6%)	4 ( 44.4%)	0 ( 0.0%)	9
Diabetic foot	0 ( 0.0%)	3 ( 33.3%)	5 ( 55.6%)	1 ( 11.1%)	9
Aortic valve replacement	0 ( 0.0%)	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	9
Aortic valve incompetence	1 ( 11.1%)	2 ( 22.2%)	4 ( 44.4%)	2 ( 22.2%)	9
Dermatitis psoriasiform	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Dermatitis diaper	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Heart rate abnormal	0 ( 0.0%)	0 ( 0.0%)	5 ( 55.6%)	4 ( 44.4%)	9
Dental disorder prophylaxis	0 ( 0.0%)	4 ( 44.4%)	4 ( 44.4%)	1 ( 11.1%)	9
Progressive relapsing multiple sclerosis	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	9
Keloid scar	8 ( 88.9%)	0 ( 0.0%)	1 ( 11.1%)	0 ( 0.0%)	9
Hepatic enzyme increased	2 ( 22.2%)	1 ( 11.1%)	6 ( 66.7%)	0 ( 0.0%)	9
Chronic active Epstein-Barr virus infection	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Abdominal tenderness	8 ( 88.9%)	0 ( 0.0%)	1 ( 11.1%)	0 ( 0.0%)	9
Thymic cancer metastatic	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Sinus node dysfunction	0 ( 0.0%)	0 ( 0.0%)	7 ( 77.8%)	2 ( 22.2%)	9
Blepharokeratoconjunctivitis	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Agoraphobia	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	9
Adrenogenital syndrome	5 ( 55.6%)	4 ( 44.4%)	0 ( 0.0%)	0 ( 0.0%)	9
Urticaria cholinergic	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Teratoma	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Upper-airway cough syndrome	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Acute graft versus host disease in skin	3 ( 33.3%)	0 ( 0.0%)	6 ( 66.7%)	0 ( 0.0%)	9
Spinal cord injury	1 ( 11.1%)	3 ( 33.3%)	5 ( 55.6%)	0 ( 0.0%)	9
Bladder cancer stage II	0 ( 0.0%)	0 ( 0.0%)	7 ( 77.8%)	2 ( 22.2%)	9
Hypotonia	1 ( 11.1%)	2 ( 22.2%)	5 ( 55.6%)	1 ( 11.1%)	9
Tonsillectomy	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Synovial sarcoma	3 ( 33.3%)	4 ( 44.4%)	2 ( 22.2%)	0 ( 0.0%)	9
Thalassaemia sickle cell	3 ( 33.3%)	2 ( 22.2%)	4 ( 44.4%)	0 ( 0.0%)	9
Hyperpituitarism	6 ( 66.7%)	2 ( 22.2%)	1 ( 11.1%)	0 ( 0.0%)	9
Tachyarrhythmia	2 ( 22.2%)	0 ( 0.0%)	6 ( 66.7%)	1 ( 11.1%)	9
Immunoglobulin therapy	1 ( 11.1%)	7 ( 77.8%)	0 ( 0.0%)	1 ( 11.1%)	9
Hypercalciuria	3 ( 33.3%)	1 ( 11.1%)	5 ( 55.6%)	0 ( 0.0%)	9

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Primary cardiac lymphoma	0 ( 0.0%)	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	9
Hodgkin's disease recurrent	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Pernicious anaemia	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Tendonitis	0 ( 0.0%)	2 ( 22.2%)	5 ( 55.6%)	2 ( 22.2%)	9
Herpes simplex encephalitis	2 ( 22.2%)	0 ( 0.0%)	6 ( 66.7%)	1 ( 11.1%)	9
Skin abrasion	4 ( 44.4%)	1 ( 11.1%)	3 ( 33.3%)	1 ( 11.1%)	9
Abscess limb	0 ( 0.0%)	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	9
Silver-Russell syndrome	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Blepharospasm	0 ( 0.0%)	0 ( 0.0%)	7 ( 77.8%)	2 ( 22.2%)	9
Carcinoid tumour of the liver	0 ( 0.0%)	2 ( 22.2%)	7 ( 77.8%)	0 ( 0.0%)	9
Blister	0 ( 0.0%)	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	9
Hypocholesterolaemia	0 ( 0.0%)	0 ( 0.0%)	7 ( 77.8%)	2 ( 22.2%)	9
Rosai-Dorfman syndrome	3 ( 33.3%)	2 ( 22.2%)	4 ( 44.4%)	0 ( 0.0%)	9
Beta haemolytic streptococcal infection	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Haemosiderosis	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Retinal vasculitis	0 ( 0.0%)	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	9
Gaucher's disease type III	8 ( 88.9%)	1 ( 11.1%)	0 ( 0.0%)	0 ( 0.0%)	9
Tracheal cancer	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Benign familial pemphigus	0 ( 0.0%)	1 ( 11.1%)	8 ( 88.9%)	0 ( 0.0%)	9
Haematochezia	0 ( 0.0%)	2 ( 22.2%)	6 ( 66.7%)	1 ( 11.1%)	9
Rectal cancer stage III	0 ( 0.0%)	2 ( 22.2%)	5 ( 55.6%)	2 ( 22.2%)	9
Graft versus host disease in liver	7 ( 77.8%)	0 ( 0.0%)	2 ( 22.2%)	0 ( 0.0%)	9
Immune enhancement therapy	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Glucocorticoid deficiency	5 ( 55.6%)	2 ( 22.2%)	2 ( 22.2%)	0 ( 0.0%)	9
Immune-mediated hepatitis	0 ( 0.0%)	1 ( 11.1%)	4 ( 44.4%)	4 ( 44.4%)	9
Procedural nausea	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Urinary tract infection bacterial	0 ( 0.0%)	3 ( 33.3%)	2 ( 22.2%)	4 ( 44.4%)	9

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Gastroesophageal cancer	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Cerebral venous thrombosis	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	0 ( 0.0%)	9
Gastrointestinal pain	0 ( 0.0%)	3 ( 33.3%)	6 ( 66.7%)	0 ( 0.0%)	9
Gastrointestinal neoplasm	0 ( 0.0%)	1 ( 11.1%)	6 ( 66.7%)	2 ( 22.2%)	9
Poor peripheral circulation	1 ( 11.1%)	0 ( 0.0%)	7 ( 77.8%)	1 ( 11.1%)	9
Urine alkalinisation therapy	1 ( 11.1%)	2 ( 22.2%)	5 ( 55.6%)	1 ( 11.1%)	9
Subcutaneous abscess	0 ( 0.0%)	5 ( 55.6%)	4 ( 44.4%)	0 ( 0.0%)	9
Gastric bypass	0 ( 0.0%)	3 ( 33.3%)	6 ( 66.7%)	0 ( 0.0%)	9
Vascular disorder prophylaxis	0 ( 0.0%)	1 ( 11.1%)	6 ( 66.7%)	2 ( 22.2%)	9
Adenosine deaminase 2 deficiency	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	9
Pharyngitis streptococcal	4 ( 44.4%)	4 ( 44.4%)	0 ( 0.0%)	1 ( 11.1%)	9
Infected fistula	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Fusobacterium infection	2 ( 22.2%)	6 ( 66.7%)	0 ( 0.0%)	1 ( 11.1%)	9
Peritoneal mesothelioma malignant	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Vasogenic cerebral oedema	1 ( 11.1%)	0 ( 0.0%)	6 ( 66.7%)	2 ( 22.2%)	9
Follicular dendritic cell sarcoma	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9
Impetigo	1 ( 11.1%)	7 ( 77.8%)	1 ( 11.1%)	0 ( 0.0%)	9
Infusion	1 ( 11.1%)	4 ( 44.4%)	4 ( 44.4%)	0 ( 0.0%)	9
Papilloedema	0 ( 0.0%)	8 ( 88.9%)	1 ( 11.1%)	0 ( 0.0%)	9
Neutrophilic dermatosis	5 ( 55.6%)	0 ( 0.0%)	4 ( 44.4%)	0 ( 0.0%)	9
Pain in jaw	0 ( 0.0%)	3 ( 33.3%)	4 ( 44.4%)	2 ( 22.2%)	9
Pachymeningitis	0 ( 0.0%)	0 ( 0.0%)	5 ( 55.6%)	4 ( 44.4%)	9
Probiotic therapy	2 ( 22.2%)	2 ( 22.2%)	4 ( 44.4%)	1 ( 11.1%)	9
Faeces soft	1 ( 11.1%)	2 ( 22.2%)	4 ( 44.4%)	2 ( 22.2%)	9
Chemotherapy cytokine prophylaxis	6 ( 66.7%)	3 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	9
Factor V Leiden mutation	1 ( 11.1%)	5 ( 55.6%)	1 ( 11.1%)	2 ( 22.2%)	9
Eye infection toxoplasmal	0 ( 0.0%)	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	9

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Zinc deficiency	1 ( 11.1%)	1 ( 11.1%)	3 ( 33.3%)	4 ( 44.4%)	9
Extraskelatal myxoid chondrosarcoma	0 ( 0.0%)	4 ( 44.4%)	5 ( 55.6%)	0 ( 0.0%)	9
Nonspecific reaction	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Ocular ischaemic syndrome	6 ( 75.0%)	1 ( 12.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Erythromelalgia	1 ( 12.5%)	0 ( 0.0%)	7 ( 87.5%)	0 ( 0.0%)	8
Nongerminomatous germ cell tumour of the CNS	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Nijmegen breakage syndrome	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	8
New onset diabetes after transplantation	7 ( 87.5%)	0 ( 0.0%)	1 ( 12.5%)	0 ( 0.0%)	8
Assisted fertilisation	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Psychotic disorder due to a general medical conditio	0 ( 0.0%)	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	8
Eosinophilic pneumonia chronic	4 ( 50.0%)	2 ( 25.0%)	2 ( 25.0%)	0 ( 0.0%)	8
Obstructive sleep apnoea syndrome	1 ( 12.5%)	0 ( 0.0%)	5 ( 62.5%)	2 ( 25.0%)	8
Oesophageal adenocarcinoma stage IV	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Neonatal respiratory distress syndrome	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Granuloma	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Cholecystitis acute	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8
Pulmonary veno-occlusive disease	0 ( 0.0%)	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	8
Endoscopy upper gastrointestinal tract	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Myosclerosis	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Endometritis	6 ( 75.0%)	2 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Burkholderia gladioli infection	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Endometrial cancer stage III	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Arthritis reactive	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Corneal abscess	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Quadriparesis	3 ( 37.5%)	1 ( 12.5%)	4 ( 50.0%)	0 ( 0.0%)	8
Radiation necrosis	6 ( 75.0%)	0 ( 0.0%)	2 ( 25.0%)	0 ( 0.0%)	8
Endocarditis staphylococcal	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Muscle disorder	1 ( 12.5%)	4 ( 50.0%)	2 ( 25.0%)	1 ( 12.5%)	8
Yolk sac tumour site unspecified	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Encephalitis brain stem	5 ( 62.5%)	3 ( 37.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Empyema	1 ( 12.5%)	2 ( 25.0%)	5 ( 62.5%)	0 ( 0.0%)	8
Multimorbidity	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Eye allergy	0 ( 0.0%)	3 ( 37.5%)	3 ( 37.5%)	2 ( 25.0%)	8
Amenorrhoea	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Abnormal faeces	0 ( 0.0%)	4 ( 50.0%)	2 ( 25.0%)	2 ( 25.0%)	8
Arteriovenous fistula	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Mouth haemorrhage	5 ( 62.5%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 37.5%)	8
Arteriospasm coronary	0 ( 0.0%)	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	8
Bronchiolitis	5 ( 62.5%)	0 ( 0.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Ectopic pregnancy termination	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Echinococciasis	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Metastatic cutaneous Crohn's disease	3 ( 37.5%)	1 ( 12.5%)	4 ( 50.0%)	0 ( 0.0%)	8
Dyspareunia	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Breast cancer in situ	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Blood bilirubin increased	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
Haematoma	2 ( 25.0%)	0 ( 0.0%)	4 ( 50.0%)	2 ( 25.0%)	8
Meningitis aseptic	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Drug withdrawal maintenance therapy	1 ( 12.5%)	5 ( 62.5%)	2 ( 25.0%)	0 ( 0.0%)	8
Medulloblastoma recurrent	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Brain stem glioma	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Haemoglobin abnormal	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Chronic fatigue syndrome	1 ( 12.5%)	5 ( 62.5%)	1 ( 12.5%)	1 ( 12.5%)	8
Appendectomy	3 ( 37.5%)	1 ( 12.5%)	1 ( 12.5%)	3 ( 37.5%)	8
Malignant neoplasm of thymus	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Allogenic bone marrow transplantation therapy	2 ( 25.0%)	1 ( 12.5%)	5 ( 62.5%)	0 ( 0.0%)	8
Disorientation	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Magnetic resonance imaging spinal	1 ( 12.5%)	5 ( 62.5%)	1 ( 12.5%)	1 ( 12.5%)	8
Allergy to animal	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	0 ( 0.0%)	8
Lung abscess	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Lumbar vertebral fracture	1 ( 12.5%)	2 ( 25.0%)	1 ( 12.5%)	4 ( 50.0%)	8
Low density lipoprotein decreased	0 ( 0.0%)	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	8
Long QT syndrome	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Liver function test increased	1 ( 12.5%)	0 ( 0.0%)	4 ( 50.0%)	3 ( 37.5%)	8
Liposarcoma	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Aortic aneurysm	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
Leukoencephalopathy	4 ( 50.0%)	2 ( 25.0%)	1 ( 12.5%)	1 ( 12.5%)	8
Delusional disorder, unspecified type	0 ( 0.0%)	5 ( 62.5%)	2 ( 25.0%)	1 ( 12.5%)	8
Lacrimation increased	1 ( 12.5%)	2 ( 25.0%)	5 ( 62.5%)	0 ( 0.0%)	8
Labour pain	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Klebsiella sepsis	0 ( 0.0%)	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	8
Jugular vein thrombosis	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Dandy-Walker syndrome	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Biliary cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	3 ( 37.5%)	5 ( 62.5%)	8
Cytomegalovirus test positive	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Antioxidant therapy	3 ( 37.5%)	2 ( 25.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Intraoperative care	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Vitrectomy	5 ( 62.5%)	0 ( 0.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Sexual dysfunction	0 ( 0.0%)	6 ( 75.0%)	0 ( 0.0%)	2 ( 25.0%)	8
Vulvovaginal disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	8
Blood growth hormone decreased	7 ( 87.5%)	1 ( 12.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Oocyte harvest	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8



### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Vaginal cancer	0 ( 0.0%)	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	8
Skin test	2 ( 25.0%)	1 ( 12.5%)	4 ( 50.0%)	1 ( 12.5%)	8
Type IV hypersensitivity reaction	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Tuberculoma of central nervous system	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	8
Hodgkin's disease lymphocyte depletion type stage II	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Transcatheter aortic valve implantation	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
Primary hypercholesterolaemia	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Acute graft versus host disease in intestine	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	0 ( 0.0%)	8
Human T-cell lymphotropic virus type I infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	8
Anal fissure	3 ( 37.5%)	2 ( 25.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Congenital megacolon	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Hyperadrenocorticism	1 ( 12.5%)	3 ( 37.5%)	2 ( 25.0%)	2 ( 25.0%)	8
Anti IFN gamma autoantibody syndrome	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	0 ( 0.0%)	8
Hyperammonaemic encephalopathy	0 ( 0.0%)	7 ( 87.5%)	0 ( 0.0%)	1 ( 12.5%)	8
Systemic sclerosis pulmonary	0 ( 0.0%)	1 ( 12.5%)	4 ( 50.0%)	3 ( 37.5%)	8
Superior vena cava occlusion	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Syphilis	3 ( 37.5%)	4 ( 50.0%)	1 ( 12.5%)	0 ( 0.0%)	8
Traumatic intracranial haemorrhage	0 ( 0.0%)	1 ( 12.5%)	1 ( 12.5%)	6 ( 75.0%)	8
Bladder pain	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Infective myositis	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Colon cancer stage II	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Amnesia	0 ( 0.0%)	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	8
Blau syndrome	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Small fibre neuropathy	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Tendon disorder	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Coeliac disease	2 ( 25.0%)	0 ( 0.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Anti-NMDA antibody	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Testicular seminoma (pure)	0 ( 0.0%)	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	8
Skin mass	1 ( 12.5%)	1 ( 12.5%)	5 ( 62.5%)	1 ( 12.5%)	8
Hernia	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Tension	0 ( 0.0%)	2 ( 25.0%)	4 ( 50.0%)	2 ( 25.0%)	8
Thinking abnormal	1 ( 12.5%)	0 ( 0.0%)	7 ( 87.5%)	0 ( 0.0%)	8
Hepatic sarcoma	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Secondary hypogonadism	0 ( 0.0%)	3 ( 37.5%)	5 ( 62.5%)	0 ( 0.0%)	8
Idiopathic pneumonia syndrome	7 ( 87.5%)	0 ( 0.0%)	1 ( 12.5%)	0 ( 0.0%)	8
Heparin-induced thrombocytopenia	1 ( 12.5%)	1 ( 12.5%)	5 ( 62.5%)	1 ( 12.5%)	8
Sarcomatoid carcinoma	0 ( 0.0%)	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	8
Retinal detachment	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Chronic graft versus host disease in intestine	5 ( 62.5%)	0 ( 0.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Haemolysis	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Gastric haemorrhage	0 ( 0.0%)	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	8
Chronic eosinophilic rhinosinusitis	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	0 ( 0.0%)	8
Chronic disease	0 ( 0.0%)	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	8
Haematopoietic neoplasm	0 ( 0.0%)	2 ( 25.0%)	5 ( 62.5%)	1 ( 12.5%)	8
Renal cell carcinoma stage I	0 ( 0.0%)	2 ( 25.0%)	0 ( 0.0%)	6 ( 75.0%)	8
Vaginal infection	0 ( 0.0%)	5 ( 62.5%)	2 ( 25.0%)	1 ( 12.5%)	8
Vaginal cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Pneumococcal infection	1 ( 12.5%)	1 ( 12.5%)	4 ( 50.0%)	2 ( 25.0%)	8
Bell's palsy	1 ( 12.5%)	1 ( 12.5%)	6 ( 75.0%)	0 ( 0.0%)	8
Chromophobe renal cell carcinoma	0 ( 0.0%)	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	8
Choroidal effusion	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Choroid melanoma	0 ( 0.0%)	4 ( 50.0%)	2 ( 25.0%)	2 ( 25.0%)	8
Blood calcium abnormal	1 ( 12.5%)	1 ( 12.5%)	6 ( 75.0%)	0 ( 0.0%)	8
Growth hormone-producing pituitary tumour	6 ( 75.0%)	2 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	8

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tuberculin test	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Bacteriuria	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	0 ( 0.0%)	8
Immune disorder prophylaxis	1 ( 12.5%)	0 ( 0.0%)	6 ( 75.0%)	1 ( 12.5%)	8
Proteus test positive	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Polyomavirus-associated nephropathy	2 ( 25.0%)	0 ( 0.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Inappropriate antidiuretic hormone secretion	1 ( 12.5%)	0 ( 0.0%)	5 ( 62.5%)	2 ( 25.0%)	8
Chemical poisoning	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	0 ( 0.0%)	8
Chelation therapy	3 ( 37.5%)	1 ( 12.5%)	4 ( 50.0%)	0 ( 0.0%)	8
Giant cell myocarditis	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Urethral cancer	0 ( 0.0%)	5 ( 62.5%)	2 ( 25.0%)	1 ( 12.5%)	8
Prenatal care	7 ( 87.5%)	1 ( 12.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Immunoglobulins decreased	0 ( 0.0%)	5 ( 62.5%)	2 ( 25.0%)	1 ( 12.5%)	8
Cerebral disorder	1 ( 12.5%)	1 ( 12.5%)	3 ( 37.5%)	3 ( 37.5%)	8
Costochondritis	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Cerebral thrombosis	0 ( 0.0%)	3 ( 37.5%)	0 ( 0.0%)	5 ( 62.5%)	8
Post inflammatory pigmentation change	2 ( 25.0%)	2 ( 25.0%)	3 ( 37.5%)	1 ( 12.5%)	8
Polypoidal choroidal vasculopathy	0 ( 0.0%)	0 ( 0.0%)	5 ( 62.5%)	3 ( 37.5%)	8
Pneumonia viral	0 ( 0.0%)	2 ( 25.0%)	4 ( 50.0%)	2 ( 25.0%)	8
Pneumonia streptococcal	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Pneumonia legionella	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Gastrointestinal ulcer	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Epiglottic cancer	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Increased appetite	2 ( 25.0%)	3 ( 37.5%)	3 ( 37.5%)	0 ( 0.0%)	8
Vasculitic rash	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Premenstrual dysphoric disorder	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	0 ( 0.0%)	8
Vasodilatation	0 ( 0.0%)	4 ( 50.0%)	4 ( 50.0%)	0 ( 0.0%)	8
Peripheral artery occlusion	0 ( 0.0%)	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	8

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Ventricular arrhythmia	0 ( 0.0%)	5 ( 62.5%)	1 ( 12.5%)	2 ( 25.0%)	8
Penile vascular disorder	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Vestibular migraine	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Vitamin B12 decreased	0 ( 0.0%)	3 ( 37.5%)	4 ( 50.0%)	1 ( 12.5%)	8
Parasitic infection prophylaxis	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	0 ( 0.0%)	8
Coronary artery stenosis	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8
Paraneoplastic dermatomyositis	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Adenoid cystic carcinoma	0 ( 0.0%)	2 ( 25.0%)	6 ( 75.0%)	0 ( 0.0%)	8
Pancreatic fistula	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Cardiorenal syndrome	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
Cutaneous tuberculosis	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Vulvovaginal discomfort	0 ( 0.0%)	1 ( 12.5%)	6 ( 75.0%)	1 ( 12.5%)	8
Familial partial lipodystrophy	6 ( 75.0%)	2 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Atrioventricular block	1 ( 12.5%)	1 ( 12.5%)	4 ( 50.0%)	2 ( 25.0%)	8
Cardiac operation	0 ( 0.0%)	0 ( 0.0%)	1 ( 12.5%)	7 ( 87.5%)	8
Cardiac flutter	0 ( 0.0%)	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	8
Atrial septal defect	5 ( 62.5%)	0 ( 0.0%)	3 ( 37.5%)	0 ( 0.0%)	8
Oropharyngeal cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	6 ( 75.0%)	2 ( 25.0%)	8
Oral submucosal fibrosis	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	8
Oral neoplasm	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Cardiac aneurysm	0 ( 0.0%)	0 ( 0.0%)	8 (100.0%)	0 ( 0.0%)	8
Abdominal abscess	1 ( 12.5%)	1 ( 12.5%)	5 ( 62.5%)	1 ( 12.5%)	8
Oligoastrocytoma	1 ( 12.5%)	0 ( 0.0%)	7 ( 87.5%)	0 ( 0.0%)	8
Asymptomatic HIV infection	0 ( 0.0%)	7 ( 87.5%)	1 ( 12.5%)	0 ( 0.0%)	8
Capnocytophaga infection	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Occipital neuralgia	1 ( 14.3%)	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	7
Normal tension glaucoma	0 ( 0.0%)	3 ( 42.9%)	2 ( 28.6%)	2 ( 28.6%)	7

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Anaemia of chronic disease	0 ( 0.0%)	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	7
Calcinosis	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	0 ( 0.0%)	7
Neuroendocrine carcinoma of the cervix	0 ( 0.0%)	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	7
Tumour associated fever	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Epidermolysis bullosa	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	0 ( 0.0%)	7
Eosinophilic pneumonia	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Eosinophilic myocarditis	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Enzyme supplementation	5 ( 71.4%)	1 ( 14.3%)	1 ( 14.3%)	0 ( 0.0%)	7
Enuresis	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Nasal disorder	0 ( 0.0%)	2 ( 28.6%)	2 ( 28.6%)	3 ( 42.9%)	7
Myelitis	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	0 ( 0.0%)	7
Bundle branch block left	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Musculoskeletal discomfort	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	7
Muscle mass	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	0 ( 0.0%)	7
Muscle haemorrhage	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Multicentric reticulohistiocytosis	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Movement disorder	1 ( 14.3%)	0 ( 0.0%)	5 ( 71.4%)	1 ( 14.3%)	7
Mononeuropathy	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Metastatic uterine cancer	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Breast pain	0 ( 0.0%)	5 ( 71.4%)	1 ( 14.3%)	1 ( 14.3%)	7
Metastases to pancreas	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Dust allergy	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	7
Meningitis meningococcal	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Arnold-Chiari malformation	4 ( 57.1%)	0 ( 0.0%)	2 ( 28.6%)	1 ( 14.3%)	7
Diverticulum	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Malignant nipple neoplasm female	0 ( 0.0%)	1 ( 14.3%)	2 ( 28.6%)	4 ( 57.1%)	7
Malignant melanoma stage II	0 ( 0.0%)	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	7

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Malaria	1 ( 14.3%)	2 ( 28.6%)	4 ( 57.1%)	0 ( 0.0%)	7
Magnetic resonance imaging heart	3 ( 42.9%)	1 ( 14.3%)	2 ( 28.6%)	1 ( 14.3%)	7
Magnetic resonance imaging breast	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Haemophilus infection	1 ( 14.3%)	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	7
Haemorrhoidal haemorrhage	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	7
Lung carcinoma cell type unspecified stage III	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Localised oedema	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Liver injury	0 ( 0.0%)	4 ( 57.1%)	1 ( 14.3%)	2 ( 28.6%)	7
Acute lymphocytic leukaemia (in remission)	2 ( 28.6%)	1 ( 14.3%)	3 ( 42.9%)	1 ( 14.3%)	7
Listeria encephalitis	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Limb immobilisation	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Body fat disorder	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	0 ( 0.0%)	7
Tinea pedis	2 ( 28.6%)	1 ( 14.3%)	3 ( 42.9%)	1 ( 14.3%)	7
Acute leukaemia in remission	0 ( 0.0%)	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	7
Large intestine infection	1 ( 14.3%)	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	7
Familial tremor	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Dedifferentiated liposarcoma	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7
Alcohol rehabilitation	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Alcohol poisoning	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Blood pressure fluctuation	1 ( 14.3%)	1 ( 14.3%)	4 ( 57.1%)	1 ( 14.3%)	7
Joint prosthesis user	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Dandruff	1 ( 14.3%)	2 ( 28.6%)	3 ( 42.9%)	1 ( 14.3%)	7
Angle closure glaucoma	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Thyroid cyst	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Citrobacter infection	0 ( 0.0%)	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	7
Blood potassium abnormal	0 ( 0.0%)	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	7
Intracranial infection	1 ( 14.3%)	2 ( 28.6%)	4 ( 57.1%)	0 ( 0.0%)	7

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Selective eating disorder	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Seizure cluster	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	0 ( 0.0%)	7
Antineutrophil cytoplasmic antibody	0 ( 0.0%)	1 ( 14.3%)	2 ( 28.6%)	4 ( 57.1%)	7
Wrong dose	0 ( 0.0%)	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	7
Wound infection staphylococcal	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Anhedonia	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Serpiginous choroiditis	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Serum ferritin decreased	1 ( 14.3%)	5 ( 71.4%)	0 ( 0.0%)	1 ( 14.3%)	7
Fibrinous bronchitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	7
Hepatorenal syndrome	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Ventricular dysfunction	4 ( 57.1%)	0 ( 0.0%)	3 ( 42.9%)	0 ( 0.0%)	7
Paraproteinaemia	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	0 ( 0.0%)	7
Herpes zoster immunisation	1 ( 14.3%)	1 ( 14.3%)	2 ( 28.6%)	3 ( 42.9%)	7
Urea cycle disorder	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	0 ( 0.0%)	7
Tumour thrombosis	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7
Tonic clonic movements	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Stenosis	0 ( 0.0%)	4 ( 57.1%)	2 ( 28.6%)	1 ( 14.3%)	7
Hyperinsulinism	6 ( 85.7%)	0 ( 0.0%)	1 ( 14.3%)	0 ( 0.0%)	7
Tenosynovitis	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	1 ( 14.3%)	7
Perioperative analgesia	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	0 ( 0.0%)	7
Bladder transitional cell carcinoma metastatic	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Surgical preconditioning	1 ( 14.3%)	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	7
Stupor	0 ( 0.0%)	4 ( 57.1%)	1 ( 14.3%)	2 ( 28.6%)	7
Stress urinary incontinence	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	7
Complement factor abnormal	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	0 ( 0.0%)	7
Hyper IgM syndrome	2 ( 28.6%)	3 ( 42.9%)	2 ( 28.6%)	0 ( 0.0%)	7
Streptococcal endocarditis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	7

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Androgen deficiency	0 ( 0.0%)	2 ( 28.6%)	4 ( 57.1%)	1 ( 14.3%)	7
Squamous cell carcinoma of the oral cavity	0 ( 0.0%)	4 ( 57.1%)	2 ( 28.6%)	1 ( 14.3%)	7
Spontaneous bacterial peritonitis	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	0 ( 0.0%)	7
Spondylolisthesis	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Peritoneal tuberculosis	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Autoimmune neutropenia	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Congenital anomaly	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Herpes zoster reactivation	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	0 ( 0.0%)	7
Testicular germ cell cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	7
Hepatomegaly	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Sexually inappropriate behaviour	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Secondary adrenocortical insufficiency	0 ( 0.0%)	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	7
Seborrhoeic keratosis	0 ( 0.0%)	1 ( 14.3%)	2 ( 28.6%)	4 ( 57.1%)	7
Cervical radiculopathy	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Seasonal affective disorder	2 ( 28.6%)	0 ( 0.0%)	5 ( 71.4%)	0 ( 0.0%)	7
Chylothorax	6 ( 85.7%)	0 ( 0.0%)	1 ( 14.3%)	0 ( 0.0%)	7
Sarcoma uterus	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	7
Salmonellosis	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	0 ( 0.0%)	7
Sympathetic ophthalmia	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Adrenal neoplasm	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Blood albumin decreased	1 ( 14.3%)	1 ( 14.3%)	3 ( 42.9%)	2 ( 28.6%)	7
Heart and lung transplant	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Eczema herpeticum	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	0 ( 0.0%)	7
Angioplasty	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Rib fracture	0 ( 0.0%)	3 ( 42.9%)	2 ( 28.6%)	2 ( 28.6%)	7
Hand dermatitis	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Chronic left ventricular failure	0 ( 0.0%)	3 ( 42.9%)	2 ( 28.6%)	2 ( 28.6%)	7



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Benign rolandic epilepsy	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Chronic kidney disease-mineral and bone disorder	0 ( 0.0%)	5 ( 71.4%)	1 ( 14.3%)	1 ( 14.3%)	7
Retinal artery occlusion	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Adrenal gland cancer metastatic	6 ( 85.7%)	0 ( 0.0%)	1 ( 14.3%)	0 ( 0.0%)	7
Respiratory disorder prophylaxis	5 ( 71.4%)	0 ( 0.0%)	1 ( 14.3%)	1 ( 14.3%)	7
Pituitary-dependent Cushing's syndrome	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Vaginal haemorrhage	0 ( 0.0%)	6 ( 85.7%)	0 ( 0.0%)	1 ( 14.3%)	7
Renal amyloidosis	0 ( 0.0%)	1 ( 14.3%)	3 ( 42.9%)	3 ( 42.9%)	7
Reflux laryngitis	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Radiation skin injury	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Pyruvate kinase deficiency anaemia	2 ( 28.6%)	2 ( 28.6%)	3 ( 42.9%)	0 ( 0.0%)	7
Putamen haemorrhage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	7
Pulmonary vasculitis	0 ( 0.0%)	2 ( 28.6%)	5 ( 71.4%)	0 ( 0.0%)	7
Pulmonary thrombosis	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Pulmonary haemorrhage	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	0 ( 0.0%)	7
Pulmonary capillary haemangiomatosis	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Illusion	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	0 ( 0.0%)	7
Type III immune complex mediated reaction	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Prostatism	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Prostatic pain	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	0 ( 0.0%)	7
Aneurysm	0 ( 0.0%)	1 ( 14.3%)	2 ( 28.6%)	4 ( 57.1%)	7
Immune-mediated myocarditis	0 ( 0.0%)	3 ( 42.9%)	1 ( 14.3%)	3 ( 42.9%)	7
Prophylaxis against Rh isoimmunisation	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Primary hyperthyroidism	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Primary hyperaldosteronism	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
General symptom	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	7
Gastrostomy	6 ( 85.7%)	0 ( 0.0%)	1 ( 14.3%)	0 ( 0.0%)	7

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Urinary tract pain	3 ( 42.9%)	2 ( 28.6%)	2 ( 28.6%)	0 ( 0.0%)	7
Polyp	0 ( 0.0%)	2 ( 28.6%)	3 ( 42.9%)	2 ( 28.6%)	7
Azotaemia	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Gastritis erosive	0 ( 0.0%)	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	7
Pneumococcal immunisation	0 ( 0.0%)	3 ( 42.9%)	0 ( 0.0%)	4 ( 57.1%)	7
Central venous catheterisation	1 ( 14.3%)	4 ( 57.1%)	2 ( 28.6%)	0 ( 0.0%)	7
Central nervous system neoplasm	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Vascular stent thrombosis	0 ( 0.0%)	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	7
Vascular stent insertion	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Infective exacerbation of bronchiectasis	0 ( 0.0%)	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	7
Periodontitis	0 ( 0.0%)	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	7
Ventricular septal defect	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Pericardial effusion malignant	0 ( 0.0%)	5 ( 71.4%)	2 ( 28.6%)	0 ( 0.0%)	7
Follicular lymphoma recurrent	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Follicle centre lymphoma, follicular grade I, II, II	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	7
Vipoma	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Abdominal neoplasm	0 ( 0.0%)	1 ( 14.3%)	5 ( 71.4%)	1 ( 14.3%)	7
Vitamin D abnormal	0 ( 0.0%)	0 ( 0.0%)	3 ( 42.9%)	4 ( 57.1%)	7
Paradoxical drug reaction	0 ( 0.0%)	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	7
Acute hepatic failure	0 ( 0.0%)	1 ( 14.3%)	6 ( 85.7%)	0 ( 0.0%)	7
Pancreatic carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Familial periodic paralysis	3 ( 42.9%)	3 ( 42.9%)	1 ( 14.3%)	0 ( 0.0%)	7
Insulin autoimmune syndrome	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Visceral pain	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	7
Ovarian granulosa cell tumour	3 ( 42.9%)	4 ( 57.1%)	0 ( 0.0%)	0 ( 0.0%)	7
Faecal management	0 ( 0.0%)	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	7
Ovarian cancer stage I	0 ( 0.0%)	2 ( 28.6%)	1 ( 14.3%)	4 ( 57.1%)	7

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Face oedema	0 ( 0.0%)	4 ( 57.1%)	3 ( 42.9%)	0 ( 0.0%)	7
Face lift	0 ( 0.0%)	0 ( 0.0%)	6 ( 85.7%)	1 ( 14.3%)	7
Eye injury	6 ( 85.7%)	0 ( 0.0%)	1 ( 14.3%)	0 ( 0.0%)	7
Extraskelatal osteosarcoma	2 ( 28.6%)	0 ( 0.0%)	5 ( 71.4%)	0 ( 0.0%)	7
Intertrigo	0 ( 0.0%)	0 ( 0.0%)	7 (100.0%)	0 ( 0.0%)	7
Ulcerative keratitis	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Asthma late onset	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Ocular pemphigoid	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Anaemia of pregnancy	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Candida sepsis	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	0 ( 0.0%)	6
Non-alcoholic fatty liver	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	6
Non-Hodgkin's lymphoma stage IV	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Non-Hodgkin's lymphoma recurrent	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
New daily persistent headache	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Abnormal uterine bleeding	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Calciphylaxis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Epileptic encephalopathy	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Neuroleptic malignant syndrome	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Epigastric discomfort	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Neurofibrosarcoma	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Gouty tophus	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Amniotic cavity infection	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Exposure during pregnancy	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Arthropod sting	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Endoscopy gastrointestinal	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Endoscopy	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Myelodysplastic syndrome with multilineage dysplasia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	6

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bulimia nervosa	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	6
Muscle tightness	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Muscle rupture	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Encephalomyelitis	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Mitochondrial cytopathy	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Microvillous inclusion disease	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Microsporidia infection	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Bronchial anastomosis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Ear discomfort	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Arterial occlusive disease	0 ( 0.0%)	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	6
Metastases to pelvis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Metastases to ovary	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Meningoencephalitis bacterial	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Mechanical urticaria	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Angiogram retina	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Mean arterial pressure	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Thyroiditis subacute	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Maternal use of illicit drugs	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Drug abuser	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Mass	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	6
Mantle cell lymphoma refractory	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Malignant mast cell neoplasm	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Bordetella infection	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Malformation venous	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Maculopathy	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Bone marrow transplant rejection	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Lung squamous cell carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Haemophilia A with anti factor VIII	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	1 ( 16.7%)	6
Lung adenocarcinoma stage I	0 ( 0.0%)	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	6
Rheumatoid factor	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Liposarcoma metastatic	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Developmental delay	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	6
Lipids decreased	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Lip swelling	2 ( 33.3%)	1 ( 16.7%)	3 ( 50.0%)	0 ( 0.0%)	6
Lip cosmetic procedure	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Body height decreased	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Dermatitis exfoliative generalised	0 ( 0.0%)	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	6
Left ventricle outflow tract obstruction	0 ( 0.0%)	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	6
Learning disability	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Laurence-Moon-Bardet-Biedl syndrome	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Laryngeal cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Demodex blepharitis	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Blood test abnormal	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Labyrinthitis	0 ( 0.0%)	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	6
Delivery	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Laboratory test abnormal	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Thyroid stimulating hormone-producing pituitary tumo	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Blood sodium decreased	0 ( 0.0%)	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	6
Deafness	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Jaundice cholestatic	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Irrigation therapy	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Cytomegalovirus gastroenteritis	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Antioestrogen therapy	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Scrotal infection	0 ( 0.0%)	4 ( 66.7%)	0 ( 0.0%)	2 ( 33.3%)	6

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Intracardiac thrombus	0 ( 0.0%)	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	6
Intestinal resection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	6
Cystitis escherichia	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Intestinal ischaemia	2 ( 33.3%)	1 ( 16.7%)	3 ( 50.0%)	0 ( 0.0%)	6
Selenium deficiency	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Wound complication	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Vitamin E deficiency	2 ( 33.3%)	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	6
Ventricle rupture	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	6
Cotard's syndrome	4 ( 66.7%)	0 ( 0.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Cortical dysplasia	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Immune-mediated pericarditis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Solid organ transplant rejection	4 ( 66.7%)	0 ( 0.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Tuberculous pleurisy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	6
Histiocytosis	2 ( 33.3%)	1 ( 16.7%)	3 ( 50.0%)	0 ( 0.0%)	6
Trigger finger	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Tooth disorder	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Thyroid hormones decreased	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Throat irritation	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Stress ulcer	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	0 ( 0.0%)	6
Temporomandibular joint syndrome	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Computerised tomogram neck	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Hyperkeratosis	3 ( 50.0%)	1 ( 16.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Superior vena cava syndrome	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Complications of transplanted lung	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Acute erythroid leukaemia	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	6
Cryptosporidiosis infection	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Human herpesvirus 7 infection	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hormonal contraception	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	6
Bladder cancer stage III	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Spinal decompression	0 ( 0.0%)	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	6
Bladder cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Computerised tomogram pelvis	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Adenomyosis	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Bladder ablation	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	6
Anti-HLA antibody test positive	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Testicular cancer metastatic	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Aesthesioneuroblastoma	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Sleep terror	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Skin irritation	0 ( 0.0%)	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	6
Central nervous system immune reconstitution inflamm	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Therapeutic skin care topical	2 ( 33.3%)	1 ( 16.7%)	3 ( 50.0%)	0 ( 0.0%)	6
Sinus headache	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Signet-ring cell carcinoma	0 ( 0.0%)	2 ( 33.3%)	0 ( 0.0%)	4 ( 66.7%)	6
Congenital hypoparathyroidism	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Serum sickness	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Hepatitis B reactivation	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Clear cell sarcoma of soft tissue	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	0 ( 0.0%)	6
Secondary amyloidosis	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Hepatic cancer stage III	0 ( 0.0%)	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	6
Scleroderma associated digital ulcer	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Scan	1 ( 16.7%)	1 ( 16.7%)	4 ( 66.7%)	0 ( 0.0%)	6
Round cell liposarcoma	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Hypolipidaemia	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Rhabdomyosarcoma recurrent	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hypoplastic left heart syndrome	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Respiratory syncytial virus bronchiolitis	2 ( 33.3%)	0 ( 0.0%)	4 ( 66.7%)	0 ( 0.0%)	6
Resorption bone increased	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Reproductive hormone	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Renal pain	3 ( 50.0%)	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Platelet disorder	2 ( 33.3%)	0 ( 0.0%)	4 ( 66.7%)	0 ( 0.0%)	6
Pneumococcal sepsis	2 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	6
Relaxation therapy	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Haemangioma-thrombocytopenia syndrome	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Haemangioblastoma	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
HLA-B*27 positive	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
HER2 protein overexpression	0 ( 0.0%)	3 ( 50.0%)	0 ( 0.0%)	3 ( 50.0%)	6
Traumatic haemorrhage	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	6
Trichodysplasia spinulosa	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Trichosporon infection	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Pyelonephritis chronic	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Purpura	1 ( 16.7%)	0 ( 0.0%)	5 ( 83.3%)	0 ( 0.0%)	6
Pupil dilation procedure	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	6
Pudendal canal syndrome	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Bacterial prostatitis	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Prostate cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	6
Chemotherapy toxicity attenuation	3 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 50.0%)	6
Gingivitis ulcerative	3 ( 50.0%)	1 ( 16.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Posterior reversible encephalopathy syndrome	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	6
Urge incontinence	0 ( 0.0%)	0 ( 0.0%)	2 ( 33.3%)	4 ( 66.7%)	6
Uterine leiomyosarcoma	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Polyserositis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Inborn error of metabolism	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	6
Pneumonia acinetobacter	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	6
Pneumomediastinum	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Pneumatosis	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Gastric pH increased	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	1 ( 16.7%)	6
Cerebellar infarction	0 ( 0.0%)	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	6
Vaginal prolapse	0 ( 0.0%)	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	6
Gastric cancer stage III	0 ( 0.0%)	0 ( 0.0%)	3 ( 50.0%)	3 ( 50.0%)	6
Incorrect route of product administration	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Vascular malformation	4 ( 66.7%)	0 ( 0.0%)	2 ( 33.3%)	0 ( 0.0%)	6
Phimosis	3 ( 50.0%)	0 ( 0.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Infective exacerbation of chronic obstructive airway	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	6
Catheter site erythema	3 ( 50.0%)	0 ( 0.0%)	3 ( 50.0%)	0 ( 0.0%)	6
Pericoronitis	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Vertebral artery occlusion	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Autoimmune enteropathy	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Abortion	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Acquired factor VIII deficiency	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	6
Vitamin A	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Fistula of small intestine	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Carotid artery occlusion	0 ( 0.0%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	6
Cutaneous sarcoidosis	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Anal fistula	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	0 ( 0.0%)	6
Felty's syndrome	0 ( 0.0%)	1 ( 16.7%)	4 ( 66.7%)	1 ( 16.7%)	6
Feeling of relaxation	2 ( 33.3%)	0 ( 0.0%)	4 ( 66.7%)	0 ( 0.0%)	6
Pancreatic cyst	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	6
Pancreas transplant	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Alagille syndrome	6 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6
Ovarian cyst	2 ( 33.3%)	4 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	6
Cardiac pacemaker insertion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	6
Factor V deficiency	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)	6
Meningoencephalitis herpetic	0 ( 0.0%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	6
Eyelid ptosis	2 ( 33.3%)	0 ( 0.0%)	3 ( 50.0%)	1 ( 16.7%)	6
X-ray with contrast	0 ( 0.0%)	0 ( 0.0%)	5 ( 83.3%)	1 ( 16.7%)	6
Oral dysaesthesia	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Oral discomfort	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Optic disc disorder	5 ( 83.3%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	6
Ophthalmoplegia	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Ophthalmic migraine	0 ( 0.0%)	1 ( 16.7%)	2 ( 33.3%)	3 ( 50.0%)	6
Facial paralysis	0 ( 0.0%)	1 ( 16.7%)	5 ( 83.3%)	0 ( 0.0%)	6
Extrapulmonary tuberculosis	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	6
Extragenital primary seminoma (pure)	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	0 ( 0.0%)	6
Carcinoid tumour of the ovary	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Astrocytoma malignant	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Ocular rosacea	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Ewing's sarcoma recurrent	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Cannabinoid hyperemesis syndrome	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Anaemia of malignant disease	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Noninfective chorioretinitis	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Non-small cell lung cancer stage II	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Acoustic neuroma	2 ( 40.0%)	0 ( 0.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Non-cardiac chest pain	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Non-alcoholic steatohepatitis	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Nodule	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Erdheim-Chester disease	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Neurological symptom	1 ( 20.0%)	1 ( 20.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Neurodegenerative disorder	1 ( 20.0%)	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	5
Nasopharyngeal cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Enteritis infectious	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Myocardial bridging	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	2 ( 40.0%)	5
Endometrial hyperplasia	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Mydriasis	2 ( 40.0%)	0 ( 0.0%)	1 ( 20.0%)	2 ( 40.0%)	5
Chondrocalcinosis	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Mycobacterium kansasii infection	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Endocrine disorder prophylaxis	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Bruxism	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Bruton's agammaglobulinaemia	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Mitral valve replacement	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Eczema eyelids	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Behavioural therapy	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Microcytic anaemia	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Metastatic bone disease prophylaxis	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Dysplasia	1 ( 20.0%)	2 ( 40.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Metastases to biliary tract	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Arrhythmia supraventricular	3 ( 60.0%)	0 ( 0.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Mesenteric panniculitis	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Duodenal ulcer haemorrhage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	5
Dumping syndrome	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Meningitis listeria	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Melaena	3 ( 60.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	5
Meibomian gland dysfunction	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Mastocytic leukaemia	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Malignant urinary tract neoplasm	2 ( 40.0%)	0 ( 0.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Malignant oligodendroglioma	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Malignant neoplasm of islets of Langerhans	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Malignant mediastinal neoplasm	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Disseminated Bacillus Calmette-Guerin infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	5
Disinhibited social engagement disorder of childhood	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Acute megakaryocytic leukaemia	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Acid fast bacilli infection	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Respiratory symptom	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Lymphopenia	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Lymphocytic infiltration	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Lymphangiosis carcinomatosa	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Allergy test	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Lymph node pain	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Lupus-like syndrome	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Aortic valve stenosis	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Diabetic gastroparesis	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Diabetic foot infection	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Acid base balance	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Diabetic complication	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Loss of libido	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Loss of consciousness	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Tobacco abuse	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Tinnitus	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Lipoprotein (a) increased	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	5
Rhodococcus infection	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Aortic bypass	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Linitis plastica	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Lice infestation	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Libido disorder	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Depression suicidal	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Leprosy	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Dental caries	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Delusion of parasitosis	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Delirium tremens	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Keratinising squamous cell carcinoma of nasopharynx	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Debridement	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Cytoreductive surgery	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Cytomegalovirus gastrointestinal infection	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Blood phosphorus	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Intradialytic parenteral nutrition	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Intestinal tuberculosis	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Cystitis haemorrhagic	3 ( 60.0%)	1 ( 20.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Intestinal perforation	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Weight	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Cutaneous sporotrichosis	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Hepatitis C virus test positive	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Vitamin B1 deficiency	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Vitamin A deficiency	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Visceral leishmaniasis	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Ventricular remodelling	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Cryptococcal meningoencephalitis	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	5
Skin discolouration	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	5

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Vaginal discharge	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Therapeutic embolisation	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Skin disorder prophylaxis	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Urticarial vasculitis	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Urticaria papular	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Immunosuppressant drug level increased	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Immunology test abnormal	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Ureteral stent insertion	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Tumefactive multiple sclerosis	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Blood catecholamines increased	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Tricuspid valve incompetence	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Transversus abdominis plane block	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Blood alkalinisation therapy	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Tocolysis	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Hypertensive encephalopathy	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Synovial cyst	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Supraventricular extrasystoles	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Supplementary motor area syndrome	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Crystal arthropathy	0 ( 0.0%)	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Susac's syndrome	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Humerus fracture	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Colostomy	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Status migrainosus	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Systemic inflammatory response syndrome	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Anorexia nervosa	2 ( 40.0%)	3 ( 60.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Sputum increased	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Sputum abnormal	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Splenomegaly	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Bladder cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Splenic vein thrombosis	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Spindle cell sarcoma	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Spinal cord neoplasm	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Somatostatinoma	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Soft tissue haemorrhage	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
High density lipoprotein increased	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Colectomy	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Herpes simplex reactivation	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Skin toxicity	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Coccydynia	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Herpes gestationis	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Ankle operation	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Skeletal injury	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Coagulation factor VIII level decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	5
Silicon granuloma	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Binge eating	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Congenital generalised lipodystrophy	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Hepato-lenticular degeneration	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Shoulder arthroplasty	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Blindness	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Septo-optic dysplasia	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Thermal burn	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Secondary hypertension	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Hepatic cyst	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Circulatory collapse	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	5

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Apathy	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Bile duct adenocarcinoma	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Schizoaffective disorder depressive type	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Hemiparesis	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Bile acid synthesis disorder	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Chronic myeloid leukaemia transformation	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
SAPHO syndrome	1 ( 20.0%)	2 ( 40.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Head and neck cancer metastatic	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Rheumatoid meningitis	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Chronic lymphocytic leukaemia (in remission)	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Retinopathy	1 ( 20.0%)	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Retinitis viral	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Retinal neovascularisation	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Chronic granulomatous disease	3 ( 60.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	5
Tracheostomy	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Renal cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Rectosigmoid cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Choroid plexus carcinoma	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
HIV carrier	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Transpupillary thermotherapy	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Idiopathic orbital inflammation	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Growth failure	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Abortion spontaneous	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Psychiatric disorder prophylaxis	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Psychiatric care	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Psoas abscess	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Bacterial pyelonephritis	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Underweight	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Prophylaxis against solar radiation	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Ileostomy	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Product dispensing error	1 ( 20.0%)	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	5
Blood corticotrophin increased	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Geotrichum infection	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
BRCA1 gene mutation	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	5
Presbyopia	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Cervicobrachial syndrome	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	5
Precursor T-lymphoblastic lymphoma/leukaemia refract	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Anastomotic stenosis	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Postpartum hypopituitarism	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Poorly differentiated thyroid carcinoma	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Polyomavirus viraemia	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Adenosquamous cell lung cancer stage IV	0 ( 0.0%)	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	5
B-cell depletion therapy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	5
Polymenorrhoea	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Polycythaemia	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Gastrointestinal angiodysplasia	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Gastroenteritis proteus	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Pneumonia necrotising	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Axillary vein thrombosis	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Pneumonia influenzal	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Cerebral artery occlusion	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Platelet count increased	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Varicella	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Platelet aggregation abnormal	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	5

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pigmentation disorder	1 ( 20.0%)	0 ( 0.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Gallbladder disorder	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Vascular graft	0 ( 0.0%)	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	5
Cryptitis	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Central nervous system lesion	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Pharyngotonsillitis	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)	5
Pharyngitis bacterial	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Autoimmune pancreatitis	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Fungal endocarditis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	5
Cellulitis orbital	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Peritonsillar abscess	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Full blood count decreased	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Anastomotic ulcer	2 ( 40.0%)	1 ( 20.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Presyncope	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Full blood count abnormal	2 ( 40.0%)	0 ( 0.0%)	3 ( 60.0%)	0 ( 0.0%)	5
Cataract operation complication	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Cat scratch disease	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Cough variant asthma	0 ( 0.0%)	1 ( 20.0%)	3 ( 60.0%)	1 ( 20.0%)	5
Infusion site erythema	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Infusion site swelling	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Carotid artery disease	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Paranasal sinus hypersecretion	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Parainfluenzae virus infection	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Vitreous degeneration	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	1 ( 20.0%)	5
Cardioversion	0 ( 0.0%)	1 ( 20.0%)	1 ( 20.0%)	3 ( 60.0%)	5
Cardiovascular insufficiency	1 ( 20.0%)	0 ( 0.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Cardiotoxicity	3 ( 60.0%)	1 ( 20.0%)	1 ( 20.0%)	0 ( 0.0%)	5

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pancreatic calcification	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Pancreas transplant rejection	4 ( 80.0%)	1 ( 20.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Fanconi syndrome	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
PIK3CA-activated mutation	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	0 ( 0.0%)	5
Cardiac valve prosthesis user	0 ( 0.0%)	0 ( 0.0%)	2 ( 40.0%)	3 ( 60.0%)	5
Cardiac valve disease	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Back injury	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Whipple's disease	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Osteomyelitis fungal	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Osteomalacia	0 ( 0.0%)	3 ( 60.0%)	2 ( 40.0%)	0 ( 0.0%)	5
Blood iron abnormal	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
X-ray gastrointestinal tract	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Xanthogranuloma	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Eye lubrication therapy	1 ( 20.0%)	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	5
Oral infection	1 ( 20.0%)	2 ( 40.0%)	0 ( 0.0%)	2 ( 40.0%)	5
Optic glioma	5 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5
Opportunistic infection	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Cardiac ablation	0 ( 0.0%)	2 ( 40.0%)	2 ( 40.0%)	1 ( 20.0%)	5
Extrasystoles	0 ( 0.0%)	0 ( 0.0%)	1 ( 20.0%)	4 ( 80.0%)	5
Onychomadesis	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)	1 ( 20.0%)	5
Oestrogen deficiency	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Extra-osseous Ewing's sarcoma	0 ( 0.0%)	0 ( 0.0%)	5 (100.0%)	0 ( 0.0%)	5
Carcinoid tumour of the pancreas	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Oesophageal haemorrhage	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Ultrasound scan	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Exfoliative rash	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Oedema due to cardiac disease	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Carbuncle	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Astroblastoma	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Ocular surface squamous neoplasia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Euthanasia	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Eustachian tube operation	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Normocytic anaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Candida pneumonia	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Non-small cell lung cancer stage I	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Anaemia macrocytic	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Cancer hormonal therapy	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Erosive oesophagitis	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Nodal arrhythmia	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Campylobacter gastroenteritis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Asteatosis	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Neutrophil count increased	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Neuropathic pruritus	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
CREST syndrome	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Epidermal naevus	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Neuritis	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Aspergillus test	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Nerve compression	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Eosinophilic gastritis	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	1 ( 25.0%)	4
CDKL5 deficiency disorder	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Neoplasm of appendix	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Natural killer-cell lymphoblastic lymphoma	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Enterococcal sepsis	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Nasal decongestion therapy	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Nasal cavity cancer	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Nail psoriasis	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Nail disorder	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Energy increased	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
NPM1 gene mutation	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Burkitt's lymphoma refractory	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Acute pulmonary oedema	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Mycotic allergy	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Ammonia abnormal	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Muscle necrosis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Murine typhus	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Acinetobacter sepsis	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Bronchitis pneumococcal	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Monogenic diabetes	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Mitochondrial toxicity	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Arteriogram carotid	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Ecthyma	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Microsatellite instability cancer	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Methylobacterium infection	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Methaemoglobinaemia	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Ear disorder	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Breast scan	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Acinetobacter bacteraemia	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Mesothelioma malignant	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Mesenteric vein thrombosis	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Dysarthria	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Dysaesthesia	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Menopausal disorder	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Menometrorrhagia	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Meniscus injury	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Breakthrough COVID-19	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Medication overuse headache	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Drug specific antibody present	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Mediastinum neoplasm	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	4
Drug ineffective	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Mastitis postpartum	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Drooling	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Mastectomy	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Marginal zone lymphoma recurrent	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Brain empyema	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Appendicitis perforated	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Marasmus	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Malignant sweat gland neoplasm	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Malignant pituitary tumour	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Malignant palate neoplasm	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Malignant nipple neoplasm	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Brachioradial pruritus	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Dissociation	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Brachial plexopathy	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Apnoea	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Malignant melanoma of eyelid	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	4
Botulism	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Malignant lymphoid neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Malignant genitourinary tract neoplasm	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Borderline leprosy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Bone sarcoma	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Allergy to arthropod sting	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Diphtheria	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Lymphocyte count decreased	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	4
Lymphocyte adoptive therapy	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Lymphatic mapping	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Lymphangioma	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Lymphangiioleiomyomatosis	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Lymphangiectasia	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Bone lesion	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Lupus endocarditis	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Allergic sinusitis	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Device therapy	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Device occlusion	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Allergic respiratory disease	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Lithiasis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Chronic lymphocytic leukaemia stage 3	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Body temperature	1 ( 25.0%)	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Body mass index abnormal	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Lipids	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Body mass index	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Dermatosis	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Limbic encephalitis	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Aortic arteriosclerosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Blood volume expansion	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Blood uric acid decreased	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Leptomeningeal myelomatosis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Lepromatous leprosy	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Leg amputation	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Left ventricular hypertrophy	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Dental operation	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Large cell lung cancer	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Lactation stimulation therapy	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Blood testosterone abnormal	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Lactation inhibition therapy	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Chronic villitis of unknown etiology	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Delftia acidovorans infection	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Knee operation	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Blood pressure systolic increased	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Joint stabilisation	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Joint range of motion decreased	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Joint injury	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Joint dislocation	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
DNMT3A gene mutation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Cytotoxic lesions of corpus callosum	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Blood potassium	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Cytokine storm	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Antinuclear antibody positive	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Intracranial mass	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Intracranial aneurysm	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Abdominal hernia obstructive	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Blood oestrogen decreased	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Intestinal anastomosis	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
International normalised ratio increased	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Hepatic neuroendocrine tumour	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Internal fixation of fracture	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Intentional product use issue	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Withdrawal catatonia	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Cyst	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Cyanosis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Waldenstrom's macroglobulinaemia recurrent	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Vulvovaginal pruritus	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	4
Vitamin C deficiency	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Vestibular disorder	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Culture urine positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Venous hypertension	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Infective aneurysm	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Vasospasm	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Vasculitis necrotising	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Infant sedation	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Urine abnormality	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Urinary tract inflammation	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Coronavirus pneumonia	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Ureteric cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Unevaluable event	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Tympanic membrane perforation	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Corneal transplant	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Solvent sensitivity	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Tropical spastic paresis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Corneal abrasion	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blood calcium increased	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Transurethral bladder resection	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Transfusion reaction	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Contrast media allergy	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Blood beta-D-glucan positive	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Tonsillitis bacterial	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Stasis syndrome	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Throat cancer	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Hypertensive nephropathy	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Tetanus	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Congenital aplastic anaemia	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Hyperreflexia	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Tachycardia paroxysmal	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Synovial sarcoma metastatic	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Adverse reaction	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Hyperinsulinaemia	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Superinfection	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Superinfection fungal	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Superficial spreading melanoma stage unspecified	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Hyperferritinaemia	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Complications of transplanted liver	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Suicidal behaviour	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Bladder neoplasm	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Complement factor	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Hungry bone syndrome	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Steroid dependence	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Blast crisis in myelogenous leukaemia	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Staphylococcal osteomyelitis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Acute disseminated encephalomyelitis	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Adult T-cell lymphoma/leukaemia stage III	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Hodgkin's disease stage III	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Spinal cord injury cervical	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Histiocytic necrotising lymphadenitis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Solitary fibrous tumour	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Collagen disorder	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Hip arthroplasty	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Small intestinal obstruction	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Small cell lung cancer limited stage	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Hypersexuality	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Coeliac artery stenosis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Herpes simplex hepatitis	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Skin hyperpigmentation	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Hereditary non-polyposis colorectal cancer syndrome	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Hereditary hypophosphataemic rickets	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Coagulation factor increased	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Coagulation factor VIII level	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Coagulation factor	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Shigella infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Hypoaesthesia eye	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Selective polysaccharide antibody deficiency	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Angular cheilitis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Biliary colic	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Hepatic fibrosis	1 ( 25.0%)	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Hepatic enzyme abnormal	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Scrub typhus	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Scrotal pain	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Abscess bacterial	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Congenital syphilitic osteochondritis	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Congenital retinoblastoma	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Rotator cuff syndrome	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Chronic lymphocytic leukaemia stage 4	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Rhupus syndrome	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Rhinocerebral mucormycosis	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Rheumatoid lung	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Hypophagia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Tonsillar inflammation	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Retroperitoneal abscess	2 ( 50.0%)	0 ( 0.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Haemorrhagic disorder	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Retinal disorder	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Renal tubular acidosis	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Renal hypertension	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Renal cell carcinoma stage II	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Haematemesis	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	4
HIV wasting syndrome	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
HIV infection CDC category A	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Rash pustular	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Ictal bradycardia syndrome	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Radiochemotherapy	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
H1N1 influenza	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Gynaecological disorder prophylaxis	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Corneal dystrophy	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Punctate keratitis	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Grief reaction	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Tuberculosis gastrointestinal	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Pulmonary function test decreased	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Graft complication	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Psychotic behaviour	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Psychogenic seizure	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Glycosylated haemoglobin abnormal	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Pseudomonas test positive	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Pseudomonas aeruginosa meningitis	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Chloasma	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Protothecosis	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Tyrosine kinase mutation	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Glossopharyngeal neuralgia	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Protein S deficiency	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Unknown immunisation status	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Chemotherapy multiple agents systemic	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Progressive supranuclear palsy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Progesterone receptor assay negative	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Product substitution issue	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Product prescribing issue	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Androgen therapy	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Adhesion	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Cervix carcinoma stage II	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Presumed ocular histoplasmosis syndrome	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Prescription drug used without a prescription	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Cervicogenic headache	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Urethritis	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Premature rupture of membranes	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
General physical condition abnormal	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Precursor B-lymphoblastic lymphoma	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Postprandial hypoglycaemia	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Urinary tract infection fungal	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Posterior fossa syndrome	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Post-traumatic epilepsy	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Blood creatinine increased	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Cerebral venous sinus thrombosis	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Post procedural inflammation	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Gastrointestinal scan	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Ileal stenosis	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Corynebacterium bacteraemia	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Cerebral nocardiosis	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Gastrointestinal hypomotility	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Polymenorrhagia	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Gastroenteritis salmonella	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Pneumonia pneumococcal	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Gastroduodenal ulcer	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Incorrect dose administered	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Axillary pain	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Pleurodesis	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Pleural mesothelioma malignant recurrent	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Cerebrovascular insufficiency	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Plasmodium falciparum infection	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Placental disorder	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Gastrectomy	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Gangrene	0 ( 0.0%)	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	4
Pituitary cancer metastatic	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Physical examination	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Photophobia	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Furuncle	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Fungal oesophagitis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Fungal foot infection	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Persecutory delusion	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Peroneal nerve palsy	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Fundoscopy	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Analgesic drug level	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Autoimmune myositis	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Frequent bowel movements	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Peripheral sensorimotor neuropathy	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Infectious pleural effusion	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Cauda equina syndrome	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	1 ( 25.0%)	4
Peripheral artery bypass	0 ( 0.0%)	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	4
Fournier's gangrene	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Peripheral T-cell lymphoma unspecified stage IV	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	4
Foot operation	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Periorbital oedema	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Perioral dermatitis	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Catheter placement	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Follicular thyroid cancer	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Pericarditis tuberculous	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Adenoma benign	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pelvic mass	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Pelvic inflammatory disease	1 ( 25.0%)	2 ( 50.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Pathological fracture prophylaxis	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Autoimmune encephalopathy	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Procedural complication	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Parasomnia	0 ( 0.0%)	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	4
Carotid artery aneurysm	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	4
Carotid arteriosclerosis	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Fibrodysplasia ossificans progressiva	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Feminisation acquired	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Feeling cold	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Pancreatic enzymes	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Atypical mycobacterial lower respiratory tract infec	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Pancreatic carcinoma stage I	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Pancreatectomy	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Fatty acid oxidation disorder	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Palindromic rheumatism	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Cardiomegaly	0 ( 0.0%)	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	4
Oxygen saturation	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Anal abscess	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Failure to thrive	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Cyclic vomiting syndrome	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Ovarian epithelial cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Insulin therapy	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Atrioventricular septal defect	4 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Otorrhoea	1 ( 25.0%)	0 ( 0.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Factor I deficiency	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	1 ( 25.0%)	4



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Facial spasm	2 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)	4
Osteopathic treatment	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Cardiac monitoring	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Osteogenesis imperfecta	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Oropharyngeal discomfort	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Anaesthesia reversal	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Eye operation	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	4
Atopy	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Eye irrigation	0 ( 0.0%)	0 ( 0.0%)	3 ( 75.0%)	1 ( 25.0%)	4
Opsoclonus myoclonus	3 ( 75.0%)	1 ( 25.0%)	0 ( 0.0%)	0 ( 0.0%)	4
Exudative retinopathy	2 ( 50.0%)	1 ( 25.0%)	1 ( 25.0%)	0 ( 0.0%)	4
Oligoarthritis	1 ( 25.0%)	1 ( 25.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Carcinoid tumour of the stomach	0 ( 0.0%)	2 ( 50.0%)	2 ( 50.0%)	0 ( 0.0%)	4
Oestrogen receptor assay positive	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Extracorporeal circulation	0 ( 0.0%)	0 ( 0.0%)	4 (100.0%)	0 ( 0.0%)	4
Anaemia vitamin B12 deficiency	0 ( 0.0%)	1 ( 25.0%)	3 ( 75.0%)	0 ( 0.0%)	4
Oesophageal disorder	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Oedema mucosal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Ocular vasculitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Ocular myasthenia	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Capillary leak syndrome	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Capillary disorder	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Nutritional condition abnormal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Escherichia urinary tract infection	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Escherichia sepsis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Asthma exercise induced	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Non-Hodgkin's lymphoma stage III	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cancer screening	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Campylobacter test	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Epstein-Barr virus test positive	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Neutrophil count abnormal	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Neutropenic infection	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Episcleritis	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Epiphyseal disorder	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Epileptic psychosis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Neuromyopathy	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Neurogenic bowel	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Neuroendocrine tumour of the lung metastatic	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Epididymal cancer	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Neurectomy	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
CHARGE syndrome	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Amputation stump pain	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Eosinophilic angiocentric fibrosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Nephrocalcinosis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Aspergilloma	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
CANDLE syndrome	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Enzyme abnormality	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Necrosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Arthroscopy	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Nail infection	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Enema administration	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
NTRK gene fusion cancer	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Myxoedema coma	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Myometritis	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Myokymia	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Myeloid leukaemia in remission	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Myelodysplastic syndrome with single lineage dysplas	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Myelodysplastic syndrome transformation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Bullous impetigo	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Mutism	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Endocarditis candida	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Muscle twitching	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Radioisotope scan	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Multisystem inflammatory syndrome in adults	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Multiple congenital abnormalities	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Mucosal disorder	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Embolic cerebral infarction	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Amaurosis fugax	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Bronchitis bacterial	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Electroencephalogram abnormal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Electrocardiogram ST segment elevation	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Electrocardiogram QT prolonged	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Electrocardiogram QRS complex prolonged	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Mite allergy	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Arteriogram	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Milk-alkali syndrome	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Bronchial artery embolisation	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Early onset familial Alzheimer's disease	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Metastatic salivary gland cancer	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Metastases to spinal cord	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Arterial graft	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Breast cyst	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Breast cellulitis	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Abnormal dreams	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Metastases to abdominal wall	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Abdomen scan	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Metabolic abnormality management	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Dyschezia	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Mental fatigue	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Menstrual discomfort	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Breast adenoma	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Meniere's disease	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Melanoma recurrent	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Aptyalism	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Megacolon	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Drug provocation test	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Mediastinal fibrosis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Mediastinal abscess	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Meckel's cave tumour	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Measles	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Drainage	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Donor specific antibody present	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Diverticulum intestinal	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Diverticulum gastric	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Malignant respiratory tract neoplasm	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Bradykinesia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Dissociative disorder	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Apocrine breast carcinoma	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Malignant neoplasm of spinal cord	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Malignant melanoma in situ	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Malignant histiocytosis	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Malignant anorectal neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Magnetic resonance imaging joint	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Apheresis	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Aphasia	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Bone marrow disorder	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Lymphatic malformation	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Dientamoeba infection	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Diastolic dysfunction	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Lymphadenopathy mediastinal	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Lymphadenitis	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Lupus enteritis	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Diabetic ketosis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Allergic transfusion reaction	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Lung carcinoma cell type unspecified stage I	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Diabetic dyslipidaemia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Bone density increased	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Lower limb fracture	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
DiGeorge's syndrome	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Aortic stent insertion	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	3
Liver sarcoidosis	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Device physical property issue	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Lithotripsy	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Lipoprotein metabolism disorder	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Lipoprotein (a) abnormal	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Lipodystrophy acquired	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Accidental overdose	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Ligament sprain	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Blood zinc decreased	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Dermatillomania	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Lemierre syndrome	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Alcoholic liver disease	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Blood triglycerides decreased	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Laryngeal cancer stage III	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Large intestine polyp	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Large cell lung cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Lactation insufficiency	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Antithrombin III deficiency	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Blood stem cell harvest	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Klebsiella urinary tract infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Kernicterus	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Kaposiform haemangioendothelioma	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Decreased interest	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Kaposi sarcoma inflammatory cytokine syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
KMT2A gene mutation	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Juvenile spondyloarthritis	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Dacryocystitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Alcohol detoxification	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Blood potassium increased	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Janus kinase 2 mutation	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Isosporiasis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Iron metabolism disorder	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Involuntary commitment	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Blood phosphorus abnormal	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Albuminuria	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Intraocular lens implant	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Antineutrophil cytoplasmic antibody positive	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Intestinal congestion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Cystic fibrosis related diabetes	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Xanthomatosis	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Blood loss anaemia	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Alanine aminotransferase	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Wolff-Parkinson-White syndrome	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
White coat hypertension	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Cyclothymic disorder	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Blood insulin increased	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Blood insulin abnormal	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Injection site rash	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Vitreous haemorrhage	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Injection	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Vitamin B6 deficiency	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Vitamin B12	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Visual snow syndrome	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Visual field defect	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Cutaneous T-cell lymphoma stage II	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Visual acuity reduced	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Very long-chain acyl-coenzyme A dehydrogenase defi	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Vertigo positional	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Ventricular tachyarrhythmia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blood glucose fluctuation	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Infectious mononucleosis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Infection reactivation	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Vasodilation procedure	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Infected cyst	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Vascular stenosis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Vascular access complication	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Vanishing bile duct syndrome	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Craniopharyngioma	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Uveitic glaucoma	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Uterine haemorrhage	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Urine flow decreased	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Ureteral disorder	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Ultrasound urinary system	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Ultrasound kidney	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Immune-mediated encephalitis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Soft tissue swelling	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Type 2 lepra reaction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Corneal disorder	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Trichomoniasis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Treatment noncompliance	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Transplantation complication	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
IRVAN syndrome	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Conversion disorder	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Ageusia	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Transitional cell cancer of renal pelvis and ureter	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Trace element deficiency	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Topical steroid withdrawal reaction	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Tonsillitis streptococcal	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Tonsillar hypertrophy	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Conjunctival hyperaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Tinea versicolour	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Tilt table test	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Thyroid operation	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Hypoglobulinaemia	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Thymoma malignant	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Congenital multiplex arthrogryposis	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Thrombosis with thrombocytopenia syndrome	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Congenital hypothyroidism	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Hydrotherapy	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Testicular pain	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Testicular failure	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	3
Bleeding time prolonged	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Tendon pain	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Hyperpyrexia	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Computerised tomogram aorta	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Hyperinsulinaemic hypoglycaemia	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Suspected COVID-19	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Bladder transitional cell carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Composite lymphoma	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Subdural abscess	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Subcutaneous emphysema	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Hyperaesthesia	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Stoma site reaction	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Stem cell donor	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Human epidermal growth factor receptor positive	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Stasis dermatitis	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Stargardt's disease	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Hypernatraemia	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Hospitalisation	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Squamous cell breast carcinoma	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Sputum retention	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Sputum purulent	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Systemic mycosis	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Anorectal stenosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Spinal operation	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hodgkin's disease mixed cellularity refractory	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Spinal column injury	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Spina bifida	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Histiocytic sarcoma	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Speech disorder	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hip surgery	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Adrenoleukodystrophy	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Skin wound	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Skin erosion	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Biopsy skin	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Sinusitis fungal	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Coagulation factor deficiency	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Hereditary alpha tryptasaemia	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Therapy change	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Adrenocorticotrophic hormone deficiency	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Sialoadenitis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Shoulder operation	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Shoulder injury related to vaccine administration	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Biliary tract infection	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Clostridium colitis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Serratia infection	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hepatitis A immunisation	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Separation anxiety disorder	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Clinical trial participant	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Selective IgM immunodeficiency	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	3
Hepatic cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Hepatic cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Congenital nephrotic syndrome	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Hepatic amoebiasis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Schnitzler's syndrome	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Hemiplegia	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Scan thyroid gland	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Hemianopia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Helminthic infection	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Saliva altered	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Activated PI3 kinase delta syndrome	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Hypokinesia	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Right ventricular dysfunction	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Rhinovirus infection	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Rheumatoid nodule	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Rheumatic fever	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Blood aldosterone decreased	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tongue neoplasm	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Retinoschisis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Chronic infantile neurological cutaneous and articul	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Retinal vascular occlusion	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Retinal oedema	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Retinal degeneration	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Retching	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Resuscitation	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Toxic shock syndrome	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Respiratory tract infection viral	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Angioimmunoblastic T-cell lymphoma stage III	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Respiratory therapy	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	3
Blood bicarbonate decreased	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Benign lung neoplasm	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Haemoglobin C disease	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Benign hydatidiform mole	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Renal artery stenosis	1 ( 33.3%)	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	3
Transaminases increased	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Refeeding syndrome	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Red blood cell count	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Rectal cancer stage II	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Actinomyces test positive	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
HIV infection CDC Group IV subgroup E	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Rasmussen encephalitis	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Rash papular	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
HER2 positive bladder cancer	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Rabies	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Quadriplegia	0 ( 0.0%)	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	3
Cholinergic syndrome	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Pyoderma	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Growth of eyelashes	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Pulpitis dental	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Greater trochanteric pain syndrome	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Barium swallow	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Pulmonary toxicity	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Balance test	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Tuberculosis immunisation	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Graft versus host disease oral	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Pulmonary eosinophilia	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Pulmonary artery stenosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Puberty	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Goodpasture's syndrome	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Pseudomembranous colitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Tumour haemorrhage	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Proteus infection	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	3
Ultrasound liver	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Prostatic obstruction	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Unknown schedule of product administration	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Propionic acidaemia	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Prophylaxis against bronchospasm	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Glaucoma surgery	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Bacterascites	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Prolymphocytic leukaemia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Acute haemolytic transfusion reaction	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Chemotherapeutic drug level above therapeutic	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Gingival bleeding	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Procedural hypertension	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Procedural anxiety	0 ( 0.0%)	0 ( 0.0%)	2 (66.7%)	1 (33.3%)	3
Genitourinary symptom	0 ( 0.0%)	1 (33.3%)	2 (66.7%)	0 ( 0.0%)	3
Primary insulin like growth factor-1 deficiency	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Urethral disorder	0 ( 0.0%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	3
Priapism	2 (66.7%)	1 (33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Ureterolithiasis	0 ( 0.0%)	2 (66.7%)	1 (33.3%)	0 ( 0.0%)	3
Premature labour	2 (66.7%)	1 (33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Cervical spinal stenosis	0 ( 0.0%)	2 (66.7%)	1 (33.3%)	0 ( 0.0%)	3
Gene mutation	1 (33.3%)	0 ( 0.0%)	2 (66.7%)	0 ( 0.0%)	3
Gastrointestinal vascular malformation haemorrhagic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
B-cell prolymphocytic leukaemia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Urine output decreased	0 ( 0.0%)	0 ( 0.0%)	1 (33.3%)	2 (66.7%)	3
Gastrointestinal procedural complication	1 (33.3%)	0 ( 0.0%)	2 (66.7%)	0 ( 0.0%)	3
Immune-mediated pancreatitis	0 ( 0.0%)	2 (66.7%)	1 (33.3%)	0 ( 0.0%)	3
Cerebral oedema management	0 ( 0.0%)	0 ( 0.0%)	2 (66.7%)	1 (33.3%)	3
Polyneuropathy alcoholic	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Inclusion body myositis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Pneumonitis aspiration	0 ( 0.0%)	0 ( 0.0%)	1 (33.3%)	2 (66.7%)	3
Azoospermia	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Blood electrolytes abnormal	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Cerebral aspergillosis	1 (33.3%)	2 (66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Cerebral artery stenosis	0 ( 0.0%)	0 ( 0.0%)	2 (66.7%)	1 (33.3%)	3
Gastric ulcer haemorrhage	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Increased upper airway secretion	1 (33.3%)	0 ( 0.0%)	1 (33.3%)	1 (33.3%)	3

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Axillary nerve injury	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Anaphylaxis treatment	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Gastric neuroendocrine carcinoma	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Pleomorphic adenoma	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Gastric mucosal lesion	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Cerebellar haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Plasmapheresis	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Cerebellar ataxia	1 ( 33.3%)	1 ( 33.3%)	1 ( 33.3%)	0 ( 0.0%)	3
Central serous chorioretinopathy	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Cryofibrinogenaemia	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Pituitary apoplexy	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Infantile genetic agranulocytosis	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Automatic bladder	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Acquired generalised lipodystrophy	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Pharyngeal swelling	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Personality change	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Frustration tolerance decreased	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Frontotemporal dementia	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Anticoagulation drug level therapeutic	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Fragile X syndrome	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Peripheral blood stem cell apheresis	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Autoimmune lymphoproliferative syndrome	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	3
Peripheral artery stenosis	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Peripheral artery angioplasty	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	3
Catheter site pain	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Anal sphincter hypertonia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Periodic limb movement disorder	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Vibrio vulnificus infection	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Pelvic fracture	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Viral myelitis	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	3
Cutaneous T-cell lymphoma stage I	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Floating-Harbor syndrome	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Parathyroid tumour malignant	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Fibrosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Fibrosarcoma	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Paranasal sinus discomfort	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Injection site erythema	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Paradoxical pain	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Injection site pruritus	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Papilloma viral infection	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	3
Cutaneous symptom	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	3
Femur fracture	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	3
Panniculitis lobular	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Panic reaction	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Pancreatitis necrotising	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Feeling of despair	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Febrile convulsion	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Cardiopulmonary failure	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Cardiopulmonary bypass	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Fasciitis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Cardio-respiratory arrest	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
POEMS syndrome	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Atrophy	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Fallot's tetralogy	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cardiac tamponade	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Ovarian hyperstimulation syndrome	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Ovarian germ cell teratoma	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Wernicke's encephalopathy	1 ( 33.3%)	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	3
Faecaloma	2 ( 66.7%)	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	3
Factor VIII inhibition	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Osteonecrosis	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Eyelid infection	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 33.3%)	3
Oropharyngeal candidiasis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Oropharyngeal cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	3
Organ donor	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Oral disorder	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Cystic fibrosis gastrointestinal disease	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Eye drop instillation	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Optic ischaemic neuropathy	0 ( 0.0%)	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	3
Atherosclerosis prophylaxis	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Ophthalmological examination	0 ( 0.0%)	2 ( 66.7%)	1 ( 33.3%)	0 ( 0.0%)	3
Oophorectomy bilateral	0 ( 0.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)	3
Onychoclasia	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Oestradiol increased	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	3
Oesophagogastroduodenoscopy	0 ( 0.0%)	0 ( 0.0%)	3 (100.0%)	0 ( 0.0%)	3
Exposure to toxic agent	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Oesophageal perforation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Exposure keratitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Oesophageal obstruction	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Oesophageal neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Exfoliation glaucoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Oedema due to renal disease	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Excessive cerumen production	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Ocular sarcoidosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Occipital lobe stroke	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Obsessive-compulsive symptom	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Obliterative bronchiolitis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Candida test positive	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Nosocomial infection	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Norovirus infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Erythrodermic atopic dermatitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cancer surgery	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Erythema nodosum	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Non-Hodgkin's lymphoma unspecified histology aggress	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Erythema dyschromicum perstans	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Non-Hodgkin's lymphoma stage I	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Nodal marginal zone B-cell lymphoma stage IV	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Newborn persistent pulmonary hypertension	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Calculus urinary	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Calcium metabolism disorder	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Neurosyphilis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neurosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Neuropsychiatric syndrome	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neuropathic arthropathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neuronal ceroid lipofuscinosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Calcification metastatic	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Neuromyotonia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Epilepsia partialis continua	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Aspiration pleural cavity	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neurological examination abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
CSF pressure	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Epidural injection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Acute stress disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Neuroendocrine carcinoma of the bladder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Neuroendocrine carcinoma of prostate	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neuroendocrine cancer of the prostate metastatic	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neuroectodermal neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neurodegeneration with brain iron accumulation disorder	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Aspergillus test positive	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
COPD assessment test	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Nephroprotective therapy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Nephrogenic diabetes insipidus	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
CHA2DS2-VASc annual stroke risk high	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Eosinophil count increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Neoplasm skin	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Amputation	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Aspartate aminotransferase	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Neonatal pulmonary hypertension	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Nematodiasis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neisseria infection	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Enterocutaneous fistula	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neck plastic surgery	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Neck injury	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bursitis infective	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Enterocolitis bacterial	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Artificial heart implant	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Nasal septal operation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Burns third degree	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Nasal obstruction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Nasal irrigation	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Enterobiasis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Nasal dryness	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Nasal discharge discolouration	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Burnout syndrome	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Burning mouth syndrome	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Enteral nutrition	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Nail discolouration	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Burn oesophageal	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Myxofibrosarcoma	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Myxoedema	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Endoscopy small intestine	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Myotonia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Endometrial sarcoma metastatic	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Burkholderia pseudomallei infection	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Endometrial sarcoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Endometrial disorder	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Endometrial cancer stage II	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Mycotic endophthalmitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mycobacterium tuberculosis complex test	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Endodontic procedure	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Bullous haemorrhagic dermatosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Endocrine neoplasm malignant	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bulbar palsy	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Endocarditis noninfective	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Endocarditis histoplasma	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Muscle strength abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Endarterectomy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Muscle rigidity	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Amino acid metabolism disorder	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Brugada syndrome	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Encephalitis viral	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Brow ptosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mumps immunisation	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Bronchostenosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Encapsulating peritoneal sclerosis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Multiple-drug resistance	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Amino acid level increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Artery dissection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Bronchoscopy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Emphysematous pyelonephritis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Multi-vitamin deficiency	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Mueller's mixed tumour	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mucosal infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Arteriovenous fistula operation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bronchopneumopathy	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Mucocutaneous disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mucocutaneous candidiasis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Mucinous adenocarcinoma of appendix	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Monoplegia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Monoclonal B-cell lymphocytosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Molluscum contagiosum	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Elbow operation	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Ejection fraction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mitral valve stenosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Mitral valve prolapse	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Altered state of consciousness	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Bronchial obstruction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mismatched donor bone marrow transplantation therapy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mismatch repair cancer syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Bronchial neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Eczema asteatotic	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Miosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Alport's syndrome	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Microscopic enteritis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Early onset primary dystonia	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Alpha-mannosidosis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Ear pruritus	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Ear neoplasm malignant	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Brief psychotic disorder with marked stressors	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Breath sounds abnormal	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Ear congestion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Metastases to urinary tract	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Metastases to thorax	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Arterial haemorrhage	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Metastases to stomach	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Metastases to soft tissue	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Dyssomnia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Alpha-1 anti-trypsin	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Breast hyperplasia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Metastases to kidney	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Metastases to heart	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Metabolic encephalopathy	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Metabolic disorder prophylaxis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Meralgia paraesthetica	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Mental status changes	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Menstruation delayed	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Dupuytren's contracture	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Menopausal depression	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Meningoradiculitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Meningoencephalitis amoebic	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Meningitis candida	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Application site reaction	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Medical procedure	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Application site discolouration	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Brain radiation necrosis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Drug level increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mechanical ileus	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Brain neoplasm benign	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Maternal distress during labour	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Brain malformation	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Mastitis bacterial	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Mastitis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Brain fog	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Manic symptom	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mammoplasty	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Diverticulitis intestinal perforated	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Mammogram	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Malignant pleural effusion	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Distributive shock	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Malignant neoplasm papilla of Vater	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Malignant neoplasm of uterine adnexa	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Allergy to plants	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Disseminated mucormycosis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Malignant hydatidiform mole	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Disorder of orbit	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Malignant atrophic papulosis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Disease susceptibility	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Magnetic resonance imaging renal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Disease complication	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Magnetic resonance imaging prostate	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bone scan	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Apical granuloma	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Magnetic resonance imaging hepatobiliary	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Madarosis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Macroprolactinaemia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Acute macular neuroretinopathy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Diffuse idiopathic skeletal hyperostosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Diarrhoea haemorrhagic	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Lupus cystitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Aortitis salmonella	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bone graft	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Bone giant cell tumour malignant	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Lung squamous cell carcinoma stage II	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Diabetic eye disease	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Lower respiratory tract congestion	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Aortic thrombosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Body temperature abnormal	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Device dislocation	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Lipoprotein increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Lipoprotein deficiency	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Lipoprotein abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Lipoedema	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Alkalosis hypochloraemic	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Dermatophytosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Lip blister	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Light anaesthesia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Lichenification	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blood urine present	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Dermal filler injection	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Dermal cyst	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Acute lung injury	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Leiomyoma	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Dental plaque	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Anuria	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Leber's congenital amaurosis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Laryngopharyngitis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Laryngeal squamous cell carcinoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Large intestinal ulcer	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blood thyroid stimulating hormone	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Language disorder	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Antiviral drug level	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Delusional disorder, somatic type	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Lactobacillus bacteraemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Delusion of replacement	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Lactation disorder	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Lacrimation decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Labile hypertension	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Alcohol use	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Delayed puberty	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Kleefstra syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Blood sodium	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Deficiency anaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Keratitis fungal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Junctional ectopic tachycardia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Dactylitis	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Blood pressure ambulatory	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Dacryoadenitis acquired	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
DNA antibody negative	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Jejunostomy	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Acute interstitial pneumonitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Iritis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Invasive papillary breast carcinoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
ALK gene rearrangement positive	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Intrauterine infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Antinuclear antibody negative	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blood osmolarity decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Blood osmolarity	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cystitis klebsiella	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Albright's disease	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Intestinal transit time	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Intestinal pseudo-obstruction	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Intestinal haemorrhage	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Antineutrophil cytoplasmic antibody negative	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Blood oestrogen abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cystic lung disease	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Yellow fever immunisation	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Interstitial lung abnormality	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cystic fibrosis carrier	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
X-ray	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Wrong schedule	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Blood iron increased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Acute hepatitis B	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
White blood cell disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
White blood cell count	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Insulin-like growth factor abnormal	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Insulin resistant diabetes	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Walking disability	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vulvovaginal injury	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Blood insulin	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vulvitis	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Injection site irritation	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Volume blood decreased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vocal cord dysfunction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blood immunoglobulin E increased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Cutaneous lymphoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vitreous floaters	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Vitamin B12 abnormal	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Cutaneous T-cell lymphoma stage III	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Influenza A virus test positive	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Viral labyrinthitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Viraemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Airway secretion clearance therapy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vertebrobasilar insufficiency	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Culture stool positive	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Inferior vena caval occlusion	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Venous occlusion	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Venous angioplasty	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Vein disorder	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Infection parasitic	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Infected skin ulcer	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Vasoactive intestinal polypeptide test abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Infected bite	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Vascular occlusion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Induction of cervix ripening	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anticoagulation drug level abnormal	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Varicella immunisation	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Vaginal douching	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anticoagulation drug level	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Incision site cellulitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Blood disorder prophylaxis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Uterine neoplasm	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Acute haemorrhagic conjunctivitis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Uterine contractions abnormal	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Urine odour abnormal	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Urine analysis abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Urinary tract infection enterococcal	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Urinary tract disorder prophylaxis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blood creatine phosphokinase increased	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cortisol decreased	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Blood corticotrophin decreased	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Upper respiratory tract congestion	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Unwanted pregnancy	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Immune-mediated neurological disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Coronary artery insufficiency	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Umbilical hernia repair	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Ultrafiltration failure	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Immune-mediated adverse reaction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Tumour of ampulla of Vater	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Antibiotic level	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Tuberculin test positive	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Truncus coeliacus thrombosis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Troponin increased	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Trisomy 8	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Trismus	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Traumatic haematoma	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Ichthyosis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
IVth nerve paralysis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Transitional cell carcinoma recurrent	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Transient hypogammaglobulinaemia of infancy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blood calcium	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Transfusion-related acute lung injury	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Tracheal dilatation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hypotonic urinary bladder	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Blood bicarbonate	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Toxic encephalopathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hyposmia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Tooth restoration	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Tooth impacted	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Tonsillar disorder	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Tongue cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Tissue adhesion prophylaxis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Tinea infection	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Tinea cruris	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hypogonadism male	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Thyroid stimulating hormone deficiency	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Thyroid neoplasm	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Bloch-Sulzberger syndrome	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hypoferritinaemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Anti-cyclic citrullinated peptide antibody positive	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Thymectomy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hypoaesthesia oral	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hypnotherapy	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Hypnic headache	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Thermohyperaesthesia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Therapy cessation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Therapeutic ovarian suppression	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Therapeutic gargle	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Tetanus immunisation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Congenital coronary artery malformation	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Testicular disorder	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Terminal state	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Tenosynovitis stenosans	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Tattoo	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hyperplasia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Blastocystis infection	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
T-cell lymphoma refractory	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anti-GAD antibody	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Computerised tomogram limb	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hypermobility syndrome	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hyperleukocytosis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Swollen tongue	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Hyperhomocysteinaemia	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Hyperglycaemic hyperosmolar nonketotic syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Superior mesenteric artery syndrome	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anterior chamber inflammation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Hypercholia	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Subperiosteal abscess	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Subdural hygroma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Complication associated with device	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bladder operation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Subacute hepatic failure	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anovulatory cycle	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Strongyloidiasis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Stress management	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Stress cardiomyopathy	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Streptococcus test positive	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Stoma site pain	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Hydrocephalus	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Stoma site abscess	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Bladder irritation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Anosmia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Stoma care	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Coma	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Stenotrophomonas test positive	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Symptom recurrence	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Human herpesvirus 8 infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Stenotrophomonas bacteraemia	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Anorgasmia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Human herpes virus 8 test positive	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Status dystonicus	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Staphylococcus test positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Staphylococcal skin infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bladder discomfort	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Colorectal cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Sputum discoloured	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Sputum culture positive	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bladder catheterisation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Spondylolysis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Homicide	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Anorectal disorder	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Spinal myelogram	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Spinal cord infarction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bladder cancer stage 0, with cancer in situ	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Speech disorder developmental	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Collateral circulation	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Hip fracture	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
High-resolution computerised tomogram of lung	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Solar lentigo	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Soft tissue disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hyperparathyroidism tertiary	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Sodium retention	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Social problem	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Colitis ischaemic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Birdshot chorioretinopathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
High density lipoprotein decreased	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Sleeve gastrectomy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Sleep study	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Coarctation of the aorta	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Herpes ophthalmic	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Skin haemorrhage	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Coagulation time prolonged	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Skin depigmentation	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Hereditary leiomyomatosis renal cell carcinoma	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Skin candida	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Skin burning sensation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Ankle fracture	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Biopsy breast	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Sinusitis aspergillus	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Biopsy bone marrow	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Sinus pain	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Acute chest syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Sinus bradycardia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Sideroblastic anaemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hepatitis D	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Sexually active	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Serum serotonin decreased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Animal attack	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Biliary tract disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Serum ferritin increased	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Serositis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Biliary sepsis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Septic embolus	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Septic cardiomyopathy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Septal myectomy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Sensory processing disorder	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Senile dementia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Self-destructive behaviour	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hepatic hydrothorax	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Sedation complication	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Hypofibrinogenaemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Biliary cirrhosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hepatic encephalopathy prophylaxis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Citrobacter bacteraemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cirrhosis alcoholic	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Angiosarcoma recurrent	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hepatic angiogram	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Sciatic nerve neuropathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Heparin neutralisation therapy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bile acids	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Sarcomatoid mesothelioma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Sarcoidosis of lymph node	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Heavy chain disease	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Heat illness	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
AIDS related complex	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Sacroiliac joint dysfunction	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Congestive hepatopathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Head discomfort	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Rheumatoid scleritis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hashimoto's encephalopathy	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Rheumatic heart disease	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
African trypanosomiasis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Chronic lymphocytic inflammation with pontine periva	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Conjunctival irritation	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hypometabolism	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Conjunctival scar	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Hair transplant	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Restrictive pulmonary disease	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Chronic graft versus host disease oral	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Haemophilic arthropathy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Haemophilia carrier	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Respiratory papilloma	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Respiratory fume inhalation disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Respiratory depression	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Reocclusion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Benign lymph node neoplasm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Contrast echocardiogram	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Renal vein thrombosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Renal tubular necrosis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Haemoglobin	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Renal stone removal	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Haemodynamic rebound	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Renal lithiasis prophylaxis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Renal injury	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Haemodialysis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Renal infarct	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Renal cyst	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Trans-sexualism	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Hypovolaemic shock	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Haematological infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Renal cancer stage III	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Haematocrit abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Renal aneurysm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Haemangioma of liver	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Refraction disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Haemangioma congenital	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Red blood cell count decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Red blood cell count abnormal	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Hysterosalpingogram	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Red blood cell abnormality	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
HIV-2 infection	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
HIV test negative	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Rectal neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Rectal abscess	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Adrenal adenoma	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Rash morbilliform	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Chorea	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Radiotherapy to prostate	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Basal ganglion degeneration	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Chondrosarcoma metastatic	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Radioimmunotherapy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
HELLP syndrome	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Radiation pneumonitis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
RPE65 gene mutation	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Basal ganglia infarction	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pyogenic sterile arthritis pyoderma gangrenosum and	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Angiodysplasia	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pupillary reflex impaired	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cholera	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cholecystitis chronic	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Granulomatous dermatitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Gram stain positive	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pulmonary dysmaturity syndrome	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Bacteroides infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cholangitis infective	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pulmonary artery aneurysm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Bacteroides bacteraemia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cholangiosarcoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pterygium	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Tumour excision	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Gorham's disease	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Psychophysiologic insomnia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Glycosylated haemoglobin decreased	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Choanal atresia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pseudocyst	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pseudoaldosteronism	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Bacterial test	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pruritus genital	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Glomerulonephropathy	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Protein C deficiency	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Prosthetic cardiac valve calcification	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Prostatitis Escherichia coli	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Undifferentiated connective tissue disease	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Glomerular vascular disorder	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Glomerular filtration rate decreased	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Prostate cancer stage 0	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Prophylaxis of abortion	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gleason grading score	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Glaucomatous optic neuropathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Glaucoma drug therapy	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Acral lentiginous melanoma stage III	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Chemotherapy cardiotoxicity attenuation	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gingival swelling	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Product dispensing issue	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Chapped lips	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Procedural vomiting	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Androgen replacement therapy	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Germ cell cancer metastatic	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Primary pulmonary melanoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Genitourinary tract neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Primary mediastinal large B-cell lymphoma stage IV	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Antibody test abnormal	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Genitourinary melanoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Primary ciliary dyskinesia	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Urethral stenosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Genital infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Immunoglobulins	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Genital candidiasis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Urethral meatus stenosis	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Premature menopause	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Precursor T-lymphoblastic lymphoma/leukaemia stage I	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Postural tremor	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Urinary tract infection pseudomonal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Postpericardiotomy syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Postpartum anxiety	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anastomotic complication	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Postinfarction angina	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Post-traumatic pain	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Implant site infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Anticipatory anxiety	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Post procedural sepsis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Post procedural hypotension	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Abdominal cavity drainage	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Anaplastic meningioma	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gastrointestinal neuroendocrine carcinoma	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Positron emission tomogram prostate	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Gastrointestinal necrosis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cerebral microinfarction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Polyradiculoneuropathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cerebral ischaemia	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Polypectomy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Uterine polyp	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Gastrointestinal disorder congenital	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cranial nerve neoplasm benign	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Gastrointestinal carcinoma in situ	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pneumoperitoneum	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pneumonia respiratory syncytial viral	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pneumonia haemophilus	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Uterine prolapse	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pneumonia cryptococcal	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gastrin secretion disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Gastric varices haemorrhage	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cerebral arteriosclerosis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Gastric neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Increased viscosity of bronchial secretion	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Adenosquamous cell carcinoma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Plasma protein metabolism disorder	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Plasma cell leukaemia in remission	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pityriasis lichenoides et varioliformis acuta	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gastric antral vascular ectasia	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Autonomic dysreflexia	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Ganglioglioma	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pituitary cyst	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Vascular headache	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gallbladder squamous cell carcinoma	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Phytotherapy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Gallbladder neoplasm	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Photodynamic diagnostic procedure	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Central nervous system lupus	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Galactosialidosis	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Gait inability	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Central nervous system inflammation	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Fusobacterium test positive	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pharyngeal cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pharyngeal cancer	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Phakomatosis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Perthes disease	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Peroneal nerve injury	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Peritumoural oedema	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Fulminant type 1 diabetes mellitus	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cellulite	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Autoimmune neuropathy	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Peritoneal neoplasm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Peritoneal mesothelioma malignant recurrent	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cryptogenic cirrhosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cell-mediated cytotoxicity	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Peritoneal dialysis complication	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Perirectal abscess	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Friedreich's ataxia	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Autoimmune myocarditis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Peripheral motor neuropathy	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Adenomatous polyposis coli	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Peripheral artery thrombosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Peripheral artery stent insertion	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Catheter site warmth	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Catheter site rash	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Foreign body sensation in eyes	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Autoimmune lung disease	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Catheter site infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Food craving	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pericardial disease	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anal pruritus	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Catarrh	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Penile pain	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Follicular disorder	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Penile erosion	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Anal injury	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pelvic infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Foetal exposure timing unspecified	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Patent ductus arteriosus repair	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Parvimonas micra infection	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Parkinsonian crisis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Infusion site pruritus	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Autoimmune demyelinating disease	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Parathyroid disorder	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Fistula	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Parasitic gastroenteritis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Fibrous histiocytoma	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Fibrous dysplasia of jaw	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Paraparesis	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Paraneoplastic syndrome	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Fibroma	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Anal fungal infection	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Fibrin D dimer increased	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Fibrillary glomerulonephritis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Femoral neck fracture	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Female reproductive tract disorder	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Female reproductive neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pancreaticoduodenectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Feeling hot	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Pancreatic enzymes increased	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Feeling abnormal	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Pancreatic enzyme replacement therapy	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Vulvovaginal burning sensation	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pancreatic carcinoma stage IV	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Febrile infection	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Fatty acid deficiency	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Fat tissue increased	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Fasting	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Pain of skin	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Paget's disease of nipple	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cardiac ventricular thrombosis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Familial hypocalciuric hypercalcaemia	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Oxygen consumption	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Familial hypertriglyceridaemia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Ovulation pain	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Aborted pregnancy	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Familial cold autoinflammatory syndrome	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Acquired epidermolysis bullosa	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Cardiac stress test abnormal	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Factor XIII deficiency	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Ovarian cancer stage II	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Anaesthetic ophthalmic procedure	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Cardiac murmur	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Facet joint syndrome	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Orthopaedic procedure	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Orchidopexy	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
International normalised ratio abnormal	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Eye movement disorder	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Oral surgery	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Optic neuropathy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Atopic keratoconjunctivitis	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Optic nerve neoplasm	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Eye disorder prophylaxis	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Eye discharge	0 ( 0.0%)	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	2
Ophthalmic herpes simplex	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	2
Atelectasis	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
17-hydroxyprogesterone increased	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Extraskkeletal ossification	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Ataxia	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	2
Oliguria	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Extramedullary haemopoiesis	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Olfacto genital dysplasia	1 ( 50.0%)	0 ( 0.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Asymptomatic gene carrier	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Extradural abscess	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Abdominal mass	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)	2
External ear pain	0 ( 0.0%)	1 ( 50.0%)	1 ( 50.0%)	0 ( 0.0%)	2
Oesophagoscopy	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Carcinoid tumour of the prostate	0 ( 0.0%)	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	2
Oesophageal varices haemorrhage	0 ( 0.0%)	2 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	2
Oesophageal ulcer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exposure via breast milk	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oesophageal stenosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Exposure to radiation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exostosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Carcinoid tumour in the large intestine	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Exophthalmos	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exocrine pancreatic function test abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Oesophageal atresia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Exfoliation syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Exercise tolerance decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Excessive granulation tissue	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anaemia postoperative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Carbohydrate antigen 125 increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Excessive gingival display	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ocular toxicity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Astigmatism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Capsular contracture associated with breast implant	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ocular melanoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Occipital lobe epilepsy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Euthyroid sick syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Obstructive pancreatitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Capillary fragility	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Obstruction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Euglycaemic diabetic ketoacidosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nutritional supplement allergy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Normochromic anaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Escherichia test positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Noninfective encephalitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Escherichia pyelonephritis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cancer with a high tumour mutational burden	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Non-cirrhotic portal hypertension	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cancer staging	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Erythema migrans	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Erythema annulare	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Asthenopia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Nodular lymphocyte predominant Hodgkin lymphoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nodal marginal zone B-cell lymphoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Erosive duodenitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Nipple resection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nipple disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Anaemia folate deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Campylobacter colitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Epstein-Barr virus antigen positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acne fulminans	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acute undifferentiated leukaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Assisted suicide	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Neutrophil function disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Epstein Barr virus positive mucocutaneous ulcer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Epiglottitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Neuroma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Aspiration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neurofibrosarcoma recurrent	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neurofibrosarcoma metastatic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Epididymal disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Asphyxia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Epidermal naevus syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ependymoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neuroborreliosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neuritic plaques	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Eosinophilic otitis media	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nervous system neoplasm	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
CNS ventriculitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nephrosclerosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nephroptosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Eosinophilic cystitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
CHA2DS2-VASc annual stroke risk moderate	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Eosinophilic colitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nephritis bacterial	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nephrectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enzyme level abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
CD4 lymphocytes decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Enzyme inhibition	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Enzyme activity decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Neonatal respiratory distress syndrome prophylaxis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Enterovirus infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enterovesical fistula	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enteropathy-associated T-cell lymphoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
C-reactive protein abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enteropathic spondylitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Amoebiasis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Butterfly rash	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enterocolitis infectious	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Neck mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enterocolitis haemorrhagic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nasopharyngeal cancer metastatic	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nasal turbinate hypertrophy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bursa disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nasal pruritus	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Enteroclysis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enterobacter bacteraemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nasal abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nail ridging	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Arthropod-borne disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enteric neuropathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Nail operation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nail hypertrophy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abdominal lymphadenopathy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Abnormal loss of weight	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Amniorrhoea	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Nail atrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
NTRK gene fusion positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Myxoid liposarcoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endothelial dysfunction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Myotonic dystrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Burkitt's lymphoma stage I	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Myopic traction maculopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Myopia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Myopathy toxic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Myofascitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Arthrogram	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Endometrial thickening	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Myocarditis bacterial	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arthrodesis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Burkholderia mallei infection	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Myelomalacia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Myelodysplastic syndrome unclassifiable	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bundle branch block right	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ammonia decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Endometrial atrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mycobacterium ulcerans infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Endocrine neoplasm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Mycobacterial peritonitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arthritis fungal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Endocrine hypertension	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mycetoma mycotic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Myasthenia gravis crisis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Musculoskeletal disorder prophylaxis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Budd-Chiari syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Muscle injury	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Muscle contracture	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Muscle atrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Muscle abscess	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Enanthema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Multiple sclerosis relapse prophylaxis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Enamel anomaly	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Multiple fractures	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Multiple endocrine neoplasia Type 1	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Emphysematous cystitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Muir-Torre syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bronchopulmonary disease	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Emotional distress	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arteriovenous malformation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Emergency care	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Mucosal haemorrhage	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mucopolysaccharidosis IV	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mucopolysaccharidosis III	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mucopolidosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acute phase reaction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Elliptocytosis hereditary	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Moyamoya disease	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mosaicism	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mononeuropathy multiplex	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Monolid eyes	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Elderly	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mole excision	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mixed delusion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bronchial ulceration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Effusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bronchial secretion retention	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mitral valve disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mitochondrial DNA mutation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Miller Fisher syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Miliaria	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bronchial dysplasia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ectopic posterior pituitary gland	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Migrainous infarction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arterial tortuosity syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Middle ear inflammation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Eclampsia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Middle ear disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Eccrine carcinoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bronchial artery hypertrophy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Ecchymosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Micrococcus infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arterial therapeutic procedure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Methylenetetrahydrofolate reductase gene mutation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Arterial stenosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ear inflammation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Breath sounds	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metastases to vagina	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Eagle Barrett syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Metastases to the respiratory system	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Dystonic tremor	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metastases to reproductive organ	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dyspraxia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metastases to rectum	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dyspnoea paroxysmal nocturnal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Arterial fibrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Breast feeding	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dysphoria	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dysphemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abdominal injury	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metal poisoning	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Metachromatic leukodystrophy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dyslexia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dysgraphia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Mesotherapy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Duodenogastric reflux	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Aromatase inhibition therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Meningoencephalitis viral	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Meningococcal bacteraemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Meningitis pneumococcal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Meningitis leptospiral	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Breast abscess	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Meningitis fungal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dry gangrene	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Argininosuccinate synthetase deficiency	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Membrane stabilising effect	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Melanosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Brain stem syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Meigs' syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Brain stem infarction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Brain stem haemorrhage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Medical device pain	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mediastinal mass	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mediastinal haemorrhage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Drug level therapeutic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Mediastinal haematoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Drug level	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Application site anaesthesia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Measles immunisation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
May-Thurner syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Maternally inherited diabetes and deafness	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Drug detoxification	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alloimmunisation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Maternal exposure during breast feeding	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Drug clearance decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Massage	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Marrow hyperplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Marginal zone lymphoma refractory	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acute monocytic leukaemia (in remission)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alloimmune hepatitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dizziness postural	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Marfan's syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Mantle cell lymphoma stage III	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Management of reproduction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Mammogram abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bradypnoea	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diverticular perforation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Apoptosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Disturbance in sexual arousal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Dissociative identity disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malignant neoplasm of thorax	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malignant neoplasm of spermatic cord	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Malignant neoplasm of pleura	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Disseminated neonatal herpes simplex	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Malignant neoplasm of conjunctiva	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Disinhibition	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Allergy to chemicals	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Borderline glaucoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Male sexual dysfunction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Discouragement	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Magnetic resonance imaging pancreas	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Magnetic resonance imaging neck	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Discharge	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Disability	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diplopia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diplegia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Magnetic resonance cholangiopancreatography	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bone non-union	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Maffucci syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Macular telangiectasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dihydropyrimidine dehydrogenase deficiency	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diffuse vasculitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Macrophage activation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bone marrow tumour cell infiltration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
MELAS syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lysozyme	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lymphoma AIDS related	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lymphocytosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bone marrow infiltration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lymphocytic oesophagitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Diffuse cutaneous mastocytosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aortogram	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lymphangiectasia intestinal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diarrhoea infectious	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Luteal phase deficiency	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Aortoenteric fistula	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Dialysis hypotension	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lupus vulgaris	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bone growth stimulation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Diagnostic aspiration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lupus anticoagulant hypoprothrombinaemia syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diabetic vascular disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aortitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bone giant cell tumour benign	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lung infiltration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diabetic metabolic decompensation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lung diffusion disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lung cyst	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bone fissure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lung carcinoma cell type unspecified stage II	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lung assist device therapy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bone development abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abdominal wall wound	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diabetic diet	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Diabetic dermopathy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Lumbar spinal drainage complication	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diabetic complication neurological	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lumbar radiculopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lumbar puncture	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Diabetes with hyperosmolarity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Aortic valve calcification	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Bone densitometry	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Low density lipoprotein normal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bone demineralisation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Low cardiac output syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Local anaesthetic systemic toxicity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lobular breast carcinoma in situ	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Liver scan	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Body tinea	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Device related bacteraemia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Device issue	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Device infusion issue	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Liposuction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Device dependence	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Developmental hip dysplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lipoprotein (a) decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lipogranuloma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aortic dilatation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dermoid cyst	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Lip neoplasm malignant stage unspecified	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Body height	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Limb mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alkalosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dermatitis infected	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Limb asymmetry	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Body dysmorphic disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aortic aneurysm repair	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ligament injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ligament disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Dermatitis artefacta	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood viscosity abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Libido increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Lewis-Sumner syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Leukoplakia oral	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Leukocyturia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Leukocytosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Leukapheresis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Leukaemoid reaction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Alcoholic psychosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Lethargy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Leriche syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood uric acid abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Depressed level of consciousness	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lentigo	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Dependence on respirator	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Leishmaniasis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blood urea increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dependence on oxygen therapy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dental necrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dental implantation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Latent syphilis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dental discomfort	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Laryngomalacia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Dental cleaning	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Laryngo-onycho-cutaneous syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abdominal wall abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Laryngeal mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Dengue fever	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood thyroid stimulating hormone abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Large intestine perforation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Demyelinating polyneuropathy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Large intestinal polypectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Large intestinal obstruction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Antiviral drug level above therapeutic	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood thromboplastin	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Large cell lung cancer stage III	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Lactose tolerance test	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lactose intolerance	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Delusional disorder, persecutory type	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood testosterone	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Lacrimial disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Laboratory test normal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Laboratory test	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Labile blood pressure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Kounis syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Knee deformity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Degenerative bone disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Kerion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood pressure systolic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Decreased ventricular preload	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Decreased ventricular afterload	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Kaposi's sarcoma AIDS related	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Decreased immune responsiveness	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Death	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Juvenile absence epilepsy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Deafness neurosensory	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blood pressure diastolic increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Joint noise	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Joint irrigation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Joint destruction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Joint contracture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Joint arthroplasty	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Joint ankylosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Job change	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Antiphospholipid antibodies	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Jaundice	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cytomegalovirus gastritis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood phosphorus decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
ACTH stimulation test	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intraventricular haemorrhage neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intrathecal pump insertion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cytokine abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Accident	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acute hepatitis C	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood pH	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood oestrogen increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cystitis bacterial	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intestinal mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intestinal fibrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood oestrogen	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cystic fibrosis respiratory infection suppression	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intervertebral disc displacement	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cystic fibrosis pancreatic	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Intervertebral disc compression	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Interventricular septum rupture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
pH body fluid abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood luteinising hormone abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cystic fibrosis hepatic disease	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Zoonotic bacterial infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Xerophthalmia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
International normalised ratio fluctuation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Internal haemorrhage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cystatin C	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intermittent claudication	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Wrist fracture	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Wound haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cyst removal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Intercapillary glomerulosclerosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Wound drainage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cyst drainage	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
White blood cell count abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
West Nile virus test positive	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood iron	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cycloplegia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Werner's syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Insulin-like growth factor	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Weight gain poor	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Weight fluctuation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cyclic neutropenia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vulvovaginitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Injury of conjunctiva	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vulvovaginal swelling	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Injury associated with device	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Injection site warmth	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Injection site urticaria	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Injection site swelling	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vulval cancer stage III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vulval cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood immunoglobulin M decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Von Willebrand's factor antigen increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Von Willebrand's factor antibody positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Von Hippel-Lindau disease	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Injection site induration	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Accelerated hypertension	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vitritis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cutaneous mucormycosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Injection site abscess	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vitreous opacities	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Injection related reaction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Inguinal hernia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ingrown hair	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood growth hormone normal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cutaneous amyloidosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Antidepressant drug level	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Blood growth hormone increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Virilism	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cutaneous T-cell lymphoma refractory	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Viral haemorrhagic cystitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vibration syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Anticonvulsant drug level therapeutic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vestibular paroxysmia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Inflammatory marker increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vestibular neuronitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Infertility tests	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ventriculo-peritoneal shunt	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anticonvulsant drug level	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cubital tunnel syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Crystalluria	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acute haemorrhagic leukoencephalitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Venomous bite	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Venogram	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Venipuncture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cryptorchism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vena cava embolism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vasoplegia syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vasectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Anticoagulation drug level below therapeutic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vascular pain	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vascular operation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Vascular insufficiency	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Infantile apnoea	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Vascular graft infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Infant	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vascular device user	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blood fibrinogen decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Induced labour	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vaginal stricture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cronkhite-Canada syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vaginal pessary insertion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Blood electrolytes decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Increased bronchial secretion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Vaginal abscess	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vaccination site pain	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vaccination site mass	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
VLth nerve paralysis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Incision site pain	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Uterovaginal prolapse	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Uterine pain	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abdominal symptom	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cranial nerve disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Inappropriate schedule of product administration	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Uterine infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Agonal respiration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Inappropriate affect	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Uterine contractions during pregnancy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
In vivo gene therapy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Implantation complication	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urine uric acid abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Implantable defibrillator insertion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urine osmolarity decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urine osmolarity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Impaired healing	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urinary tract spasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Impaired fasting glucose	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood creatinine decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cortisol increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urinary tract infection staphylococcal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Anticholinergic syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cortisol free urine increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urinary hesitation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Immunoglobulins abnormal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cortisol abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Urethral pain	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood creatine increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urethral haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urethral cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Immunodeficiency congenital	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urethral atrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ureteric obstruction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ureteric cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Immune-mediated thyroiditis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Upper respiratory tract infection bacterial	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Upper limb fracture	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Agitated depression	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Immune-mediated neuropathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Upper airway obstruction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood corticotrophin	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Unevaluable therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Undifferentiated spondyloarthritis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Coronary artery dissection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Undifferentiated nasopharyngeal carcinoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood cholesterol normal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Immune-mediated hepatic disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Immune-mediated gastritis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Immune-mediated encephalopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ulcer haemorrhage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Typical aura without headache	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Immune-mediated cholangitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Typhoid fever immunisation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Immune-mediated arthritis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Antibiotic level above therapeutic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cornelia de Lange syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tumour pruritus	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Tumour marker abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Corneal opacity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tumour inflammation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tumour flare	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Corneal oedema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Imaging procedure abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Corneal lesion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood chloride increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tuberculosis of intrathoracic lymph nodes	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tuberculosis liver	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acariasis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood chloride abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Corneal erosion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Iliac artery occlusion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Aggregatibacter infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Antiangiogenic therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Troponin I increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tricuspid valve disease	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Trichotillomania	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Idiopathic neutropenia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Idiopathic inflammatory myopathy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Treatment boosted antibody positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cor pulmonale acute	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Idiopathic CD4 lymphocytopenia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Traumatic fracture	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cooling therapy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Illrd nerve paralysis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hysterosalpingo-oophorectomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Transgender operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypozaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood calcitonin increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Contrast media reaction	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Transaminases decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Transaminases	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tractional retinal detachment	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Trachoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Anti-platelet factor 4 antibody positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypoventilation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Tracheomalacia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Tracheo-oesophageal fistula	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypotrichosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tracheal stenosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Trabeculectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypothermia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Toxic optic neuropathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Toxic nodular goitre	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Toxic neuropathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypothalamic pituitary adrenal axis suppression	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Toxic goitre	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypoproteinaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypopnoea	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypophosphataemic osteomalacia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Blood alkaline phosphatase increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypopharyngeal neoplasm	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tongue tie operation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tongue movement disturbance	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hypopharyngeal cancer recurrent	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tongue disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anti-interferon antibody positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tongue carcinoma stage IV	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tongue cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Tolosa-Hunt syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Conjunctival abrasion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Tissue irritation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blood albumin increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tissue injury	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tick-borne fever	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thyroxine increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital subglottic stenosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypokalaemic syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroxine free decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroxine decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thyroxine abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital pulmonary airway malformation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypogonadism female	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thyroiditis chronic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Abdominal rigidity	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abstains from alcohol	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital osteodystrophy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypoglycaemia neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital neuropathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroid hormones increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thyroid dysfunction in pregnancy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Thyroid cancer stage I	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypocitraturia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital musculoskeletal disorder of limbs	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thymus disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thymoma malignant recurrent	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypoaldosteronism	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thrombotic cerebral infarction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Thrombopoietin level abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thrombophlebitis septic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypo HDL cholesterolaemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Thrombophlebitis migrans	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Anti-aquaporin-4 antibody	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital hepatitis B infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hyperventilation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thrombin time prolonged	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hypertrophic scar	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Thoracic radiculopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital fibrosarcoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Therapy responder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Therapy partial responder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Congenital dysfibrinogenaemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Therapeutic product effect increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Congenital dyserythropoietic anaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hyperthermia malignant	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Therapeutic drug monitoring	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Testicular germ cell tumour	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypertelorism	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Congenital chylothorax	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypersplenism	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Teratogenicity	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypersensitivity vasculitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tendon injury	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Telangiectasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blastomycosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Teething	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tearfulness	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Tachyphrenia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hyperphagia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aerophagia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
T-cell lymphoma recurrent	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Computerised tomogram liver	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Systolic hypertension	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Systolic dysfunction	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hyperoxaluria	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Systemic lupus erythematosus rash	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Computerised tomogram kidney	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Systemic infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Systemic bacterial infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blast cell crisis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Computerised tomogram intestine	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypermagnesaemia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hyperlactacidaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hyperkinesia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Symblepharon	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Suture rupture	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Abscess of eyelid	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anterograde amnesia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Computerised tomogram abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Suspected suicide attempt	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Supraventricular tachyarrhythmia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hyperglycinaemia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Compression fracture	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Supine hypertension	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hyperglobulinaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypergastrinaemia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Superficial siderosis of central nervous system	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Superficial inflammatory dermatosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sudden visual loss	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Complications of transplanted kidney	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sudden hearing loss	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Complication of pregnancy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Substance abuser	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hyperchloraemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hypercapnia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Subcorneal pustular dermatosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Complicated malaria	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Subconjunctival injection procedure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Subacute endocarditis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stridor	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Stress fracture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bladder metaplasia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hydrotubation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stomach mass	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Community acquired infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Stoma site erythema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stoma site discharge	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Combined pulmonary fibrosis and emphysema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hydrocele	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Stoma complication	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bladder irrigation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stent removal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Colour vision tests abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Human rhinovirus test positive	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hypermetropia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stem cell therapy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bladder hypertrophy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Human herpesvirus 6 infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Steatohepatitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Human ehrlichiosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Colorectal cancer stage II	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Huerthle cell carcinoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Colorectal cancer stage I	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Staphylococcal abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Stag horn calculus	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sports injury	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spontaneous heparin-induced thrombocytopenia syndrom	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spondylitic myelopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Abscess neck	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Splenic infarction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Colon operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Splenectomy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spinal synovial cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Spinal stroke	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anorectal discomfort	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spinal cord disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Spinal cord compression	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Spinal cord abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sperm concentration decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hirsutism	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Spasmodic dysphonia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Anomalous pulmonary venous connection	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hippocampal sclerosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Somnambulism	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Solar urticaria	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
High risk sexual behaviour	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Soft tissue injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
High risk pregnancy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
High risk infant	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Social avoidant behaviour	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Social (pragmatic) communication disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
High density lipoprotein abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
High density lipoprotein	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bipolar disorder relapse prophylaxis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Small intestinal haemorrhage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Anogenital lichen planus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sluggishness	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Herpes zoster infection neurological	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Slipping rib syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sleep-related eating disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cogan's syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Herpes zoster cutaneous disseminated	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Herpes simplex viraemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Herpes simplex pneumonia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Skin swelling	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Skin plaque	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Biphasic mesothelioma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Skin neoplasm excision	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Skin necrosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Herpes dermatitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Skin implant removal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hernia pain	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Skin hypertrophy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Biopsy stomach	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Coagulation time shortened	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Skin fibrosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hereditary spastic paraplegia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Coagulation test abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Coagulation factor inhibitor assay	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Skin adhesion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sinusitis bacterial	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sinus rhythm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Coagulation factor VIII level increased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sinus operation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hepatopulmonary syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Animal scratch	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Biopsy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sinus cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Sinonasal obstruction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blepharoplasty	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Coagulation factor V level	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Simple mastectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Coagulation factor IX level	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sickle cell trait	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatitis toxoplasmal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Shunt malfunction	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Biliary tract infection bacterial	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hepatitis toxic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Shoulder fracture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatitis neonatal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatitis cholestatic	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Sexually transmitted disease	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatitis C antibody	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sexual activity decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Severe asthma with fungal sensitisation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatitis B virus test	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hepatitis B surface antigen	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatitis B immunisation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatitis B core antibody positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Seroma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Closed fracture manipulation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatitis B DNA decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Clonic convulsion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Septic coagulopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Blister infected	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Biliary dilatation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cleft palate	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Acute biphenotypic leukaemia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatic mass	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hepatic lesion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Seizure like phenomena	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Secretion gastric absent	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Secondary syphilis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Claustrophobia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Secondary hyperthyroidism	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Sebaceous gland disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Screaming	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Scratch	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bile duct stenosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Sclerotherapy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Scleral disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Scan brain	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Scan adrenal gland	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Salpingitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Salpingectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Salmonella bacteraemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Salivary gland neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Heart valve incompetence	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
STING-associated vasculopathy with onset in infancy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
SMN2 status assay	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
SARS-CoV-2 antibody test positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bicytopenia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Rubella immunisation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Rotavirus infection	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Bickerstaff's encephalitis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Right ventricular dilatation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hearing therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rickets	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bezoar	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rhinophyma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rhinitis prophylaxis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Head and neck cancer stage III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Haploinsufficiency of A20	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Rheumatoid bursitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Bentall procedure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Halo vision	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rhesus incompatibility	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Tongue injury	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Rhabdomyoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Angiomyolipoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Benign uterine neoplasm	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Hairy cell leukaemia recurrent	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rhabdoid tumour of the kidney	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Reversal of sedation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Reversal of opiate activity	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Retroperitoneum cyst	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Retroperitoneal neoplasm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Hair texture abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Retroperitoneal lymphadenopathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Hair growth rate abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Actinomycotic pulmonary infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Adrenal haemorrhage	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Angiolipoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Benign renal neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Retinitis pigmentosa	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Retinal vein thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Retinal vascular disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Retinal tear	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Benign recurrent intrahepatic cholestasis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haemorrhagic ovarian cyst	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Retinal operation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Haemorrhagic fever with renal syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Retinal neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Retinal ischaemia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Retinal injury	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Angiokeratoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chronic hepatitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haemorrhage urinary tract	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chronic hepatic failure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Benign ovarian tumour	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Respiratory tract neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Haemophilus influenzae type b immunisation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Respiratory tract malformation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Benign neoplasm of islets of Langerhans	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Respiratory tract infection bacterial	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Benign neoplasm of adrenal gland	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Respiratory arrest	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renin-angiotensin system inhibition	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Haemoglobinuria	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renin decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Actinomycosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haemoglobin increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renal-limited thrombotic microangiopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renal vein embolism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renal tuberculosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renal transplant failure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Contrast media deposition	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Renal hamartoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Renal cyst ruptured	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Chronic coronary syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Angiogram pulmonary	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Benign breast neoplasm	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Chronic allograft nephropathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haematocolpos	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Benign bone neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Remission not achieved	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Chromosomal deletion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Regurgitation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Angiogram peripheral	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Regressive behaviour	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Haemangioma of skin	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Refsum's disease	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chromaturia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Red blood cell sedimentation rate abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rectosigmoid cancer stage II	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Rebound effect	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Becker's muscular dystrophy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Rathke's cleft cyst	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Rash vesicular	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rash papulosquamous	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chorioretinal disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
HIV antigen	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Basilar artery occlusion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
HER2 positive salivary gland cancer	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rapid eye movements sleep abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Rapid correction of hyponatraemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Radius fracture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Angiofibroma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Radiosensitisation therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Radiologically isolated syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Basal ganglia stroke	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Radical hysterectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chondropathy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Radiation retinopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Radiation proctitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Adolescence	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gynaecological examination normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Radiation injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chondroma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gynaecological examination	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Quality of life decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Pyomyositis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Cholesterosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pyelonephritis fungal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bartholin's abscess	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cholestasis of pregnancy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Purpura fulminans	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pure white cell aplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Puncture site inflammation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adnexa uteri pain	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cholelithiasis obstructive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary vascular disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Granulomatous rosacea	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulmonary renal syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary infarction	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary imaging procedure abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulmonary imaging procedure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Granulocyte count decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary hypoplasia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulmonary haemosiderosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulmonary haematoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary contusion	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pulmonary blastomycosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary artery thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pulmonary artery therapeutic procedure	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pubertal failure	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Immobile	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cholangiogram	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Psychomotor skills impaired	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Choking	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Glycosuria	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pseudostrabismus	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pseudophakia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Glucose urine present	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bacterial translocation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Glucose tolerance test	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pseudomonal skin infection	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Glucose tolerance impaired in pregnancy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chlamydial infection	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pseudofolliculitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adjustment disorder with mixed disturbance of emotio	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Glucocorticoids normal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pseudo Cushing's syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chimerism	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Glucocorticoids abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Providencia urinary tract infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Glucagonoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Glottis carcinoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Bacterial sepsis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Childhood depression	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Protein total decreased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Protein total abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Protein total	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Protein deficiency	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Aneurysmal bone cyst	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Childhood asthma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Glomerulosclerosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Protein albumin ratio	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Prosthesis implantation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Aneurysm repair	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Chest injury	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prostatic mass	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prostatic hypoplasia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Prostate cancer stage II	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Glomerular filtration rate	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Chemotherapy urothelial toxicity attenuation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gliososis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prostate ablation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gliosarcoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gliomatosis cerebri	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Immune-mediated optic neuritis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Abortion of ectopic pregnancy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prophylaxis against alcoholic withdrawal syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Promotion of peripheral circulation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prolonged pregnancy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Glanzmann's disease	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prolapse repair	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Progesterone increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gingival hypertrophy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Progesterone	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gingival blister	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Product prescribing error	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Giardiasis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Change of bowel habit	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Procedural hypotension	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gestational alloimmune liver disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cervix neoplasm	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Procalcitonin increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Primary stabbing headache	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Genitourinary operation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Primary hypoparathyroidism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Genitourinary chlamydia infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Genitalia external ambiguous	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Genital rash	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Preterm premature rupture of membranes	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prescribed overdose	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Acral lentiginous melanoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Adenovirus infection	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Genital abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Generalised resistance to thyroid hormone	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
BK virus infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Precursor T-lymphoblastic leukaemia acute	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Precerebral artery embolism	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cerumen removal	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Prealbumin	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cerumen impaction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Postpartum state	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Postpartum disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adenoviral encephalitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Postoperative delirium	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Postoperative abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Urinary tract toxicity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Posterior capsule opacification	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastrointestinal ulcer management	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cerebral ventricular rupture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastrointestinal tube insertion	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Post vaccination syndrome	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastrointestinal tract mucosal discolouration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Post thrombotic syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Post stroke seizure	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Gastrointestinal tract irritation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Post stroke epilepsy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Post procedural swelling	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastrointestinal stenosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Post procedural haemorrhage	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Post procedural diarrhoea	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gastrointestinal polyp haemorrhage	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abdominal operation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abortion missed	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adenotonsillectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Gastrointestinal perforation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cerebral small vessel ischaemic disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Post breast therapy pain syndrome	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Post abortion complication	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Portal vein phlebitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Portal shunt procedure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Porphyria non-acute	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Porphyria	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Poor venous access	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Polyneuropathy in malignant disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Polyneuropathy chronic	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cerebral hypoperfusion	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Polyglandular disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cerebral fungal infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cerebral endovascular aneurysm repair	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastroenteritis viral	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cerebral cyst	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cerebral cavernous malformation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pneumonia lipoid	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adenosquamous cell lung cancer stage III	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cerebral artery thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastrinoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Craniosynostosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pneumoconiosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastric residual assessment	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pneumococcal bacteraemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cerebral artery embolism	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Gastric polyps	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cerebellar stroke	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Platelet count abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Platelet aggregation test	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gastric mucosa erythema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Platelet aggregation normal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Avoidant personality disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Gastric infection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Platelet aggregation increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cerebellar atrophy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Gastric dilatation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Plaque shift	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Central sleep apnoea syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pityriasis alba	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pituitary scan	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pituitary hyperplasia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pinealoblastoma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Phytosterolaemia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Physical assault	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Photosensitivity reaction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Photosensitive seizure	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Gallbladder cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Photodynamic therapy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Phonophobia	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Phobic postural vertigo	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Phlebotomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Gadolinium deposition disease	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
GM2 gangliosidosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pharyngeal ulceration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pharyngeal oedema	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pharyngeal erythema	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pharyngeal disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Phaeohyphomycosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cellulitis staphylococcal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1



### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Personal hygiene	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Peritoneal permeability decreased	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Full blood count	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Cell death	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peristalsis visible	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cavernous sinus thrombosis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Freezing phenomenon	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Peripheral primitive neuroectodermal tumour of soft	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Peripheral embolism	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Acquired foramen magnum stenosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peripheral circulatory failure	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Fractional exhaled nitric oxide increased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fractional exhaled nitric oxide abnormal	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peripheral artery aneurysm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peripheral arteriogram	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Foraminotomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Periorbital swelling	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Periorbital haematoma	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Foot fracture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Periorbital discomfort	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Foot deformity	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Periorbital cellulitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Autoimmune inner ear disease	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Foot amputation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Periodontal disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Perineal injury	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Perineal disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Pericardial haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Follicular lymphoma refractory	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Perfume sensitivity	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cataract subcapsular	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Peptic ulcer haemorrhage	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Penile erythema	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Penile cancer	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Inflammatory marker test	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Follicle centre lymphoma diffuse small cell lymphoma	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pelvic venous thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pelvic organ prolapse	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Foetal therapeutic procedure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Foetal heart rate abnormal	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pelvic floor dysfunction	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Pelvic discomfort	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pelvic abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Patent ductus arteriosus	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Patellofemoral pain syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Patella fracture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Adenoidal hypertrophy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anal infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Passive smoking	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cartilage-hair hypoplasia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Partner stress	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Parotitis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fluid balance assessment	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Parosmia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Carotid intima-media thickness increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Parkinsonism hyperpyrexia syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Carotid bruit	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fixed eruption	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Parietal lobe stroke	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Carotid artery stent insertion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Fistula repair	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Parathyroid tumour benign	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Paraspinal abscess	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Finger deformity	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Parapsoriasis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Paraplegia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Paraphilia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Fibrous dysplasia of bone	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adenoidal disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anal haemorrhage	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Autoimmune cerebellar ataxia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Paraneoplastic retinopathy	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Paraneoplastic hypoglycaemia	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Paranasal sinus neoplasm	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Paranasal sinus inflammation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Carotid angioplasty	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Fibroadenoma of breast	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Paradoxical psoriasis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Carnitine deficiency	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fibrinolysis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Paradoxical embolism	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Fibrinogen degradation products increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Paracentesis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Aura	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Carnitine abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Papule	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Auditory nerve disorder	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Carney complex	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pancreatogenous diabetes	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiovascular symptom	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Pancreatitis relapsing	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Vulval ulceration	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Feeding disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pancreatic enzyme abnormality	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pancreatic atrophy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Pallor	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Anal cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Atypical migraine	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Fat necrosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Painful erection	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Family stress	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
PD-L1 protein expression	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
PCDH19 gene-related epilepsy	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
PASH syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiac valve vegetation	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
PACS1 neurodevelopmental disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ovulation disorder	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Overchelation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Ovarian low malignant potential tumour	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ovarian granulosa-theca cell tumour	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ovarian germ cell cancer	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Failed back surgery syndrome	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ovarian failure postoperative	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ovarian failure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ovarian epithelial cancer stage IV	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Ovarian epithelial cancer metastatic	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cardiac septal defect	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ovarian disorder	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Atrioventricular block complete	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Factor X deficiency	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiac output decreased	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Otospondylomegapiphyseal dysplasia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Adenocarcinoma of salivary gland	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Atrial thrombosis	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Factor II mutation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiac imaging procedure	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Osteo-meningeal breaches	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiac function test abnormal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Osmotic demyelination syndrome	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Anaesthetic complication	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Orthostatic tremor	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Eyelid ptosis congenital	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Orthopoxvirus test positive	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oropharyngeal plaque	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cyst rupture	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1

### Indication Summary Table

#### Derived Age Group

	Group1 (0-25) (N=&AGEGRP1)	Group2 (26-50) (N=&AGEGRP2)	Group3 (51-75) (N=&AGEGRP3)	Group4 (75+) (N=&AGEGRP4)	Total (N=&AGEGRP5)
Eyelid myoclonus	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oropharyngeal oedema	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oropharyngeal fistula	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Cardiac failure high output	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Eyelid haemangioma	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Acquired Von Willebrand's disease	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Eye swelling	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Orofacial granulomatosis	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ornithine transcarbamoylase deficiency	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Eye naevus	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Orbital myositis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Orbital decompression	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Atrial appendage closure	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oral mucosal scar	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oral mucosal blistering	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiac discomfort	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Eye infection bacterial	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Optic perineuritis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Cardiac assistance device user	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Optic nerve hypoplasia	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Ophthalmologic treatment	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Extubation	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oophorectomy	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
pH urine increased	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
ACTH-producing pituitary tumour	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Carcinoma in situ	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
Oncologic complication	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1

**Indication Summary Table**  
**Derived Age Group**

	<i>Group1 (0-25)</i> <i>(N=&amp;AGEGRP1)</i>	<i>Group2 (26-50)</i> <i>(N=&amp;AGEGRP2)</i>	<i>Group3 (51-75)</i> <i>(N=&amp;AGEGRP3)</i>	<i>Group4 (75+)</i> <i>(N=&amp;AGEGRP4)</i>	<i>Total</i> <i>(N=&amp;AGEGRP5)</i>
Omphalitis	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Carcinoma ex-pleomorphic adenoma	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oligohydramnios	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Abnormal weight gain	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	1
Oil acne	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1
Oestrogen receptor assay	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (100.0%)	1
External ear inflammation	0 ( 0.0%)	1 (100.0%)	0 ( 0.0%)	0 ( 0.0%)	1