

Obs	title	subjectsAffectedBySeriousAdverseEvents	subjectsAffectedByNonSeriousAdverseEvents
1	Control	15	15
2	Experimental	32	24

Obs	deathsResultingFromAdverseEvents	subjectsExposed	deathsAllCauses
1	9	60	9
2	22	67	22

Obs	term	title	occurrences	occurrencesCausallyRelatedToTreatment	deaths
1	B-cell lymphoma	Control	1	0	0
2	B-cell lymphoma	Experimental	0	0	0
3	Cardiac arrest	Control	1	0	1
4	Cardiac arrest	Experimental	0	0	0
5	Cardiac failure congestive	Control	0	0	0
6	Cardiac failure congestive	Experimental	1	0	0
7	Abdominal pain	Control	1	0	0
8	Abdominal pain	Experimental	0	0	0
9	Gastroenteritis viral	Control	0	0	0
10	Gastroenteritis viral	Experimental	1	0	1
11	Gastrointestinal haemorrhage	Control	0	0	0
12	Gastrointestinal haemorrhage	Experimental	1	0	1
13	Oesophageal spasm	Control	0	0	0
14	Oesophageal spasm	Experimental	1	0	1
15	Oesophagitis	Control	0	0	0
16	Oesophagitis	Experimental	1	0	0
17	Chest pain	Control	0	0	0
18	Chest pain	Experimental	1	0	0

Obs	deathsCausallyRelatedToTreatment	subjectsAffected	eutctid
1	0	1	100000004851
2	0	0	100000004851
3	0	1	100000004849
4	0	0	100000004849
5	0	0	100000004849
6	0	1	100000004849
7	0	1	100000004856
8	0	0	100000004856
9	0	0	100000004856
10	0	1	100000004856
11	0	0	100000004856
12	0	1	100000004856
13	0	0	100000004856
14	0	1	100000004856
15	0	0	100000004856
16	0	1	100000004856
17	0	0	100000004867
18	0	1	100000004867

Serious group-term level data

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Obs	term	title	occurrences	occurrencesCausallyRelatedToTreatment	deaths
19	Cholecystitis acute	Control	1	0	0
20	Cholecystitis acute	Experimental	1	0	0
21	Pulmonary vasculitis	Control	1	0	0
22	Pulmonary vasculitis	Experimental	0	0	0
23	Vasculitis	Control	1	0	1
24	Vasculitis	Experimental	2	0	2
25	Cellulitis	Control	0	0	0
26	Cellulitis	Experimental	1	1	1
27	Escherichia urinary tract infec	Control	1	0	1
28	Escherichia urinary tract infec	Experimental	0	0	0
29	Gastroenteritis Escherichia col	Control	0	0	0
30	Gastroenteritis Escherichia col	Experimental	1	0	1
31	Influenza	Control	0	0	0
32	Influenza	Experimental	1	0	1
33	Lower respiratory tract infecti	Control	1	1	1
34	Lower respiratory tract infecti	Experimental	0	0	0
35	Pneumonia	Control	0	0	0
36	Pneumonia	Experimental	3	3	1

Obs	deathsCausallyRelatedToTreatment	subjectsAffected	eutctId
19	0	1	100000004871
20	0	1	100000004871
21	0	1	100000004870
22	0	0	100000004870
23	0	1	100000004870
24	0	2	100000004870
25	0	0	100000004862
26	1	1	100000004862
27	0	1	100000004862
28	0	0	100000004862
29	0	0	100000004862
30	0	1	100000004862
31	0	0	100000004862
32	0	1	100000004862
33	1	1	100000004862
34	0	0	100000004862
35	0	0	100000004862
36	1	3	100000004862

Obs	term	title	occurrences	occurrencesCausallyRelatedToTreatment	deaths
37	Respiratory tract infection	Control	0	0	0
38	Respiratory tract infection	Experimental	2	1	2
39	Urinary tract infection	Control	0	0	0
40	Urinary tract infection	Experimental	2	1	1
41	Fall	Control	0	0	0
42	Fall	Experimental	1	0	0
43	Post procedural complication	Control	0	0	0
44	Post procedural complication	Experimental	1	0	1
45	Medical observation	Control	0	0	0
46	Medical observation	Experimental	1	0	1
47	Hyperglycaemia	Control	1	0	1
48	Hyperglycaemia	Experimental	0	0	0
49	Hyperkalaemia	Control	0	0	0
50	Hyperkalaemia	Experimental	1	0	0
51	Bladder papilloma	Control	0	0	0
52	Bladder papilloma	Experimental	1	0	0
53	Cerebrovascular accident	Control	1	0	1
54	Cerebrovascular accident	Experimental	0	0	0

Obs	deathsCausallyRelatedToTreatment	subjectsAffected	eutctId
37	0	0	100000004862
38	1	2	100000004862
39	0	0	100000004862
40	1	1	100000004862
41	0	0	100000004863
42	0	1	100000004863
43	0	0	100000004863
44	0	1	100000004863
45	0	0	100000004848
46	0	1	100000004848
47	0	1	100000004861
48	0	0	100000004861
49	0	0	100000004861
50	0	1	100000004861
51	0	0	100000004864
52	0	1	100000004864
53	0	1	100000004852
54	0	0	100000004852

Obs	term	title	occurrences	occurrencesCausallyRelatedToTreatment	deaths
55	Sleep apnoea syndrome	Control	1	0	1
56	Sleep apnoea syndrome	Experimental	0	0	0
57	Conversion disorder	Control	0	0	0
58	Conversion disorder	Experimental	1	1	1
59	Proteinuria	Control	0	0	0
60	Proteinuria	Experimental	1	0	0
61	Laryngeal stenosis	Control	0	0	0
62	Laryngeal stenosis	Experimental	4	0	1
63	Pneumomediastinum	Control	0	0	0
64	Pneumomediastinum	Experimental	1	0	0
65	Pneumonia klebsiella	Control	0	0	0
66	Pneumonia klebsiella	Experimental	1	1	1
67	Pneumonia staphylococcal	Control	0	0	0
68	Pneumonia staphylococcal	Experimental	1	1	1
69	Pneumonia viral	Control	1	0	1
70	Pneumonia viral	Experimental	0	0	0
71	Pulmonary embolism	Control	0	0	0
72	Pulmonary embolism	Experimental	1	0	0

Obs	deathsCausallyRelatedToTreatment	subjectsAffected	eutctid
55	0	1	100000004852
56	0	0	100000004852
57	0	0	100000004873
58	1	1	100000004873
59	0	0	100000004857
60	0	1	100000004857
61	0	0	100000004855
62	0	2	100000004855
63	0	0	100000004855
64	0	1	100000004855
65	0	0	100000004855
66	1	1	100000004855
67	0	0	100000004855
68	1	1	100000004855
69	0	1	100000004855
70	0	0	100000004855
71	0	0	100000004855
72	0	1	100000004855

Obs	term	title	occurrences	occurrencesCausallyRelatedToTreatment	deaths
73	Aortic valve replacement	Control	1	0	0
74	Aortic valve replacement	Experimental	0	0	0
75	Cholecystectomy	Control	0	0	0
76	Cholecystectomy	Experimental	1	0	0
77	Dacryocystorhinostomy	Control	0	0	0
78	Dacryocystorhinostomy	Experimental	1	0	0
79	Hip arthroplasty	Control	1	0	1
80	Hip arthroplasty	Experimental	2	0	2
81	Small intestinal resection	Control	0	0	0
82	Small intestinal resection	Experimental	1	0	1
83	Deep vein thrombosis	Control	1	0	1
84	Deep vein thrombosis	Experimental	3	0	2
85	Pulmonary embolism	Control	1	0	0
86	Pulmonary embolism	Experimental	1	0	1

Obs	deathsCausallyRelatedToTreatment	subjectsAffected	eutctId
73	0	1	100000004865
74	0	0	100000004865
75	0	0	100000004865
76	0	1	100000004865
77	0	0	100000004865
78	0	1	100000004865
79	0	1	100000004865
80	0	2	100000004865
81	0	0	100000004865
82	0	1	100000004865
83	0	1	100000004866
84	0	3	100000004866
85	0	1	100000004866
86	0	1	100000004866

Obs	term	title	occurrences	subjectsAffected	eutctId
1	Neutropenia	Control	0	0	100000004851
2	Neutropenia	Experimental	1	1	100000004851
3	Acute coronary syndrome	Control	1	1	100000004849
4	Acute coronary syndrome	Experimental	0	0	100000004849
5	Acute myocardial infarction	Control	0	0	100000004849
6	Acute myocardial infarction	Experimental	1	1	100000004849
7	Angina pectoris	Control	0	0	100000004849
8	Angina pectoris	Experimental	1	1	100000004849
9	Atrial fibrillation	Control	0	0	100000004849
10	Atrial fibrillation	Experimental	1	1	100000004849
11	Atrioventricular block complete	Control	0	0	100000004849
12	Atrioventricular block complete	Experimental	1	1	100000004849
13	Abdominal pain	Control	0	0	100000004856
14	Abdominal pain	Experimental	1	1	100000004856
15	Duodenal ulcer	Control	0	0	100000004856
16	Duodenal ulcer	Experimental	1	1	100000004856
17	Intestinal perforation	Control	1	1	100000004856
18	Intestinal perforation	Experimental	0	0	100000004856
19	Pyrexia	Control	1	1	100000004867
20	Pyrexia	Experimental	1	1	100000004867
21	Cholecystitis	Control	0	0	100000004871
22	Cholecystitis	Experimental	1	1	100000004871
23	Drug hypersensitivity	Control	0	0	100000004870
24	Drug hypersensitivity	Experimental	1	1	100000004870
25	Hypersensitivity	Control	0	0	100000004870
26	Hypersensitivity	Experimental	1	1	100000004870
27	Vasculitis	Control	4	3	100000004870
28	Vasculitis	Experimental	3	3	100000004870
29	Escherichia urinary tract infec	Control	0	0	100000004862
30	Escherichia urinary tract infec	Experimental	1	1	100000004862
31	Influenza	Control	0	0	100000004862
32	Influenza	Experimental	1	1	100000004862
33	Pneumonia	Control	2	2	100000004862
34	Pneumonia	Experimental	4	3	100000004862
35	Pneumonia pseudomonal	Control	0	0	100000004862
36	Pneumonia pseudomonal	Experimental	1	1	100000004862
37	Respiratory tract infection	Control	2	2	100000004862
38	Respiratory tract infection	Experimental	1	1	100000004862

Obs	term	title	occurrences	subjectsAffected	eutctId
39	Sinusitis	Control	0	0	100000004862
40	Sinusitis	Experimental	1	1	100000004862
41	Urinary tract infection	Control	0	0	100000004862
42	Urinary tract infection	Experimental	1	1	100000004862
43	Wound dehiscence	Control	0	0	100000004863
44	Wound dehiscence	Experimental	1	1	100000004863
45	Dehydration	Control	0	0	100000004861
46	Dehydration	Experimental	1	1	100000004861
47	Osteoarthritis	Control	0	0	100000004859
48	Osteoarthritis	Experimental	1	1	100000004859
49	Anal squamous cell carcinoma	Control	0	0	100000004864
50	Anal squamous cell carcinoma	Experimental	1	1	100000004864
51	Squamous cell carcinoma	Control	1	1	100000004864
52	Squamous cell carcinoma	Experimental	0	0	100000004864
53	Sleep apnoea syndrome	Control	2	1	100000004852
54	Sleep apnoea syndrome	Experimental	0	0	100000004852
55	Enterovesical fistula	Control	0	0	100000004857
56	Enterovesical fistula	Experimental	1	1	100000004857
57	Renal impairment	Control	1	1	100000004857
58	Renal impairment	Experimental	0	0	100000004857
59	Bronchospasm	Control	0	0	100000004855
60	Bronchospasm	Experimental	1	1	100000004855
61	Dyspnoea	Control	0	0	100000004855
62	Dyspnoea	Experimental	1	1	100000004855
63	Laryngeal stenosis	Control	1	1	100000004855
64	Laryngeal stenosis	Experimental	1	1	100000004855
65	Lower respiratory tract infecti	Control	1	1	100000004855
66	Lower respiratory tract infecti	Experimental	0	0	100000004855
67	Lung adenocarcinoma	Control	1	1	100000004855
68	Lung adenocarcinoma	Experimental	0	0	100000004855
69	Pneumonia	Control	1	1	100000004855
70	Pneumonia	Experimental	0	0	100000004855
71	Pneumonia streptococcal	Control	0	0	100000004855
72	Pneumonia streptococcal	Experimental	1	1	100000004855
73	Pneumonitis	Control	1	1	100000004855
74	Pneumonitis	Experimental	0	0	100000004855
75	Respiratory failure	Control	0	0	100000004855
76	Respiratory failure	Experimental	1	1	100000004855

Obs	term	title	occurrences	subjectsAffected	eutctId
77	Colostomy closure	Control	0	0	100000004865
78	Colostomy closure	Experimental	1	1	100000004865
79	Aortic dissection	Control	0	0	100000004866
80	Aortic dissection	Experimental	1	1	100000004866
81	Deep vein thrombosis	Control	0	0	100000004866
82	Deep vein thrombosis	Experimental	1	1	100000004866