16.2.2.4 Adverse Events

						Relationshi	0
Subj.	Adverse Event/Primary System Organ	Start	End	Serious		t.o	٢
No.	Class/ Preferred term		Date/Time	Event	Action taken		Outcome
043-18101-	740 ALT Increase/Investigations/Alanine	2019-05-20)	N	DOSE NOT	RELATED	NOT
01-001	aminotransferase increased				CHANGED		RECOVERED/NO T RESOLVED
	AST Increase/Investigations/Aspartat	e 2019-05-20	C	N	DOSE NOT	RELATED	NOT
	aminotransferase increased				CHANGED		RECOVERED/NO T RESOLVED
	Blood Bilirubin	2019-05-17	7	N	DOSE NOT	RELATED	NOT
	Increase/Investigations/Blood				CHANGED		RECOVERED/NO
	bilirubin increased						T RESOLVED
	Confusion/Psychiatric	2019-05-17	7	N	DOSE NOT	NOT RELATED	
	disorders/Confusional state				CHANGED		RECOVERED/NO
							T RESOLVED
	Delirium/Psychiatric	2019-05-17	7	N	DOSE NOT	NOT RELATED	
	disorders/Delirium			CHANGED		RECOVERED/NO	
							T RESOLVED
	Diarrhea/Gastrointestinal	2019-05-18	3	N	DOSE NOT	RELATED	NOT
	disorders/Diarrhoea				CHANGED		RECOVERED/NO
							T RESOLVED
	Worsening Fatigue/General disorders ar	Worsening Fatigue/General disorders and 2019-05-12			DRUG WITHDRAW	NRELATED	NOT
	administration site conditions/Fatigu	ıe					RECOVERED/NO
							T RESOLVED
	Gastroesophageal reflux	2019-05-09	9	N	DOSE NOT	RELATED	NOT
	disease/Gastrointestinal				CHANGED		RECOVERED/NO
	disorders/Gastrooesophageal reflux						T RESOLVED
	disease						
	Vomiting/Gastrointestinal	2019-05-10	O	N	DOSE NOT	RELATED	NOT
	disorders/Vomiting				CHANGED		RECOVERED/NO
							T RESOLVED
043-18101-	740 Tumor pain/Neoplasms benign, malignar	nt2019-06-24	4	N	NOT APPLICABL	ENOT RELATED	NOT
01-002	and unspecified (incl cysts and						RECOVERED/NO
	polyps)/Tumour pain						T RESOLVED

16.2.2.4 Adverse Events

Subj.	Adverse Event/Primary System Organ	Start	End	Serious		Relationshi to	p
No.	Class/ Preferred term	Date/Time	Date/Time	Event	Action taken	Study Drug	Outcome
043-18101- 01-003	-740 Worsening Abdominal pain/Gastrointestinal disorders/Abdominal pain	2019-05-20)	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Anemia/Blood and lymphatic system disorders/Anaemia	2019-05-20	2019-05-22	2 Y	DRUG WITHDRAW	NRELATED	RECOVERED/RE SOLVED
	AST Increase/Investigations/Aspartate aminotransferase increased	2019-05-20)	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Blood Bilirubin Increase/Investigations/Blood bilirubin increased	2019-05-13	3 2019-05-19	N (DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED WITH SEQUELAE
	Blood Bilirubin Increase/Investigations/Blood bilirubin increased	2019-05-20)	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Worsening Fatigue/General disorders an administration site conditions/Fatigu		5	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Hepatic Failure/Hepatobiliary disorders/Hepatic failure	2019-05-20	2019-05-26	5 Y	NOT APPLICABL	ERELATED	FATAL
	Laryngeal Mucositis/Respiratory, thoracic and mediastinal disorders/Laryngeal inflammation	iratory, 2019-05-16 2019-05-19 N D	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED		
	Laryngeal Mucositis/Respiratory, thoracic and mediastinal disorders/Laryngeal inflammation	2019-05-20)	Y	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Nausea/Gastrointestinal disorders/Nausea	2019-05-16	5	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Neutropenia/Blood and lymphatic syste disorders/Neutropenia			5 Y	DRUG WITHDRAW	NRELATED	RECOVERED/RE SOLVED
	Thrombocytopenia/Blood and lymphatic system disorders/Thrombocytopenia	2019-05-20)	Y	DRUG WITHDRAW	NRELATED	NOT RECOVERED/NO T RESOLVED

16.2.2.4 Adverse Events

						Relationshi	2
Subj.	Adverse Event/Primary System Organ	Start	End	Serious		t.o	ř
No.	Class/ Preferred term		Date/Time		Action taken		Outcome
	White blood cell decrease/Investigations/White blood cell count decreased	2019-05-20	2019-05-25	5 N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
043-18101-740 01-004	O ALT Increase/Investigations/Alanine aminotransferase increased	2019-10-04	2019-10-11	. N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	ALT Increase/Investigations/Alanine aminotransferase increased	2019-10-24	2019-12-06	5 N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Alopecia/Skin and subcutaneous tissue disorders/Alopecia	2019-11-06		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Worsening Anemia/Blood and lymphatic system disorders/Anaemia	2019-09-16	2019-09-20) N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Worsening Anemia/Blood and lymphatic system disorders/Anaemia	2019-10-30		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	AST Increase/Investigations/Aspartate aminotransferase increased	2019-10-04	2019-10-11	. N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	AST Increase/Investigations/Aspartate aminotransferase increased	2019-10-24		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Alkaline phosphatase increase/Investigations/Blood alkaline phosphatase increased		2019-12-15	5 N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED WITH SEOUELAE
	Worsening alkaline phosphatase Increase/Investigations/Blood alkaline phosphatase increased	2019-12-16 e		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Diarrhea/Gastrointestinal disorders/Diarrhoea	2019-09-13	2019-09-20) N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Diarrhea/Gastrointestinal disorders/Diarrhoea	2019-09-30	l	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED

16.2.2.4 Adverse Events

						Relationship	0
Subj.	Adverse Event/Primary System Organ	Start	End	Serious	7	to	0
No.	Class/ Preferred term	Date/Time		Event	Action taken		Outcome
	Dyspnea/Respiratory, thoracic and	2019-10-29	9	N	DOSE NOT	NOT RELATED	NOT RECOVERED/NO
	mediastinal disorders/Dyspnoea				CHANGED		T RESOLVED
	Fatigue/General disorders and	2019-09-14	1 2019-11-07	7 N	DOSE NOT	NOT RELATED	RECOVERED/RE
	administration site conditions/Fatigu		1 2019 11 0	/ 11	CHANGED	NOI KELAIED	SOLVED SOLVED
	Hypercalcemia/Metabolism and nutritic		3 2019-10-24	4 N	DOSE NOT	NOT RELATED	RECOVERED/RE
	disorders/Hypercalcaemia		, 2013 10 2		CHANGED	1,01 1,0211122	SOLVED
	Hypercalcemia/Metabolism and nutritic	n2019-12-19	9	Y		NOT RELATED	RECOVERING/R
	disorders/Hypercalcaemia						ESOLVING
	Hypoxia/Respiratory, thoracic and	2019-10-29	9	N	DOSE NOT	NOT RELATED	NOT
	mediastinal disorders/Hypoxia				CHANGED		RECOVERED/NO
							T RESOLVED
	Nausea/Gastrointestinal	2019-09-14	1	N	DOSE NOT	RELATED	NOT
	disorders/Nausea			CHANGED		RECOVERED/NO	
				_			T RESOLVED
	Pleural effusion/Respiratory, thoraci	.c2019-10-29	9 2019-11-01	LY	DOSE NOT	NOT RELATED	RECOVERED/RE
	and mediastinal disorders/Pleural				CHANGED		SOLVED
	effusion Oral mucositis/Gastrointestinal	2010 00 1	1 2019-11-05	- >7	DOGE NOW		RECOVERED/RE
	disorders/Stomatitis	2019-09-14	1 2019-11-05	O N	DOSE NOT CHANGED	RELATED	SOLVED WITH
	disorders/scomatrus				CHANGED		SEQUELAE
	Worsening oral	2019-11-06	5 2019-11-13	R M	DOSE NOT	RELATED	RECOVERED/RE
	mucositis/Gastrointestinal	2015 11 00	7 2017 11 10	J 11	CHANGED	RELATED	SOLVED
	disorders/Stomatitis				CIIIIIVOLD		DOLVED
	Weight loss/Investigations/Weight	2019-09-18	3 2019-10-11	L N	DOSE NOT	RELATED	RECOVERED/RE
	decreased				CHANGED		SOLVED
043-18101-74	O Abdominal pain/Gastrointestinal	2019-12-22	2	N	DOSE NOT	NOT RELATED	NOT
01-005	disorders/Abdominal pain				CHANGED		RECOVERED/NO
							T RESOLVED
	Alopecia/Skin and subcutaneous tissue	e 2020-01-09	9 2020-01-15	5 N	DOSE NOT	NOT RELATED	RECOVERED/RE
	disorders/Alopecia				CHANGED		SOLVED WITH
							SEQUELAE

16.2.2.4 Adverse Events

						Relationship	
_		Start	End	Serious		to	
			Date/Time		Action taken		Outcome
	- 9 -1,	2020-01-16		N	DOSE NOT	NOT RELATED	
subcı	utaneous tissue disorders/Alopecia				CHANGED		RECOVERED/NO
_							T RESOLVED
	F,	2020-01-05		N	DOSE NOT	NOT RELATED	
conne	ective tissue disorders/Bone pain				CHANGED		RECOVERED/NO
_		0000 01 10	0000 01 10				T RESOLVED
	,	2020-01-10	2020-01-16) N	DOSE NOT	NOT RELATED	RECOVERED/RE
	stations/Bronchitis	0000 01 00	0000 01 00		CHANGED		SOLVED
		2020-01-28	2020-01-30	N	DOSE NOT	NOT RELATED	RECOVERED/RE
	stations/Cystitis	0000 01 00			CHANGED		SOLVED
<u> </u>		2020-01-09		N	DOSE NOT	NOT RELATED	
diso	rders/Dysaesthesia				CHANGED		RECOVERED/NO
	/0 1 1' 1	0000 01 16	0000 01 00		D000 1100		T RESOLVED
	2 .		2020-01-28	N	DOSE NOT	RELATED	RECOVERED/RE
	nistration site conditions/Fatigue ea/Gastrointestinal	2019-12-21		27	CHANGED		SOLVED NOT
	ea/Gastrointestinai rders/Nausea	2019-12-21		N	DOSE NOT	RELATED	
also	rders/Nausea				CHANGED		RECOVERED/NO
Manh	washil same	2020 01 00	2020-02-24	NT	DOSE NOT	RELATED	T RESOLVED RECOVERED/RE
	- <u>+</u>	2020-01-09	2020-02-24	: IN	CHANGED	KELATED	SOLVED SOLVED
	eased/Investigations/Neutrophil t decreased				CHANGED		SOLVED
Feve:	r/General disorders and	2020-01-28	2020-01-29	N	DOSE NOT	RELATED	RECOVERED/RE
admin	nistration site conditions/Pyrexia				CHANGED		SOLVED
Skin	papiloma/Neoplasms benign,	2020-01-27		N	DOSE NOT	NOT RELATED	NOT
malio	gnant and unspecified (incl cysts and				CHANGED		RECOVERED/NO
poly	ps)/Skin papilloma						T RESOLVED
Vert:	igo/Ear and labyrinth	2020-02-01		N	DOSE NOT	NOT RELATED	NOT
diso	rders/Vertigo				CHANGED		RECOVERED/NO
							T RESOLVED
White	e blood cell	2020-01-09		N	DOSE NOT		NOT
decre	eased/Investigations/White blood				CHANGED		RECOVERED/NO
cell	count decreased						T RESOLVED

16.2.2.4 Adverse Events

						Relationshi	p
Subj.	Adverse Event/Primary System Organ	Start	End	Serious		to	L
No.	Class/ Preferred term	Date/Time	Date/Time	Event	Action taken	Study Drug	Outcome
043-18101-740 02-001	O Anemia/Blood and lymphatic system disorders/Anaemia	2019-11-14	4 2019-12-18	3 N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Anemia/Blood and lymphatic system disorders/Anaemia	2019-12-19	9 2020-01-03	3 N	NOT APPLICABL	ENOT RELATED	RECOVERED/RE SOLVED
	Anemia/Blood and lymphatic system disorders/Anaemia	2020-01-04	4 2020-01-06	5 N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Anemia/Blood and lymphatic system disorders/Anaemia	2020-01-0	7	N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Hypokalemia/Metabolism and nutrition disorders/Hypokalaemia	2019-12-04	4 2019-12-11	N	NOT APPLICABL	RECOVERED/RE SOLVED	
	Hypokalemia/Metabolism and nutrition disorders/Hypokalaemia	2019-12-19	9	N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Colonic Obstruction/Gastrointestinal disorders/Large intestinal obstructio		3 2019-11-27	7 Y	DRUG INTERRUPTED	NOT RELATED	RECOVERED/RE SOLVED
	Muscle Cramp - Hands/Musculoskeletal an connective tissue disorders/Muscle spasms		0	N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Small Bowel Obstruction/Gastrointestinal disorders/Small intestinal obstructio		1 2020-01-08	3 Y	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Vomiting/Gastrointestinal disorders/Vomiting	2019-11-11	1	N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
043-18101-740 02-002	O STROKE/Nervous system disorders/Cerebrovascular accident	2019-12-02	2 2019-12-06	5 Y	NOT APPLICABL	ENOT RELATED	RECOVERED/RE SOLVED
	STROKE/Nervous system disorders/Cerebrovascular accident	2019-12-0	7	N	NOT APPLICABL	ENOT RELATED	NOT RECOVERED/NO T RESOLVED
043-18101-740 03-001	O Upper Gastrointestinal Bleed/Gastrointestinal disorders/Uppe gastrointestinal haemorrhage		9 2019-10-03	3 Y	NOT APPLICABL	ENOT RELATED	RECOVERED/RE SOLVED

Protocol: 043-1810

16.2.2.4 Adverse Events

						D 3	
Subj.	Adverse Event/Primary System Organ	Start	End	Serious		Relationship to	D
No.	Class/ Preferred term		Date/Time		Action taken		Outcome
043-18101-740			3 2019-10-20		NOT APPLICABLE		
03-002	Obstruction/Gastrointestinal	2023 20 00	, 2013 10 20	-	.,01 111111101101		SOLVED
** **-	disorders/Small intestinal obstruction	า					
043-18101-740) Small Bowel	2019-10-16	5 2019-10-21	LY	NOT APPLICABLE	ENOT RELATED	RECOVERED/RE
03-003	Obstruction/Gastrointestinal						SOLVED
	disorders/Small intestinal obstruction	า					
	Small Bowel	2019-10-23	3 2019-11-11	l Y	NOT APPLICABLE	ENOT RELATED	RECOVERED/RE
	Obstruction/Gastrointestinal						SOLVED
	disorders/Small intestinal obstruction	า					
043-18101-740	Right upper back pain/Musculoskeletal	2019-10-30)	N	NOT APPLICABLE	ENOT RELATED	NOT
03-004	and connective tissue disorders/Back						RECOVERED/NO
	pain						T RESOLVED
	Right flank pain/Musculoskeletal and	2019-10-30)	N	NOT APPLICABLE	ENOT RELATED	NOT
	connective tissue disorders/Flank pair	า					RECOVERED/NO
							T RESOLVED
	Tongue Soreness/Gastrointestinal	2019-11-24	1 2019-12-30) N	DOSE NOT	NOT RELATED	RECOVERED/RE
	disorders/Glossodynia				CHANGED		SOLVED
	Numbness to left toes/Nervous system	2019-10-30)	N	NOT APPLICABLE	ENOT RELATED	
	disorders/Hypoaesthesia						RECOVERED/NO
							T RESOLVED
	Paralysis of Left Vocal Fold/Nervous		3 2020-01-28	3 Y	NOT APPLICABLE	ENOT RELATED	,
	system disorders/Vocal cord paralysis						SOLVED
	Atrial Fibrillation with rapid	2019-11-26	5 2019-12-02	2 Y	NOT APPLICABLE	ENOT RELATED	,
03-005	ventricular response/Cardiac						SOLVED
	disorders/Atrial fibrillation						
	Variceal Bleed/Gastrointestinal	2019-12-06	5 2019-12-13	3 Y	NOT APPLICABLE	ENOT RELATED	
	disorders/Oesophageal varices						SOLVED
040 10101 744	haemorrhage	0010 10 11	0010 10 1				DEGG!!EDED /DE
	Malignant obstructive	2019-12-13	3 2019-12-15) Y	NOT APPLICABLE	ENOT RELATED	
03-006	jaundice/Hepatobiliary						SOLVED
	disorders/Jaundice cholestatic						

16.2.2.4 Adverse Events

Gerla d	Advance Proof (Poline or Contra	Q b a sub-	End	Serious		Relationshi	
Subj. No.	Adverse Event/Primary System Organ Class/ Preferred term	Start Date/Time		Serious Event	Action taken	to Study Drug	Outcome
	ALT Increased/Investigations/Alanine aminotransferase increased	2020-02-25	, -	N	DRUG INTERRUPTED	RELATED	NOT RECOVERED/NO T RESOLVED
	Anxiety/Psychiatric disorders/Anxiety	2020-01-20)	N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	AST increased/Investigations/Aspartate aminotransferase increased	2020-02-25	5	N	DRUG INTERRUPTED	RELATED	NOT RECOVERED/NO T RESOLVED
	Atrial Fibrillation/Cardiac disorders/Atrial fibrillation	2020-01-13	2020-01-21	. Y	DRUG INTERRUPTED	RELATED	RECOVERED/RE SOLVED
	Alkaline phosphatase increased/Investigations/Blood alkaline phosphatase increased	2020-02-25	5	N	DRUG INTERRUPTED	RELATED	NOT RECOVERED/NO T RESOLVED
	Bronchial Stricture/Respiratory, thoracic and mediastinal disorders/Bronchostenosis	2020-02-18	:	N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Constipation/Gastrointestinal disorders/Constipation	2020-01-10	2020-02-10) N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	<pre>intermittent Constipation/Gastrointestinal disorders/Constipation</pre>	2020-01-10	1	N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Diarrhea/Gastrointestinal disorders/Diarrhoea	2020-01-24	2020-01-24	l N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Hypermagnesemia/Metabolism and nutrition disorders/Hypermagnesaemia	2020-01-13	2020-01-28	3 N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Hypocalcemia/Metabolism and nutrition disorders/Hypocalcaemia	2020-01-21	2020-01-28	3 N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Hypocalcemia/Metabolism and nutrition disorders/Hypocalcaemia	2020-02-18	1	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED

16.2.2.4 Adverse Events

Subj.	Adverse Event/Primary System Organ	Start	End	Serious		Relationship	Þ
No.	Class/ Preferred term	Date/Time		Event	Action taken		Outcome
	Hyponatremia/Metabolism and nutrition disorders/Hyponatraemia	2020-02-10)	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Hypophosphatemia/Metabolism and nutrition disorders/Hypophosphataemia		3 2020-01-21	. N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Hypophosphatemia/Metabolism and nutrition disorders/Hypophosphataemia	2020-01-21	-	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	subclinical hypothyroidism/Endocrine disorders/Hypothyroidism	2020-01-13	3	N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Insomnia/Psychiatric disorders/Insomnia	2020-01-21	-	N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Leg Cramps/Musculoskeletal and connective tissue disorders/Muscle spasms	2020-02-06	5	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Muscle cramp-left calf/Musculoskeleta and connective tissue disorders/Muscl spasms		5	N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	intermittent Nausea/Gastrointestinal disorders/Nausea	2020-01-07	7	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	nausea/Gastrointestinal disorders/Nausea	2020-01-30)	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Edema limbs (bilateral ankles)/Genera disorders and administration site conditions/Oedema peripheral	12020-02-17	7	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Paresthesia/Nervous system disorders/Paraesthesia	2020-01-14	2020-01-25	5 N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED

16.2.2.4 Adverse Events

						Relationship	O .
Subj.	Adverse Event/Primary System Organ	Start	End	Serious		to	
No.	Class/ Preferred term		Date/Time		Action taken		Outcome
	Paresthesia-Tingling - right axilla an	d2020-01-14	1 2020-01-25	N N	DOSE NOT	NOT RELATED	RECOVERED/RE
	right hip/Nervous system				CHANGED		SOLVED
	disorders/Paraesthesia	0000 00 05					
	Platelet count	2020-02-25)	N	DRUG	RELATED	NOT
	decreased/Investigations/Platelet				INTERRUPTED		RECOVERED/NO
	count decreased			_			T RESOLVED
	Vomiting/Gastrointestinal	2020-01-08	3 2020-01-08	3 N	DOSE NOT	RELATED	RECOVERED/RE
	disorders/Vomiting		_		CHANGED		SOLVED
	White blood cell count	2020-02-25)	N	DRUG	RELATED	NOT
	decreased/Investigations/White blood				INTERRUPTED		RECOVERED/NO
	cell count decreased						T RESOLVED
	Constipation/Gastrointestinal	2020-02-10	2020-02-11	L N	DOSE NOT	RELATED	RECOVERED/RE
04-003	disorders/Constipation	0000 01 00			CHANGED		SOLVED
	appetite loss/Metabolism and nutritio	n2020-01-29)	N	DOSE NOT	RELATED	NOT
	disorders/Decreased appetite				CHANGED		RECOVERED/NO
		0000 00 10					T RESOLVED
	Diarrhea/Gastrointestinal	2020-02-12	2	N	DOSE NOT	RELATED	NOT
	disorders/Diarrhoea				CHANGED		RECOVERED/NO
		0000 01 00			D000 1100		T RESOLVED
	belching after oric dose/Gastrointestinal	2020-01-28	3	N	DOSE NOT	NOT RELATED	
	,				CHANGED		RECOVERED/NO
	disorders/Eructation	2020 02 04	2000 00 10		DOGE NOE		T RESOLVED
	fatigue/General disorders and		5 2020-02-10) N	DOSE NOT	RELATED	RECOVERED/RE
	administration site conditions/Fatigu		0 0 0 0 0 0 0 10	7.77	CHANGED DRUG	NOT DELIGED	SOLVED RECOVERED/RE
	Hemoptysis/Respiratory, thoracic and	2020-02-13	3 2020-02-13	3 Y		NOT RELATED	'
	mediastinal disorders/Haemoptysis	2020 02 10		27	INTERRUPTED DOSE NOT	NOT DELIGED	SOLVED
	Subclinical hypothyroidism/Endocrine	2020-02-18)	N		NOT RELATED	
	disorders/Hypothyroidism				CHANGED		RECOVERED/NO
	Navaaa /Caataa intaatinal	2020 02 04	1 2020 02 04	~ NT	DOGE NOW	DELAMED	T RESOLVED
	Nausea/Gastrointestinal	2020-02-04	1 2020-02-06	N C	DOSE NOT	RELATED	RECOVERED/RE
	disorders/Nausea				CHANGED		SOLVED