A4: CUMMULATIVE SUMMARY TABULATION OF ALL ADVERSE EVENTS (RELATED AND UNRELATED TO STUDY TREATMENT) FROM DIDB TO 29-May-2024

SOC CTCAE v.5.0	Grade 1		Grade 2		Grade 3		Grade 4	Grade 5	UK	Total
Symptom CTCAE v 5.0 preferred term	**NR**	**R**	**NR**	**R**	**NR**	**R**	**NR**	**NR**	**NR**	
Cardiac disorders	**1**								**1**	**2**
Chest pain - cardiac									1	1
Palpitations	1									1
Ear and labyrinth disorders	**2**									**2**
Vertigo	2									2
Endocrine disorders	**1**									**1**
Hyperthyroidism	1									1
Eye disorders	**2**		**1**	**2**	**1**					**6**
Blurred vision	1									1
Eye pain	1									1
Glaucoma			1							1
Uveitis				2						2
Cataract					1					1
Gastrointestinal disorders	**62**	**27**	**17**	**11**	**4**	**7**				**128**
Abdominal pain	9		8	3		2				22
Ascites			2		1					3
Belching	1									1
Bloating	2									2
Colitis						3				3
Constipation	12		2							14
Diarrhea	10	6		1		2				19
Dry mouth		2		1						3
Duodenal stenosis					1					1
Gastroesophageal reflux disease	1									1
Ileus					1					1
Mucositis oral	2	4		1						7
Nausea	9	6	3	2						20
Oral hemorrhage	1									1
Other	3		1							4
Pancreatitis					1					1
Stomach pain	1		1							2
Vomiting	11	9		3						23
General disorders and administration site conditions	**34**	**6**	**11**	**5**	**2**	**1**				**59**
Edema face	1									1
Edema limbs	7		2							9
Fatigue	9	6	6	4		1				26
Fever	4			1						5
Malaise	2									2
Other	4									4
Pain	7		3		2					12
Hepatobiliary disorders					**1**					**1**
Other					1					1
Infections and infestations	**3**		**7**							**10**
Bacteremia			1							1
Bladder infection			1							1
Corneal infection			1							1
Laryngitis	1									1
Lip infection	1									1
Tooth infection	1									1
Urinary tract infection			4							4
Injury, poisoning and procedural complications	**1**							**1**		**2**
Other	1									1
Postoperative hemorrhage								1		1
Investigations	**6**		**5**		**5**					**16**
Alanine aminotransferase increased	1		2							3
Alkaline phosphatase increased	1		1		1					3
Aspartate aminotransferase increased	1		1							2
Neutrophil count decreased			1		3					4
Other					1					1
Platelet count decreased	2									2
Weight loss	1									1
Metabolism and nutrition disorders	**11**	**5**	**4**	**2**	**1**	**1**				**24**
Anorexia	10	4	4	2	1					21
Hyperglycemia		1				1				2
Hyperlipedemia	1									1

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SOC CTCAE v.5.0	Grade 1		Grade 2		Grade 3		Grade 4	Grade 5	UK	Total
Symptom CTCAE v 5.0 preferred term	**NR**	**R**	**NR**	**R**	**NR**	**R**	**NR**	**NR**	**NR**	
Musculoskeletal and connective tissue disorders	**5**	**1**	**2**			**1**				**9**
Arthralgia	1									1
Back pain	2									2
Generalized muscle weakness						1				1
Muscle cramp		1								1
Myalgia	1		1							2
Osteoporosis	1									1
Scoliosis			1							1
Neoplasms benign, malignant and unspecified (incl. cysts and polyps)	**1**									**1**
Other	1									1
Nervous system disorders	**6**	**2**		**2**					**1**	**11**
Amnesia	1									1
Dizziness	1									1
Dysgeusia	2	2		2						6
Headache	1									1
Hypersomnia									1	1
Peripheral sensory neuropathy	1									1
Psychiatric disorder	**3**		**1**							**4**
Depression	1		1							2
Insomnia	2									2
Renal and urinary disorders	**4**						**1**			**5**
Cystitis noninfective	1									1
Dysuria	1									1
Other							1			1
Urinary incontinence	1									1
Urinary retention	1									1
Reproductive system and breast disorders	**2**									**2**
Other	2									2
Respiratory, thoracic and mediastinal disorder	**4**									**4**
Allergic rhinitis	1									1
Cough	1									1
Dyspnea	1									1
Other	1									1
Skin and subcutaneous tissue disorders	**6**	**12**		**3**						**21**
Dry skin	2									2
Nail ridging	1									1
Other	1									1
Pruritus	2	5		1						8
Rash acneiform		2		1						3
Rash maculo-papular		5		1						6
Vascular disorders	**4**		**6**		**5**				**1**	**16**
Hematoma	1									1
Hypertension	3		6		5					14
Other									1	1
Grand Total	**158**	**53**	**54**	**25**	**19**	**10**	**1**	**1**	**3**	**324**

Abbreviations: AE adverse event, AESI adverse event of special interest, DIBD Development International Birth Date, IMP investigational medicinal product, NA not applicable, NR not related to IMP, R related to IMP, SAE serious adverse event, SOC System organ class, UK unknown

Laboratory abnormalities have been inconsistently reported and coded as AEs (as this was not a protocol requirement) and thus only partial data on laboratory modifications appear in this listing, as associated to SAEs. A separate analysis of all laboratory abnormalities has been performed directly on the lab data reported for each patient and is presented in Appendix 5.