

A3: LINE LISTINGS OF ALL ADVERSE EVENTS (RELATED AND UNRELATED TO STUDY TREATMENT) FROM DIDB TO 29-May-2024

Record ID	Signature of consent	Time of event occurrence	SOC (NCI CTCAE v.5.0)	Symptom (NCI CTCAE v.5.0 preferred term)	Severity (CTCAE v.5.0 grade)	SAE	Relation to IMPs	AESI	Relation to Gem	Relation to MIS-MWA	Duration (days)	Outcome	Patient permanently discontinued due to event?	Actions taken
1	09-05-2020	0 Pretreatment	Metabolism and nutrition disorders	Hyperlipidemia	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
1	09-05-2020	0 Pretreatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
1	09-05-2020	0 Pretreatment	Gastrointestinal disorders	Abdominal pain	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication, Further investigation performed
1	09-05-2020	On treatment	Skin and subcutaneous tissue disorders	Pruritus	Grade 1	No	R		NR	NR	UNK	Ongoing	No	None
1	09-05-2020	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	NR		NR	NR	5	Recovered	No	Medication
1	09-05-2020	On treatment	Gastrointestinal disorders	Ascites	Grade 2	No	NR		NR	NR	6	Recovered	No	Non-drug therapy
1	09-05-2020	On treatment	Gastrointestinal disorders	Ascites	Grade 2	No	NR		NR	NR	14	Recovered	No	Medication, Hospitalisation, Further investigation performed
1	09-05-2020	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	NR		NR	NR	12	Recovered	No	Medication, Further investigation performed
1	09-05-2020	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	NR		R	NR	UNK	Ongoing	No	Medication
1	09-05-2020	On treatment	Gastrointestinal disorders	Colitis	Grade 3	Yes	R	Yes	R	NR	10	Recovered	No	Medication, Hospitalisation, Further investigation performed
1	09-05-2020	On treatment	Infections and infestations	Bacteremia	Grade 2	No	NR		R	NR	7	Recovered	No	Medication, Hospitalisation, Further investigation performed
1	09-05-2020	On treatment	General disorders and administration site conditions	Fever	Grade 1	No	NR		R	NR	5	Recovered	No	Medication, Hospitalisation, Further investigation performed
1	09-05-2020	On treatment	Musculoskeletal and connective tissue disorders	Muscle cramp	Grade 1	No	R		R	NR	7	Recovered	No	None
1	09-05-2020	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	NR		R	NR	7	Recovered	No	None
1	09-05-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	NR		R	NR	7	Recovered	No	None
1	09-05-2020	On treatment	Gastrointestinal disorders	Dry mouth	Grade 2	No	R		NR	NR	0	Recovered	No	None
1	09-05-2020	On treatment	Gastrointestinal disorders	Nausea	Grade 2	No	NR		R	NR	12	Recovered	No	Medication
1	09-05-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 2	No	NR		R	NR	49	Recovered	No	None
1	09-05-2020	On treatment	Investigations	Other	Grade 3	Yes	NR		NR	NR	2	Recovered	No	Hospitalisation, Non-drug therapy, Further investigation performed
1	09-05-2020	On treatment	Investigations	Aspartate aminotransferase increased	Grade 1	No	NR		NR	NR	2	Recovered	No	Hospitalisation, Non-drug therapy
1	09-05-2020	On treatment	Investigations	Alanine aminotransferase increased	Grade 2	No	NR		NR	NR	2	Recovered	No	Hospitalisation, Non-drug therapy
1	09-05-2020	On treatment	Investigations	Alkaline phosphatase increased	Grade 3	No	NR		NR	NR	8	Recovered	No	Hospitalisation, Non-drug therapy
1	09-05-2020	On treatment	Gastrointestinal disorders	Abdominal pain	Grade 2	No	NR		NR	NR	8	Recovered	No	Medication, Hospitalisation
1	09-05-2020	On treatment	Investigations	Alanine aminotransferase increased	Grade 1	No	NR		NR	NR	6	Recovered	No	None
1	09-05-2020	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	NR		R	NR	35	Recovered	No	None
1	09-05-2020	On treatment	Investigations	Alkaline phosphatase increased	Grade 2	No	NR		NR	NR	6	Recovered	No	None
1	09-05-2020	On treatment	Neoplasms benign, malignant and unspecified (incl.	Other	Grade 1	No	NR		NR	NR	UNK	Ongoing	Yes	Further investigation performed
1	09-05-2020	On treatment	Investigations	Alkaline phosphatase increased	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
1	09-05-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	NR		R	NR	UNK	Ongoing	No	Medication
1	09-05-2020	On treatment	Investigations	Aspartate aminotransferase increased	Grade 2	No	NR		NR	NR	UNK	Ongoing	No	None
1	09-05-2020	On treatment	Investigations	Alanine aminotransferase increased	Grade 2	No	NR		NR	NR	UNK	Ongoing	No	None
1	09-05-2020	On treatment	General disorders and administration site conditions	Fatigue	Grade 2	No	NR		R	NR	UNK	Ongoing	No	None
1	09-05-2020	Post-operative	Gastrointestinal disorders	Abdominal pain	Grade 2	Yes	R		NR	R	15	Recovered	No	Medication, Hospitalisation, Further investigation performed
1	09-05-2020	Post-operative	General disorders and administration site conditions	Fever	Grade 1	No	NR		NR	R	3	Recovered	No	Medication, Hospitalisation, Further investigation performed
1	09-05-2020	Post-operative	Gastrointestinal disorders	Abdominal pain	Grade 3	Yes	R		NR	R	4	Recovered	No	Hospitalisation, Non-drug therapy, Further investigation performed
1	09-05-2020	Post-operative	Gastrointestinal disorders	Ascites	Grade 3	No	NR		NR	R	4	Recovered	No	Hospitalisation, Non-drug therapy, Further investigation performed
1	09-05-2020	Post-operative	Gastrointestinal disorders	Nausea	Grade 1	No	NR		NR	R	4	Recovered	No	Hospitalisation, Further investigation performed
1	09-05-2020	Post-operative	Gastrointestinal disorders	Vomiting	Grade 1	No	NR		NR	R	4	Recovered	No	Hospitalisation, Further investigation performed
3	25-06-2020	0 Pretreatment	Gastrointestinal disorders	Abdominal pain	Grade 1	No	NR		NR	NR	92	Recovered	No	Medication
3	25-06-2020	0 Pretreatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	0	Recovered	No	Medication
3	25-06-2020	On treatment	Skin and subcutaneous tissue disorders	Pruritus	Grade 1	No	NR		NR	NR	19	Recovered	No	None
3	25-06-2020	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	R		NR	NR	66	Recovered	No	Medication
3	25-06-2020	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	NR		NR	NR	0	Recovered	No	None
3	25-06-2020	On treatment	Metabolism and nutrition disorders	Hyperglycemia	Grade 3	No	R	Yes	NR	NR	6	Recovered	No	Medication, Further investigation performed
3	25-06-2020	On treatment	Metabolism and nutrition disorders	Hyperglycemia	Grade 1	No	R		NR	NR	UNK	Ongoing	No	Medication
3	25-06-2020	On treatment	Skin and subcutaneous tissue disorders	Pruritus	Grade 1	No	NR		NR	NR	35	Recovered	No	Medication
3	25-06-2020	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	NR		NR	NR	0	Recovered	No	Medication
3	25-06-2020	On treatment	Musculoskeletal and connective tissue disorders	Arthralgia	Grade 1	No	NR		R	NR	35	Recovered	No	None
3	25-06-2020	On treatment	Gastrointestinal disorders	Mucositis oral	Grade 1	No	R		R	NR	28	Recovered	No	None

A3: LINE LISTINGS OF ALL ADVERSE EVENTS (RELATED AND UNRELATED TO STUDY TREATMENT) FROM DIDB TO 29-May-2024

Record ID	Signature of consent	Time of event occurrence	SOC (NCI CTCAE v.5.0)	Symptom (NCI CTCAE v.5.0 preferred term)	Severity (CTCAE v.5.0 grade)	SAE	Relation to IMPs	AESI	Relation to Gem	Relation to MIS-MWA	Duration (days)	Outcome	Patient permanently discontinued due to event?	Actions taken
3	25-06-2020	On treatment	Gastrointestinal disorders	Abdominal pain	Grade 2	No	R		R	NR	20	Recovered	No	Medication
3	25-06-2020	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	R		R	NR	28	Recovered	No	None
3	25-06-2020	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	NR		R	NR	28	Recovered	No	None
3	25-06-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	NR		R	NR	28	Recovered	No	None
3	25-06-2020	On treatment	Gastrointestinal disorders	Mucositis oral	Grade 1	No	R		R	NR	28	Recovered	No	None
3	25-06-2020	On treatment	Gastrointestinal disorders	Abdominal pain	Grade 2	No	R		R	NR	28	Recovered	No	None
3	25-06-2020	On treatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	10	Recovered	No	None
3	25-06-2020	On treatment	Gastrointestinal disorders	Colitis	Grade 3	Yes	R	Yes	NR	NR	5	Recovered	Yes	Medication,Hospitalisation,Further investigation performed
3	25-06-2020	On treatment	Gastrointestinal disorders	Diarrhea	Grade 3	No	R	Yes	NR	NR	3	Recovered	Yes	Medication,Hospitalisation,Further investigation performed
3	25-06-2020	Post-operative	Gastrointestinal disorders	Colitis	Grade 3	Yes	R	Yes	NR	NR	4	Recovered	No	Medication,Hospitalisation,Further investigation performed
3	25-06-2020	Post-operative	General disorders and administration site conditions	Fever	Grade 2	No	R		NR	NR	4	Recovered	No	Medication,Hospitalisation,Further investigation performed
3	25-06-2020	Post-operative	Gastrointestinal disorders	Diarrhea	Grade 3	No	R	Yes	NR	NR	1	Recovered	No	Medication,Hospitalisation,Further investigation performed
3	25-06-2020	Post-operative	Gastrointestinal disorders	Abdominal pain	Grade 3	No	R		NR	NR	3	Recovered	No	Medication,Hospitalisation,Further investigation performed
3	25-06-2020	Post-operative	Gastrointestinal disorders	Nausea	Grade 1	No	R		NR	NR	0	Recovered	No	Medication
6	16-09-2020	0 Pretreatment	Musculoskeletal and connective tissue disorders	Osteoporosis	Grade 1	No	NR		NR	NA	UNK	Not yet recovered a	No	None
6	16-09-2020	0 Pretreatment	Psychiatric disorder	Depression	Grade 1	No	NR		NR	NA	UNK	Not yet recovered a	No	None
6	16-09-2020	0 Pretreatment	Reproductive system and breast disorders	Other	Grade 1	No	NR		NR	NA	UNK	Not yet recovered a	No	None
6	16-09-2020	On treatment	Skin and subcutaneous tissue disorders	Pruritus	Grade 1	No	R		NR	NR	90	Recovered	No	Medication
6	16-09-2020	On treatment	Skin and subcutaneous tissue disorders	Rash maculo-papular	Grade 1	No	R		R	NR	199	Recovered	No	None
6	16-09-2020	On treatment	Gastrointestinal disorders	Dry mouth	Grade 1	No	R		R	NR	UNK	Ongoing	No	None
6	16-09-2020	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	NR		NR	R	38	Recovered	No	None
6	16-09-2020	On treatment	Gastrointestinal disorders	Duodenal stenosis	Grade 3	Yes	NR		NR	NR	7	Recovered	No	Hospitalisation,Non-drug therapy
6	16-09-2020	On treatment	Gastrointestinal disorders	Abdominal pain	Grade 2	No	NR		NR	NR	6	Recovered	No	Medication
6	16-09-2020	On treatment	Gastrointestinal disorders	Nausea	Grade 2	No	NR		NR	NR	91	Recovered	No	None
6	16-09-2020	On treatment	Gastrointestinal disorders	Other	Grade 2	No	NR		NR	NR	7	Recovered	No	None
6	16-09-2020	On treatment	Gastrointestinal disorders	Stomach pain	Grade 2	No	NR		NR	NR	7	Recovered	No	Non-drug therapy
6	16-09-2020	On treatment	General disorders and administration site conditions	Fatigue	Grade 2	No	NR		R	NR	53	Recovered	No	None
6	16-09-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 2	No	NR		NR	NR	6	Recovered	No	Hospitalisation,Non-drug therapy
6	16-09-2020	On treatment	Skin and subcutaneous tissue disorders	Rash maculo-papular	Grade 2	No	R	Yes	R	NR	19	Recovered	No	Medication
6	16-09-2020	On treatment	Skin and subcutaneous tissue disorders	Pruritus	Grade 2	No	R		NR	NR	20	Recovered	No	Medication
6	16-09-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	NR		NR	NR	83	Recovered	No	Non-drug therapy
6	16-09-2020	On treatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
6	16-09-2020	On treatment	Skin and subcutaneous tissue disorders	Rash maculo-papular	Grade 1	No	R		NR	NR	7	Recovered	No	Medication
6	16-09-2020	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	R		R	NR	7	Recovered	No	Medication
6	16-09-2020	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	R		R	NR	18	Recovered	No	Medication
6	16-09-2020	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
6	16-09-2020	On treatment	Psychiatric disorder	Depression	Grade 2	No	NR		NR	NR	UNK	Ongoing	No	None
6	16-09-2020	On treatment	Nervous system disorders	Dysgeusia	Grade 1	No	NR		R	NR	UNK	Ongoing	No	None
6	16-09-2020	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	NR		NR	NR	71	Recovered	No	None
6	16-09-2020	On treatment	Skin and subcutaneous tissue disorders	Rash maculo-papular	Grade 1	No	R		NR	NR	UNK	Ongoing	No	None
6	16-09-2020	On treatment	Gastrointestinal disorders	Constipation	Grade 2	No	NR		NR	NR	UNK	Ongoing	No	Medication
6	16-09-2020	On treatment	Skin and subcutaneous tissue disorders	Rash maculo-papular	Grade 1	No	R		NR	NR	7	Recovered	No	Medication
6	16-09-2020	On treatment	Nervous system disorders	Headache	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
6	16-09-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 2	No	NR		NR	NR	90	Recovered	No	Medication
6	16-09-2020	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
6	16-09-2020	On treatment	Skin and subcutaneous tissue disorders	Rash maculo-papular	Grade 1	No	R		NR	NR	35	Recovered	No	Medication
6	16-09-2020	On treatment	Gastrointestinal disorders	Abdominal pain	Grade 2	No	NR		NR	NR	6	Recovered	No	Medication
6	16-09-2020	On treatment	General disorders and administration site conditions	Fatigue	Grade 2	No	NR		NR	NR	UNK	Ongoing	No	None
6	16-09-2020	On treatment	General disorders and administration site conditions	Edema limbs	Grade 1	No	NR		NR	NR	28	Recovered	No	Medication

A3: LINE LISTINGS OF ALL ADVERSE EVENTS (RELATED AND UNRELATED TO STUDY TREATMENT) FROM DIDB TO 29-May-2024

Record ID	Signature of consent	Time of event occurrence	SOC (NCI CTCAE v.5.0)	Symptom (NCI CTCAE v.5.0 preferred term)	Severity (CTCAE v.5.0 grade)	SAE	Relation to IMPs	AESI	Relation to Gem	Relation to MIS-MWA	Duration (days)	Outcome	Patient permanently discontinued due to event?	Actions taken
6	16-09-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 3	No	NR		NR	NR	UNK	Ongoing	No	None
6	16-09-2020	Post-operative	Gastrointestinal disorders	Abdominal pain	Grade 2	No	NR		NR	R	13	Recovered	No	Medication
6	16-09-2020	Post-operative	General disorders and administration site conditions	Fatigue	Grade 2	No	NR		NR	R	13	Recovered	No	None
7	17-09-2020	0 Pretreatment	Reproductive system and breast disorders	Other	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
7	17-09-2020	0 Pretreatment	Gastrointestinal disorders	Abdominal pain	Grade 1	No	NR		NR	NR	183	Recovered	No	Medication, Further investigation performed
7	17-09-2020	0 Pretreatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	NR		NR	NR	30	Recovered	No	None
7	17-09-2020	0 Pretreatment	Infections and infestations	Tooth infection	Grade 1	No	NR		NR	NR	30	Recovered	No	Medication
7	17-09-2020	0 Pretreatment	General disorders and administration site conditions	Fatigue	Grade 2	No	NR		NR	NR	30	Recovered	No	None
7	17-09-2020	0 Pretreatment	Gastrointestinal disorders	Other	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
8	23-09-2020	0 Pretreatment	General disorders and administration site conditions	Fatigue	Grade 1	No	NR		NR	NR	194	Recovered	No	None
8	23-09-2020	0 Pretreatment	Gastrointestinal disorders	Abdominal pain	Grade 1	No	NR		NR	NA	171	Recovered	No	Further investigation performed
8	23-09-2020	0 Pretreatment	Gastrointestinal disorders	Gastroesophageal reflux disease	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
8	23-09-2020	On treatment	Skin and subcutaneous tissue disorders	Pruritus	Grade 1	No	R		NR	NR	151	Recovered	No	None
8	23-09-2020	On treatment	Skin and subcutaneous tissue disorders	Rash acneiform	Grade 1	No	R		NR	NR	151	Recovered	No	Medication
9	07-10-2020	0 Pretreatment	Eye disorders	Glaucoma	Grade 2	No	NR		NR	NR	UNK	Ongoing	No	Medication, Non-drug therapy
9	07-10-2020	0 Pretreatment	Renal and urinary disorders	Other	Grade 4	No	NR		NR	NR	UNK	Ongoing	No	Non-drug therapy, Further investigation performed
9	07-10-2020	0 Pretreatment	Respiratory, thoracic and mediastinal disorder	Allergic rhinitis	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
9	07-10-2020	On treatment	Vascular disorders	Hypertension	Grade 3	No	NR		NR	NR	57	Recovered	No	Medication
9	07-10-2020	On treatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	94	Recovered	No	Medication
9	07-10-2020	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	NR		NR	NR	71	Recovered	No	Medication
9	07-10-2020	On treatment	Injury, poisoning and procedural complications	Other	Grade 1	No	NR		NR	NR	56	Recovered	No	Medication
9	07-10-2020	On treatment	General disorders and administration site conditions	Edema limbs	Grade 1	No	NR		NR	NR	14	Recovered	No	None
9	07-10-2020	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	NR		R	NR	UNK	Ongoing	No	None
9	07-10-2020	On treatment	Skin and subcutaneous tissue disorders	Dry skin	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
9	07-10-2020	On treatment	Vascular disorders	Hypertension	Grade 2	No	NR		NR	NR	10	Recovered	No	Medication
9	07-10-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	NR		R	NR	14	Recovered	No	None
9	07-10-2020	On treatment	Investigations	Neutrophil count decreased	Grade 3	No	NR		R	NR	6	Recovered	No	Other
9	07-10-2020	On treatment	General disorders and administration site conditions	Fever	Grade 1	Yes	NR		R	NR	6	Recovered	No	Hospitalisation, Further investigation performed
9	07-10-2020	On treatment	General disorders and administration site conditions	Malaise	Grade 1	No	NR		R	NR	4	Recovered	No	None
9	07-10-2020	On treatment	Skin and subcutaneous tissue disorders	Rash acneiform	Grade 2	No	R	Yes	R	NR	11	Recovered	No	Medication, Further investigation performed
9	07-10-2020	On treatment	General disorders and administration site conditions	Edema limbs	Grade 1	No	NR		NR	NR	24	Recovered	No	Non-drug therapy
9	07-10-2020	On treatment	Gastrointestinal disorders	Mucositis oral	Grade 1	No	NR		R	NR	22	Recovered	No	Medication
9	07-10-2020	On treatment	Eye disorders	Uveitis	Grade 2	No	R	Yes	NR	NR	28	Recovered with seq	No	Medication
9	07-10-2020	On treatment	Respiratory, thoracic and mediastinal disorder	Other	Grade 1	No	NR		NR	NR	7	Recovered	No	None
9	07-10-2020	On treatment	General disorders and administration site conditions	Malaise	Grade 1	No	NR		R	NR	UNK	Ongoing	No	None
9	07-10-2020	On treatment	Infections and infestations	Urinary tract infection	Grade 2	No	NR		NR	NR	5	Recovered	No	Medication
9	07-10-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	NR		R	NR	273	Recovered	No	None
9	07-10-2020	On treatment	Infections and infestations	Urinary tract infection	Grade 2	No	NR		NR	NR	13	Recovered	No	Medication
9	07-10-2020	On treatment	Investigations	Neutrophil count decreased	Grade 2	No	NR		R	NR	14	Recovered	No	None
9	07-10-2020	On treatment	Infections and infestations	Urinary tract infection	Grade 2	No	NR		NR	NR	6	Recovered	No	Medication
9	07-10-2020	On treatment	Infections and infestations	Urinary tract infection	Grade 2	No	NR		NR	NR	4	Recovered	No	Medication
9	07-10-2020	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	NR		NR	NR	4	Recovered	No	None
9	07-10-2020	On treatment	Investigations	Neutrophil count decreased	Grade 3	No	NR		R	NR	13	Recovered	No	None
9	07-10-2020	On treatment	Eye disorders	Cataract,	Grade 3	No	NR		NR	NR	332	Recovered	No	Hospitalisation, Non-drug therapy
9	07-10-2020	On treatment	General disorders and administration site conditions	Edema limbs	Grade 2	No	NR		R	NR	18	Recovered	No	Medication, Non-drug therapy
9	07-10-2020	On treatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	55	Recovered	No	Medication
9	07-10-2020	On treatment	General disorders and administration site conditions	Edema limbs	Grade 1	No	NR		R	NR	27	Recovered	No	None
9	07-10-2020	On treatment	General disorders and administration site conditions	Other	Grade 1	No	NR		NR	NR	1	Recovered	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	NR		NR	NR	22	Recovered	No	None

A3: LINE LISTINGS OF ALL ADVERSE EVENTS (RELATED AND UNRELATED TO STUDY TREATMENT) FROM DIDB TO 29-May-2024

Record ID	Signature of consent	Time of event occurrence	SOC (NCI CTCAE v.5.0)	Symptom (NCI CTCAE v.5.0 preferred term)	Severity (CTCAE v.5.0 grade)	SAE	Relation to IMPs	AESI	Relation to Gem	Relation to MIS-MWA	Duration (days)	Outcome	Patient permanently discontinued due to event?	Actions taken
9	07-10-2020	On treatment	Cardiac disorders	Palpitations	Grade 1	No	NR		NR	NR	0	Recovered	No	Further investigation performed
9	07-10-2020	On treatment	Vascular disorders	Hypertension	Grade 3	No	NR		NR	NR	7	Recovered	No	Further investigation performed
9	07-10-2020	On treatment	Renal and urinary disorders	Cystitis noninfective	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
9	07-10-2020	On treatment	Gastrointestinal disorders	Mucositis oral	Grade 1	No	NR		R	NR	25	Recovered	No	None
9	07-10-2020	On treatment	Infections and infestations	Laryngitis	Grade 1	No	NR		NR	NR	7	Recovered	No	None
9	07-10-2020	On treatment	Musculoskeletal and connective tissue disorders	Back pain	Grade 1	No	NR		NR	NR	196	Recovered	No	Medication
9	07-10-2020	On treatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	196	Recovered	No	Medication
9	07-10-2020	On treatment	Gastrointestinal disorders	Stomach pain	Grade 1	No	NR		NR	NR	91	Recovered	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	NR		NR	NR	0	Recovered	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Belching	Grade 1	No	NR		NR	NR	8	Recovered	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	NR		NR	NR	8	Recovered	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	NR		NR	NR	1	Recovered	No	None
9	07-10-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	NR		R	NR	78	Recovered	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	NR		NR	NR	27	Recovered	No	None
9	07-10-2020	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	NR		R	NR	UNK	Ongoing	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	NR		NR	NR	3	Recovered	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	NR		NR	NR	0	Recovered	No	Medication
9	07-10-2020	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	NR		NR	NR	1	Recovered	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	NR		NR	NR	12	Recovered	No	None
9	07-10-2020	On treatment	Eye disorders	Eye pain	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
9	07-10-2020	On treatment	Eye disorders	Blurred vision	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
9	07-10-2020	On treatment	Infections and infestations	Corneal infection	Grade 2	No	NR		NR	NR	UNK	Ongoing	No	Medication
9	07-10-2020	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	NR		NR	NR	24	Recovered	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	NR		NR	NR	21	Recovered	No	None
9	07-10-2020	On treatment	Investigations	Neutrophil count decreased	Grade 3	No	NR		R	NR	7	Recovered	No	Other
9	07-10-2020	On treatment	Infections and infestations	Bladder infection	Grade 2	No	NR		NR	NR	20	Recovered	No	Medication
9	07-10-2020	On treatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	48	Recovered	No	Medication
9	07-10-2020	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	NR		NR	NR	61	Recovered	No	None,Medication
9	07-10-2020	On treatment	Vascular disorders	Hypertension	Grade 3	No	NR		NR	NR	14	Recovered	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Abdominal pain	Grade 2	No	NR		NR	NR	6	Recovered	No	None
9	07-10-2020	On treatment	Vascular disorders	Hypertension	Grade 2	No	NR		NR	NR	34	Recovered	No	None
9	07-10-2020	On treatment	Nervous system disorders	Amnesia	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
9	07-10-2020	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	R		R	NR	1	Recovered	No	Medication
9	07-10-2020	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	NR		NR	NR	7	Recovered	No	Medication
9	07-10-2020	On treatment	Vascular disorders	Hypertension	Grade 3	No	NR		NR	NR	UNK	Ongoing	No	None
9	07-10-2020	On treatment	Eye disorders	Uveitis	Grade 2	No	R	Yes	NR	NR	UNK	Ongoing	No	Medication
9	07-10-2020	On treatment	Renal and urinary disorders	Urinary incontinence	Grade 1	No	NR		NR	NR	UNK	Recovered	No	None
9	07-10-2020	Post-operative	Gastrointestinal disorders	Bloating	Grade 1	No	NR		NR	NR	77	Recovered	No	None
10	05-02-2021	0 Pretreatment	Endocrine disorders	Hyperthyroidism	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
10	05-02-2021	0 Pretreatment	Vascular disorders	Hypertension	Grade 1	No	NR		NR	NR	UNK	Recovered	No	Medication
11	26-03-2021	0 Pretreatment	Gastrointestinal disorders	Abdominal pain	Grade 2	No	NR		NR	NR	173	Not yet recovered a	No	Medication
11	26-03-2021	0 Pretreatment	Musculoskeletal and connective tissue disorders	Scoliosis	Grade 2	No	NR		NR	NR	UNK	Not yet recovered a	No	Medication
11	26-03-2021	Post-operative	Gastrointestinal disorders	Ileus	Grade 3	Yes	NR		NR	R	8	Recovered	No	Medication,Hospitalisation
11	26-03-2021	Post-operative	Injury, poisoning and procedural complications	Postoperative hemorrhage	Grade 5	Yes	NR		NR	R	5	Fatal	Yes	Medication,Hospitalisation,Further investigation performed
12	02-07-2021	0 Pretreatment	General disorders and administration site conditions	Pain	Grade 1	No	NR		NR	NR	UNK	Recovered	No	Medication
12	02-07-2021	On treatment	Skin and subcutaneous tissue disorders	Rash acneiform	Grade 1	No	R		R	NR	298	Recovered	No	None
12	02-07-2021	On treatment	Gastrointestinal disorders	Abdominal pain	Grade 1	No	NR		NR	NR	21	Recovered	No	Medication
12	02-07-2021	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
12	02-07-2021	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	R		R	NR	20	Recovered	No	None

A3: LINE LISTINGS OF ALL ADVERSE EVENTS (RELATED AND UNRELATED TO STUDY TREATMENT) FROM DIDB TO 29-May-2024

Record ID	Signature of consent	Time of event occurrence	SOC (NCI CTCAE v.5.0)	Symptom (NCI CTCAE v.5.0 preferred term)	Severity (CTCAE v.5.0 grade)	SAE	Relation to IMPs	AESI	Relation to Gem	Relation to MIS-MWA	Duration (days)	Outcome	Patient permanently discontinued due to event?	Actions taken
12	02-07-2021	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	R		R	NR	58	Recovered	No	None
12	02-07-2021	On treatment	Skin and subcutaneous tissue disorders	Nail ridging	Grade 1	No	NR		NR	NR	146	Recovered	No	None
12	02-07-2021	On treatment	General disorders and administration site conditions	Pain	Grade 1	No	NR		NR	NR	40	Recovered	No	None
12	02-07-2021	On treatment	General disorders and administration site conditions	Fatigue	Grade 2	No	R		R	NR	36	Recovered	No	None
12	02-07-2021	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	R		R	NR	UNK	Ongoing	No	Medication
12	02-07-2021	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	R		R	NR	30	Recovered	No	None
12	02-07-2021	On treatment	Gastrointestinal disorders	Abdominal pain	Grade 1	No	NR		NR	NR	70	Recovered	No	Medication
12	02-07-2021	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	R		R	NR	102	Recovered	No	None
12	02-07-2021	On treatment	General disorders and administration site conditions	Other	Grade 1	No	NR		NR	NR	20	Recovered	No	None
12	02-07-2021	On treatment	General disorders and administration site conditions	Pain	Grade 1	No	NR		NR	NR	13	Recovered	No	None
12	02-07-2021	On treatment	Gastrointestinal disorders	Bloating	Grade 1	No	NR		NR	NR	28	Recovered	No	None
12	02-07-2021	On treatment	Respiratory, thoracic and mediastinal disorder	Cough	Grade 1	No	NR		NR	NR	16	Recovered	No	None
12	02-07-2021	On treatment	General disorders and administration site conditions	Pain	Grade 1	No	NR		R	NR	104	Recovered	No	Other
12	02-07-2021	On treatment	Gastrointestinal disorders	Other	Grade 1	No	NR		NR	NR	16	Recovered	No	None
12	02-07-2021	On treatment	Musculoskeletal and connective tissue disorders	Myalgia	Grade 2	No	NR		NR	NR	62	Recovered	No	None
12	02-07-2021	On treatment	Respiratory, thoracic and mediastinal disorder	Dyspnea	Grade 1	No	NR		NR	NR	7	Recovered	No	None
12	02-07-2021	On treatment	General disorders and administration site conditions	Pain	Grade 1	No	NR		R	NR	48	Recovered	No	Medication
12	02-07-2021	On treatment	General disorders and administration site conditions	Edema limbs	Grade 1	No	NR		R	NR	76	Recovered	No	Non-drug therapy,Other
12	02-07-2021	On treatment	General disorders and administration site conditions	Edema face	Grade 1	No	NR		NR	NR	23	Recovered	No	None
12	02-07-2021	On treatment	Nervous system disorders	Peripheral sensory neuropathy	Grade 1	No	NR		NR	NR	7	Recovered	No	None
12	02-07-2021	On treatment	Nervous system disorders	Dysgeusia	Grade 1	No	NR		NR	NR	6	Recovered	No	None
12	02-07-2021	On treatment	Gastrointestinal disorders	Other	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
12	02-07-2021	On treatment	Musculoskeletal and connective tissue disorders	Myalgia	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
12	02-07-2021	On treatment	Gastrointestinal disorders	Mucositis oral	Grade 2	No	R		R	NR	28	Recovered	No	None
12	02-07-2021	On treatment	Investigations	Platelet count decreased	Grade 1	No	NR		R	NR	14	Recovered	No	None
12	02-07-2021	On treatment	Skin and subcutaneous tissue disorders	Pruritus	Grade 1	No	R		R	NR	13	Recovered	No	None
12	02-07-2021	On treatment	Vascular disorders	Hypertension	Grade 2	No	NR		NR	NR	1	Recovered	No	None
12	02-07-2021	On treatment	Gastrointestinal disorders	Mucositis oral	Grade 1	No	R		R	NR	13	Recovered	No	None
12	02-07-2021	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	NR		R	NR	UNK	Ongoing	No	None
12	02-07-2021	On treatment	General disorders and administration site conditions	Pain	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
12	02-07-2021	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	NR		NR	NR	0	Recovered	No	Medication
12	02-07-2021	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	NR		NR	NR	0	Recovered	No	Medication
12	02-07-2021	On treatment	Investigations	Platelet count decreased	Grade 1	No	NR		R	NR	47	Recovered	No	None
12	02-07-2021	On treatment	Nervous system disorders	Dysgeusia	Grade 2	No	R		R	NR	UNK	Ongoing	No	None
12	02-07-2021	On treatment	General disorders and administration site conditions	Pain	Grade 2	Yes	NR		NR	NR	15	Recovered	No	Medication,Hospitalisation,Further investigation performed
12	02-07-2021	On treatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	37	Recovered	No	Medication
12	02-07-2021	On treatment	Gastrointestinal disorders	Nausea	Grade 2	No	NR		NR	NR	37	Recovered	No	Medication
12	02-07-2021	On treatment	Investigations	Weight loss	Grade 1	No	NR		NR	NR	37	Recovered	No	None
12	02-07-2021	On treatment	General disorders and administration site conditions	Other	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Further investigation performed
12	02-07-2021	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	NR		NR	NR	28	Recovered	No	Medication
12	02-07-2021	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
12	02-07-2021	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 2	No	NR		NR	NR	UNK	Ongoing	No	None
12	02-07-2021	On treatment	Vascular disorders	Hypertension	Grade 3	No	NR		NR	NR	UNK	Ongoing	No	Medication
12	02-07-2021	On treatment	Gastrointestinal disorders	Abdominal pain	Grade 2	Yes	NR		NR	NA	6	Recovered	No	Medication,Hospitalisation,Further investigation performed
12	02-07-2021	On treatment	Vascular disorders	Hypertension	Grade 2	No	NR		NR	NR	UNK	Ongoing	No	Medication
14	16-02-2022	0 Pretreatment	Gastrointestinal disorders	Abdominal pain	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
14	16-02-2022	0 Pretreatment	Vascular disorders	Other	UK	No	NR		NR	NR	UNK	Ongoing	No	Medication
14	16-02-2022	0 Pretreatment	Cardiac disorders	Chest pain - cardiac	UK	No	NR		NR	NR	UNK	Ongoing	No	Medication
14	16-02-2022	0 Pretreatment	Nervous system disorders	Hypersomnia	UK	No	NR		NR	NR	UNK	Ongoing	No	Medication

A3: LINE LISTINGS OF ALL ADVERSE EVENTS (RELATED AND UNRELATED TO STUDY TREATMENT) FROM DIDB TO 29-May-2024

Record ID	Signature of consent	Time of event occurrence	SOC (NCI CTCAE v.5.0)	Symptom (NCI CTCAE v.5.0 preferred term)	Severity (CTCAE v.5.0 grade)	SAE	Relation to IMPs	AESI	Relation to Gem	Relation to MIS-MWA	Duration (days)	Outcome	Patient permanently discontinued due to event?	Actions taken
14	16-02-2022	On treatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
14	16-02-2022	On treatment	Renal and urinary disorders	Urinary retention	Grade 1	No	NR		NR	NR	0	Recovered	No	Medication,Non-drug therapy,Further investigation performed
14	16-02-2022	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	R		NR	NR	UNK	Ongoing	No	None
15	16-05-2022	0 Pretreatment	Gastrointestinal disorders	Pancreatitis	Grade 3	Yes	NR		NR	NR	15	Recovered	No	Medication,Hospitalisation,Further investigation performed
15	16-05-2022	0 Pretreatment	Gastrointestinal disorders	Abdominal pain	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
15	16-05-2022	0 Pretreatment	Psychiatric disorder	Insomnia	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
15	16-05-2022	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	NR		NR	NR	73	Recovered	No	None
15	16-05-2022	On treatment	Ear and labyrinth disorders	Vertigo	Grade 1	No	NR		NR	NR	32	Recovered	No	None
15	16-05-2022	On treatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
15	16-05-2022	On treatment	General disorders and administration site conditions	Fever	Grade 1	No	NR		NR	NR	3	Recovered	No	Medication
15	16-05-2022	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	NR		NR	NR	28	Recovered	No	None
15	16-05-2022	On treatment	Vascular disorders	Hypertension	Grade 1	No	NR		NR	NR	63	Recovered	No	None
15	16-05-2022	On treatment	Skin and subcutaneous tissue disorders	Pruritus	Grade 1	No	R		R	NR	90	Recovered	No	Medication
15	16-05-2022	On treatment	Gastrointestinal disorders	Oral hemorrhage	Grade 1	No	NR		NR	NR	77	Recovered	No	None
15	16-05-2022	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	R		R	NR	19	Recovered	No	Medication
15	16-05-2022	On treatment	Ear and labyrinth disorders	Vertigo	Grade 1	No	NR		NR	NR	76	Recovered	No	None
15	16-05-2022	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	R		R	NR	13	Recovered	No	Medication
15	16-05-2022	On treatment	General disorders and administration site conditions	Fatigue	Grade 2	No	R		NR	NR	63	Recovered	No	None
15	16-05-2022	On treatment	Gastrointestinal disorders	Nausea	Grade 2	No	R		R	NR	35	Recovered	No	Medication
15	16-05-2022	On treatment	Gastrointestinal disorders	Vomiting	Grade 2		R		R	NR	7	Recovered	No	Medication
15	16-05-2022	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 2	No	R		NR	NR	49	Recovered	No	Other
15	16-05-2022	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	NR		NR	NR	2	Recovered	No	None
15	16-05-2022	On treatment	Vascular disorders	Hypertension	Grade 2	No	NR		NR	NR	21	Recovered	No	None
15	16-05-2022	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	R		R	NR	6	Recovered	No	Medication
15	16-05-2022	On treatment	Gastrointestinal disorders	Vomiting	Grade 2	No	R		R	NR	15	Recovered	No	Medication
15	16-05-2022	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	R		R	NR	14	Recovered	No	Medication
15	16-05-2022	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	R		R	NR	14	Recovered	No	Medication
15	16-05-2022	On treatment	Vascular disorders	Hypertension	Grade 1	No	NR		NR	NR	14	Recovered	No	None
15	16-05-2022	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	R		NR	NR	146	Recovered	No	Other
15	16-05-2022	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	R		NR	NR	42	Recovered	No	None
15	16-05-2022	On treatment	Vascular disorders	Hypertension	Grade 2	No	NR		NR	NR	14	Recovered	No	None
15	16-05-2022	On treatment	General disorders and administration site conditions	Edema limbs	Grade 1	No	NR		R	NR	49	Recovered	No	Medication
15	16-05-2022	On treatment	Skin and subcutaneous tissue disorders	Other	Grade 1	No	NR		NR	NR	35	Recovered	No	None
15	16-05-2022	On treatment	Vascular disorders	Hematoma	Grade 1	No	NR		NR	NR	20	Recovered	No	None
15	16-05-2022	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	R		R	NR	20	Recovered	No	None
15	16-05-2022	On treatment	Nervous system disorders	Dysgeusia	Grade 1	No	R		R	NR	UNK	Ongoing	No	None
15	16-05-2022	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	R		R	NR	56	Recovered	No	None
15	16-05-2022	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	R		R	NR	13	Recovered	No	None
15	16-05-2022	On treatment	Gastrointestinal disorders	Vomiting	Grade 2	No	R		R	NR	14	Recovered	No	None
15	16-05-2022	On treatment	General disorders and administration site conditions	Fatigue	Grade 2	No	R		R	NR	42	Recovered	No	Other
15	16-05-2022	On treatment	Gastrointestinal disorders	Abdominal pain	Grade 1	No	NR		NR	NR	2	Recovered	No	Medication
15	16-05-2022	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	R		R	NR	6	Recovered	No	Other
15	16-05-2022	On treatment	Gastrointestinal disorders	Vomiting	Grade 1	No	R		R	NR	8	Recovered	No	None
15	16-05-2022	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	R		R	NR	UNK	Ongoing	No	None
15	16-05-2022	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	R		R	NR	8	Recovered	No	None
15	16-05-2022	On treatment	Musculoskeletal and connective tissue disorders	Back pain	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
15	16-05-2022	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	R		R	NR	56	Recovered	No	Other
15	16-05-2022	On treatment	General disorders and administration site conditions	Fatigue	Grade 2	No	R		R	NR	27	Recovered	No	Other
15	16-05-2022	On treatment	General disorders and administration site conditions	Fatigue	Grade 3	No	R		R	NR	UNK	Ongoing	No	Other

A3: LINE LISTINGS OF ALL ADVERSE EVENTS (RELATED AND UNRELATED TO STUDY TREATMENT) FROM DIBD TO 29-May-2024

Record ID	Signature of consent	Time of event occurrence	SOC (NCI CTCAE v.5.0)	Symptom (NCI CTCAE v.5.0 preferred term)	Severity (CTCAE v.5.0 grade)	SAE	Relation to IMPs	AESI	Relation to Gem	Relation to MIS-MWA	Duration (days)	Outcome	Patient permanently discontinued due to event?	Actions taken
15	16-05-2022	On treatment	Gastrointestinal disorders	Abdominal pain	Grade 2	No	NR		NR	NR	UNK	Ongoing	No	Medication
15	16-05-2022	Safety follow-up	General disorders and administration site conditions	Pain	Grade 3	No	NR		NR	NR	UNK	Ongoing	No	Medication
15	16-05-2022	Safety follow-up	Hepatobiliary disorders	Other	Grade 3	Yes	NR		NR	NR	8	Recovered	No	Hospitalisation
16	14-06-2022	0 Pretreatment	Renal and urinary disorders	Dysuria	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Further investigation performed
16	14-06-2022	0 Pretreatment	General disorders and administration site conditions	Pain	Grade 2	No	NR		NR	NR	UNK	Ongoing	No	Medication
16	14-06-2022	On treatment	Gastrointestinal disorders	Nausea	Grade 1	No	R		NR	NR	UNK	Ongoing	No	Medication
16	14-06-2022	On treatment	General disorders and administration site conditions	Fatigue	Grade 1	No	R		NR	NR	55	Recovered with seq	No	None
16	14-06-2022	On treatment	General disorders and administration site conditions	Pain	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
16	14-06-2022	On treatment	General disorders and administration site conditions	Pain	Grade 3	No	NR		NR	NR	34	Recovered	No	Medication
16	14-06-2022	On treatment	Gastrointestinal disorders	Constipation	Grade 2	No	NR		NR	NR	68	Recovered	No	Medication
16	14-06-2022	On treatment	Gastrointestinal disorders	Diarrhea	Grade 1	No	R		R	NR	UNK	Ongoing	No	Medication
16	14-06-2022	On treatment	Nervous system disorders	Dysgeusia	Grade 1	No	R		R	NR	111	Recovered with seq	No	None
16	14-06-2022	On treatment	Gastrointestinal disorders	Dry mouth	Grade 1	No	R		NR	NR	UNK	Ongoing	No	None
16	14-06-2022	On treatment	Gastrointestinal disorders	Nausea	Grade 2	No	R		R	NR	UNK	Ongoing	No	Medication
16	14-06-2022	On treatment	Nervous system disorders	Dizziness	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
16	14-06-2022	On treatment	Infections and infestations	Lip infection	Grade 1	No	NR		NR	NR	21	Recovered	No	Medication
16	14-06-2022	On treatment	Gastrointestinal disorders	Mucositis oral	Grade 1	No	R		R	NR	30	Recovered	No	None
16	14-06-2022	On treatment	General disorders and administration site conditions	Fatigue	Grade 2	No	NR		R	NR	UNK	Ongoing	No	None
16	14-06-2022	On treatment	Gastrointestinal disorders	Diarrhea	Grade 2	No	R	Yes	R	NR	UNK	Ongoing	No	Medication
16	14-06-2022	On treatment	General disorders and administration site conditions	Other	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
16	14-06-2022	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 1	No	R		R	NR	UNK	Ongoing	No	Medication
16	14-06-2022	On treatment	General disorders and administration site conditions	Pain	Grade 2	No	NR		NR	NR	55	Recovered	No	Medication
16	14-06-2022	On treatment	General disorders and administration site conditions	Edema limbs	Grade 1	No	NR		R	NR	UNK	Ongoing	No	Medication
16	14-06-2022	On treatment	Metabolism and nutrition disorders	Anorexia	Grade 2	No	R		R	NR	UNK	Ongoing	No	Medication
16	14-06-2022	On treatment	Psychiatric disorder	Insomnia	Grade 1	No	NR		NR	NR	43	Recovered	No	None
16	14-06-2022	On treatment	Skin and subcutaneous tissue disorders	Dry skin	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	None
16	14-06-2022	On treatment	Gastrointestinal disorders	Constipation	Grade 1	No	NR		NR	NR	UNK	Ongoing	No	Medication
16	14-06-2022	On treatment	General disorders and administration site conditions	Edema limbs	Grade 2	No	NR		R	NR	15	Recovered with seq	No	Medication
16	14-06-2022	On treatment	Nervous system disorders	Dysgeusia	Grade 2	No	R		R	NR	UNK	Ongoing	No	None
16	14-06-2022	On treatment	Musculoskeletal and connective tissue disorders	Generalized muscle weakness	Grade 3	No	R		R	NR	UNK	Ongoing	No	None

Abbreviations: AE adverse event, AESI adverse event of special interest, DIBD Development International Birth Date, IMP investigational medicinal product, MIS-MWA Minimally Invasive Surgical Microwave Ablation, NA not applicable, NR not related to IMP, R related to IMP, SAE serious adverse event, SOC System organ class, UNK 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.