

Adverse Event/Serious Adverse Event CTCAE v4 NCI Standard Template Form

326567v2.0
As-of 8-22-2013

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Mandatory Adverse Event Questions

Must be included when this data is collected for reporting.

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1. Adverse Event Term (v4.0) caDSR CDE = 3125302 Ver.1.1

Instructions: Code used to identify the adverse event using a standard mechanism that facilitates analysis. CTEP's code list and associated Category/Term is currently a standard.

- Abdominal distension
- Abdominal infection
- Abdominal pain
- Abdominal soft tissue necrosis
- Abducens nerve disorder
- Accessory nerve disorder
- Acidosis
- Acoustic nerve disorder NOS
- Activated partial thromboplastin time prolonged
- Acute coronary syndrome
- Acute kidney injury
- Adrenal insufficiency
- Adult respiratory distress syndrome
- Agitation
- Akathisia
- Alanine aminotransferase increased
- Alcohol intolerance
- Alkaline phosphatase increased
- Alkalosis
- Allergic reaction
- Allergic rhinitis
- Alopecia
- Amnesia
- Anal fistula
- Anal hemorrhage

Anal mucositis
 Anal necrosis
 Anal pain
 Anal stenosis
 Anal ulcer
 Anaphylaxis
 Anemia
 Ankle fracture
 Anorectal infection
 Anorexia
 Anorgasmia
 Anxiety
 Aortic injury
 Aortic valve disease
 Aphonia
 Apnea
 Appendicitis
 Appendicitis perforated
 Arachnoiditis
 Arterial injury
 Arteritis infective
 Arthralgia
 Arthritis
 Ascites
 Aspartate aminotransferase increased
 Aspiration
 Asystole
 Ataxia
 Atelectasis
 Atrial fibrillation
 Atrial flutter
 Atrioventricular block complete
 Atrioventricular block first degree
 Autoimmune disorder
 Avascular necrosis
 Azoospermia
 Back pain
 Bile duct stenosis
 Biliary anastomotic leak
 Biliary fistula
 Biliary tract infection
 Bladder anastomotic leak
 Bladder infection
 Bladder perforation
 Bladder spasm
 Bloating

- ___ Blood and lymphatic system disorders - Other, Specify
- ___ Blood antidiuretic hormone abnormal
- ___ Blood bilirubin increased
- ___ Blood corticotrophin decreased
- ___ Blood gonadotrophin abnormal
- ___ Blood prolactin abnormal
- ___ Blurred vision
- ___ Body odor
- ___ Bone infection
- ___ Bone marrow hypocellular
- ___ Bone pain
- ___ Brachial plexopathy
- ___ Breast atrophy
- ___ Breast infection
- ___ Breast pain
- ___ Bronchial fistula
- ___ Bronchial infection
- ___ Bronchial obstruction
- ___ Bronchial stricture
- ___ Bronchopleural fistula
- ___ Bronchopulmonary hemorrhage
- ___ Bronchospasm
- ___ Bruising
- ___ Bullous dermatitis
- ___ Burn
- ___ Buttock pain
- ___ Capillary leak syndrome
- ___ Carbon monoxide diffusing capacity decreased
- ___ Cardiac arrest
- ___ Cardiac disorders - Other, Specify
- ___ Cardiac troponin I increased
- ___ Cardiac troponin T increased
- ___ Cataract
- ___ Catheter related infection
- ___ CD4 lymphocytes decreased
- ___ Cecal hemorrhage
- ___ Cecal infection
- ___ Central nervous system necrosis
- ___ Cerebrospinal fluid leakage
- ___ Cervicitis infection
- ___ Cheilitis
- ___ Chest pain - cardiac
- ___ Chest wall pain
- ___ Chills
- ___ Cholecystitis
- ___ Cholesterol high

- ___ Chronic kidney disease
- ___ Chylothorax
- ___ Cognitive disturbance
- ___ Colitis
- ___ Colonic fistula
- ___ Colonic hemorrhage
- ___ Colonic obstruction
- ___ Colonic perforation
- ___ Colonic stenosis
- ___ Colonic ulcer
- ___ Concentration impairment
- ___ Conduction disorder
- ___ Confusion
- ___ Congenital, familial and genetic disorders - Other, Specify
- ___ Conjunctivitis
- ___ Conjunctivitis infective
- ___ Constipation
- ___ Constrictive pericarditis
- ___ Corneal infection
- ___ Corneal ulcer
- ___ Cough
- ___ CPK increased
- ___ Cranial nerve infection
- ___ Creatinine increased
- ___ Cushingoid
- ___ Cystitis noninfective
- ___ Cytokine release syndrome
- ___ Death neonatal
- ___ Death NOS
- ___ Dehydration
- ___ Delayed orgasm
- ___ Delayed puberty
- ___ Delirium
- ___ Delusions
- ___ Dental caries
- ___ Depressed level of consciousness
- ___ Depression
- ___ Dermatitis radiation
- ___ Device related infection
- ___ Diarrhea
- ___ Disseminated intravascular coagulation
- ___ Dizziness
- ___ Dry eye
- ___ Dry mouth
- ___ Dry skin
- ___ Duodenal fistula

Duodenal hemorrhage
 Duodenal infection
 Duodenal obstruction
 Duodenal perforation
 Duodenal stenosis
 Duodenal ulcer
 Dysarthria
 Dysesthesia
 Dysgeusia
 Dysmenorrhea
 Dyspareunia
 Dyspepsia
 Dysphagia
 Dysphasia
 Dyspnea
 Ear and labyrinth disorders - Other, Specify
 Ear pain
 Edema cerebral
 Edema face
 Edema limbs
 Edema trunk
 Ejaculation disorder
 Ejection fraction decreased
 Electrocardiogram QT corrected interval prolonged
 Encephalitis infection
 Encephalomyelitis infection
 Encephalopathy
 Endocarditis infective
 Endocrine disorders - Other, Specify
 Endophthalmitis
 Enterocolitis
 Enterocolitis infectious
 Enterovesical fistula
 Epistaxis
 Erectile dysfunction
 Erythema multiforme
 Erythroderma
 Esophageal anastomotic leak
 Esophageal fistula
 Esophageal hemorrhage
 Esophageal infection
 Esophageal necrosis
 Esophageal obstruction
 Esophageal pain
 Esophageal perforation
 Esophageal stenosis

Esophageal ulcer
 Esophageal varices hemorrhage
 Esophagitis
 Euphoria
 Exostosis
 External ear inflammation
 External ear pain
 Extraocular muscle paresis
 Extrapyrarnidal disorder
 Eye disorders - Other, Specify
 Eye infection
 Eye pain
 Eyelid function disorder
 Facial muscle weakness
 Facial nerve disorder
 Facial pain
 Fall
 Fallopian tube anastomotic leak
 Fallopian tube obstruction
 Fallopian tube perforation
 Fallopian tube stenosis
 Fat atrophy
 Fatigue
 Febrile neutropenia
 Fecal incontinence
 Female genital tract fistula
 Feminization acquired
 Fetal death
 Fetal growth retardation
 Fever
 Fibrinogen decreased
 Fibrosis deep connective tissue
 Flank pain
 Flashing lights
 Flatulence
 Floaters
 Flu like symptoms
 Flushing
 Forced expiratory volume decreased
 Fracture
 Gait disturbance
 Gallbladder fistula
 Gallbladder infection
 Gallbladder necrosis
 Gallbladder obstruction
 Gallbladder pain

- ___ Gallbladder perforation
- ___ Gastric anastomotic leak
- ___ Gastric fistula
- ___ Gastric hemorrhage
- ___ Gastric necrosis
- ___ Gastric perforation
- ___ Gastric stenosis
- ___ Gastric ulcer
- ___ Gastritis
- ___ Gastroesophageal reflux disease
- ___ Gastrointestinal anastomotic leak
- ___ Gastrointestinal disorders - Other, Specify
- ___ Gastrointestinal fistula
- ___ Gastrointestinal pain
- ___ Gastrointestinal stoma necrosis
- ___ Gastroparesis
- ___ General disorders and administration site conditions - Other, Specify ** Value Length = 89
- ___ Generalized muscle weakness
- ___ Genital edema
- ___ GGT increased
- ___ Gingival pain
- ___ Glaucoma
- ___ Glossopharyngeal nerve disorder
- ___ Glucose intolerance
- ___ Growth accelerated
- ___ Growth hormone abnormal
- ___ Growth suppression
- ___ Gum infection
- ___ Gynecomastia
- ___ Hallucinations
- ___ Haptoglobin decreased
- ___ Head soft tissue necrosis
- ___ Headache
- ___ Hearing impaired
- ___ Heart failure
- ___ Hematoma
- ___ Hematosalpinx
- ___ Hematuria
- ___ Hemoglobin increased
- ___ Hemoglobinuria
- ___ Hemolysis
- ___ Hemolytic uremic syndrome
- ___ Hemorrhoidal hemorrhage
- ___ Hemorrhoids
- ___ Hepatic failure

Hepatic hemorrhage
 Hepatic infection
 Hepatic necrosis
 Hepatic pain
 Hepatitis viral
 Hepatobiliary disorders - Other, Specify
 Hiccups
 Hip fracture
 Hirsutism
 Hoarseness
 Hot flashes
 Hydrocephalus
 Hypercalcemia
 Hyperglycemia
 Hyperhidrosis
 Hyperkalemia
 Hypermagnesemia
 Hyponatremia
 Hyperparathyroidism
 Hypersomnia
 Hypertension
 Hyperthyroidism
 Hypertrichosis
 Hypertriglyceridemia
 Hyperuricemia
 Hypoalbuminemia
 Hypocalcemia
 Hypoglossal nerve disorder
 Hypoglycemia
 Hypohidrosis
 Hypokalemia
 Hypomagnesemia
 Hyponatremia
 Hypoparathyroidism
 Hypophosphatemia
 Hypotension
 Hypothermia
 Hypothyroidism
 Hypoxia
 Ileal fistula
 Ileal hemorrhage
 Ileal obstruction
 Ileal perforation
 Ileal stenosis
 Ileal ulcer
 Ileus

- ___ Immune system disorders - Other, Specify
- ___ Infections and infestations - Other, Specify
- ___ Infective myositis
- ___ Infusion related reaction
- ___ Infusion site extravasation
- ___ Injection site reaction
- ___ Injury to carotid artery
- ___ Injury to inferior vena cava
- ___ Injury to jugular vein
- ___ Injury to superior vena cava
- ___ Injury, poisoning and procedural complications - Other, Specify
- ___ INR increased
- ___ Insomnia
- ___ Intestinal stoma leak
- ___ Intestinal stoma obstruction
- ___ Intestinal stoma site bleeding
- ___ Intra-abdominal hemorrhage
- ___ Intracranial hemorrhage
- ___ Intraoperative arterial injury
- ___ Intraoperative breast injury
- ___ Intraoperative cardiac injury
- ___ Intraoperative ear injury
- ___ Intraoperative endocrine injury
- ___ Intraoperative gastrointestinal injury
- ___ Intraoperative head and neck injury
- ___ Intraoperative hemorrhage
- ___ Intraoperative hepatobiliary injury
- ___ Intraoperative musculoskeletal injury
- ___ Intraoperative neurological injury
- ___ Intraoperative ocular injury
- ___ Intraoperative renal injury
- ___ Intraoperative reproductive tract injury
- ___ Intraoperative respiratory injury
- ___ Intraoperative skin injury
- ___ Intraoperative splenic injury
- ___ Intraoperative urinary injury
- ___ Intraoperative venous injury
- ___ Investigations - Other, Specify
- ___ Iron overload
- ___ Irregular menstruation
- ___ Irritability
- ___ Ischemia cerebrovascular
- ___ IVth nerve disorder
- ___ Jejunal fistula
- ___ Jejunal hemorrhage

Jejunum obstruction
 Jejunum perforation
 Jejunum stenosis
 Jejunum ulcer
 Joint effusion
 Joint infection
 Joint range of motion decreased
 Joint range of motion decreased cervical spine
 Joint range of motion decreased lumbar spine
 Keratitis
 Kidney anastomotic leak
 Kidney infection
 Kyphosis
 Lactation disorder
 Large intestinal anastomotic leak
 Laryngeal edema
 Laryngeal fistula
 Laryngeal hemorrhage
 Laryngeal inflammation
 Laryngeal mucositis
 Laryngeal obstruction
 Laryngeal stenosis
 Laryngitis
 Laryngopharyngeal dysesthesia
 Laryngospasm
 Left ventricular systolic dysfunction
 Lethargy
 Leukemia secondary to oncology chemotherapy
 Leukocytosis
 Leukoencephalopathy
 Libido decreased
 Libido increased
 Lip infection
 Lip pain
 Lipase increased
 Lipohypertrophy
 Localized edema
 Lordosis
 Lower gastrointestinal hemorrhage
 Lung infection
 Lymph gland infection
 Lymph leakage
 Lymph node pain
 Lymphedema
 Lymphocele
 Lymphocyte count decreased

- ___ Lymphocyte count increased
- ___ Malabsorption
- ___ Malaise
- ___ Mania
- ___ Mediastinal hemorrhage
- ___ Mediastinal infection
- ___ Memory impairment
- ___ Meningismus
- ___ Meningitis
- ___ Menopause
- ___ Menorrhagia
- ___ Metabolism and nutrition disorders - Other, Specify
- ___ Middle ear inflammation
- ___ Mitral valve disease
- ___ Mobitz (type) II atrioventricular block
- ___ Mobitz type I
- ___ Movements involuntary
- ___ Mucosal infection
- ___ Mucositis oral
- ___ Multi-organ failure
- ___ Muscle weakness left-sided
- ___ Muscle weakness lower limb
- ___ Muscle weakness right-sided
- ___ Muscle weakness trunk
- ___ Muscle weakness upper limb
- ___ Musculoskeletal and connective tissue disorders - Other,
Specify
- ___ Musculoskeletal deformity
- ___ Myalgia
- ___ Myelitis
- ___ Myelodysplastic syndrome
- ___ Myocardial infarction
- ___ Myocarditis
- ___ Myositis
- ___ Nail discoloration
- ___ Nail infection
- ___ Nail loss
- ___ Nail ridging
- ___ Nasal congestion
- ___ Nausea
- ___ Neck edema
- ___ Neck pain
- ___ Neck soft tissue necrosis
- ___ Neoplasms benign, malignant and unspecified (incl cysts and polyps) -
Other, Specify ** Value Length = 104
- ___ Nervous system disorders - Other, Specify

Neuralgia
 Neutrophil count decreased
 Night blindness
 Nipple deformity
 Non-cardiac chest pain
 Nystagmus
 Obesity
 Obstruction gastric
 Oculomotor nerve disorder
 Olfactory nerve disorder
 Oligospermia
 Optic nerve disorder
 Oral cavity fistula
 Oral dysesthesia
 Oral hemorrhage
 Oral pain
 Osteonecrosis of jaw
 Osteoporosis
 Otitis externa
 Otitis media
 Ovarian hemorrhage
 Ovarian infection
 Ovarian rupture
 Ovulation pain
 Pain
 Pain in extremity
 Pain of skin
 Palmar-plantar erythrodysesthesia syndrome
 Palpitations
 Pancreas infection
 Pancreatic anastomotic leak
 Pancreatic duct stenosis
 Pancreatic enzymes decreased
 Pancreatic fistula
 Pancreatic hemorrhage
 Pancreatic necrosis
 Pancreatitis
 Papilledema
 Papulopustular rash
 Paresthesia
 Paronychia
 Paroxysmal atrial tachycardia
 Pelvic floor muscle weakness
 Pelvic infection
 Pelvic pain
 Pelvic soft tissue necrosis

Penile infection
 Penile pain
 Perforation bile duct
 Pericardial effusion
 Pericardial tamponade
 Pericarditis
 Perineal pain
 Periodontal disease
 Periorbital edema
 Periorbital infection
 Peripheral ischemia
 Peripheral motor neuropathy
 Peripheral nerve infection
 Peripheral sensory neuropathy
 Peritoneal infection
 Peritoneal necrosis
 Personality change
 Phantom pain
 Pharyngeal anastomotic leak
 Pharyngeal fistula
 Pharyngeal hemorrhage
 Pharyngeal mucositis
 Pharyngeal necrosis
 Pharyngeal stenosis
 Pharyngitis
 Pharyngolaryngeal pain
 Phlebitis
 Phlebitis infective
 Photophobia
 Photosensitivity
 Platelet count decreased
 Pleural effusion
 Pleural hemorrhage
 Pleural infection
 Pleuritic pain
 Pneumonitis
 Pneumothorax
 Portal hypertension
 Portal vein thrombosis
 Postnasal drip
 Postoperative hemorrhage
 Postoperative thoracic procedure complication
 Precocious puberty
 Pregnancy, puerperium and perinatal conditions - Other,
Specify
 Premature delivery

- ___ Premature menopause
- ___ Presyncope
- ___ Proctitis
- ___ Productive cough
- ___ Prolapse of intestinal stoma
- ___ Prolapse of urostomy
- ___ Prostate infection
- ___ Prostatic hemorrhage
- ___ Prostatic obstruction
- ___ Prostatic pain
- ___ Proteinuria
- ___ Pruritus
- ___ Psychiatric disorders - Other, Specify
- ___ Psychosis
- ___ Pulmonary edema
- ___ Pulmonary fibrosis
- ___ Pulmonary fistula
- ___ Pulmonary hypertension
- ___ Pulmonary valve disease
- ___ Purpura
- ___ Pyramidal tract syndrome
- ___ Radiation recall reaction (dermatologic)
- ___ Radiculitis
- ___ Rash acneiform
- ___ Rash maculo-papular
- ___ Rash pustular
- ___ Rectal anastomotic leak
- ___ Rectal fistula
- ___ Rectal hemorrhage
- ___ Rectal mucositis
- ___ Rectal necrosis
- ___ Rectal obstruction
- ___ Rectal pain
- ___ Rectal perforation
- ___ Rectal stenosis
- ___ Rectal ulcer
- ___ Recurrent laryngeal nerve palsy
- ___ Renal and urinary disorders - Other, Specify
- ___ Renal calculi
- ___ Renal colic
- ___ Renal hemorrhage
- ___ Reproductive system and breast disorders - Other, Specify
- ___ Respiratory failure
- ___ Respiratory, thoracic and mediastinal disorders - Other,
Specify
- ___ Restlessness

- ___ Restrictive cardiomyopathy
- ___ Retinal detachment
- ___ Retinal tear
- ___ Retinal vascular disorder
- ___ Retinoic acid syndrome
- ___ Retinopathy
- ___ Retroperitoneal hemorrhage
- ___ Reversible posterior leukoencephalopathy syndrome
- ___ Rhinitis infective
- ___ Right ventricular dysfunction
- ___ Salivary duct inflammation
- ___ Salivary gland fistula
- ___ Salivary gland infection
- ___ Scalp pain
- ___ Scleral disorder
- ___ Scoliosis
- ___ Scrotal infection
- ___ Scrotal pain
- ___ Seizure
- ___ Sepsis
- ___ Seroma
- ___ Serum amylase increased
- ___ Serum sickness
- ___ Sick sinus syndrome
- ___ Sinus bradycardia
- ___ Sinus disorder
- ___ Sinus pain
- ___ Sinus tachycardia
- ___ Sinusitis
- ___ Skin and subcutaneous tissue disorders - Other, Specify
- ___ Skin atrophy
- ___ Skin hyperpigmentation
- ___ Skin hypopigmentation
- ___ Skin induration
- ___ Skin infection
- ___ Skin ulceration
- ___ Sleep apnea
- ___ Small intestinal anastomotic leak
- ___ Small intestinal mucositis
- ___ Small intestinal obstruction
- ___ Small intestinal perforation
- ___ Small intestinal stenosis
- ___ Small intestine infection
- ___ Small intestine ulcer
- ___ Sneezing
- ___ Social circumstances - Other, Specify

- ___ Soft tissue infection
- ___ Soft tissue necrosis lower limb
- ___ Soft tissue necrosis upper limb
- ___ Somnolence
- ___ Sore throat
- ___ Spasticity
- ___ Spermatic cord anastomotic leak
- ___ Spermatic cord hemorrhage
- ___ Spermatic cord obstruction
- ___ Spinal fracture
- ___ Spleen disorder
- ___ Splenic infection
- ___ Stenosis of gastrointestinal stoma
- ___ Stevens-Johnson syndrome
- ___ Stoma site infection
- ___ Stomach pain
- ___ Stomal ulcer
- ___ Stridor
- ___ Stroke
- ___ Sudden death NOS
- ___ Suicidal ideation
- ___ Suicide attempt
- ___ Superficial soft tissue fibrosis
- ___ Superficial thrombophlebitis
- ___ Superior vena cava syndrome
- ___ Supraventricular tachycardia
- ___ Surgical and medical procedures - Other, Specify
- ___ Syncope
- ___ Telangiectasia
- ___ Testicular disorder
- ___ Testicular hemorrhage
- ___ Testicular pain
- ___ Thromboembolic event
- ___ Thrombotic thrombocytopenic purpura
- ___ Tinnitus
- ___ Tooth development disorder
- ___ Tooth discoloration
- ___ Tooth infection
- ___ Toothache
- ___ Toxic epidermal necrolysis
- ___ Tracheal fistula
- ___ Tracheal hemorrhage
- ___ Tracheal mucositis
- ___ Tracheal obstruction
- ___ Tracheal stenosis
- ___ Tracheitis

Tracheostomy site bleeding
 Transient ischemic attacks
 Treatment related secondary malignancy
 Tremor
 Tricuspid valve disease
 Trigeminal nerve disorder
 Trismus
 Tumor lysis syndrome
 Tumor pain
 Typhlitis
 Unequal limb length
 Unintended pregnancy
 Upper gastrointestinal hemorrhage
 Upper respiratory infection
 Ureteric anastomotic leak
 Urethral anastomotic leak
 Urethral infection
 Urinary fistula
 Urinary frequency
 Urinary incontinence
 Urinary retention
 Urinary tract infection
 Urinary tract obstruction
 Urinary tract pain
 Urinary urgency
 Urine discoloration
 Urine output decreased
 Urostomy leak
 Urostomy obstruction
 Urostomy site bleeding
 Urostomy stenosis
 Urticaria
 Uterine anastomotic leak
 Uterine fistula
 Uterine hemorrhage
 Uterine infection
 Uterine obstruction
 Uterine pain
 Uterine perforation
 Uveitis
 Vaginal anastomotic leak
 Vaginal discharge
 Vaginal dryness
 Vaginal fistula
 Vaginal hemorrhage
 Vaginal infection

- ___ Vaginal inflammation
- ___ Vaginal obstruction
- ___ Vaginal pain
- ___ Vaginal perforation
- ___ Vaginal stricture
- ___ Vaginismus
- ___ Vagus nerve disorder
- ___ Vas deferens anastomotic leak
- ___ Vascular access complication
- ___ Vascular disorders - Other, Specify
- ___ Vasculitis
- ___ Vasovagal reaction
- ___ Venous injury
- ___ Ventricular arrhythmia
- ___ Ventricular fibrillation
- ___ Ventricular tachycardia
- ___ Vertigo
- ___ Vestibular disorder
- ___ Virilization
- ___ Visceral arterial ischemia
- ___ Vital capacity abnormal
- ___ Vitreous hemorrhage
- ___ Voice alteration
- ___ Vomiting
- ___ Vulval infection
- ___ Watering eyes
- ___ Weight gain
- ___ Weight loss
- ___ Wheezing
- ___ White blood cell decreased
- ___ Wolff-Parkinson-White syndrome
- ___ Wound complication
- ___ Wound dehiscence
- ___ Wound infection
- ___ Wrist fracture

2. Describe 'Other' Adverse Event caDSR CDE = 2188132 Ver.1.0

Instructions: Verbatim AE Description used to 'reinforce' selected AE Type Code.

3. Adverse Event Grade caDSR CDE = 2944515 Ver.1.0

Instructions: A coded value to identify the severity of the AE.

- 1 = Mild Adverse Event
- 2 = Moderate Adverse Event
- 3 = Severe Adverse Event
- 4 = Life Threatening Adverse Event
- 5 = Death Related to Adverse Event

Conditional Adverse Event Questions

There are business rules to indicate situations under which this data element should be used in a CRF.

1. AE Start Date caDSR CDE = 2744993 Ver.1.0

Instructions: Date on which the AE was first evident. Conditionality Rule: Condition is that this is based on the needs of the Sponsor. CTEP does not currently collect Adverse Event onset dates for routine AEs reported via reporting systems.

Unknown

2. Was patient hospitalized for toxicity? caDSR CDE = 2552398 Ver.1.0

Instructions: Normally required only if AE is deemed 'serious'. Conditionality Rule: Conditional based on the reporting of this variable through other means, such as caAERS, AdEERS. If those systems are not in use, this variable needs to be collected.

Yes
 No

3. Cycle # caDSR CDE = 2744948 Ver.1.0

Instructions: A repeating period of activity involving treatment and rest. Several cycles can make up a course. Conditionality Rule: Studies use cycles.

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Optional Adverse Event Questions

No requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data, this is the element to include on the CRF.

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1. To what is the AE attributed? caDSR CDE = 2179892 Ver.2.0

Instructions: List of other therapies (surgery, radiation, etc), disease, concomitant meds, other. Select MOST likely.

- Biological Therapy
- Chemotherapy
- Combined modality
- Concomitant medication
- Device
- Disease
- Endocrine Therapy
- Immunotherapy
- Investigational agent
- Other
- Radiation therapy
- Surgery

2. Other Attribution, Specify caDSR CDE = 2201348 Ver.1.0

Instructions: If 'other' selected in data element above, must provide a description of the presumed cause.

3. AE Stop Date caDSR CDE = 2189843 Ver.1.0

Instructions: Date on which the AE resolved.

- Unknown
- Ongoing

4. MedDRA System Organ Class (SOC) caDSR CDE = 2943864 Ver.1.0

Instructions: None

- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and administration site conditions
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- Investigations
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl cysts and polyps) ** Value Length = 87
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders

5. MedDRA AE Code (CTCAE v4.0) caDSR CDE = 3133353 Ver.1.0

Instructions: Code used to identify the adverse event using a standard mechanism that facilitates analysis. CTEP's code list and associated Category/Term is currently a standard.

- 10000060 = Abdominal distension
- 10000081 = Abdominal pain
- 10000486 = Acidosis
- 10000521 = Acoustic nerve disorder NOS
- 10000636 = Activated partial thromboplastin time prolonged
- 10001367 = Adrenal insufficiency
- 10001409 = Adult respiratory distress syndrome

10001497 = Agitation
10001540 = Akathisia
10001551 = Alanine aminotransferase increased
10001598 = Alcohol intolerance
10001675 = Alkaline phosphatase increased
10001680 = Alkalosis
10001718 = Allergic reaction
10001723 = Allergic rhinitis
10001760 = Alopecia
10001949 = Amnesia
10002156 = Anal fistula
10002167 = Anal pain
10002176 = Anal stenosis
10002180 = Anal ulcer
10002218 = Anaphylaxis
10002272 = Anemia
10002544 = Ankle fracture
10002646 = Anorexia
10002652 = Anorgasmia
10002855 = Anxiety
10002899 = Aortic injury
10002953 = Aphonia
10002972 = Apnea
10003011 = Appendicitis
10003012 = Appendicitis perforated
10003074 = Arachnoiditis
10003162 = Arterial injury
10003239 = Arthralgia
10003246 = Arthritis
10003445 = Ascites
10003481 = Aspartate aminotransferase increased
10003504 = Aspiration
10003586 = Asystole
10003591 = Ataxia
10003598 = Atelectasis
10003658 = Atrial fibrillation
10003662 = Atrial flutter
10003673 = Atrioventricular block complete
10003674 = Atrioventricular block first degree
10003883 = Azoospermia
10003988 = Back pain
10004665 = Biliary fistula
10005047 = Bladder infection
10005265 = Bloating
10005329 = Blood and lymphatic system disorders - Other, specify
10005332 = Blood antidiuretic hormone abnormal

10005364 = Blood bilirubin increased
10005452 = Blood corticotrophin decreased
10005561 = Blood gonadotrophin abnormal
10005778 = Blood prolactin abnormal
10005886 = Blurred vision
10005901 = Body odor
10006002 = Bone pain
10006179 = Breast atrophy
10006259 = Breast infection
10006298 = Breast pain
10006437 = Bronchial fistula
10006440 = Bronchial obstruction
10006482 = Bronchospasm
10006504 = Bruising
10006556 = Bullous dermatitis
10006634 = Burn
10007196 = Capillary leak syndrome
10007515 = Cardiac arrest
10007541 = Cardiac disorders - Other, specify
10007612 = Cardiac troponin I increased
10007613 = Cardiac troponin T increased
10007739 = Cataract
10007810 = Catheter related infection
10007839 = CD4 lymphocytes decreased
10008164 = Cerebrospinal fluid leakage
10008330 = Cervicitis infection
10008417 = Cheilitis
10008481 = Chest pain - cardiac
10008496 = Chest wall pain
10008531 = Chills
10008612 = Cholecystitis
10008661 = Cholesterol high
10009845 = Cognitive disturbance
10009887 = Colitis
10009995 = Colonic fistula
10009998 = Colonic hemorrhage
10010000 = Colonic obstruction
10010001 = Colonic perforation
10010004 = Colonic stenosis
10010006 = Colonic ulcer
10010250 = Concentration impairment
10010276 = Conduction disorder
10010300 = Confusion
10010331 = Congenital, familial and genetic disorders - Other, specify
10010741 = Conjunctivitis
10010742 = Conjunctivitis infective

10010774 = Constipation
10010783 = Constrictive pericarditis
10011224 = Cough
10011268 = CPK increased
10011368 = Creatinine increased
10011655 = Cushingoid
10011912 = Death neonatal
10011914 = Death NOS
10012174 = Dehydration
10012205 = Delayed puberty
10012218 = Delirium
10012260 = Delusions
10012318 = Dental caries
10012373 = Depressed level of consciousness
10012378 = Depression
10012727 = Diarrhea
10013442 = Disseminated intravascular coagulation
10013573 = Dizziness
10013774 = Dry eye
10013781 = Dry mouth
10013786 = Dry skin
10013828 = Duodenal fistula
10013830 = Duodenal obstruction
10013832 = Duodenal perforation
10013836 = Duodenal ulcer
10013887 = Dysarthria
10013911 = Dysgeusia
10013934 = Dysmenorrhea
10013941 = Dyspareunia
10013946 = Dyspepsia
10013950 = Dysphagia
10013951 = Dysphasia
10013963 = Dyspnea
10013993 = Ear and labyrinth disorders - Other, specify
10014020 = Ear pain
10014217 = Edema cerebral
10014222 = Edema face
10014326 = Ejaculation disorder
10014383 = Electrocardiogram QT corrected interval prolonged
10014594 = Encephalitis infection
10014621 = Encephalomyelitis infection
10014625 = Encephalopathy
10014678 = Endocarditis infective
10014698 = Endocrine disorders - Other, specify
10014801 = Endophthalmitis
10014893 = Enterocolitis

10015090 = Epistaxis
10015218 = Erythema multiforme
10015277 = Erythroderma
10015384 = Esophageal hemorrhage
10015387 = Esophageal obstruction
10015388 = Esophageal pain
10015448 = Esophageal stenosis
10015451 = Esophageal ulcer
10015453 = Esophageal varices hemorrhage
10015461 = Esophagitis
10015533 = Euphoria
10015688 = Exostosis
10015829 = Extraocular muscle paresis
10015832 = Extrapramidal disorder
10015919 = Eye disorders - Other, specify
10015929 = Eye infection
10015958 = Eye pain
10016059 = Facial pain
10016173 = Fall
10016241 = Fat atrophy
10016256 = Fatigue
10016288 = Febrile neutropenia
10016296 = Fecal incontinence
10016479 = Fetal death
10016558 = Fever
10016596 = Fibrinogen decreased
10016750 = Flank pain
10016757 = Flashing lights
10016766 = Flatulence
10016778 = Floaters
10016791 = Flu like symptoms
10016825 = Flushing
10016987 = Forced expiratory volume decreased
10017076 = Fracture
10017577 = Gait disturbance
10017631 = Gallbladder fistula
10017636 = Gallbladder obstruction
10017638 = Gallbladder pain
10017639 = Gallbladder perforation
10017789 = Gastric hemorrhage
10017815 = Gastric perforation
10017822 = Gastric ulcer
10017853 = Gastritis
10017877 = Gastrointestinal fistula
10017947 = Gastrointestinal disorders - Other, specify
10017999 = Gastrointestinal pain

10018043 = Gastroparesis
10018065 = General disorders and administration site conditions - Other, specify
10018146 = Genital edema
10018286 = Gingival pain
10018304 = Glaucoma
10018746 = Growth accelerated
10018748 = Growth hormone abnormal
10018761 = Growth suppression
10018784 = Gum infection
10018801 = Gynecomastia
10019077 = Hallucinations
10019150 = Haptoglobin decreased
10019211 = Headache
10019245 = Hearing impaired
10019279 = Heart failure
10019428 = Hematoma
10019450 = Hematuria
10019489 = Hemoglobinuria
10019491 = Hemolysis
10019515 = Hemolytic uremic syndrome
10019611 = Hemorrhoids
10019663 = Hepatic failure
10019678 = Hepatic hemorrhage
10019692 = Hepatic necrosis
10019705 = Hepatic pain
10019799 = Hepatitis viral
10019805 = Hepatobiliary disorders - Other, specify
10020039 = Hiccups
10020100 = Hip fracture
10020112 = Hirsutism
10020201 = Hoarseness
10020407 = Hot flashes
10020508 = Hydrocephalus
10020587 = Hypercalcemia
10020639 = Hyperglycemia
10020642 = Hyperhidrosis
10020647 = Hyperkalemia
10020670 = Hypermagnesemia
10020680 = Hypernatremia
10020705 = Hyperparathyroidism
10020765 = Hypersomnia
10020772 = Hypertension
10020850 = Hyperthyroidism
10020864 = Hypertrichosis
10020870 = Hypertriglyceridemia
10020907 = Hyperuricemia

10020943 = Hypoalbuminemia
10020949 = Hypocalcemia
10021005 = Hypoglycemia
10021013 = Hypohidrosis
10021018 = Hypokalemia
10021028 = Hypomagnesemia
10021038 = Hyponatremia
10021041 = Hypoparathyroidism
10021059 = Hypophosphatemia
10021097 = Hypotension
10021113 = Hypothermia
10021114 = Hypothyroidism
10021143 = Hypoxia
10021305 = Ileal perforation
10021307 = Ileal stenosis
10021309 = Ileal ulcer
10021328 = Ileus
10021428 = Immune system disorders - Other, specify
10021881 = Infections and infestations - Other, specify
10021918 = Infective myositis
10022095 = Injection site reaction
10022117 = Injury, poisoning and procedural complications - Other, specify
10022161 = Injury to carotid artery
10022213 = Injury to inferior vena cava
10022356 = Injury to superior vena cava
10022402 = INR increased
10022437 = Insomnia
10022763 = Intracranial hemorrhage
10022891 = Investigations - Other, specify
10022992 = Irregular menstruation
10022998 = Irritability
10023030 = Ischemia cerebrovascular
10023174 = Jejunal perforation
10023176 = Jejunal stenosis
10023177 = Jejunal ulcer
10023215 = Joint effusion
10023216 = Joint infection
10023332 = Keratitis
10023424 = Kidney infection
10023509 = Kyphosis
10023838 = Laryngeal edema
10023862 = Laryngeal stenosis
10023874 = Laryngitis
10023891 = Laryngospasm
10024264 = Lethargy
10024378 = Leukocytosis

10024382 = Leukoencephalopathy
10024419 = Libido decreased
10024421 = Libido increased
10024561 = Lip pain
10024574 = Lipase increased
10024842 = Lordosis
10025182 = Lymph node pain
10025233 = Lymphedema
10025256 = Lymphocyte count decreased
10025258 = Lymphocyte count increased
10025476 = Malabsorption
10025482 = Malaise
10026749 = Mania
10027175 = Memory impairment
10027198 = Meningismus
10027199 = Meningitis
10027308 = Menopause
10027313 = Menorrhagia
10027433 = Metabolism and nutrition disorders - Other, specify
10027786 = Mobitz (type) II atrioventricular block
10027787 = Mobitz type I
10028041 = Movements involuntary
10028130 = Mucositis oral
10028154 = Multi-organ failure
10028395 = Musculoskeletal and connective tissue disorder - Other, specify
10028411 = Myalgia
10028524 = Myelitis
10028533 = Myelodysplastic syndrome
10028596 = Myocardial infarction
10028606 = Myocarditis
10028653 = Myositis
10028691 = Nail discoloration
10028735 = Nasal congestion
10028813 = Nausea
10028836 = Neck pain
10029104 = Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, specify
10029205 = Nervous system disorders - Other, specify
10029223 = Neuralgia
10029366 = Neutrophil count decreased
10029404 = Night blindness
10029864 = Nystagmus
10029883 = Obesity
10029957 = Obstruction gastric
10030300 = Oligospermia
10030980 = Oral hemorrhage
10031009 = Oral pain

10031282 = Osteoporosis
10033072 = Otitis externa
10033078 = Otitis media
10033279 = Ovarian rupture
10033314 = Ovulation pain
10033371 = Pain
10033425 = Pain in extremity
10033474 = Pain of skin
10033557 = Palpitations
10033626 = Pancreatic hemorrhage
10033645 = Pancreatitis
10033703 = Papilledema
10033987 = Paresthesia
10034016 = Paronychia
10034040 = Paroxysmal atrial tachycardia
10034263 = Pelvic pain
10034310 = Penile pain
10034405 = Perforation bile duct
10034474 = Pericardial effusion
10034484 = Pericarditis
10034536 = Periodontal disease
10034578 = Peripheral ischemia
10034580 = Peripheral motor neuropathy
10034620 = Peripheral sensory neuropathy
10034719 = Personality change
10034825 = Pharyngeal fistula
10034835 = Pharyngitis
10034844 = Pharyngolaryngeal pain
10034879 = Phlebitis
10034960 = Photophobia
10034966 = Photosensitivity
10035528 = Platelet count decreased
10035598 = Pleural effusion
10035623 = Pleuritic pain
10035742 = Pneumonitis
10035759 = Pneumothorax
10036200 = Portal hypertension
10036206 = Portal vein thrombosis
10036402 = Postnasal drip
10036585 = Pregnancy, puerperium and perinatal conditions - Other, specify
10036595 = Premature delivery
10036601 = Premature menopause
10036653 = Presyncope
10036774 = Proctitis
10036790 = Productive cough
10036968 = Prostatic pain

10037032 = Proteinuria
10037087 = Pruritus
10037175 = Psychiatric disorders - Other, specify
10037234 = Psychosis
10037375 = Pulmonary edema
10037383 = Pulmonary fibrosis
10037400 = Pulmonary hypertension
10037549 = Purpura
10037767 = Radiation recall reaction (dermatologic)
10037847 = Rash acneiform
10037868 = Rash maculo-papular
10037888 = Rash pustular
10038062 = Rectal fistula
10038064 = Rectal hemorrhage
10038072 = Rectal pain
10038073 = Rectal perforation
10038079 = Rectal stenosis
10038080 = Rectal ulcer
10038130 = Recurrent laryngeal nerve palsy
10038359 = Renal and urinary disorders - Other, specify
10038385 = Renal calculi
10038419 = Renal colic
10038463 = Renal hemorrhage
10038604 = Reproductive system and breast disorders - Other, specify
10038695 = Respiratory failure
10038738 = Respiratory, thoracic and mediastinal disorders - Other, specify
10038743 = Restlessness
10038748 = Restrictive cardiomyopathy
10038848 = Retinal detachment
10038897 = Retinal tear
10038901 = Retinal vascular disorder
10038921 = Retinoic acid syndrome
10038923 = Retinopathy
10038981 = Retroperitoneal hemorrhage
10039411 = Salivary gland fistula
10039413 = Salivary gland infection
10039722 = Scoliosis
10039757 = Scrotal pain
10039906 = Seizure
10040047 = Sepsis
10040102 = Seroma
10040139 = Serum amylase increased
10040400 = Serum sickness
10040639 = Sick sinus syndrome
10040741 = Sinus bradycardia
10040747 = Sinus pain

10040752 = Sinus tachycardia
10040753 = Sinusitis
10040785 = Skin and subcutaneous tissue disorders - Other, specify
10040799 = Skin atrophy
10040865 = Skin hyperpigmentation
10040868 = Skin hypopigmentation
10040872 = Skin infection
10040947 = Skin ulceration
10040975 = Sleep apnea
10041101 = Small intestinal obstruction
10041103 = Small intestinal perforation
10041133 = Small intestine ulcer
10041232 = Sneezing
10041244 = Social circumstances - Other, specify
10041349 = Somnolence
10041367 = Sore throat
10041416 = Spasticity
10041569 = Spinal fracture
10041633 = Spleen disorder
10042033 = Stevens-Johnson syndrome
10042112 = Stomach pain
10042127 = Stomal ulcer
10042241 = Stridor
10042244 = Stroke
10042435 = Sudden death NOS
10042458 = Suicidal ideation
10042464 = Suicide attempt
10042554 = Superficial thrombophlebitis
10042569 = Superior vena cava syndrome
10042604 = Supraventricular tachycardia
10042613 = Surgical and medical procedures - Other, specify
10042772 = Syncope
10043189 = Telangiectasia
10043306 = Testicular disorder
10043345 = Testicular pain
10043565 = Thromboembolic event
10043648 = Thrombotic thrombocytopenic purpura
10043882 = Tinnitus
10044030 = Tooth development disorder
10044031 = Tooth discoloration
10044055 = Toothache
10044223 = Toxic epidermal necrolysis
10044291 = Tracheal obstruction
10044302 = Tracheitis
10044391 = Transient ischemic attacks
10044565 = Tremor

10044684 = Trismus
10045152 = Tumor lysis syndrome
10045158 = Tumor pain
10045271 = Typhlitis
10045542 = Unintended pregnancy
10046300 = Upper respiratory infection
10046539 = Urinary frequency
10046543 = Urinary incontinence
10046555 = Urinary retention
10046571 = Urinary tract infection
10046593 = Urinary urgency
10046628 = Urine discoloration
10046735 = Urticaria
10046789 = Uterine hemorrhage
10046809 = Uterine pain
10046810 = Uterine perforation
10046851 = Uveitis
10046901 = Vaginal discharge
10046904 = Vaginal dryness
10046912 = Vaginal hemorrhage
10046914 = Vaginal infection
10046916 = Vaginal inflammation
10046937 = Vaginal pain
10046947 = Vaginismus
10047065 = Vascular disorders - Other, specify
10047115 = Vasculitis
10047166 = Vasovagal reaction
10047228 = Venous injury
10047281 = Ventricular arrhythmia
10047290 = Ventricular fibrillation
10047302 = Ventricular tachycardia
10047340 = Vertigo
10047386 = Vestibular disorder
10047488 = Virilization
10047580 = Vital capacity abnormal
10047656 = Vitreous hemorrhage
10047681 = Voice alteration
10047700 = Vomiting
10047848 = Watering eyes
10047896 = Weight gain
10047900 = Weight loss
10047924 = Wheezing
10048015 = Wolff-Parkinson-White syndrome
10048031 = Wound dehiscence
10048038 = Wound infection
10048049 = Wrist fracture

10048293 = Leukemia secondary to oncology chemotherapy
10048492 = Corneal ulcer
10048580 = Bone marrow hypocellular
10048642 = Lymphocele
10048677 = Buttock pain
10048706 = Joint range of motion decreased
10048762 = Tooth infection
10048994 = Bladder spasm
10049120 = Scalp pain
10049182 = White blood cell decreased
10049192 = Pancreatic fistula
10049281 = Nail loss
10049468 = Intestinal stoma site bleeding
10049737 = Treatment related secondary malignancy
10050028 = Pharyngeal stenosis
10050068 = Edema limbs
10050094 = Duodenal stenosis
10050457 = Pancreatic anastomotic leak
10050458 = Biliary anastomotic leak
10050528 = Ejection fraction decreased
10050662 = Prostate infection
10050816 = Tracheal stenosis
10050823 = Lymph gland infection
10051228 = Chylothorax
10051272 = Facial muscle weakness
10051341 = Bile duct stenosis
10051472 = Periorbital infection
10051592 = Acute coronary syndrome
10051741 = Pancreas infection
10051746 = Lower gastrointestinal hemorrhage
10051792 = Infusion related reaction
10051837 = Skin induration
10051886 = Gastric necrosis
10052015 = Cytokine release syndrome
10052298 = Urethral infection
10052426 = Glucose intolerance
10053481 = Bronchopleural fistula
10053496 = Vaginal stricture
10053565 = Pericardial tamponade
10053661 = Oculomotor nerve disorder
10053662 = Abducens nerve disorder
10053692 = Wound complication
10054382 = Feminization acquired
10054482 = Neck edema
10054520 = Oral dysesthesia
10054524 = Palmar-plantar erythrodysesthesia syndrome

10054541 = Periorbital edema
10054692 = Visceral arterial ischemia
10054746 = Fetal growth retardation
10055005 = Ovarian infection
10055026 = Prostatic obstruction
10055078 = Bronchial infection
10055226 = Anal hemorrhage
10055242 = Duodenal hemorrhage
10055287 = Ileal hemorrhage
10055291 = Intra-abdominal hemorrhage
10055298 = Intraoperative hemorrhage
10055300 = Jejunal hemorrhage
10055315 = Pharyngeal hemorrhage
10055319 = Pleural hemorrhage
10055322 = Postoperative hemorrhage
10055325 = Prostatic hemorrhage
10055347 = Testicular hemorrhage
10055356 = Upper gastrointestinal hemorrhage
10055472 = Esophageal perforation
10055599 = Hemoglobin increased
10056238 = Phantom pain
10056356 = Mediastinal hemorrhage
10056388 = Olfactory nerve disorder
10056519 = Abdominal infection
10056522 = Hepatic infection
10056627 = Phlebitis infective
10056681 = Salivary duct inflammation
10056745 = Postoperative thoracic procedure complication
10056910 = GGT increased
10057066 = Delayed orgasm
10057262 = Peritoneal infection
10057483 = Mediastinal infection
10058084 = Precocious puberty
10058096 = Pancreatic necrosis
10058597 = Right ventricular dysfunction
10058674 = Pelvic infection
10058720 = Edema trunk
10058804 = Esophageal infection
10058838 = Enterocolitis infectious
10059094 = Intestinal stoma obstruction
10059095 = Intestinal stoma leak
10059446 = Gallbladder necrosis
10059639 = Laryngeal obstruction
10059827 = Rhinitis infective
10059895 = Urine output decreased
10060602 = Hematosalpinx

10060640 = Hemorrhoidal hemorrhage
10060890 = Trigeminal nerve disorder
10060929 = Accessory nerve disorder
10061017 = Bone infection
10061103 = Dermatitis radiation
10061145 = Eyelid function disorder
10061149 = Female genital tract fistula
10061185 = Glossopharyngeal nerve disorder
10061212 = Hypoglossal nerve disorder
10061229 = Lung infection
10061261 = Lactation disorder
10061304 = Nail infection
10061322 = Optic nerve disorder
10061339 = Perineal pain
10061351 = Pleural infection
10061389 = Tricuspid valve disease
10061403 = Vagus nerve disorder
10061457 = Facial nerve disorder
10061461 = Erectile dysfunction
10061510 = Scleral disorder
10061532 = Mitral valve disease
10061541 = Pulmonary valve disease
10061574 = Urinary tract obstruction
10061589 = Aortic valve disease
10061640 = Anorectal infection
10061664 = Autoimmune disorder
10061695 = Biliary tract infection
10061788 = Corneal infection
10061912 = Penile infection
10061928 = Radiculitis
10061970 = Gastric stenosis
10062112 = Splenic infection
10062156 = Scrotal infection
10062169 = Vascular access complication
10062225 = Urinary tract pain
10062233 = Uterine infection
10062244 = Sinus disorder
10062255 = Soft tissue infection
10062263 = Small intestinal stenosis
10062283 = Nail ridging
10062315 = Lipohypertrophy
10062466 = Localized edema
10062501 = Non-cardiac chest pain
10062548 = Tracheal hemorrhage
10062570 = Enterovesical fistula
10062572 = Generalized muscle weakness

10062632 = Gallbladder infection
10062646 = Pancreatic enzymes decreased
10062667 = Laryngopharyngeal dysesthesia
10062872 = Dysesthesia
10063057 = Cystitis noninfective
10063190 = Rectal mucositis
10063524 = Bronchial stricture
10063575 = Bladder perforation
10063636 = Pyramidal tract syndrome
10063761 = Reversible posterior leukoencephalopathy syndrome
10064026 = Pelvic floor muscle weakness
10064505 = Stoma site infection
10064658 = Osteonecrosis of jaw
10064687 = Device related infection
10064774 = Infusion site extravasation
10064848 = Chronic kidney disease
10065368 = Urinary fistula
10065417 = Brachial plexopathy
10065703 = Pancreatic duct stenosis
10065704 = Peritoneal necrosis
10065705 = Pharyngeal anastomotic leak
10065706 = Pharyngeal necrosis
10065707 = Rectal obstruction
10065709 = Rectal necrosis
10065710 = Small intestinal mucositis
10065712 = Gastrointestinal stoma necrosis
10065713 = Gastric fistula
10065719 = Jejunal fistula
10065720 = Oral cavity fistula
10065721 = Anal mucositis
10065722 = Anal necrosis
10065727 = Esophageal necrosis
10065728 = Ileal fistula
10065730 = Ileal obstruction
10065732 = Jejunal obstruction
10065735 = Laryngeal inflammation
10065738 = Unequal limb length
10065744 = Arteritis infective
10065745 = Prolapse of intestinal stoma
10065746 = Bronchopulmonary hemorrhage
10065747 = Cecal hemorrhage
10065748 = Urostomy site bleeding
10065749 = Tracheostomy site bleeding
10065752 = Duodenal infection
10065755 = Lip infection
10065759 = Laryngeal hemorrhage

10065761 = Cecal infection
10065762 = Spermatic cord hemorrhage
10065763 = Ovarian hemorrhage
10065764 = Mucosal infection
10065765 = Cranial nerve infection
10065766 = Peripheral nerve infection
10065771 = Small intestine infection
10065772 = Vulval infection
10065773 = Lymph leakage
10065775 = Abdominal soft tissue necrosis
10065776 = Muscle weakness lower limb
10065777 = Soft tissue necrosis lower limb
10065778 = Soft tissue necrosis upper limb
10065779 = Head soft tissue necrosis
10065780 = Muscle weakness left-sided
10065781 = Neck soft tissue necrosis
10065783 = Musculoskeletal deformity
10065784 = Central nervous system necrosis
10065785 = External ear pain
10065786 = Laryngeal fistula
10065787 = Tracheal fistula
10065788 = Fallopian tube anastomotic leak
10065789 = Fallopian tube obstruction
10065790 = Fallopian tube perforation
10065791 = Fallopian tube stenosis
10065793 = Pelvic soft tissue necrosis
10065794 = Muscle weakness right-sided
10065795 = Muscle weakness trunk
10065796 = Joint range of motion decreased cervical spine
10065798 = Superficial soft tissue fibrosis
10065799 = Fibrosis deep connective tissue
10065800 = Joint range of motion decreased lumbar spine
10065802 = Bladder anastomotic leak
10065803 = Kidney anastomotic leak
10065805 = Spermatic cord obstruction
10065811 = Uterine fistula
10065813 = Vaginal fistula
10065814 = Ureteric anastomotic leak
10065815 = Urethral anastomotic leak
10065817 = Vaginal obstruction
10065818 = Vaginal perforation
10065822 = Prolapse of urostomy
10065823 = Nipple deformity
10065825 = Intraoperative gastrointestinal injury
10065826 = Intraoperative arterial injury
10065827 = Intraoperative hepatobiliary injury

10065828 = Intraoperative urinary injury
10065829 = Intraoperative musculoskeletal injury
10065830 = Intraoperative neurological injury
10065831 = Intraoperative breast injury
10065832 = Intraoperative respiratory injury
10065834 = Intraoperative endocrine injury
10065836 = IVth nerve disorder
10065837 = External ear inflammation
10065838 = Middle ear inflammation
10065840 = Intraoperative reproductive tract injury
10065841 = Intraoperative ocular injury
10065842 = Intraoperative head and neck injury
10065843 = Intraoperative cardiac injury
10065844 = Intraoperative ear injury
10065845 = Intraoperative renal injury
10065846 = Intraoperative skin injury
10065847 = Intraoperative splenic injury
10065848 = Intraoperative venous injury
10065849 = Injury to jugular vein
10065851 = Esophageal fistula
10065873 = Pulmonary fistula
10065879 = Gastrointestinal anastomotic leak
10065880 = Laryngeal mucositis
10065881 = Pharyngeal mucositis
10065882 = Urostomy leak
10065883 = Urostomy obstruction
10065885 = Urostomy stenosis
10065886 = Uterine anastomotic leak
10065887 = Vaginal anastomotic leak
10065888 = Vas deferens anastomotic leak
10065891 = Large intestinal anastomotic leak
10065892 = Small intestinal anastomotic leak
10065893 = Gastric anastomotic leak
10065894 = Rectal anastomotic leak
10065895 = Muscle weakness upper limb
10065897 = Spermatic cord anastomotic leak
10065898 = Stenosis of gastrointestinal stoma
10065900 = Tracheal mucositis
10065906 = Carbon monoxide diffusing capacity decreased
10065928 = Uterine obstruction
10065961 = Esophageal anastomotic leak
10065973 = Iron overload
10066480 = Avascular necrosis
10066874 = Gastroesophageal reflux disease
10069138 = Papulopustular rash
10069339 = Acute kidney injury

10069501 = Left ventricular systolic dysfunction

6. AE Attribution caDSR CDE = 1285 Ver.3.0

Instructions: This question is not asked for baseline assessments. Question should be asked (mandatory) for all studies that involve drug therapy.

- Definite
- Possible
- Probable
- Unlikely
- Unrelated

7. Reporting Period End Date caDSR CDE = 2006851 Ver.4.0

_____ (MM/DD/YYYY)

Instructions: End of the assessment period.

8. Were adverse events assessed during most recent period caDSR CDE = 2179971 Ver.1.0

Instructions: Indicator to clarify whether any AEs were identified during the reporting period. This is confirmation that the remainder of the form was intentionally left blank.

- Yes
- No
- Unknown

9. Expected? (Yes/No) caDSR CDE = 2183619 Ver.1.0

Instructions: None

- Yes
- No

10. Serious? caDSR CDE = 2199908 Ver.1.0

Instructions: If a 'yes' response is entered, complete the SAE section for this AE.

- Yes

No

11. Event Onset Time caDSR CDE = 2585234 Ver.1.0

_____ (TIME (HR(24):MN))

Instructions: Enter the time of day when AE was first evident. Used when Date of Onset is insufficient.

12. Course caDSR CDE = 2732184 Ver.1.0

Instructions: May be used during protocol therapy period to automatically set the evaluation start/end dates to the period of the course of treatment (e.g. user supplies course# and evaluation period derived).

13. AE Evaluation Period Start Date caDSR CDE = 2744943 Ver.1.0

_____ (MM/DD/YYYY)

Instructions: Date of the beginning (start) of the assessment period.

14. Pre-existing AE? caDSR CDE = 2746280 Ver.1.0

Instructions: Should be derivable if you capture AEs for specified periods; not needed if you track an AE until it resolves (including worsening) rather than for a defined assessment period.

Yes

No

15. AE Resolved Time caDSR CDE = 2746301 Ver.1.0

_____ (TIME (HR(24):MN))

Instructions: Enter the time of day when AE was resolved.

16. AE Ongoing? caDSR CDE = 2746311 Ver.1.0

Instructions: Flag to indicate whether AE has resolved or not. This ensures that leaving 'Stop Date' blank was not done inadvertently.

- Yes
- No

17. Participant Status/Outcome caDSR CDE = 2746517 Ver.1.0

Instructions: None

- Fatal
- Not Recovered/Not Resolved
- Recovered/Resolved
- Recovered/Resolved with Sequelae
- Recovering/Resolving
- Unknown

18. Adverse Event Condition Pattern caDSR CDE = 2008418 Ver.1.0

Instructions: This should be derivable from a review of AEs over time.

- 1 = single episode
- 2 = intermittent
- 3 = CONTINUOUS

19. Did event reappear after study agent was reintroduced? caDSR CDE = 2179615 Ver.1.0

Instructions: Enter response from choice list.

- Yes
- No
- N/A

20. Comments caDSR CDE = 797 Ver.5.0

Instructions: A general comment that should not be specific to a single AE.

.....
Optional Serious Adverse Event Questions

The following additional elements are optional on a SAE form.

.....

1. Why serious? caDSR CDE = 2179679 Ver.3.0

Instructions: Select the appropriate response.

1 = Results in Death

2 = Is life-threatening

3 = Requires inpatient hospitalization or prolongation of existing hospitalization

4 = Results in persistent or significant disability/incapacity

5 = Is a congenital anomaly/birth defect

6 = In the medical judgment of the treating physician and/or investigator, it may jeopardize the participant or require intervention to prevent one of these outcomes

7 = Other, specify

8 = Meets criteria per protocol but does not meet other criterion (above)

2. Dose-Limiting Toxicity? caDSR CDE = 2004106 Ver.3.0

Instructions: Select the appropriate response.

___N

___Y