Adverse Event/Serious Adverse Event CTCAE v3 NCI Standard
Template Form
2748814v2.0
As-of 8-22-2013

Mandatory Adverse Event Questions

Must be included when this data is collected for reporting.

1. Adverse Event Name (v3.0) caDSR CDE = 323 Ver.3.0

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.

___Acidosis (metabolic or respiratory)
___Acute vascular leak syndrome
___Adrenal insufficiency
___Adult respiratory distress syndrome (ARDS)
___Albumin, serum-low (hypoalbuminemia)
___Alcohol intolerance syndrome (antabuse-like syndrome)
___Alkaline phosphatase
___Alkalosis (metabolic or respiratory)
___Allergic reaction/hypersensitivity (including drug fever)
___Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)
___Allergy/Immunology-Other (Specify)
___ALT, SGPT (serum glutamic pyruvic transaminase)
___Amylase
___Anorexia
___Apnea
___Arachnoiditis/meningismus/radiculitis
___Arthritis (non-septic)
___Ascites (non-malignant)
___Aspiration
___AST, SGOT (serum glutamic oxaloacetic transaminase)
___Ataxia (incoordination)
___Atelectasis
___Atrophy, skin
___Atrophy, subcutaneous fat
___Auditory/Ear-Other (Specify)
___Autoimmune reaction
___Bicarbonate, serum-low
___Bilirubin (hyperbilirubinemia)
___Bladder spasms
___Blood/Bone Marrow-Other (Specify)
___Bone age (alteration in bone age)
___Bone growth: femoral head; slipped capital femoral epiphysis
___Bone growth: limb length discrepancy
___Bone growth: spine kyphosis/lordosis
___Bone marrow cellularity
___Bone: spine-scoliosis
___Brachial plexopathy
___Breast function/lactation
___Breast nipple/areolar deformity
___Breast volume/hypoplasia
___Bronchospasm, wheezing
___Bruising (in absence of grade 3 or 4 thrombocytopenia)
___Burn
___Calcium, serum-high (hypercalcemia)
___Calcium, serum-low (hypocalcemia)
___Carbon monoxide diffusion capacity (DL(co))
___Cardiac Arrhythmia-Other (Specify)
___Cardiac General-Other (Specify)
___Cardiac ischemia/infarction
___Cardiac troponin I (cTnI)
___Cardiac troponin T (cTnT)
___Cardiopulmonary arrest, cause unknown (non-fatal)
___Cataract
___CD4 count
___Cervical spine-range of motion
___Cheilitis
___Cholecystitis
___Cholesterol, serum-high (hypercholesteremia)
___Chyle or lymph leakage
___Chylothorax
___CNS cerebrovascular ischemia
___CNS necrosis/cystic progression
___Coagulation-Other (Specify)
___Cognitive disturbance
___Colitis
___Colitis, infectious (e.g., Clostridium difficile)
___Conduction abnormality/Atrioventricular heart block - Asystole
___Conduction abnormality/Atrioventricular heart block - AV block-first degree Mobitz Type I (Wenckebach)
___Conduction abnormality/Atrioventricular heart block - AV block-second degree Mobitz Type II
___Conduction abnormality/Atrioventricular heart block - AV block-third degree (complete AV block)
Conduction abnormality/Atrioventricular heart block - Conduction abnormality NOS
Conduction abnormality/Atrioventricular heart block - Sick sinus syndrome
Conduction abnormality/Atrioventricular heart block - Stokes-Adams syndrome
Conduction abnormality/Atrioventricular heart block - Wolff-Parkinson-White syndrome
Confusion
Constipation
Constitutional Symptoms-Other (Specify)
Cough
CPK (creatine phosphokinase)
Creatinine
Cushingoid appearance (e.g., moon face, buffalo hump, centripetal obesity, cutaneous striae)
Cystitis
Cytokine release syndrome/acute infusion reaction
Death not associated with CTCAE term - Death NOS
Death not associated with CTCAE term - Disease progression NOS
Death not associated with CTCAE term - Multi-organ failure
Death not associated with CTCAE term - Sudden death
Dehydration
Dental: dentures or prosthesis
Dental: periodontal disease
Dental: teeth
Dental: teeth development
Dermal change lymphedema, phlebolymphedema
Dermatology/Skin-Other (Specify)
Diarrhea
DIC (disseminated intravascular coagulation)
Distention/bloating, abdominal
Dizziness
Dry eye syndrome
Dry mouth/salivary gland (xerostomia)
Dry skin
Dysphagia (difficulty swallowing)
Dyspnea (shortness of breath)
Edema, larynx
Edema: head and neck
Edema: limb
Edema: trunk/genital
Edema: viscera
Ejaculatory dysfunction
Encephalopathy
Endocrine-Other (Specify)
Enteritis (inflammation of the small bowel)
Erectile dysfunction
Esophagitis
Exostosis
Extrapyramidal/involuntary movement/restlessness
Extremity-lower (gait/walking)
Extremity-upper (function)
Eyelid dysfunction
Fatigue (asthenia, lethargy, malaise)
Febrile neutropenia
Feminization of male
FEV(1)
Fever (in the absence of neutropenia, where neutropenia is defined as ANC < 1.0 x 10^9/L)
Fibrinogen
Fibrosis-cosmesis
Fibrosis-deep connective tissue
Fistula, GI - Abdomen NOS
Fistula, GI - Anus
Fistula, GI - Biliary tree
Fistula, GI - Colon/cecum/appendix
Fistula, GI - Duodenum
Fistula, GI - Esophagus
Fistula, GI - Gallbladder
Fistula, GI - Ileum
Fistula, GI - Jejunum
Fistula, GI - Oral cavity
Fistula, GI - Pancreas
Fistula, GI - Pharynx
Fistula, GI - Rectum
Fistula, GI - Salivary gland
Fistula, GI - Small bowel NOS
Fistula, GI - Stomach
Fistula, GU - Bladder
Fistula, GU - Genital tract-female
Fistula, GU - Kidney
Fistula, GU - Ureter
Fistula, GU - Urethra
Fistula, GU - Uterus
Fistula, GU - Vagina
Fistula, pulmonary/upper respiratory - Bronchus
Fistula, pulmonary/upper respiratory - Larynx
Fistula, pulmonary/upper respiratory - Lung
Fistula, pulmonary/upper respiratory - Oral cavity
Fistula, pulmonary/upper respiratory - Pharynx
Fistula, pulmonary/upper respiratory - Pleura
Fistula, pulmonary/upper respiratory - Trachea
Flatulence
Flu-like syndrome
Flushing
Fracture
Gastritis (including bile reflux gastritis)
Gastrointestinal-Other (Specify)
GGT (gamma-glutamyl transpeptidase)
Glaucoma
Glomerular filtration rate
Glucose, serum-high (hyperglycemia)
Glucose, serum-low (hypoglycemia)
Growth and Development-Other (Specify)
Growth velocity (reduction in growth velocity)
Gynecomastia
Hair loss/Alopecia (scalp or body)
Haptoglobin
Hearing: patients with/without baseline audiogram and enrolled in a monitoring program
Hearing: patients without baseline audiogram and not enrolled in a monitoring program
Heartburn/dyspepsia
Hematoma
Hemoglobin
Hemoglobinuria
Hemolysis (e.g., immune hemolytic anemia, drug related hemolysis)
Hemorrhage, CNS
Hemorrhage, GI - Abdomen NOS
Hemorrhage, GI - Anus
Hemorrhage, GI - Biliary tree
Hemorrhage, GI - Cecum/appendix
Hemorrhage, GI - Colon
Hemorrhage, GI - Duodenum
Hemorrhage, GI - Esophagus
Hemorrhage, GI - Ileum
Hemorrhage, GI - Jejunum
Hemorrhage, GI - Liver
Hemorrhage, GI - Lower GI NOS
Hemorrhage, GI - Oral cavity
Hemorrhage, GI - Pancreas
Hemorrhage, GI - Peritoneal cavity
Hemorrhage, GI - Rectum
Hemorrhage, GI - Stoma
Hemorrhage, GI - Stomach
Hemorrhage, GI - Upper GI NOS
Hemorrhage, GI - Varices (esophageal)
Hemorrhage, GI - Varices (rectal)
- Hemorrhage, GU - Bladder
- Hemorrhage, GU - Fallopian tube
- Hemorrhage, GU - Kidney
- Hemorrhage, GU - Ovary
- Hemorrhage, GU - Prostate
- Hemorrhage, GU - Retroperitoneum
- Hemorrhage, GU - Spermatic cord
- Hemorrhage, GU - Stoma
- Hemorrhage, GU - Testes
- Hemorrhage, GU - Ureter
- Hemorrhage, GU - Urethra
- Hemorrhage, GU - Urinary NOS
- Hemorrhage, GU - Uterus
- Hemorrhage, GU - Vagina
- Hemorrhage, GU - Vas deferens
- Hemorrhage, pulmonary/upper respiratory - Bronchopulmonary NOS
- Hemorrhage, pulmonary/upper respiratory - Bronchus
- Hemorrhage, pulmonary/upper respiratory - Larynx
- Hemorrhage, pulmonary/upper respiratory - Lung
- Hemorrhage, pulmonary/upper respiratory - Mediastinum
- Hemorrhage, pulmonary/upper respiratory - Nose
- Hemorrhage, pulmonary/upper respiratory - Pharynx
- Hemorrhage, pulmonary/upper respiratory - Pleura
- Hemorrhage, pulmonary/upper respiratory - Respiratory tract NOS
- Hemorrhage, pulmonary/upper respiratory - Stoma
- Hemorrhage, pulmonary/upper respiratory - Trachea
- Hemorrhage/bleeding associated with surgery, intra-operative or post-operative
- Hemorrhage/Bleeding-Other (Specify)
- Hemorrhoids
- Hepatobiliary/Pancreas-Other (Specify)
- Hiccoughs (hiccups, singultus)
- Hot flashes/flushes
- Hydrocephalus
- Hyperpigmentation
- Hypertension
- Hypopigmentation
- Hypotension
- Hypothermia
- Hypoxia
- Ileus, GI (functional obstruction of bowel, i.e., neuroconstipation)
- Incontinence, anal
- Incontinence, urinary
- Induration/fibrosis (skin and subcutaneous tissue)
- Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Abdomen NOS
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Anal/perianal
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Appendix
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Artery
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Biliary tree
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Bladder (urinary)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Blood
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Bone (osteomyelitis)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Brain (encephalitis, infectious)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Brain + Spinal cord (encephalomyelitis)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Bronchus
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Catheter-related
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Cecum
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Cervix
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Colon
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Conjunctiva
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Cornea
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Dental-tooth
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Duodenum
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Esophagus
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - External ear (otitis externa)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Eye NOS
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Fallopian tube
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Foreign body (e.g., graft, implant, prosthesis, stent)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Gallbladder (cholecystitis)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Heart (endocarditis)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Ileum
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Jejunum
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Joint
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Kidney
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Larynx
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Lens
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Lip/perioral
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Liver
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Lung (pneumonia)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Lymphatic
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Mediastinum NOS
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Meninges (meningitis)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Middle ear (otitis media)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Mucosa
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Muscle (infection myositis)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Neck NOS
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Nerve-cranial
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Nerve-peripheral
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Nose
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Oral cavity-gums (gingivitis)
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Pancreas
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Paranasal
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Pelvis NOS
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Penis
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Peristomal
Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Peritoneal cavity
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Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Sinus
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Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Urinary tract NOS

Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Uterus

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Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Vein

Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Vulva

Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Wound

Infection with normal ANC or Grade 1 or 2 neutrophils - Abdomen NOS

Infection with normal ANC or Grade 1 or 2 neutrophils - Anal/perianal

Infection with normal ANC or Grade 1 or 2 neutrophils - Appendix

Infection with normal ANC or Grade 1 or 2 neutrophils - Artery

Infection with normal ANC or Grade 1 or 2 neutrophils - Biliary tree

Infection with normal ANC or Grade 1 or 2 neutrophils - Bladder (urinary)

Infection with normal ANC or Grade 1 or 2 neutrophils - Blood

Infection with normal ANC or Grade 1 or 2 neutrophils - Bone (osteomyelitis)

Infection with normal ANC or Grade 1 or 2 neutrophils - Brain (encephalitis, infectious)

Infection with normal ANC or Grade 1 or 2 neutrophils - Brain + Spinal cord (encephalomyelitis)

Infection with normal ANC or Grade 1 or 2 neutrophils - Bronchus

Infection with normal ANC or Grade 1 or 2 neutrophils - Catheter-related

Infection with normal ANC or Grade 1 or 2 neutrophils - Cecum

Infection with normal ANC or Grade 1 or 2 neutrophils - Cervix

Infection with normal ANC or Grade 1 or 2 neutrophils - Colon

Infection with normal ANC or Grade 1 or 2 neutrophils - Conjunctiva

Infection with normal ANC or Grade 1 or 2 neutrophils - Cornea

Infection with normal ANC or Grade 1 or 2 neutrophils - Dental-tooth

Infection with normal ANC or Grade 1 or 2 neutrophils - Duodenum

Infection with normal ANC or Grade 1 or 2 neutrophils - Esophagus

Infection with normal ANC or Grade 1 or 2 neutrophils - External ear (otitis externa)

Infection with normal ANC or Grade 1 or 2 neutrophils - Eye NOS

Infection with normal ANC or Grade 1 or 2 neutrophils - Fallopian tube

Infection with normal ANC or Grade 1 or 2 neutrophils - Foreign body (e.g., graft, implant, prosthesis, stent)

Infection with normal ANC or Grade 1 or 2 neutrophils - Gallbladder (cholecystitis)

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Infection with normal ANC or Grade 1 or 2 neutrophils - Ileum
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Infection with normal ANC or Grade 1 or 2 neutrophils - Small bowel NOS
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Infection with normal ANC or Grade 1 or 2 neutrophils - Spleen
Infection with normal ANC or Grade 1 or 2 neutrophils - Stomach
Infection with normal ANC or Grade 1 or 2 neutrophils - Trachea
Infection with normal ANC or Grade 1 or 2 neutrophils - Ungual (nails)
Infection with normal ANC or Grade 1 or 2 neutrophils - Upper aerodigestive
Infection with normal ANC or Grade 1 or 2 neutrophils:
- Upper airway NOS
- Ureter
- Urethra
- Urinary tract NOS
- Uterus
- Vagina
- Vein
- Vulva
- Wound

Infection with unknown ANC:
- Abdomen NOS
- Anal/perianal
- Appendix
- Artery
- Biliary tree
- Bladder (urinary)
- Blood
- Bone (osteomyelitis)
- Brain (encephalitis, infectious)
- Brain + Spinal cord (encephalomyelitis)
- Bronchus
- Catheter-related
- Cecum
- Cervix
- Colon
- Conjunctiva
- Cornea
- Dental-tooth
- Duodenum
- Esophagus
- External ear (otitis externa)
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- Foreign body (e.g., graft, implant, prosthesis, stent)
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- Heart (endocarditis)
- Ileum
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- Joint
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- Lung (pneumonia)
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<tbody>
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<td>Lymphatic</td>
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<td>Other (Specify)</td>
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<td>Infertility/sterility</td>
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<td>Injection site reaction/extravasation changes</td>
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<td>INR (International Normalized Ratio of prothrombin time)</td>
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___Inomnia
___Intra-operative injury - Abdomen NOS
___Intra-operative injury - Adrenal gland
___Intra-operative injury - Anal sphincter
___Intra-operative injury - Anus
___Intra-operative injury - Appendix
___Intra-operative injury - Artery NOS
___Intra-operative injury - Artery-aorta
___Intra-operative injury - Artery-carotid
___Intra-operative injury - Artery-cerebral
___Intra-operative injury - Artery-extremity (lower)
___Intra-operative injury - Artery-extremity (upper)
___Intra-operative injury - Artery-hepatic
___Intra-operative injury - Artery-major visceral artery
___Intra-operative injury - Artery-pulmonary
___Intra-operative injury - Biliary tree NOS
___Intra-operative injury - Biliary tree-common bile duct
___Intra-operative injury - Biliary tree-common hepatic duct
___Intra-operative injury - Biliary tree-left hepatic duct
___Intra-operative injury - Biliary tree-right hepatic duct
___Intra-operative injury - Bladder
___Intra-operative injury - Bone
___Intra-operative injury - Brachial plexus
___Intra-operative injury - Brain
___Intra-operative injury - Breast
___Intra-operative injury - Bronchus
___Intra-operative injury - Cartilage
___Intra-operative injury - Cecum
___Intra-operative injury - Cervix
___Intra-operative injury - CN I (olfactory)
___Intra-operative injury - CN II (optic)
___Intra-operative injury - CN III (oculomotor)
___Intra-operative injury - CN IV (trochlear)
___Intra-operative injury - CN IX (glossopharyngeal) motor pharynx
___Intra-operative injury - CN IX (glossopharyngeal) sensory ear-pharynx-tongue
___Intra-operative injury - CN V (trigeminal) motor
___Intra-operative injury - CN V (trigeminal) sensory
___Intra-operative injury - CN VI (abducens)
___Intra-operative injury - CN VII (facial) motor-face
___Intra-operative injury - CN VII (facial) sensory-taste
___Intra-operative injury - CN VIII (vestibulocochlear)
___Intra-operative injury - CN X (vagus)
___Intra-operative injury - CN XI (spinal accessory)
___Intra-operative injury - CN XII (hypoglossal)
___Intra-operative injury - Colon
___Intra-operative injury - Conjunctiva
Intra-operative injury - Peripheral sensory NOS
Intra-operative injury - Peritoneal cavity
Intra-operative injury - Pharynx
Intra-operative injury - Pituitary
Intra-operative injury - Pleura
Intra-operative injury - Prostate
Intra-operative injury - Rectum
Intra-operative injury - Recurrent laryngeal
Intra-operative injury - Retina
Intra-operative injury - Sacral plexus
Intra-operative injury - Salivary duct
Intra-operative injury - Salivary gland
Intra-operative injury - Sciatic
Intra-operative injury - Scrotum
Intra-operative injury - Sinus
Intra-operative injury - Skin
Intra-operative injury - Small bowel NOS
Intra-operative injury - Soft tissue NOS
Intra-operative injury - Spinal cord
Intra-operative injury - Spleen
Intra-operative injury - Stoma (GI)
Intra-operative injury - Stomach
Intra-operative injury - Teeth
Intra-operative injury - Tendon
Intra-operative injury - Testis
Intra-operative injury - Thoracic duct
Intra-operative injury - Thoracodorsal
Intra-operative injury - Thyroid
Intra-operative injury - Tongue
Intra-operative injury - Trachea
Intra-operative injury - Upper aerodigestive NOS
Intra-operative injury - Upper airway NOS
Intra-operative injury - Ureter
Intra-operative injury - Urethra
Intra-operative injury - Urinary conduit
Intra-operative injury - Urinary tract NOS
Intra-operative injury - Uterus
Intra-operative injury - Vagina
Intra-operative injury - Vein NOS
Intra-operative injury - Vein-extremity (lower)
Intra-operative injury - Vein-extremity (upper)
Intra-operative injury - Vein-hepatic
Intra-operative injury - Vein-inferior vena cava
Intra-operative injury - Vein-jugular
Intra-operative injury - Vein-major visceral vein
Intra-operative injury - Vein-portal vein
Intra-operative injury - Vein-pulmonary
Intra-operative injury - Vein-superior vena cava
Intra-operative injury - Vulva
Intra-operative Injury-Other (Specify)
Iron overload
Irregular menses (change from baseline)
Irritability (children <3 years of age)
Joint-effusion
Joint-function
Keratitis (corneal inflammation/corneal ulceration)
Laryngeal nerve dysfunction
Leak (including anastomotic), GI - Biliary tree
Leak (including anastomotic), GI - Esophagus
Leak (including anastomotic), GI - Large bowel
Leak (including anastomotic), GI - Leak NOS
Leak (including anastomotic), GI - Pancreas
Leak (including anastomotic), GI - Pharynx
Leak (including anastomotic), GI - Rectum
Leak (including anastomotic), GI - Small bowel
Leak (including anastomotic), GI - Stoma
Leak (including anastomotic), GI - Stomach
Leak (including anastomotic), GU - Bladder
Leak (including anastomotic), GU - Fallopian tube
Leak (including anastomotic), GU - Kidney
Leak (including anastomotic), GU - Spermatic cord
Leak (including anastomotic), GU - Stoma
Leak (including anastomotic), GU - Ureter
Leak (including anastomotic), GU - Urethra
Leak (including anastomotic), GU - Uterus
Leak (including anastomotic), GU - Vagina
Leak (including anastomotic), GU - Vas deferens
Leak, cerebrospinal fluid (CSF)
Left ventricular diastolic dysfunction
Left ventricular systolic dysfunction
Leukocytes (total WBC)
Leukoencephalopathy (radiological findings)
Libido
Lipase
Liver dysfunction/failure (clinical)
Local complication - device/prosthesis-related
Lumbar spine-range of motion
Lymphatics-Other (Specify)
Lymphedema-related fibrosis
Lymphocele
Lymphopenia
Magnesium, serum-high (hypermagnesemia)
Magnesium, serum-low (hypomagnesemia)
Malabsorption
Masculinization of female
Memory impairment
Mental status
Metabolic/Laboratory-Other (Specify)
Mood alteration - agitation
Mood alteration - anxiety
Mood alteration - depression
Mood alteration - euphoria
Mucositis/stomatitis (clinical exam) - Anus
Mucositis/stomatitis (clinical exam) - Esophagus
Mucositis/stomatitis (clinical exam) - Large bowel
Mucositis/stomatitis (clinical exam) - Larynx
Mucositis/stomatitis (clinical exam) - Oral cavity
Mucositis/stomatitis (clinical exam) - Pharynx
Mucositis/stomatitis (clinical exam) - Rectum
Mucositis/stomatitis (clinical exam) - Small bowel
Mucositis/stomatitis (clinical exam) - Stomach
Mucositis/stomatitis (clinical exam) - Trachea
Mucositis/stomatitis (functional/symptomatic) - Anus
Mucositis/stomatitis (functional/symptomatic) - Esophagus
Mucositis/stomatitis (functional/symptomatic) - Large bowel
Mucositis/stomatitis (functional/symptomatic) - Larynx
Mucositis/stomatitis (functional/symptomatic) - Oral cavity
Mucositis/stomatitis (functional/symptomatic) - Pharynx
Mucositis/stomatitis (functional/symptomatic) - Rectum
Mucositis/stomatitis (functional/symptomatic) - Small bowel
Mucositis/stomatitis (functional/symptomatic) - Stomach
Mucositis/stomatitis (functional/symptomatic) - Trachea
Muscle weakness, generalized or specific area (not due to neuropathy) - Extraocular
Muscle weakness, generalized or specific area (not due to neuropathy) - Extremity-lower
Muscle weakness, generalized or specific area (not due to neuropathy) - Extremity-upper
Muscle weakness, generalized or specific area (not due to neuropathy) - Facial
Muscle weakness, generalized or specific area (not due to neuropathy) - Left-sided
Muscle weakness, generalized or specific area (not due to neuropathy) - Ocular
Muscle weakness, generalized or specific area (not due to neuropathy) - Pelvic
Muscle weakness, generalized or specific area (not due to neuropathy) - Right-sided
Muscle weakness, generalized or specific area (not due to neuropathy) - Trunk
Muscle weakness, generalized or specific area (not due to neuropathy) -
Whole body/generalized
   ____Muscular/skeletal hypoplasia
   ____Musculoskeletal/Soft Tissue-Other (Specify)
   ____Myelitis
   ____Myelodysplasia
   ____Myocarditis
   ____Myositis (inflammation/damage of muscle)
   ____Nail changes
   ____Nasal cavity/paranasal sinus reactions
   ____Nausea
   ____Necrosis, GI - Anus
   ____Necrosis, GI - Colon/cecum/appendix
   ____Necrosis, GI - Duodenum
   ____Necrosis, GI - Esophagus
   ____Necrosis, GI - Gallbladder
   ____Necrosis, GI - Hepatic
   ____Necrosis, GI - Ileum
   ____Necrosis, GI - Jejunum
   ____Necrosis, GI - Oral
   ____Necrosis, GI - Pancreas
   ____Necrosis, GI - Peritoneal cavity
   ____Necrosis, GI - Pharynx
   ____Necrosis, GI - Rectum
   ____Necrosis, GI - Small bowel NOS
   ____Necrosis, GI - Stoma
   ____Necrosis, GI - Stomach
   ____Neuroendocrine: ACTH deficiency
   ____Neuroendocrine: ADH secretion abnormality (e.g., SIADH or low ADH)
   ____Neuroendocrine: gonadotropin secretion abnormality
   ____Neuroendocrine: growth hormone secretion abnormality
   ____Neuroendocrine: prolactin hormone secretion abnormality
   ____Neurology-Other (Specify)
   ____Neuropathy: cranial - CN I Smell
   ____Neuropathy: cranial - CN II Vision
   ____Neuropathy: cranial - CN III Pupil, upper eyelid, extra ocular movements
   ____Neuropathy: cranial - CN IV Downward, inward movement of eye
   ____Neuropathy: cranial - CN IX Motor-pharynx; Sensory-ear, pharynx, tongue
   ____Neuropathy: cranial - CN V Motor-jaw muscles; Sensory-facial
   ____Neuropathy: cranial - CN VI Lateral deviation of eye
   ____Neuropathy: cranial - CN VII Motor-face; Sensory-taste
   ____Neuropathy: cranial - CN VIII Hearing and balance
   ____Neuropathy: cranial - CN X Motor-palate; pharynx, larynx
   ____Neuropathy: cranial - CN XI Motor-sternomastoid and trapezius
   ____Neuropathy: cranial - CN XII Motor-tongue
   ____Neuropathy: motor
   ____Neuropathy: sensory
Neutrophils/granulocytes (ANC/AGC)
Night blindness (nyctalopia)
Nystagmus
Obesity
Obstruction, GI - Cecum
Obstruction, GI - Colon
Obstruction, GI - Duodenum
Obstruction, GI - Esophagus
Obstruction, GI - Gallbladder
Obstruction, GI - Ileum
Obstruction, GI - Jejunum
Obstruction, GI - Rectum
Obstruction, GI - Small bowel NOS
Obstruction, GI - Stoma
Obstruction, GI - Stomach
Obstruction, GU - Bladder
Obstruction, GU - Fallopian tube
Obstruction, GU - Prostate
Obstruction, GU - Spermatic cord
Obstruction, GU - Stoma
Obstruction, GU - Testes
Obstruction, GU - Ureter
Obstruction, GU - Urethra
Obstruction, GU - Uterus
Obstruction, GU - Vagina
Obstruction, GU - Vas deferens
Obstruction/stenosis of airway - Bronchus
Obstruction/stenosis of airway - Larynx
Obstruction/stenosis of airway - Pharynx
Obstruction/stenosis of airway - Trachea
Ocular surface disease
Ocular/Visual-Other (Specify)
Odor (patient odor)
Ophthalmoplegia/diplopia (double vision)
Opportunistic infection associated with >=Grade 2 lymphopenia
Optic disc edema
Orgasmic dysfunction
Osteonecrosis (avascular necrosis)
Osteoporosis
Otitis, external ear (non-infectious)
Otitis, middle ear (non-infectious)
Pain - Abdomen NOS
Pain - Anus
Pain - Back
Pain - Bladder
Pain - Bone
Pain - Breast
Pain - Buttock
Pain - Cardiac/heart
Pain - Chest wall
Pain - Chest/thorax NOS
Pain - Dental/teeth/peridontal
Pain - Esophagus
Pain - External ear
Pain - Extremity-limb
Pain - Eye
Pain - Face
Pain - Gallbladder
Pain - Head/headache
Pain - Intestine
Pain - Joint
Pain - Kidney
Pain - Larynx
Pain - Lip
Pain - Liver
Pain - Lymph node
Pain - Middle ear
Pain - Muscle
Pain - Neck
Pain - Neuralgia/peripheral nerve
Pain - Oral cavity
Pain - Oral-gums
Pain - Ovulatory
Pain - Pain NOS
Pain - Pelvis
Pain - Penis
Pain - Pericardium
Pain - Perineum
Pain - Peritoneum
Pain - Phantom (pain associated with missing limb)
Pain - Pleura
Pain - Prostate
Pain - Rectum
Pain - Scalp
Pain - Scrotum
Pain - Sinus
Pain - Skin
Pain - Stomach
Pain - Testicle
Pain - Throat/pharynx/larynx
Pain - Tumor pain
Pain - Urethra
- Pain - Uterus
- Pain - Vagina
- Pain-Other (Specify)
- Palpitations
- Pancreas, exocrine enzyme deficiency
- Pancreatic endocrine: glucose intolerance
- Pancreatitis
- Parathyroid function, low (hypoparathyroidism)
- Perforation, GI - Appendix
- Perforation, GI - Biliary tree
- Perforation, GI - Cecum
- Perforation, GI - Colon
- Perforation, GI - Duodenum
- Perforation, GI - Esophagus
- Perforation, GI - Gallbladder
- Perforation, GI - Ileum
- Perforation, GI - Jejunum
- Perforation, GI - Rectum
- Perforation, GI - Small bowel NOS
- Perforation, GI - Stomach
- Perforation, GU - Bladder
- Perforation, GU - Fallopian tube
- Perforation, GU - Kidney
- Perforation, GU - Ovary
- Perforation, GU - Prostate
- Perforation, GU - Spermatic cord
- Perforation, GU - Stoma
- Perforation, GU - Testes
- Perforation, GU - Ureter
- Perforation, GU - Urethra
- Perforation, GU - Uterus
- Perforation, GU - Vagina
- Perforation, GU - Vas deferens
- Pericardial effusion (non-malignant)
- Pericarditis
- Peripheral arterial ischemia
- Personality/behavioral
- Petechiae/purpura (hemorrhage/bleeding into skin or mucosa)
- Phlebitis (including superficial thrombosis)
- Phlebolymphatic cording
- Phosphate, serum-low (hypophosphatemia)
- Photosensitivity
- Phrenic nerve dysfunction
- Platelets
- Pleural effusion (non-malignant)
- Pneumonitis/pulmonary infiltrates
___Pneumothorax
___Portal vein flow
___Potassium, serum-high (hyperkalemia)
___Potassium, serum-low (hypokalemia)
___Proctitis
___Prolapse of stoma, GI
___Prolapse of stoma, GU
___Prolonged chest tube drainage or air leak after pulmonary resection
___Prolonged intubation after pulmonary resection (>24 hrs after surgery)
___Prolonged QTc interval
___Proptosis/enophthalmos
___Proteinuria
___Pruritus/itching
___Psychosis (hallucinations/delusions)
___PTT (Partial thromboplastin time)
___Puberty (delayed)
___Puberty (precocious)
___Pulmonary fibrosis (radiographic changes)
___Pulmonary hypertension
___Pulmonary/Upper Respiratory-Other (Specify)
___Pyramidal tract dysfunction (e.g., increased tone, hyperreflexia, positive Babinski, decreased fine motor coordination)
___Rash/desquamation
___Rash: acne/acneiform
___Rash: dermatitis associated with radiation - Chemoradiation
___Rash: dermatitis associated with radiation - Radiation
___Rash: erythema multiforme (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis)
___Rash: hand-foot skin reaction
___Renal failure
___Renal/Genitourinary-Other (Specify)
___ Restrictive cardiomyopathy
___ Retinal detachment
___ Retinoic acid syndrome
___ Retinopathy
___ Right ventricular dysfunction (cor pulmonale)
___ Rigors/chills
___ Salivary gland changes/saliva
___ Scleral necrosis/melt
___ Secondary Malignancy-possibly related to cancer treatment (Specify)
___ Seizure
___ Seroma
___ Serum sickness
___ Sexual/Reproductive Function-Other (Specify)
___ Short stature
___ Skin breakdown/decubitus ulcer
Sodium, serum-high (hypernatremia)
Sodium, serum-low (hyponatremia)
Soft tissue necrosis - Abdomen
Soft tissue necrosis - Extremity-lower
Soft tissue necrosis - Extremity-upper
Soft tissue necrosis - Head
Soft tissue necrosis - Neck
Soft tissue necrosis - Pelvic
Soft tissue necrosis - Thorax
Somnolence/depressed level of consciousness
Speech impairment (e.g., dysphasia or aphasia)
Spleenic function
Striae
Stricture/stenosis (including anastomotic), GI - Anus
Stricture/stenosis (including anastomotic), GI - Biliary tree
Stricture/stenosis (including anastomotic), GI - Cecum
Stricture/stenosis (including anastomotic), GI - Colon
Stricture/stenosis (including anastomotic), GI - Duodenum
Stricture/stenosis (including anastomotic), GI - Esophagus
Stricture/stenosis (including anastomotic), GI - Ileum
Stricture/stenosis (including anastomotic), GI - Jejunum
Stricture/stenosis (including anastomotic), GI - Pancreas/pancreatic duct
Stricture/stenosis (including anastomotic), GI - Pharynx
Stricture/stenosis (including anastomotic), GI - Rectum
Stricture/stenosis (including anastomotic), GI - Small bowel NOS
Stricture/stenosis (including anastomotic), GI - Stoma
Stricture/stenosis (including anastomotic), GI - Stomach
Stricture/stenosis (including anastomotic), GU - Bladder
Stricture/stenosis (including anastomotic), GU - Fallopian tube
Stricture/stenosis (including anastomotic), GU - Prostate
Stricture/stenosis (including anastomotic), GU - Spermatic cord
Stricture/stenosis (including anastomotic), GU - Stoma
Stricture/stenosis (including anastomotic), GU - Testes
Stricture/stenosis (including anastomotic), GU - Ureter
Stricture/stenosis (including anastomotic), GU - Urethra
Stricture/stenosis (including anastomotic), GU - Uterus
Stricture/stenosis (including anastomotic), GU - Vagina
Stricture/stenosis (including anastomotic), GU - Vas deferens
Supraventricular and nodal arrhythmia - Atrial fibrillation
Supraventricular and nodal arrhythmia - Atrial flutter
Supraventricular and nodal arrhythmia - Atrial tachycardia/paroxysmal atrial tachycardia
Supraventricular and nodal arrhythmia - Nodal/junctional
Supraventricular and nodal arrhythmia - Sinus arrhythmia
Supraventricular and nodal arrhythmia - Sinus bradycardia
Supraventricular and nodal arrhythmia - Sinus tachycardia
Supraventricular and nodal arrhythmia - Supraventricular arrhythmia NOS
Supraventricular and nodal arrhythmia - Supraventricular extrasystoles (premature atrial contractions; premature nodal/junctional contractions)
Supraventricular and nodal arrhythmia - Supraventricular tachycardia
Sweating (diaphoresis)
Syncope (fainting)
 Syndromes-Other (Specify)
Taste alteration (dysgeusia)
 Telangiectasia
Thrombosis/embolism (vascular access-related)
Thrombosis/thrombus/embolism
Thrombotic microangiopathy (e.g., thrombotic thrombocytopenic purpura or hemolytic uremic syndrome)
Thyroid function, high (hyperthyroidism, thyrotoxicosis)
Thyroid function, low (hypothyroidism)
Tinnitus
Tremor
Triglyceride, serum-high (hypertriglyceridemia)
Trismus (difficulty, restriction or pain when opening mouth)
Tumor flare
Tumor lysis syndrome
Typhlitis (cecal inflammation)
Ulcer, GI - Anus
Ulcer, GI - Cecum
Ulcer, GI - Colon
Ulcer, GI - Duodenum
Ulcer, GI - Esophagus
Ulcer, GI - Ileum
Ulcer, GI - Jejunum
Ulcer, GI - Rectum
Ulcer, GI - Small bowel NOS
Ulcer, GI - Stoma
Ulcer, GI - Stomach
Ulceration
Uric acid, serum-high (hyperuricemia)
Urinary electrolyte wasting (e.g., Fanconi’s syndrome, renal tubular acidosis)
Urinary frequency/urgency
Urinary retention (including neurogenic bladder)
Urine color change
Urticaria (hives, welts, wheals)
Uveitis
Vaginal discharge (non-infectious)
Vaginal dryness
Vaginal mucositis
Vaginal stenosis/length
Vaginitis (not due to infection)
Valvular heart disease
Vascular-Other (Specify)
Vasculitis
Vasovagal episode
Ventricular arrhythmia - Bigeminy
Ventricular arrhythmia - Idioventricular rhythm
Ventricular arrhythmia - PVCs
Ventricular arrhythmia - Torsade de pointes
Ventricular arrhythmia - Trigeminy
Ventricular arrhythmia - Ventricular arrhythmia NOS
Ventricular arrhythmia - Ventricular fibrillation
Ventricular arrhythmia - Ventricular flutter
Ventricular arrhythmia - Ventricular tachycardia
Vessel injury-artery - Aorta
Vessel injury-artery - Carotid
Vessel injury-artery - Extremity-lower
Vessel injury-artery - Extremity-upper
Vessel injury-artery - Other NOS
Vessel injury-artery - Visceral
Vessel injury-vein - Extremity-lower
Vessel injury-vein - Extremity-upper
Vessel injury-vein - IVC
Vessel injury-vein - Jugular
Vessel injury-vein - Other NOS
Vessel injury-vein - SVC
Vessel injury-vein - Viscera
Viral hepatitis
Visceral arterial ischemia (non-myocardial)
Vision-blurred vision
Vision-flashing lights/floaters
Vision-photophobia
Vital capacity
Vitreous hemorrhage
Voice changes/dysarthria (e.g., hoarseness, loss or alteration in voice, laryngitis)
Vomiting
Watery eye (epiphora, tearing)
Weight gain
Weight loss
Wound complication, non-infectious

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 = 2201188 Ver.1.0

Instructions: A coded value to identify the severity of the AE.
   1 (1) = MILD ADVERSE EVENT
   2 (1) = MODERATE ADVERSE EVENT
   3 (1) = SEVERE ADVERSE EVENT
   4 (1) = LIFE-THREATENING OR DISABLING ADVERSE EVENT
   5 (1) = 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 courses.

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.

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)
   ___ 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 v3.0)  caDSR CDE = 2538246 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.

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.
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 (1) = single episode
2 (1) = intermittent
3 (1) = 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 (1) = Results in Death
   2 (1) = Is life-threatening
   3 (1) = Requires inpatient hospitalization or prolongation of existing hospitalization
   4 (1) = Results in persistent or significant disability/incapacity
   5 (1) = Is a congenital anomaly/birth defect
   6 (1) = 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 (1) = Other, specify
   8 (1) = 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