

**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
- \_\_\_ Conduction abnormality/Atrioventricular heart block - AV block-Second 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
- \_\_\_ Extrapyrarnidal/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 <math><1.0 \times 10^9/L</math>)
- \_\_\_ 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

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Pharynx

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Pleura (empyema)

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Prostate

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Rectum

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Salivary gland

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Scrotum

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Sinus

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Skin (cellulitis)

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Small bowel NOS

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Soft tissue NOS

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Spinal cord (myelitis)

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Spleen

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Stomach

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Trachea

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Ungual (nails)

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Upper aerodigestive NOS

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Upper airway NOS

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Ureter

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Urethra

\_\_\_\_ 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

\_\_\_\_ Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils - Vagina

\_\_\_\_ 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)

\_\_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Heart (endocarditis)

\_\_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Ileum

- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Jejunum
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Joint
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Kidney
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Larynx
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Lens
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Lip/perioral
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Liver
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Lung (pneumonia)
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Lymphatic
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Mediastinum NOS
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Meninges  
(meningitis)
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Middle ear (otitis media)
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Mucosa
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Muscle (infection myositis)
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Neck NOS
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Nerve-cranial
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Nerve-peripheral
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Nose
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Oral cavity-gums  
(gingivitis)
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Pancreas
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Paranasal
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Pelvis NOS
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Penis
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Peristomal
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Peritoneal cavity
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Pharynx
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Pleura (empyema)
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Prostate
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Rectum
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Salivary gland
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Scrotum
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Sinus
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Skin (cellulitis)
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Small bowel NOS
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Soft tissue NOS
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Spinal cord  
(myelitis)
- \_\_\_ 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

NOS

- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Upper airway NOS
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Ureter
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Urethra
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Urinary tract NOS
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Uterus
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Vagina
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Vein
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Vulva
- \_\_\_ Infection with normal ANC or Grade 1 or 2 neutrophils - Wound
- \_\_\_ Infection with unknown ANC - Abdomen NOS
- \_\_\_ Infection with unknown ANC - Anal/perianal
- \_\_\_ Infection with unknown ANC - Appendix
- \_\_\_ Infection with unknown ANC - Artery
- \_\_\_ Infection with unknown ANC - Biliary tree
- \_\_\_ Infection with unknown ANC - Bladder (urinary)
- \_\_\_ Infection with unknown ANC - Blood
- \_\_\_ Infection with unknown ANC - Bone (osteomyelitis)
- \_\_\_ Infection with unknown ANC - Brain (encephalitis, infectious)
- \_\_\_ Infection with unknown ANC - Brain + Spinal cord (encephalomyelitis)
- \_\_\_ Infection with unknown ANC - Bronchus
- \_\_\_ Infection with unknown ANC - Catheter-related
- \_\_\_ Infection with unknown ANC - Cecum
- \_\_\_ Infection with unknown ANC - Cervix
- \_\_\_ Infection with unknown ANC - Colon
- \_\_\_ Infection with unknown ANC - Conjunctiva
- \_\_\_ Infection with unknown ANC - Cornea
- \_\_\_ Infection with unknown ANC - Dental-tooth
- \_\_\_ Infection with unknown ANC - Duodenum
- \_\_\_ Infection with unknown ANC - Esophagus
- \_\_\_ Infection with unknown ANC - External ear (otitis externa)
- \_\_\_ Infection with unknown ANC - Eye NOS
- \_\_\_ Infection with unknown ANC - Fallopian tube
- \_\_\_ Infection with unknown ANC - Foreign body (e.g., graft, implant, prosthesis, stent)
- \_\_\_ Infection with unknown ANC - Gallbladder (cholecystitis)
- \_\_\_ Infection with unknown ANC - Heart (endocarditis)
- \_\_\_ Infection with unknown ANC - Ileum
- \_\_\_ Infection with unknown ANC - Jejunum
- \_\_\_ Infection with unknown ANC - Joint
- \_\_\_ Infection with unknown ANC - Kidney
- \_\_\_ Infection with unknown ANC - Larynx
- \_\_\_ Infection with unknown ANC - Lens
- \_\_\_ Infection with unknown ANC - Lip/perioral
- \_\_\_ Infection with unknown ANC - Liver
- \_\_\_ Infection with unknown ANC - Lung (pneumonia)

Infection with unknown ANC - Lymphatic  
 Infection with unknown ANC - Mediastinum NOS  
 Infection with unknown ANC - Meninges (meningitis)  
 Infection with unknown ANC - Middle ear (otitis media)  
 Infection with unknown ANC - Mucosa  
 Infection with unknown ANC - Muscle (infection myositis)  
 Infection with unknown ANC - Neck NOS  
 Infection with unknown ANC - Nerve-cranial  
 Infection with unknown ANC - Nerve-peripheral  
 Infection with unknown ANC - Nose  
 Infection with unknown ANC - Oral cavity-gums (gingivitis)  
 Infection with unknown ANC - Pancreas  
 Infection with unknown ANC - Paranasal  
 Infection with unknown ANC - Pelvis NOS  
 Infection with unknown ANC - Penis  
 Infection with unknown ANC - Peristomal  
 Infection with unknown ANC - Peritoneal cavity  
 Infection with unknown ANC - Pharynx  
 Infection with unknown ANC - Pleura (empyema)  
 Infection with unknown ANC - Prostate  
 Infection with unknown ANC - Rectum  
 Infection with unknown ANC - Salivary gland  
 Infection with unknown ANC - Scrotum  
 Infection with unknown ANC - Sinus  
 Infection with unknown ANC - Skin (cellulitis)  
 Infection with unknown ANC - Small bowel NOS  
 Infection with unknown ANC - Soft tissue NOS  
 Infection with unknown ANC - Spinal cord (myelitis)  
 Infection with unknown ANC - Spleen  
 Infection with unknown ANC - Stomach  
 Infection with unknown ANC - Trachea  
 Infection with unknown ANC - Ungual (nails)  
 Infection with unknown ANC - Upper aerodigestive NOS  
 Infection with unknown ANC - Upper airway NOS  
 Infection with unknown ANC - Ureter  
 Infection with unknown ANC - Urethra  
 Infection with unknown ANC - Urinary tract NOS  
 Infection with unknown ANC - Uterus  
 Infection with unknown ANC - Vagina  
 Infection with unknown ANC - Vein  
 Infection with unknown ANC - Vulva  
 Infection with unknown ANC - Wound  
 Infection-Other (Specify)  
 Infertility/sterility  
 Injection site reaction/extravasation changes  
 INR (International Normalized Ratio of prothrombin time)

\_\_\_ Insomnia  
\_\_\_ 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 - Cornea  
\_\_\_ Intra-operative injury - Cranial nerve or branch NOS  
\_\_\_ Intra-operative injury - Duodenum  
\_\_\_ Intra-operative injury - Esophagus  
\_\_\_ Intra-operative injury - Extremity-lower  
\_\_\_ Intra-operative injury - Extremity-upper  
\_\_\_ Intra-operative injury - Eye NOS  
\_\_\_ Intra-operative injury - Face NOS  
\_\_\_ Intra-operative injury - Fallopian tube  
\_\_\_ Intra-operative injury - Gallbladder  
\_\_\_ Intra-operative injury - Gingiva  
\_\_\_ Intra-operative injury - Heart  
\_\_\_ Intra-operative injury - Ileum  
\_\_\_ Intra-operative injury - Inner ear  
\_\_\_ Intra-operative injury - Jejunum  
\_\_\_ Intra-operative injury - Joint  
\_\_\_ Intra-operative injury - Kidney  
\_\_\_ Intra-operative injury - Larynx  
\_\_\_ Intra-operative injury - Lens  
\_\_\_ Intra-operative injury - Ligament  
\_\_\_ Intra-operative injury - Lingual  
\_\_\_ Intra-operative injury - Lip/perioral area  
\_\_\_ Intra-operative injury - Liver  
\_\_\_ Intra-operative injury - Lung  
\_\_\_ Intra-operative injury - Lung thoracic  
\_\_\_ Intra-operative injury - Mediastinum  
\_\_\_ Intra-operative injury - Meninges  
\_\_\_ Intra-operative injury - Middle ear  
\_\_\_ Intra-operative injury - Muscle  
\_\_\_ Intra-operative injury - Nails  
\_\_\_ Intra-operative injury - Nasal cavity  
\_\_\_ Intra-operative injury - Nasopharynx  
\_\_\_ Intra-operative injury - Neck NOS  
\_\_\_ Intra-operative injury - Nose  
\_\_\_ Intra-operative injury - Oral  
\_\_\_ Intra-operative injury - Oral cavity NOS  
\_\_\_ Intra-operative injury - Outer ear NOS  
\_\_\_ Intra-operative injury - Outer ear-pinna  
\_\_\_ Intra-operative injury - Ovary  
\_\_\_ Intra-operative injury - Pancreas  
\_\_\_ Intra-operative injury - Pancreatic duct  
\_\_\_ Intra-operative injury - Parathyroid  
\_\_\_ Intra-operative injury - Parotid gland  
\_\_\_ Intra-operative injury - Pelvis NOS  
\_\_\_ Intra-operative injury - Penis  
\_\_\_ Intra-operative injury - Peripheral motor NOS

\_\_\_\_ 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 (radiographic 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  $\geq$ 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)  
 Phlebolympathic 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)
- \_\_\_ Splenic 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.

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 (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

—Y