

NWU2017-09-01 - Adverse Events Data Dictionary

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Document Summary

Property	Value
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NWU2017-09-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	ptid	Participant ID		Char

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_action	Action		1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unknown" 6="Not Applicable" 7="Agent Interrupted"
01. Principal	ae_attribution	AE Attribution		1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	ae_comments	Comments		Char

Class	Variable	Label	Description	Format Text
01. Principal	ae_ctcae	AE: Common Terminology Criteria for Adverse Events (CTCAE) Term		Vascular disorders - Other, specify" specify"=Vascular disorders - Other, specify" 1="Abdominal distension" 2="Abdominal infection" 3="Abdominal pain" 4="Abdominal soft tissue necrosis" 5="Abducens nerve disorder" 6="Accessory nerve disorder" 7="Acidosis" 8="Acoustic nerve disorder NOS" 9="Activated partial thromboplastin time prolonged" 10="Acute coronary syndrome" 11="Acute kidney injury" 12="Adrenal insufficiency" 13="Adult respiratory distress syndrome" 14="Agitation" 15="Akathisia" 16="Alanine aminotransferase increased" 17="Alcohol intolerance" 18="Alkaline phosphatase increased" 19="Alkalosis" 20="Allergic reaction" 21="Allergic rhinitis" 22="Alopecia" 23="Amnesia" 24="Anal fistula" 25="Anal hemorrhage" 26="Anal mucositis" 27="Anal necrosis" 28="Anal pain" 29="Anal stenosis" 30="Anal ulcer" 31="Anaphylaxis" 32="Anemia" 33="Ankle fracture" 34="Anorectal infection" 35="Anorexia" 36="Anorgasmia" 37="Anxiety" 38="Aortic injury" 39="Aortic valve disease" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			[...continued] 40="Aphonia" 41="Apnea" 42="Appendicitis" 43="Appendicitis perforated" 44="Arachnoiditis" 45="Arterial injury" 46="Arteritis infective" 47="Arthralgia" 48="Arthritis" 49="Ascites" 50="Aspartate aminotransferase increased" 51="Aspiration" 52="Asystole" 53="Ataxia" 54="Atelectasis" 55="Atrial fibrillation" 56="Atrial flutter" 57="Atrioventricular block complete" 58="Atrioventricular block first degree" 59="Autoimmune disorder" 60="Avascular necrosis" 61="Azoospermia" 62="Back pain" 63="Bile duct stenosis" 64="Biliary anastomotic leak" 65="Biliary fistula" 66="Biliary tract infection" 67="Bladder anastomotic leak" 68="Bladder infection" 69="Bladder perforation" 70="Bladder spasm" 71="Bloating" 72="Blood and lymphatic system disorders - Other, specify" 73="Blood antidiuretic hormone abnormal" 74="Blood bilirubin increased" 75="Blood corticotrophin decreased" 76="Blood gonadotrophin abnormal" 77="Blood prolactin abnormal" 78="Blurred vision" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>79="Body odor" 80="Bone infection" 81="Bone marrow hypocellular" 82="Bone pain" 83="Brachial plexopathy" 84="Breast atrophy" 85="Breast infection" 86="Breast pain" 87="Bronchial fistula" 88="Bronchial infection" 89="Bronchial obstruction" 90="Bronchial stricture" 91="Bronchopleural fistula" 92="Bronchopulmonary hemorrhage" 93="Bronchospasm" 94="Bruising" 95="Bullous dermatitis" 96="Burn" 97="Buttock pain" 98="Capillary leak syndrome" 99="Carbon monoxide diffusing capacity decreased" 100="Cardiac arrest" 101="Cardiac disorders - Other, specify" 102="Cardiac troponin I increased" 103="Cardiac troponin T increased" 104="Cataract" 105="Catheter related infection" 106="CD4 lymphocytes decreased" 107="Cecal hemorrhage" 108="Cecal infection" 109="Central nervous system necrosis" 110="Cerebrospinal fluid leakage" 111="Cervicitis infection" 112="Cheilitis" 113="Chest pain - cardiac" 114="Chest wall pain" 115="Chills" 116="Cholecystitis" 117="Cholesterol high" 118="Chronic kidney disease" 119="Chylothorax" 120="Cognitive disturbance"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>121="Colitis" 122="Colonic fistula" 123="Colonic hemorrhage" 124="Colonic obstruction" 125="Colonic perforation" 126="Colonic stenosis" 127="Colonic ulcer" 128="Concentration impairment" 129="Conduction disorder" 130="Confusion" 131="Congenital, familial and genetic disorders - Other, specify" 132="Conjunctivitis" 133="Conjunctivitis infective" 134="Constipation" 135="Constrictive pericarditis" 136="Corneal infection" 137="Corneal ulcer" 138="Cough" 139="CPK increased" 140="Cranial nerve infection" 141="Creatinine increased" 142="Cushingoid" 143="Cystitis noninfective" 144="Cytokine release syndrome" 145="Death neonatal" 146="Death NOS" 147="Dehydration" 148="Delayed orgasm" 149="Delayed puberty" 150="Delirium" 151="Delusions" 152="Dental caries" 153="Depressed level of consciousness" 154="Depression" 155="Dermatitis radiation" 156="Device related infection" 157="Diarrhea" 158="Disseminated intravascular coagulation" 159="Dizziness" 160="Dry eye" 161="Dry mouth" 162="Dry skin"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>163="Duodenal fistula" 164="Duodenal hemorrhage" 165="Duodenal infection" 166="Duodenal obstruction" 167="Duodenal perforation" 168="Duodenal stenosis" 169="Duodenal ulcer" 170="Dysarthria" 171="Dysesthesia" 172="Dysgeusia" 173="Dysmenorrhea" 174="Dyspareunia" 175="Dyspepsia" 176="Dysphagia" 177="Dysphasia" 178="Dyspnea" 179="Ear and labyrinth disorders - Other, specify" 180="Ear pain" 181="Edema cerebral" 182="Edema face" 183="Edema limbs" 184="Edema trunk" 185="Ejaculation disorder" 186="Ejection fraction decreased" 187="Electrocardiogram QT corrected interval prolonged" 188="Encephalitis infection" 189="Encephalomyelitis infection" 190="Encephalopathy" 191="Endocarditis infective" 192="Endocrine disorders - Other, specify" 193="Endophthalmitis" 194="Enterocolitis" 195="Enterocolitis infectious" 196="Enterovesical fistula" 197="Epistaxis" 198="Erectile dysfunction" 199="Erythema multiforme" 200="Erythroderma" 201="Esophageal anastomotic leak" 202="Esophageal fistula" 203="Esophageal hemorrhage" 204="Esophageal infection"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			[...continued] 205="Esophageal necrosis" 206="Esophageal obstruction" 207="Esophageal pain" 208="Esophageal perforation" 209="Esophageal stenosis" 210="Esophageal ulcer" 211="Esophageal varices hemorrhage" 212="Esophagitis" 213="Euphoria" 214="Exostosis" 215="External ear inflammation" 216="External ear pain" 217="Extraocular muscle paresis" 218="Extrapyramidal disorder" 219="Eye disorders - Other, specify" 220="Eye infection" 221="Eye pain" 222="Eyelid function disorder" 223="Facial muscle weakness" 224="Facial nerve disorder" 225="Facial pain" 226="Fall" 227="Fallopian tube anastomotic leak" 228="Fallopian tube obstruction" 229="Fallopian tube perforation" 230="Fallopian tube stenosis" 231="Fat atrophy" 232="Fatigue" 233="Febrile neutropenia" 234="Fecal incontinence" 235="Female genital tract fistula" 236="Feminization acquired" 237="Fetal death" 238="Fetal growth retardation" 239="Fever" 240="Fibrinogen decreased" 241="Fibrosis deep connective tissue" 242="Flank pain" 243="Flashing lights" 244="Flatulence" 245="Floaters" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>246="Flu like symptoms" 247="Flushing" 248="Forced expiratory volume decreased" 249="Fracture" 250="Gait disturbance" 251="Gallbladder fistula" 252="Gallbladder infection" 253="Gallbladder necrosis" 254="Gallbladder obstruction" 255="Gallbladder pain" 256="Gallbladder perforation" 257="Gastric anastomotic leak" 258="Gastric fistula" 259="Gastric hemorrhage" 260="Gastric necrosis" 261="Gastric perforation" 262="Gastric stenosis" 263="Gastric ulcer" 264="Gastritis" 265="Gastroesophageal reflux disease" 266="Gastrointestinal anastomotic leak" 267="Gastrointestinal disorders - Other, specify" 268="Gastrointestinal fistula" 269="Gastrointestinal pain" 270="Gastrointestinal stoma necrosis" 271="Gastroparesis" 272="General disorders and administration site conditions - Other, specify" 273="Generalized muscle weakness" 274="Genital edema" 275="GGT increased" 276="Gingival pain" 277="Glaucoma" 278="Glossopharyngeal nerve disorder" 279="Glucose intolerance" 280="Growth accelerated" 281="Growth hormone abnormal" 282="Growth suppression"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			[...continued] 283="Gum infection" 284="Gynecomastia" 285="Hallucinations" 286="Haptoglobin decreased" 287="Head soft tissue necrosis" 288="Headache" 289="Hearing impaired" 290="Heart failure" 291="Hematoma" 292="Hematosalpinx" 293="Hematuria" 294="Hemoglobin increased" 295="Hemoglobinuria" 296="Hemolysis" 297="Hemolytic uremic syndrome" 298="Hemorrhoidal hemorrhage" 299="Hemorrhoids" 300="Hepatic failure" 301="Hepatic hemorrhage" 302="Hepatic infection" 303="Hepatic necrosis" 304="Hepatic pain" 305="Hepatitis viral" 306="Hepatobiliary disorders - Other, specify" 307="Hiccups" 308="Hip fracture" 309="Hirsutism" 310="Hoarseness" 311="Hot flashes" 312="Hydrocephalus" 313="Hypercalcemia" 314="Hyperglycemia" 315="Hyperhidrosis" 316="Hyperkalemia" 317="Hypermagnesemia" 318="Hypernatremia" 319="Hyperparathyroidism" 320="Hypersomnia" 321="Hypertension" 322="Hyperthyroidism" 323="Hypertrichosis" 324="Hypertriglyceridemia" 325="Hyperuricemia" 326="Hypoalbuminemia" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>327="Hypocalcemia" 328="Hypoglossal nerve disorder" 329="Hypoglycemia" 330="Hypohidrosis" 331="Hypokalemia" 332="Hypomagnesemia" 333="Hyponatremia" 334="Hypoparathyroidism" 335="Hypophosphatemia" 336="Hypotension" 337="Hypothermia" 338="Hypothyroidism" 339="Hypoxia" 340="Ileal fistula" 341="Ileal hemorrhage" 342="Ileal obstruction" 343="Ileal perforation" 344="Ileal stenosis" 345="Ileal ulcer" 346="Ileus" 347="Immune system disorders - Other, specify" 348="Infections and infestations - Other, specify" 349="Infective myositis" 350="Infusion related reaction" 351="Infusion site extravasation" 352="Injection site reaction" 353="Injury to carotid artery" 354="Injury to inferior vena cava" 355="Injury to jugular vein" 356="Injury to superior vena cava" 357="Injury, poisoning and procedural complications - Other, specify" 358="INR increased" 359="Insomnia" 360="Intestinal stoma leak" 361="Intestinal stoma obstruction" 362="Intestinal stoma site bleeding" 363="Intra-abdominal hemorrhage" 364="Intracranial hemorrhage" 365="Intraoperative arterial injury" 366="Intraoperative breast injury"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>367="Intraoperative cardiac injury" 368="Intraoperative ear injury" 369="Intraoperative endocrine injury" 370="Intraoperative gastrointestinal injury" 371="Intraoperative head and neck injury" 372="Intraoperative hemorrhage" 373="Intraoperative hepatobiliary injury" 374="Intraoperative musculoskeletal injury" 375="Intraoperative neurological injury" 376="Intraoperative ocular injury" 377="Intraoperative renal injury" 378="Intraoperative reproductive tract injury" 379="Intraoperative respiratory injury" 380="Intraoperative skin injury" 381="Intraoperative splenic injury" 382="Intraoperative urinary injury" 383="Intraoperative venous injury" 384="Investigations - Other, specify" 385="Iron overload" 386="Irregular menstruation" 387="Irritability" 388="Ischemia cerebrovascular" 389="IVth nerve disorder" 390="Jejunal fistula" 391="Jejunal hemorrhage" 392="Jejunal obstruction" 393="Jejunal perforation" 394="Jejunal stenosis" 395="Jejunal ulcer" 396="Joint effusion" 397="Joint infection" 398="Joint range of motion decreased"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>399="Joint range of motion decreased cervical spine" 400="Joint range of motion decreased lumbar spine" 401="Keratitis" 402="Kidney anastomotic leak" 403="Kidney infection" 404="Kyphosis" 405="Lactation disorder" 406="Large intestinal anastomotic leak" 407="Laryngeal edema" 408="Laryngeal fistula" 409="Laryngeal hemorrhage" 410="Laryngeal inflammation" 411="Laryngeal mucositis" 412="Laryngeal obstruction" 413="Laryngeal stenosis" 414="Laryngitis" 415="Laryngopharyngeal dysesthesia" 416="Laryngospasm" 417="Left ventricular systolic dysfunction" 418="Lethargy" 419="Leukemia secondary to oncology chemotherapy" 420="Leukocytosis" 421="Leukoencephalopathy" 422="Libido decreased" 423="Libido increased" 424="Lip infection" 425="Lip pain" 426="Lipase increased" 427="Lipohypertrophy" 428="Localized edema" 429="Lordosis" 430="Lower gastrointestinal hemorrhage" 431="Lung infection" 432="Lymph gland infection" 433="Lymph leakage" 434="Lymph node pain" 435="Lymphedema" 436="Lymphocele"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>437="Lymphocyte count decreased" 438="Lymphocyte count increased" 439="Malabsorption" 440="Malaise" 441="Mania" 442="Mediastinal hemorrhage" 443="Mediastinal infection" 444="Memory impairment" 445="Meningismus" 446="Meningitis" 447="Menopause" 448="Menorrhagia" 449="Metabolism and nutrition disorders - Other, specify" 450="Middle ear inflammation" 451="Mitral valve disease" 452="Mobitz (type) II atrioventricular block" 453="Mobitz type I" 454="Movements involuntary" 455="Mucosal infection" 456="Mucositis oral" 457="Multi-organ failure" 458="Muscle weakness left-sided" 459="Muscle weakness lower limb" 460="Muscle weakness right-sided" 461="Muscle weakness trunk" 462="Muscle weakness upper limb" 463="Musculoskeletal and connective tissue disorder - Other, specify" 464="Musculoskeletal deformity" 465="Myalgia" 466="Myelitis" 467="Myelodysplastic syndrome" 468="Myocardial infarction" 469="Myocarditis" 470="Myositis" 471="Nail discoloration" 472="Nail infection" 473="Nail loss" 474="Nail ridging" 475="Nasal congestion" 476="Nausea" 477="Neck edema" 478="Neck pain"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>479="Neck soft tissue necrosis" 480="Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, specify" 481="Nervous system disorders - Other, specify" 482="Neuralgia" 483="Neutrophil count decreased" 484="Night blindness" 485="Nipple deformity" 486="Non-cardiac chest pain" 487="Nystagmus" 488="Obesity" 489="Obstruction gastric" 490="Oculomotor nerve disorder" 491="Olfactory nerve disorder" 492="Oligospermia" 493="Optic nerve disorder" 494="Oral cavity fistula" 495="Oral dysesthesia" 496="Oral hemorrhage" 497="Oral pain" 498="Osteonecrosis of jaw" 499="Osteoporosis" 500="Otitis externa" 501="Otitis media" 502="Ovarian hemorrhage" 503="Ovarian infection" 504="Ovarian rupture" 505="Ovulation pain" 506="Pain" 507="Pain in extremity" 508="Pain of skin" 509="Palmar-plantar erythrodysesthesia syndrome" 510="Palpitations" 511="Pancreas infection" 512="Pancreatic anastomotic leak" 513="Pancreatic duct stenosis" 514="Pancreatic enzymes decreased" 515="Pancreatic fistula" 516="Pancreatic hemorrhage" 517="Pancreatic necrosis" 518="Pancreatitis" 519="Papilledema"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>520="Papulopustular rash" 521="Paresthesia" 522="Paronychia" 523="Paroxysmal atrial tachycardia" 524="Pelvic floor muscle weakness" 525="Pelvic infection" 526="Pelvic pain" 527="Pelvic soft tissue necrosis" 528="Penile infection" 529="Penile pain" 530="Perforation bile duct" 531="Pericardial effusion" 532="Pericardial tamponade" 533="Pericarditis" 534="Perineal pain" 535="Periodontal disease" 536="Periorbital edema" 537="Periorbital infection" 538="Peripheral ischemia" 539="Peripheral motor neuropathy" 540="Peripheral nerve infection" 541="Peripheral sensory neuropathy" 542="Peritoneal infection" 543="Peritoneal necrosis" 544="Personality change" 545="Phantom pain" 546="Pharyngeal anastomotic leak" 547="Pharyngeal fistula" 548="Pharyngeal hemorrhage" 549="Pharyngeal mucositis" 550="Pharyngeal necrosis" 551="Pharyngeal stenosis" 552="Pharyngitis" 553="Pharyngolaryngeal pain" 554="Phlebitis" 555="Phlebitis infective" 556="Photophobia" 557="Photosensitivity" 558="Platelet count decreased" 559="Pleural effusion" 560="Pleural hemorrhage" 561="Pleural infection" 562="Pleuritic pain"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>563="Pneumonitis" 564="Pneumothorax" 565="Portal hypertension" 566="Portal vein thrombosis" 567="Postnasal drip" 568="Postoperative hemorrhage" 569="Postoperative thoracic procedure complication" 570="Precocious puberty" 571="Pregnancy, puerperium and perinatal conditions - Other, specify" 572="Premature delivery" 573="Premature menopause" 574="Presyncope" 575="Proctitis" 576="Productive cough" 577="Prolapse of intestinal stoma" 578="Prolapse of urostomy" 579="Prostate infection" 580="Prostatic hemorrhage" 581="Prostatic obstruction" 582="Prostatic pain" 583="Proteinuria" 584="Pruritus" 585="Psychiatric disorders - Other, specify" 586="Psychosis" 587="Pulmonary edema" 588="Pulmonary fibrosis" 589="Pulmonary fistula" 590="Pulmonary hypertension" 591="Pulmonary valve disease" 592="Purpura" 593="Pyramidal tract syndrome" 594="Radiation recall reaction (dermatologic)" 595="Radiculitis" 596="Rash acneiform" 597="Rash maculo-papular" 598="Rash pustular" 599="Rectal anastomotic leak" 600="Rectal fistula" 601="Rectal hemorrhage" 602="Rectal mucositis" 603="Rectal necrosis"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			<p>[...continued]</p> <p>604="Rectal obstruction" 605="Rectal pain" 606="Rectal perforation" 607="Rectal stenosis" 608="Rectal ulcer" 609="Recurrent laryngeal nerve palsy" 610="Renal and urinary disorders - Other, specify" 611="Renal calculi" 612="Renal colic" 613="Renal hemorrhage" 614="Reproductive system and breast disorders - Other, specify" 615="Respiratory failure" 616="Respiratory, thoracic and mediastinal disorders - Other, specify" 617="Restlessness" 618="Restrictive cardiomyopathy" 619="Retinal detachment" 620="Retinal tear" 621="Retinal vascular disorder" 622="Retinoic acid syndrome" 623="Retinopathy" 624="Retroperitoneal hemorrhage" 625="Reversible posterior leukoencephalopathy syndrome" 626="Rhinitis infective" 627="Right ventricular dysfunction" 628="Salivary duct inflammation" 629="Salivary gland fistula" 630="Salivary gland infection" 631="Scalp pain" 632="Scleral disorder" 633="Scoliosis" 634="Scrotal infection" 635="Scrotal pain" 636="Seizure" 637="Sepsis" 638="Seroma" 639="Serum amylase increased" 640="Serum sickness" 641="Sick sinus syndrome" 642="Sinus bradycardia"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			[...continued] 643="Sinus disorder" 644="Sinus pain" 645="Sinus tachycardia" 646="Sinusitis" 647="Skin and subcutaneous tissue disorders - Other, specify" 648="Skin atrophy" 649="Skin hyperpigmentation" 650="Skin hypopigmentation" 651="Skin induration" 652="Skin infection" 653="Skin ulceration" 654="Sleep apnea" 655="Small intestinal anastomotic leak" 656="Small intestinal mucositis" 657="Small intestinal obstruction" 658="Small intestinal perforation" 659="Small intestinal stenosis" 660="Small intestine infection" 661="Small intestine ulcer" 662="Sneezing" 663="Social circumstances - Other, specify" 664="Soft tissue infection" 665="Soft tissue necrosis lower limb" 666="Soft tissue necrosis upper limb" 667="Somnolence" 668="Sore throat" 669="Spasticity" 670="Spermatic cord anastomotic leak" 671="Spermatic cord hemorrhage" 672="Spermatic cord obstruction" 673="Spinal fracture" 674="Spleen disorder" 675="Splenic infection" 676="Stenosis of gastrointestinal stoma" 677="Stevens-Johnson syndrome" 678="Stoma site infection" 679="Stomach pain" 680="Stomal ulcer" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			[...continued] 681="Stridor" 682="Stroke" 683="Sudden death NOS" 684="Suicidal ideation" 685="Suicide attempt" 686="Superficial soft tissue fibrosis" 687="Superficial thrombophlebitis" 688="Superior vena cava syndrome" 689="Supraventricular tachycardia" 690="Surgical and medical procedures - Other, specify" 691="Syncope" 692="Telangiectasia" 693="Testicular disorder" 694="Testicular hemorrhage" 695="Testicular pain" 696="Thromboembolic event" 697="Thrombotic thrombocytopenic purpura" 698="Tinnitus" 699="Tooth development disorder" 700="Tooth discoloration" 701="Tooth infection" 702="Toothache" 703="Toxic epidermal necrolysis" 704="Tracheal fistula" 705="Tracheal hemorrhage" 706="Tracheal mucositis" 707="Tracheal obstruction" 708="Tracheal stenosis" 709="Tracheitis" 710="Tracheostomy site bleeding" 711="Transient ischemic attacks" 712="Treatment related secondary malignancy" 713="Tremor" 714="Tricuspid valve disease" 715="Trigeminal nerve disorder" 716="Trismus" 717="Tumor lysis syndrome" 718="Tumor pain" 719="Typhlitis" 720="Unequal limb length" 721="Unintended pregnancy" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			[...continued] 722="Upper gastrointestinal hemorrhage" 723="Upper respiratory infection" 724="Ureteric anastomotic leak" 725="Urethral anastomotic leak" 726="Urethral infection" 727="Urinary fistula" 728="Urinary frequency" 729="Urinary incontinence" 730="Urinary retention" 731="Urinary tract infection" 732="Urinary tract obstruction" 733="Urinary tract pain" 734="Urinary urgency" 735="Urine discoloration" 736="Urine output decreased" 737="Urostomy leak" 738="Urostomy obstruction" 739="Urostomy site bleeding" 740="Urostomy stenosis" 741="Urticaria" 742="Uterine anastomotic leak" 743="Uterine fistula" 744="Uterine hemorrhage" 745="Uterine infection" 746="Uterine obstruction" 747="Uterine pain" 748="Uterine perforation" 749="Uveitis" 750="Vaginal anastomotic leak" 751="Vaginal discharge" 752="Vaginal dryness" 753="Vaginal fistula" 754="Vaginal hemorrhage" 755="Vaginal infection" 756="Vaginal inflammation" 757="Vaginal obstruction" 758="Vaginal pain" 759="Vaginal perforation" 760="Vaginal stricture" 761="Vaginismus" 762="Vagus nerve disorder" 763="Vas deferens anastomotic leak" 764="Vascular access complication" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae			[...continued] 766="Vasculitis" 767="Vasovagal reaction" 768="Venous injury" 769="Ventricular arrhythmia" 770="Ventricular fibrillation" 771="Ventricular tachycardia" 772="Vertigo" 773="Vestibular disorder" 774="Virilization" 775="Visceral arterial ischemia" 776="Vital capacity abnormal" 777="Vitreous hemorrhage" 778="Voice alteration" 779="Vomiting" 780="Vulval infection" 781="Watering eyes" 782="Weight gain" 783="Weight loss" 784="Wheezing" 785="White blood cell decreased" 786="Wolff-Parkinson-White syndrome" 787="Wound complication" 788="Wound dehiscence" 789="Wound infection" 790="Wrist fracture"
01. Principal	ae_ctcae_other	AE: Other Adverse Events Not Listed In CTCAE Term, Specify		Char
01. Principal	ae_dropped	Dropped Due To AE?		0="No" 1="Yes"
01. Principal	ae_end_date	End Date		Char
01. Principal	ae_end_date_time	End Date And Time		Char
01. Principal	ae_grade	AE Grade		0="Absent Adverse Event" 1="Mild Adverse Event" 2="Moderate Adverse Event" 3="Severe Adverse Event" 4="Life-threatening Adverse Event" 5="Death Related to Adverse Event"
01. Principal	ae_outcome	Outcome		1="Recovered/Resolved" 2="Recovered/Resolved with Sequelae" 3="Not Recovered/Not Resolved" 4="Fatal" 5="Recovering/Resolving" 99="Unknown"
01. Principal	ae_sae	Reported As SAE?		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	ae_soc	MedDRA System Organ Class (SOC)		Congenital, familial and genetic disorders" =Congenital, familial and genetic disorders" 1="Blood and lymphatic system disorders" 2="Cardiac disorders" 4="Ear and labyrinth disorders" 5="Endocrine disorders" 6="Eye disorders" 7="Gastrointestinal disorders" 8="General disorders and administration site conditions" 9="Hepatobiliary disorders" 10="Immune system disorders" 11="Infections and infestations" 12="Injury, poisoning and procedural complications" 13="Investigations" 14="Metabolism and nutrition disorders" 15="Musculoskeletal and connective tissue disorders" 16="Neoplasms benign, malignant and unspecified (incl cysts and polyps)" 17="Nervous system disorders" 18="Pregnancy, puerperium and perinatal conditions" 19=" Psychiatric disorders" 20="Renal and urinary disorders" 21="Reproductive system and breast disorders" 22="Respiratory, thoracic and mediastinal disorders" 23="Skin and subcutaneous tissue disorders" 24="Social circumstances" 25="Surgical and medical procedures" 26="Vascular disorders"
01. Principal	ae_start_date	Start Date		Char
01. Principal	ae_start_date_time	Start Date And Time		Char
01. Principal	ae_tac	Treatment Assignment Code (TAC)		0="TAC-0" 1="TAC1" 2="TAC2" 3="TAC3" 4="TAC4"
01. Principal	ae_verbatim	Adverse Event Verbatim Term		Char