

UWI2016-07-01 - Adverse Events Data Dictionary

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Document Summary

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UWI2016-07-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	SEQUENCE_NO_	Patient ID		Numeric

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	ae_tac	Treatment Assignment Code		.N="N/A" 1="TAC1" 2="TAC2" 3="TAC3"
01. Principal	visit_dt	Visit Date		SAS Date .M="Missing" .N="N/A"

Section 3: Event Details

Class	Variable	Label	Description	Format Text
01. Principal	ae_action	Change (If Any) in Agent Dose Due to Adverse Event		.M="Missing" .N="N/A" 1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unknown" 6="Not Applicable" 7="Agent Interrupted"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	Likelihood Adverse Event Was Caused by Treatment		.M="Missing" .N="N/A" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"

Class	Variable	Label	Description	Format Text
01. Principal	ae_ctcae_term	CTCAE Term v4.0	Common Terminology Criteria for Adverse Events term v4.0.	"Abdominal pain"="Abdominal pain" "Allergic rhinitis"="Allergic rhinitis" "Amnesia"="Amnesia" "Anorexia"="Anorexia" "Arthralgia"="Arthralgia" "Aspiration"="Aspiration" "Bladder spasm"="Bladder spasm" "Bloating"="Bloating" "Blood and lymphatic system disorders - Other, specify"="Blood and lymphatic system disorders - Other, specify" "Blood bilirubin increased"="Blood bilirubin increased" "Bruising"="Bruising" "Cognitive disturbance"="Cognitive disturbance" "Cough"="Cough" "Diarrhea"="Diarrhea" "Dizziness"="Dizziness" "Dry eye"="Dry eye" "Dry mouth"="Dry mouth" "Dry skin"="Dry skin" "Dyspepsia"="Dyspepsia" "Dyspnea"="Dyspnea" "Endocrine disorders - Other, specify"="Endocrine disorders - Other, specify" "Epistaxis"="Epistaxis" "Fatigue"="Fatigue" "Flushing"="Flushing" "Gastroesophageal reflux disease"="Gastroesophageal reflux disease" "Gastrointestinal disorders - Other, specify"="Gastrointestinal disorders - Other, specify" "Gastrointestinal pain"="Gastrointestinal pain" "Headache"="Headache" "Hematuria"="Hematuria" "Hot flashes"="Hot flashes" "Hypersomnia"="Hypersomnia" "Hypertension"="Hypertension" "Infections and infestations - Other, specify"="Infections and infestations" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae_term			[...continued] - Other, specify" "Investigations - Other, specify"="Investigations - Other, specify" "Joint range of motion decreased"="Joint range of motion decreased" "Leukocytosis"="Leukocytosis" "Lower gastrointestinal hemorrhage"="Lower gastrointestinal hemorrhage" "Lymph node pain"="Lymph node pain" "Mucositis oral"="Mucositis oral" "Muscle weakness upper limb"="Muscle weakness upper limb" "Musculoskeletal and connective tissue disorder - Other, specify"="Musculoskeletal and connective tissue disorder - Other, specify" "Nasal congestion"="Nasal congestion" "Nausea"="Nausea" "Oral pain"="Oral pain" "Pain in extremity"="Pain in extremity" "Paresthesia"="Paresthesia" "Pruritus"="Pruritus" "Rash acneiform"="Rash acneiform" "Rash maculo-papular"="Rash maculo-papular" "Respiratory, thoracic and mediastinal disorders - Other, specify"="Respiratory, thoracic and mediastinal disorders - Other, specify" "Scalp pain"="Scalp pain" "Skin and subcutaneous tissue disorders - Other, specify"="Skin and subcutaneous tissue disorders - Other, specify" "Sneezing"="Sneezing" "Sore throat"="Sore throat" "Surgical and medical procedures - Other, specify"="Surgical and medical procedures - Other, specify" "Tinnitus"="Tinnitus" "Tremor"="Tremor" "Urinary incontinence"="Urinary incontinence" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ae_ctcae_term			[...continued] "Urinary retention"="Urinary retention" "Urinary tract infection"="Urinary tract infection" "Urinary tract pain"="Urinary tract pain" "Urinary urgency"="Urinary urgency" "Urticaria"="Urticaria" "Vomiting"="Vomiting" "Wheezing"="Wheezing"
01. Principal	ae_dropped	Dropped Due to this Adverse Event?		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	ae_end_dt	End Date of Adverse Event		SAS Date .M="Missing" .N="N/A"
01. Principal	ae_event	Adverse Event as Described Verbatim		Char " "="Missing"
01. Principal	ae_grade	Severity of Adverse Event		.M="Missing" .N="N/A" 1="Mild" 2="Moderate" 3="Severe" 4="Life-Threatening" 5="Lethal"
01. Principal	ae_meddra_v12	MedDRA v12.0 Code	Medical Dictionary for Regulatory Activities v12.0 code.	Numeric .M="Missing" .N="No Adverse Events Reported" 99999999="No MedDRA Code Associated with CTCAE Term"
01. Principal	ae_onset_dt	Onset Date of Adverse Event		SAS Date .M="Missing" .N="N/A"
01. Principal	ae_outcome	Outcome of Adverse Event		.M="Missing" .N="N/A" 1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not recovering/Not Resolved" 4="Recovered/Resolved with sequelae" 5="Fatal" 6="Unknown"
01. Principal	ae_rpt_dt	Report Date of Adverse Event		SAS Date .M="Missing" .N="N/A"
01. Principal	ae_sae	Serious Adverse Event?		.M="Missing" .N="N/A" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	ae_tox_group	Toxicity Group		.M="Missing" .N="N/A" 1="Blood and Lymphatic System Disorders" 2="Cardiac Disorders" 3="Congenital, Familial and Genetic 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 (Including 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" 99="No Toxicity Group Associated With CTCAE Term"