UWI2016-08-01 - Enhanced Person Data Dictionary

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Document Summary

Property	Value
Document Title	UWI2016-08-01 - Enhanced Person: Data Dictionary
Date Created	12/27/2024
Sections	2
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Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	**build_dt**	Build Date		SAS Date
01. Principal	**SEQUENCE_NO_**	Participant ID		Char

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	**ae_action**	Change (If Any) In Agent Dose Due To Adverse Event		.M="Missing" .N="No Adverse Events Reported" 1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unknown" 6="Not Applicable" 7="Agent Interrupted"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 Study Agent		.M="Missing" 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		"Abdominal pain"="Abdominal pain" "Akathisia"="Akathisia" "Alanine aminotransferase increased"="Alanine aminotransferase increased" "Alkaline phosphatase increased"="Alkaline phosphatase increased" "Allergic reaction"="Allergic reaction" "Allergic rhinitis"="Allergic rhinitis" "Alopecia"="Alopecia" "Anxiety"="Anxiety" "Arthralgia"="Arthralgia" "Arthritis"="Arthritis" "Aspartate aminotransferase increased"="Aspartate aminotransferase increased" "Back pain"="Back pain" "Bladder spasm"="Bladder spasm" "Bloating"="Bloating" "Blood bilirubin increased"="Blood bilirubin increased" "Blurred vision"="Blurred vision" "Bone pain"="Bone pain" "Breast pain"="Breast pain" "Chest pain - cardiac"="Chest pain - cardiac" "Chest wall pain"="Chest wall pain" "Chills"="Chills" "Concentration impairment"="Concentration impairment" "Constipation"="Constipation" "Cough"="Cough" "Diarrhea"="Diarrhea" "Dizziness"="Dizziness" "Dysgeusia"="Dysgeusia" "Dyspepsia"="Dyspepsia" "Dyspnea"="Dyspnea" "Edema face"="Edema face" "Edema limbs"="Edema limbs" "Erythema multiforme"="Erythema multiforme" "Eye disorders - Other, specify"="Eye disorders - Other, specify" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	**[...continued]**			[...continued]
	ae_ctcae_term			"Fatigue"="Fatigue" "Fever"="Fever" "Flu like symptoms"="Flu like symptoms" "Flushing"="Flushing" "Gallbladder pain"="Gallbladder pain" "Gastroesophageal reflux disease"="Gastroesophageal reflux disease" "Headache"="Headache" "Hot flashes"="Hot flashes" "Hyperglycemia"="Hyperglycemia" "Hyperhidrosis"="Hyperhidrosis" "Hypertension"="Hypertension" "Hyperthyroidism"="Hyperthyroidism" "Hypokalemia"="Hypokalemia" "Hyponatremia"="Hyponatremia" "Hypotension"="Hypotension" "Hypoxia"="Hypoxia" "Infections and infestations - Other, specify"="Infections and infestations - Other, specify" "Injection site reaction"="Injection site reaction" "Insomnia"="Insomnia" "Investigations - Other, specify"="Investigations - Other, specify" "Lymphedema"="Lymphedema" "Lymphocyte count decreased"="Lymphocyte count decreased" "Malaise"="Malaise" "Muscle weakness lower limb"="Muscle weakness lower limb" "Musculoskeletal and connective tissue disorder - Other, specify"="Musculoskeletal and connective tissue disorder - Other, specify" "Musculoskeletal and connective tissue disorder - Other, specify"="Musculoskeletal and connective tissue disorder - Other, specify" "Myalgia"="Myalgia" "Nasal congestion"="Nasal congestion" [continued...]

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Class	Variable	Label	Description	Format Text
01. Principal	**[...continued]** **ae_ctcae_term**			[...continued] "Nausea"="Nausea" "Neck pain"="Neck pain" "Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, specify"="Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, specify" "Non-cardiac chest pain"="Non-cardiac chest pain" "Oral dysesthesia"="Oral dysesthesia" "Pain in extremity"="Pain in extremity" "Pain"="Pain" "Palpitations"="Palpitations" "Paresthesia"="Paresthesia" "Phantom pain"="Phantom pain" "Postnasal drip"="Postnasal drip" "Presyncope"="Presyncope" "Pruritus"="Pruritus" "Rash acneiform"="Rash acneiform" "Rash maculo-papular"="Rash maculo-papular" "Renal calculi"="Renal calculi" "Respiratory, thoracic and mediastinal disorders - Other, specify"="Respiratory, thoracic and mediastinal disorders - Other, specify" "Sinus tachycardia"="Sinus tachycardia" "Skin and subcutaneous tissue disorders - Other, specify"="Skin and subcutaneous tissue disorders - Other, specify" "Sneezing"="Sneezing" "Somnolence"="Somnolence" "Sore throat"="Sore throat" "Stomach pain"="Stomach pain" "Surgical and medical procedures - Other, specify"="Surgical and medical procedures - Other, specify" "Upper respiratory infection"="Upper respiratory infection" "Urinary frequency"="Urinary frequency" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	**[...continued]** **ae_ctcae_term**			[...continued] "Urinary tract infection"="Urinary tract infection" "Urinary urgency"="Urinary urgency" "Urine discoloration"="Urine discoloration" "Vomiting"="Vomiting" "Wheezing"="Wheezing" "White blood cell decreased"="White blood cell decreased"
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"
01. Principal	**ae_event**	Adverse Event As Described Verbatim		Char
01. Principal	**ae_grade**	Severity Of Adverse Event		.M="Missing" 1="Mild" 2="Moderate" 3="Severe" 4="Life-Threatening" 5="Lethal"
01. Principal	**ae_meddra_v12**	MedDRA 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
01. Principal	**ae_outcome**	Outcome Of Adverse Event		.M="Missing" 1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not recovering/Not Resolved" 4="Recovered/Resolved with sequelae" 5="Fatal" 6="Unknown"
01. Principal	**ae_report_dt**	Report Date Of Adverse Event		SAS Date
01. Principal	**ae_sae**	Serious Adverse Event?		.M="Missing" .N="N/A" 0="No" 1="Yes"

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Class	Variable	Label	Description	Format Text
01. Principal	**ae_tox_group**	Toxicity Group		.M="Missing" .N="No Adverse Events Reported" 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"