

UAZ2015-05-02 - ADVERSE EVENTS: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	UAZ2015-05-02 - Adverse Events: Data Dictionary
Date Created	11/27/2019
Sections	2
Entries	15
Document Filename	dictionary_ae.rtf

UAZ2015-05-02 - Adverse Events: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
build_dt	Build Date		SAS Date
ParticipantID	Participant ID		Char

Section 2: Adverse Events

Variable	Label	Description	Format Text
ae_action	Change (If Any) in Agent Dose Due to Adverse Event		.M="Missing" 1="Agent Withdrawn" 2="Agent Dose Reduced" 4="Agent Dose Not Changed" 6="Not Applicable"
ae_attribution	Likelihood Adverse Event was Caused by Study Agent		.M="Missing" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"
ae_ctcae_term	CTCAE Term v4.0		"Abdominal pain"="Abdominal pain" "Allergic reaction"="Allergic reaction" "Anorexia"="Anorexia" "Anxiety"="Anxiety" "Bloating"="Bloating" "Blurred vision"="Blurred vision" "Bronchial infection"="Bronchial infection" "Bronchospasm"="Bronchospasm" "Constipation"="Constipation" "Cough"="Cough" "Dehydration"="Dehydration" "Diarrhea"="Diarrhea" "Dizziness"="Dizziness" "Dry mouth"="Dry mouth" "Dysgeusia"="Dysgeusia" "Dyspepsia"="Dyspepsia" "Fatigue"="Fatigue" "Flatulence"="Flatulence" "Gastrointestinal disorders - Other, specify"="Gastrointestinal disorders - Other, specify" "Gastrointestinal pain"="Gastrointestinal pain" "Headache"="Headache" "Hematuria"="Hematuria" "Infections and infestations - Other, specify"="Infections and infestations - Other, specify" "Injury, poisoning and procedural complications - Other, specify"="Injury, poisoning and procedural complications - Other, specify" "Insomnia"="Insomnia" "Irritability"="Irritability" "Musculoskeletal and connective tissue disorder - Other, specify"="Musculoskeletal and connective tissue disorder - Other, specify" "Myalgia"="Myalgia" "Nausea"="Nausea" "Neuralgia"="Neuralgia" "Oral pain"="Oral pain" "Palpitations"="Palpitations" "Psychiatric disorders - Other, specify"="Psychiatric [continued...]

Variable	Label	Description	Format Text
[...continued] ae_ctcae_term			[...continued] disorders - Other, specify" "Rash acneiform"="Rash acneiform" "Renal and urinary disorders - Other, specify"="Renal and urinary disorders - Other, specify" "Renal calculi"="Renal calculi" "Renal colic"="Renal colic" "Sore throat"="Sore throat" "Stomach pain"="Stomach pain" "Surgical and medical procedures - Other, specify"="Surgical and medical procedures - Other, specify" "Tooth infection"="Tooth infection" "Upper respiratory infection"="Upper respiratory infection" "Urinary tract infection"="Urinary tract infection" "Vaginal discharge"="Vaginal discharge" "Vomiting"="Vomiting" "Weight loss"="Weight loss" "Wheezing"="Wheezing" "Wound complication"="Wound complication"
ae_dropped	Dropped Due to This Adverse Event?		.M="Missing" 0="No" 1="Yes"
ae_end_dt	End Date of Adverse Event		SAS Date
ae_event	Adverse Event as Described Verbatim		Char
ae_grade	Severity of Adverse Event		.M="Missing" 1="Mild" 2="Moderate" 3="Severe"
ae_meddra_v12	MedDRA v12.0 Code		Numeric .M="Missing"
ae_onset_dt	Onset Date of Adverse Event		SAS Date
ae_outcome	Outcome of Adverse Event		.M="Missing" 1="Recovered/Resolved" 3="Not recovering/Not Resolved"
ae_report_dt	Report Date of Adverse Event		SAS Date
ae_sae	Serious Adverse Event?		.M="Missing" 0="No" 1="Yes"

Variable	Label	Description	Format Text
ae_tox_group	Toxicity Group		.M="Missing" 2="Cardiac Disorders" 6="Eye Disorders" 7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 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" 17="Nervous System Disorders" 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" 25="Surgical and Medical Procedures"