UAZ2013-01-01 - ADVERSE EVENTS: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	UAZ2013-01-01 - Adverse Events: Data Dictionary
Date Created	09/11/2019
Sections	3
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Document Filename	dictionary_ae.rtf

UAZ2013-01-01 - Adverse Events: Data Dictionary
Section 1: Identifiers

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

Section 2: Event Details

Variable	Label	Description	Format Text
ae_ctcae_term	Toxicity CTCAE v4.0	Toxicity CTCAE v4.0	Char " "="Missing"
ae_end_dt	End Date of Adverse Event	End date of adverse event	SAS Date .M="Missing" .N="No Adverse Events Reported"
ae_event	Adverse Event as Described Verbatim	Adverse event as described verbatim	Char " "="Missing"
ae_grade	Severity of Adverse Event	Severity of adverse event	.N="No Adverse Events Reported" 1="Mild" 2="Moderate"
ae_meddra_v12	MedDRA v12.0 Code	MedDRA v12.0 Code	Numeric .N="No Adverse Events Reported"
ae_onset_dt	Start Date of Adverse Event	Start date of adverse event	SAS Date .N="No Adverse Events Reported"
ae_outcome	Outcome of Adverse Event	Outcome of adverse event	.N="No Adverse Events Reported" 1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not recovering/Not Resolved"
ae_report_dt	Report Date of Adverse Event	Report date of adverse event	SAS Date .N="No Adverse Events Reported"
ae_sae	Serious Adverse Event?	Serious adverse event?	.N="No Adverse Events Reported" 0="No"
ae_tox_group	Toxicity Group	Toxicity Group	.N="No Adverse Events Reported" 1="Blood and Lymphatic System Disorders" 2="Cardiac Disorders" 7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 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" 21="Reproductive System and Breast Disorders" 22="Respiratory, Thoracic and Mediastinal Disorders" 23="Skin and Subcutaneous Tissue Disorders"

Section 3: Event Results

Variable	Label	Description	Format Text
ae_action	Change (if any) in Agent Dose Due to Adverse Event	Change (if any) in agent dose due to adverse events	.N="No Adverse Events Reported" 4="Agent Dose Not Changed" 6="Not Applicable"
ae_attribution	Likelihood Adverse Event was Caused by Agent	Likelihood adverse event was caused by agent	.N="No Adverse Events Reported" 1="Unrelated" 2="Unlikely" 3="Possible"
ae_dropped	Dropped from Study Due to this Adverse Event?	Dropped from study due to this AE?	.N="No Adverse Events Reported" 0="No"