UAZ2014-03-01 - Adverse Events Data Dictionary

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UAZ2014-03-01 - Adverse Events: Data Dictionary

Section 1: Study-wide

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

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	**ae_action**	Action - [Adverse Events]		.M="Missing" 1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unknown" 6="Not Applicable" 7="Agent Interrupted"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**	Attribution - [Adverse Events]		.M="Missing" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	**ae_comments**	Comments - [Adverse Events]		Char
01. Principal	**ae_ctcae**	Toxicity CTCAE v4.0 - [Adverse Events]		Char
01. Principal	**ae_dropped**	Dropped Due To This AE - [Adverse Events]		.M="Missing" 0="No" 1="Yes"
01. Principal	**ae_event_onset_dt**	Event Onset Date - [Adverse Events]		SAS Date .M="Missing"
01. Principal	**ae_grade**	Grade - [Adverse Events]		.M="Missing" 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_meddra_v12**	MedDRA Adverse Event Code (CTCAE V4.0) - [Adverse Events]		Numeric .M="Missing"
01. Principal	**ae_outcome**	Outcome - [Adverse Events]		.M="Missing" 1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not Recovered/Not Resolved" 4="Recovered/Resolved with sequelae" 5="Fatal" 6="Unknown"
01. Principal	**ae_report_dt**	Adverse Event Report Date - [Adverse Events]		SAS Date .M="Missing"
01. Principal	**ae_report_sae**	Reported As Serious Adverse Events (SAE) - [Adverse Events]		.M="Missing" 0="No" 1="Yes"
01. Principal	**ae_resolved_dt**	Resolved Date - [Adverse Events]		SAS Date .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	**ae_system_organ**	Toxicity Group (DRA) - [Adverse Events]		.M="Missing" 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 (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_verbatim**	AE Verbatim Term - [Adverse Events]		Char