

# UAZ2013-02-01 - Adverse Events Data Dictionary

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## Document Summary

Property	Value
Document Title	UAZ2013-02-01 - Adverse Events: Data Dictionary
Date Created	10/21/2021
Sections	2
Entries	15
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# UAZ2013-02-01 - Adverse Events: Data Dictionary

## Section 1: Identifiers

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Class	Variable	Label	Description	Format Text
01. Principal	<b>build_dt</b>	Build Date		SAS Date
01. Principal	<b>ParticipantID</b>	Participant ID		Char

## Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	<b>ae_action</b>	Change (If Any) in Agent Dose Due to Adverse Event		.M="Missing" 1="Agent Withdrawn" 4="Agent Dose Not Changed" 6="Not Applicable"
01. Principal	<b>ae_attribution</b>	Likelihood Adverse Event was Caused by Study Agent		.M="Missing" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"
01. Principal	<b>ae_ctcae_term</b>	CTCAE Term v4.0		"Abdominal pain"="Abdominal pain" "Alanine aminotransferase increased"="Alanine aminotransferase increased" "Alkaline phosphatase increased"="Alkaline phosphatase increased" "Allergic rhinitis"="Allergic rhinitis" "Anemia"="Anemia" "Aspartate aminotransferase increased"="Aspartate aminotransferase increased" "Back pain"="Back pain" "Bladder infection"="Bladder infection" "Blood and lymphatic system disorders - Other, specify"="Blood and lymphatic system disorders - Other, specify" "Blood bilirubin increased"="Blood bilirubin increased" "Bone pain"="Bone pain" "Bruising"="Bruising" "Chest pain - cardiac"="Chest pain - cardiac" "Dehydration"="Dehydration" "Depression"="Depression" "Diarrhea"="Diarrhea" "Dizziness"="Dizziness" "Dyspepsia"="Dyspepsia" "Ear and labyrinth disorders - Other, specify"="Ear and labyrinth disorders - Other, specify" "Ear pain"="Ear pain" "Fatigue"="Fatigue" "Flu like symptoms"="Flu like symptoms" "Fracture"="Fracture" "Gastrointestinal disorders - Other, specify"="Gastrointestinal disorders - Other, specify" "Headache"="Headache" "Hemorrhoids"="Hemorrhoids" "Hyperglycemia"="Hyperglycemia" "Hypertension"="Hypertension" "Hypotension"="Hypotension" "Injury, poisoning and procedural complications"  [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	<b>[...continued]</b> <b>ae_ctcae_term</b>			<p>[...continued]</p> <p>- Other, specify"="Injury, poisoning and procedural complications - Other, specify"</p> <p>"Investigations - Other, specify"="Investigations - Other, specify"</p> <p>"Joint range of motion decreased lumbar spine"="Joint range of motion decreased lumbar spine"</p> <p>"Joint range of motion decreased"="Joint range of motion decreased"</p> <p>"Lethargy"="Lethargy"</p> <p>"Mania"="Mania"</p> <p>"Musculoskeletal and connective tissue disorder - Other, specify"="Musculoskeletal and connective tissue disorder - Other, specify"</p> <p>"Myalgia"="Myalgia"</p> <p>"Nausea"="Nausea"</p> <p>"Neck pain"="Neck pain"</p> <p>"Non-cardiac chest pain"="Non-cardiac chest pain"</p> <p>"Oral pain"="Oral pain"</p> <p>"Otitis media"="Otitis media"</p> <p>"Pain in extremity"="Pain in extremity"</p> <p>"Pain"="Pain"</p> <p>"Platelet count decreased"="Platelet count decreased"</p> <p>"Postnasal drip"="Postnasal drip"</p> <p>"Pruritus"="Pruritus"</p> <p>"Rash acneiform"="Rash acneiform"</p> <p>"Rash maculo-papular"="Rash maculo-papular"</p> <p>"Respiratory, thoracic and mediastinal disorders - Other, specify"="Respiratory, thoracic and mediastinal disorders - Other, specify"</p> <p>"Seizure"="Seizure"</p> <p>"Sinus disorder"="Sinus disorder"</p> <p>"Stomach pain"="Stomach pain"</p> <p>"Tooth infection"="Tooth infection"</p> <p>"Upper respiratory infection"="Upper respiratory infection"</p> <p>"Urinary tract infection"="Urinary</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	<b>[...continued]</b> <b>ae_ctcae_term</b>			[...continued] tract infection" "Vomiting"="Vomiting" "Weight gain"="Weight gain" "Weight loss"="Weight loss"
01. Principal	<b>ae_dropped</b>	Dropped Due to This Adverse Event?		.M="Missing" 0="No" 1="Yes"
01. Principal	<b>ae_end_dt</b>	End Date of Adverse Event		SAS Date
01. Principal	<b>ae_event</b>	Adverse Event as Described Verbatim		Char
01. Principal	<b>ae_grade</b>	Severity of Adverse Event		.M="Missing" 1="Mild" 2="Moderate"
01. Principal	<b>ae_meddra_v12</b>	MedDRA v12.0 Code		Numeric .M="Missing"
01. Principal	<b>ae_onset_dt</b>	Onset Date of Adverse Event		SAS Date
01. Principal	<b>ae_outcome</b>	Outcome of Adverse Event		.M="Missing" 1="Recovered/Resolved" 3="Not recovering/Not Resolved"
01. Principal	<b>ae_report_dt</b>	Report Date of Adverse Event		SAS Date
01. Principal	<b>ae_sae</b>	Serious Adverse Event?		.M="Missing" 0="No"
01. Principal	<b>ae_tox_group</b>	Toxicity Group		.M="Missing" 1="Blood and Lymphatic System Disorders" 2="Cardiac Disorders" 4="Ear and Labyrinth 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" 22="Respiratory, Thoracic and Mediastinal Disorders" 23="Skin and Subcutaneous Tissue Disorders" 26="Vascular Disorders"