

# 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	3
Entries	16
Document Filename	dictionary_ae.rtf

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## UAZ2015-05-02 - Adverse Events: Data Dictionary

### Section 1: Identifiers

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Variable	Label	Description	Format Text
<b>ParticipantID</b>	Participant ID		Char

## Section 2: Study-wide

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Variable	Label	Description	Format Text
<b>COMMENTS</b>	Comments		Char
<b>InstitutionCode</b>	Institution Code		Char

## Section 3: Adverse Events

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Variable	Label	Description	Format Text
<b>ACTION</b>	Action		"1 Agent Withdrawn"="1 Agent Withdrawn" "2 Agent Dose Reduced"="2 Agent Dose Reduced" "4 Agent Dose Not Changed"="4 Agent Dose Not Changed" "6 Not Applicable"="6 Not Applicable"
<b>AdverseEvents</b>	Adverse Events		"None"="None"
<b>AEReportDate</b>	AE Report Date		SAS Date
<b>AEVerbatimTerm</b>	AE Verbatim Term		Char
<b>Attribution</b>	Attribution		"1 Unrelated"="1 Unrelated" "2 Unlikely"="2 Unlikely" "3 Possible"="3 Possible" "4 Probable"="4 Probable"
<b>DroppedDuetoThisAE</b>	Dropped Due to This AE		"1 Yes"="1 Yes" "2 No"="2 No"
<b>EventOnsetDate</b>	Event Onset Date		SAS Date
<b>GRADE</b>	Grade		"1 Mild"="1 Mild" "2 Moderate"="2 Moderate" "3 Severe"="3 Severe"
<b>OUTCOME</b>	Outcome		"1 Recovered Resolved"="1 Recovered Resolved" "3 Not Recovering Not Resolved"="3 Not Recovering Not Resolved"
<b>ReportedasSAE</b>	Reported as SAE		"1 Yes"="1 Yes" "2 No"="2 No"
<b>ResolvedDate</b>	Resolved Date		SAS Date

Variable	Label	Description	Format Text
<b>ToxicityCTCAEv40</b>	Toxicity CTCAE 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
<p>[...continued]</p> <p><b>ToxicityCTCAEv40</b></p>			<p>[...continued]</p> <p>disorders - Other, specify"</p> <p>"Rash acneiform"="Rash acneiform"</p> <p>"Renal and urinary disorders - Other, specify"="Renal and urinary disorders - Other, specify"</p> <p>"Renal calculi"="Renal calculi"</p> <p>"Renal colic"="Renal colic"</p> <p>"Sore throat"="Sore throat"</p> <p>"Stomach pain"="Stomach pain"</p> <p>"Surgical and medical procedures - Other, specify"="Surgical and medical procedures - Other, specify"</p> <p>"Tooth infection"="Tooth infection"</p> <p>"Upper respiratory infection"="Upper respiratory infection"</p> <p>"Urinary tract infection"="Urinary tract infection"</p> <p>"Vaginal discharge"="Vaginal discharge"</p> <p>"Vomiting"="Vomiting"</p> <p>"Weight loss"="Weight loss"</p> <p>"Wheezing"="Wheezing"</p> <p>"Wound complication"="Wound complication"</p>
<b>ToxicityGroupDRA</b>	Toxicity Group (DRA)		<p>"Cardiac disorders"="Cardiac disorders"</p> <p>"Eye disorders"="Eye disorders"</p> <p>"Gastrointestinal disorders"="Gastrointestinal disorders"</p> <p>"General disorders and administration site conditions"="General disorders and administration site conditions"</p> <p>"Immune system disorders"="Immune system disorders"</p> <p>"Infections and infestations"="Infections and infestations"</p> <p>"Injury, poisoning and procedural complications"="Injury, poisoning and procedural complications"</p> <p>"Investigations"="Investigations"</p> <p>"Metabolism and nutrition disorders"="Metabolism and nutrition disorders"</p> <p>"Musculoskeletal and connective tissue disorders"="Musculoskeletal and connective tissue disorders"</p> <p>"Nervous system disorders"="Nervous system disorders"</p> <p>"Psychiatric disorders"="Psychiatric disorders"</p> <p>"Renal and urinary disorders"="Renal and urinary disorders"</p> <p>"Reproductive system and breast disorders"="Reproductive system and breast disorders"</p> <p>"Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders"</p> <p>"Skin and subcutaneous tissue disorders"="Skin and subcutaneous tissue disorders"</p> <p>"Surgical and medical procedures"="Surgical and medical procedures"</p>