

UAZ2013-02-01 - Adverse Events Data Dictionary

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Document Summary

Property	Value
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UAZ2013-02-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

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

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	InstitutionCode	Institution Code		"AZ017"="AZ017"

Section 3: Adverse Events

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 Principal	ACTION	Action		"1 Agent Withdrawn"="1 Agent Withdrawn" "4 Agent Dose Not Changed"="4 Agent Dose Not Changed" "6 Not Applicable"="6 Not Applicable"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

Class	Variable	Label	Description	Format Text
01. Principal	ToxicityCTCAEv40	Toxicity CTCAE 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" "Hypertension"="Hypertension" "Hypotension"="Hypotension" "Injury, poisoning and procedural complications [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] ToxicityCTCAEv40			<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	[...continued] ToxicityCTCAEv40			[...continued] tract infection" "Vomiting"="Vomiting" "Weight gain"="Weight gain" "Weight loss"="Weight loss"
01. Principal	ToxicityGroupDRA	Toxicity Group (DRA)		"Blood and lymphatic system disorders"="Blood and lymphatic system disorders" "Cardiac disorders"="Cardiac disorders" "Ear and labyrinth disorders"="Ear and labyrinth disorders" "Gastrointestinal disorders"="Gastrointestinal disorders" "General disorders and administration site conditions"="General disorders and administration site conditions" "Infections and infestations"="Infections and infestations" "Injury, poisoning and procedural complications"="Injury, poisoning and procedural complications" "Investigations"="Investigations" "Metabolism and nutrition disorders"="Metabolism and nutrition disorders" "Musculoskeletal and connective tissue disorders"="Musculoskeletal and connective tissue disorders" "Nervous system disorders"="Nervous system disorders" "Psychiatric disorders"="Psychiatric disorders" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders" "Skin and subcutaneous tissue disorders"="Skin and subcutaneous tissue disorders" "Vascular disorders"="Vascular disorders"