

UAZ2017-09-02 - Adverse Events Data Dictionary

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Document Summary

Property	Value
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UAZ2017-09-02 - 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 Principal	ACTION	Action		"1 Agent Withdrawn"="Agent Withdrawn" "2 Agent Dose Reduced"="Agent Dose Reduced" "4 Agent Dose Not Changed"="Agent Dose Not Changed"
01. Principal	AdverseEvents	Adverse Events		"None"="None"
01. Principal	AEReportedDate	AE Reported Date		SAS Date
01. Principal	AEVerbatimTerm	AE Verbatim Term		"Anxiety"="Anxiety" "Cramping"="Cramping" "Depression"="Depression" "Diarrhea"="Diarrhea" "Flatulence"="Flatulence" "Flu symptoms"="Flu symptoms" "Gas pain"="Gas pain" "Gas"="Gas" "Heart attack"="Heart attack" "Hypothyroidism"="Hypothyroidism" "Indigestion"="Indigestion" "Indigestion, reflux, nausea"="Indigestion, reflux, nausea" "Intermittent cramping"="Intermittent cramping" "Intermittent diarrhea"="Intermittent diarrhea" "Intermittent distention (abdominal)"="Intermittent distention (abdominal)" "Intermittent flatulence"="Intermittent flatulence" "Intermittent gas (flatulence)"="Intermittent gas (flatulence)" "Intermittent gas"="Intermittent gas" "Intermittent loose stool"="Intermittent loose stool" "Intermittent loose stools"="Intermittent loose stools" "Left hand pain"="Left hand pain" "Left hand trigger finger surgery"="Left hand trigger finger surgery" "Loose bowel movements"="Loose bowel movements" "Loose stool (intermittent)"="Loose stool (intermittent)" "Loose stool (once)"="Loose stool (once)" "Loose stool"="Loose stool" "Mild gas"="Mild gas" "Muscle pain in shoulders"="Muscle pain in shoulders" "Nasal congestion"="Nasal congestion" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] AEVerbatimTerm			[...continued] "Nausea"="Nausea" "Nausea/vomiting"="Nausea/vomiting" "Possible bite on back of neck, swelling, redness, itching, pain"="Possible bite on back of neck, swelling, redness, itching, pain" "Seasonal allergies"="Seasonal allergies" "Sinus infection"="Sinus infection" "Slight stomach cramps"="Slight stomach cramps" "Stomach ache"="Stomach ache" "Stomach cramps"="Stomach cramps" "Stomach pain"="Stomach pain" "Stomach virus"="Stomach virus" "Stomachache/cramps"="Stomachache/cramps" "Threw up"="Threw up" "Upset stomach (cramps)"="Upset stomach (cramps)" "Weight loss"="Weight loss"
01. Principal	Attribution	Attribution		"1 Unrelated"="Unrelated" "2 Unlikely"="Unlikely" "3 Possible"="Possible" "4 Probable"="Probable"
01. Principal	COMMENTS	Comments		Char
01. Principal	DroppedDueToThisAE	Dropped Due to This AE		"1 Yes"="Yes" "2 No"="No"
01. Principal	EventEndDate	Event End Date		SAS Date
01. Principal	EventOnsetDate	Event Onset Date		SAS Date
01. Principal	GRADE	Grade		"1 Mild"="Mild" "2 Moderate"="Moderate" "4 Life Threatening"="Life Threatening"
01. Principal	OUTCOME	Outcome		"1 Recovered/Resolved"="Recovered/Resolved" "3 Not Recovering/Not Resolved"="Not Recovering/Not Resolved"
01. Principal	ReportedasSAE	Reported as SAE		"1 Yes"="Yes" "2 No"="No"

Class	Variable	Label	Description	Format Text
01. Principal	ToxicityCTCAEv40	Toxicity CTCAE v4.0		"Abdominal pain"="Abdominal pain" "Allergic rhinitis"="Allergic rhinitis" "Anxiety"="Anxiety" "Bloating"="Bloating" "Depression"="Depression" "Diarrhea"="Diarrhea" "Dyspepsia"="Dyspepsia" "Flatulence"="Flatulence" "Flu like symptoms"="Flu like symptoms" "Gastrointestinal disorders - Other, specify"="Gastrointestinal disorders - Other, specify" "General disorders and administration site conditions - Other, specify"="General disorders and administration site conditions - Other, specify" "Hypothyroidism"="Hypothyroidism" "Musculoskeletal and connective tissue disorder - Other, specify"="Musculoskeletal and connective tissue disorder - Other, specify" "Myalgia"="Myalgia" "Myocardial infarction"="Myocardial infarction" "Nasal congestion"="Nasal congestion" "Nausea"="Nausea" "Pain"="Pain" "Sinusitis"="Sinusitis" "Vomiting"="Vomiting" "Weight loss"="Weight loss"
01. Principal	ToxicityGroupDRA	Toxicity Group (DRA)		"Cardiac disorders"="Cardiac disorders" "Endocrine disorders"="Endocrine disorders" "Gastrointestinal disorders"="Gastrointestinal disorders" "General disorders and administration site conditions"="General disorders and administration site conditions" "Infections and infestations"="Infections and infestations" "Investigations"="Investigations" "Musculoskeletal and connective tissue disorders"="Musculoskeletal and connective tissue disorders" "Psychiatric disorders"="Psychiatric disorders" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders"