

# UAZ2017-09-02 - Adverse Events Data Dictionary

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## Document Summary

Property	Value
Document Title	UAZ2017-09-02 - Adverse Events: Data Dictionary
Date Created	09/20/2022
Sections	2
Entries	15
Document Filename	dictionary_adverse_events.rtf

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# UAZ2017-09-02 - 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	Change (If Any) in Agent Dose Due to Adverse Event		1="Agent Withdrawn" 2="Agent Dose Reduced" 4="Agent Dose Not Changed"
01. Principal	<b>ae_attribution</b>	Likelihood Adverse Event was Caused by Study Agent		1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"
01. Principal	<b>ae_ctcae_term</b>	CTCAE Term 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	<b>ae_dropped</b>	Dropped Due to This Adverse Event?		0="No" 1="Yes"
01. Principal	<b>ae_end_dt</b>	End Date of Adverse Event		SAS Date .M="Missing"
01. Principal	<b>ae_event</b>	Adverse Event as Described Verbatim		Char
01. Principal	<b>ae_grade</b>	Severity of Adverse Event		1="Mild" 2="Moderate" 4="Life-Threatening"
01. Principal	<b>ae_meddra_v12</b>	MedDRA v12.0 Code		Numeric
01. Principal	<b>ae_onset_dt</b>	Onset Date of Adverse Event		SAS Date

Class	Variable	Label	Description	Format Text
01. Principal	<b>ae_outcome</b>	Outcome of Adverse Event		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?		0="No" 1="Yes"
01. Principal	<b>ae_tox_group</b>	Toxicity Group		2="Cardiac Disorders" 5="Endocrine Disorders" 7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 11="Infections and Infestations" 13="Investigations" 15="Musculoskeletal and Connective Tissue Disorders" 19="Psychiatric Disorders" 22="Respiratory, Thoracic and Mediastinal Disorders"