

UWI2013-00-01 - ADVERSE EVENTS: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	UWI2013-00-01 - Adverse Events: Data Dictionary
Date Created	06/23/2020
Sections	2
Entries	14
Document Filename	dictionary_adverse.rtf

UWI2013-00-01 - Adverse Events: Data Dictionary

Section 1: Identifier

Variable	Label	Description	Format Text
Sequence_No_	Patient ID		Numeric

Section 2: Adverse Events

Variable	Label	Description	Format Text
adverse_action	Action - [Adverse Events]		.M="Missing" 1="Agent Withdrawn" 4="Agent Dose Not Changed" 6="Not Applicable" 7="Agent Interruption"
adverse_ae_attribution	Attribution - [Adverse Events]		.M="Missing" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"
adverse_ae_grade	Grade - [Adverse Events]		.M="Missing" 1="Mild AE" 2="Moderate AE" 3="Severe AE"
adverse_comments	Comments - [Adverse Events]		Char, 509
adverse_ctcae_term	CTCAE Term (v4.0) - [Adverse Events]		Char, 86
adverse_dropped	Dropped Due To This AE - [Adverse Events]		.M="Missing" 0="No"
adverse_event_ae_verbatim	Verbatim Term - [Adverse Events]		Char, 105
adverse_event_end_dt	End Date - [Adverse Events]		SAS Date .M="Missing"
adverse_event_onset_dt	Onset Date - [Adverse Events]		SAS Date .M="Missing"
adverse_event_reported_dt	Reported Date - [Adverse Events]		SAS Date .M="Missing"
adverse_meddra_soc	MedDRA System Organ Class (SOC) (v12.0) - [Adverse Events]		Char, 69
adverse_outcome	Outcome - [Adverse Events]		.M="Missing" 1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not Recovered/Not Resolved" 6="Unknown"
adverse_reported_sae	Reported as SAE - [Adverse Events]		.M="Missing" 0="No" 1="Yes"