

FINAL ADVERSE EVENTS: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	Final Adverse Events: Data Dictionary
Date Created	11/19/2019
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Final Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	MRNO	Participant ID (MRNO)	Participant ID (MRNO)	numeric

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	adverse_action	Action		1="1= Agent Withdrawn" 4="4=Agent Dose Not Changed" 6="6=Not Applicable"
01. Principal	adverse_ae_attribution	AE Attribution		1="1 = Unrelated" 2="2 = Unlikely" 3="3 = Possible" 4="4 = Probable"
01. Principal	adverse_ae_grade	AE Grade		numeric
01. Principal	adverse_comment	Comments		char, 141 " "="Not Applicable"
01. Principal	adverse_ctcae_term	CTCAE Term		char, 86
01. Principal	adverse_dropped	Dropped due to this AE?		1="Yes" 2="No"
01. Principal	adverse_end_dt	End Date		SAS Date .M="Missing"
01. Principal	adverse_meddra_soc	medDRA System Organ Class (SOC)		char, 69
01. Principal	adverse_onset_dt	Onset Date		SAS Date
01. Principal	adverse_outcome	Outcome		numeric
01. Principal	adverse_report_dt	Reported Date		SAS Date
01. Principal	adverse_reported_sae	Reported as SAE?		numeric
01. Principal	adverse_verbatim	Verbatim Term		char, 73