

NWU2013-02-01 - Adverse Events Data Dictionary

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Document Summary

Property	Value
Document Title	NWU2013-02-01 - Adverse Events: Data Dictionary
Date Created	03/10/2021
Sections	2
Entries	16
Document Filename	dictionary_ae.rtf

NWU2013-02-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	Participant_Identifier	Participant Identifier	Participant Identifier	Char

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_action	Adverse Event Action	Adverse Event Action	1="Agent Withdrawn" 4="Agent Dose Not Changed" 6="Not Applicable" 7="Agent Interrupted"
01. Principal	ae_attribution	Adverse Event Attribution	Likelihood Adverse Event Was Caused By Study Agent	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	ae_comments	Adverse Event Comments	Adverse Event Comments	Char
01. Principal	ae_ctcae_term	CTCAE Verbatim	CTCAE Term v4.0	Char
01. Principal	ae_dropped	Dropped Due To Adverse Event	Dropped Due To This Adverse Event?	0="No" 1="Yes"
01. Principal	ae_end_dt	Adverse Event End Date	End Date Of Adverse Event	SAS Date .M="Missing"
01. Principal	ae_grade	Adverse Event Grade	Severity Of Adverse Event	1="Mild adverse event" 2="Moderate adverse event" 3="Severe adverse event" 4="Life threatening adverse event"
01. Principal	ae_meddra_v12	CTCAE Number	Meddra v12.0 Code	Numeric
01. Principal	ae_onset_dt	Adverse Event Onset Date	Onset Date Of Adverse Event	SAS Date
01. Principal	ae_other_specify	Adverse Event Comment, Other Specify	Adverse Event Comment, Other Specify	Char
01. Principal	ae_outcome	Outcome	Outcome Of Adverse Event	1="Recovered/Resolved" 3="Not recovered/Not resolved" 4="Recovered/Resolved with Sequelae" 9="Unknown"
01. Principal	ae_sae	Reported As SAE?	Serious Adverse Event?	0="No" 1="Yes"
01. Principal	ae_tac_code	TAC Code	TAC Code	Numeric

Class	Variable	Label	Description	Format Text
01. Principal	ae_tox_group	System Of Concern	System Of Concern	1="Blood and lymphatic system disorders" 2="Cardiac disorders" 4="Ear and labyrinth disorders" 6="Eye disorders" 7="Gastrointestinal disorders" 8="General disorders and administration site conditions" 11="Infections and infestations" 12="Injury, poisoning and procedural complications" 13="Investigations" 14="Metabolism and nutrition disorders" 15="Musculoskeletal and connective tissue disorders" 17="Nervous system disorders" 22="Respiratory, thoracic and mediastinal disorders" 23="Skin and subcutaneous tissue disorders" 26="Vascular disorders"
01. Principal	ae_verbatim	Adverse Event Verbatim	Adverse Event Verbatim	Char