

NWU2014-04-01 - Adverse Events Data Dictionary

TABLE OF CONTENTS

Document Summary.....	2
NWU2014-04-01 - Adverse Events: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Adverse Events	4

Document Summary

Property	Value
Document Title	NWU2014-04-01 - Adverse Events: Data Dictionary
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NWU2014-04-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	Participant_ID	Participant ID	Participant ID	Char

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_action	Action	Action	4="Agent Dose Not Changed" 6="Not Applicable" 7="Agent Interrupted"
01. Principal	ae_attribute	AE Attribution	AE Attribution	1="Unrelated" 2="Unlikely" 3="Possible"
01. Principal	ae_comment	Comments	Comments	Char
01. Principal	ae_ctcae	CTCAE Term	CTCAE Term	Char
01. Principal	ae_dropped	Dropped Due To Adverse Event(s)	Dropped Due To Adverse Event(s)	0="No"
01. Principal	ae_end_dt	End Date	End Date	SAS Date .M="Missing"
01. Principal	ae_grade	AE Grade	AE Grade	1="Mild Adverse Event" 2="Moderate Adverse Event" 3="Severe Adverse Event"
01. Principal	ae_outcome	Outcome	Outcome	0="Not Recovered/Not Resolved" 1="Recovered/Resolved" 2="Recovered/Resolved with Sequelae" 9="Unknown"
01. Principal	ae_reported	Reported As SAE?	Reported As SAE?	0="No" 1="Yes"
01. Principal	ae_start_dt	Start Date	Start Date	SAS Date .M="Missing"
01. Principal	ae_system_organ	MedDRA System Organ Class (SOC)	MedDRA System Organ Class (SOC)	.M="Missing" 1="Blood and lymphatic system disorders" 7="Gastrointestinal disorders" 8="General disorders and administration site conditions" 10="Immune system disorders" 11="Infections and infestations" 12="Injury, poisoning and procedural complications" 13="Investigations" 14="Metabolism and nutrition disorders" 15="Musculoskeletal and connective tissue disorders" 16="Neoplasms benign, malignant and unspecified (incl cysts and polyps)" 17="Nervous system disorders" 21="Reproductive system and breast disorders" 22="Respiratory, thoracic and mediastinal disorders" 23="Skin and subcutaneous tissue disorders" 26="Vascular disorders"
01. Principal	ae_system_other	Other, Specify	Other, Specify	Char

Class	Variable	Label	Description	Format Text
01. Principal	ae_tac	Treatment Assignment Code (TAC)	Treatment Assignment Code (TAC)	0="TAC-0" 1="TAC1"
01. Principal	ae_verbatim	Adverse Event Verbatim Term	Adverse Event Verbatim Term	Char