

NWU2015-06-04 - Adverse Events Data Dictionary

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Document Summary

Property	Value
Document Title	NWU2015-06-04 - Adverse Events: Data Dictionary
Date Created	06/30/2023
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NWU2015-06-04 - Adverse Events: Data Dictionary

Section 1: Identifiers

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

Section 3: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_action	Action		1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unknown" 6="Not Applicable" 7="Agent Interrupted"
01. Principal	ae_attribution	Attribution		1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	ae_comments	Adverse Events, Comments		Char
01. Principal	ae_ctcae	Common Terminology Criteria For Adverse Events (CTCAE) Term		
01. Principal	ae_ctcae_other	Other Adverse Events Not Listed In CTCAE Term, Specify		Char
01. Principal	ae_dropped	Dropped Due To AE?		0="No" 1="Yes"
01. Principal	ae_end_date	End Date		SAS Date
01. Principal	ae_grade	Grade		0="Absent Adverse Event" 1="Mild Adverse Event" 2="Moderate Adverse Event" 3="Severe Adverse Event" 4="Life-Threatening Adverse Event" 5="Death Related To Adverse Event"
01. Principal	ae_outcome	Outcome		1="Recovered/Resolved" 2="Recovered/Resolved With Sequelae" 3="Not Recovered/Not Resolved" 4="Fatal" 5="Recovering/Resolving" 9="Unknown"
01. Principal	ae_SAE	Reported As SAE?		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	ae_soc	MedDRA System Organ Class (SOC)		1="Blood And Lymphatic System Disorders" 2="Cardiac Disorders" 3="Congenital, Familial And Genetic Disorders" 4="Ear And Labyrinth Disorders" 5="Endocrine Disorders" 6="Eye Disorders" 7="Gastrointestinal Disorders" 8="General Disorders And Administration Site Conditions" 9="Hepatobiliary Disorders" 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" 18="Pregnancy, Puerperium And Perinatal Conditions" 19="Psychiatric Disorders" 20="Renal And Urinary Disorders" 21="Reproductive System And Breast Disorders" 22="Respiratory, Thoracic And Mediastinal Disorders" 23="Skin And Subcutaneous Tissue Disorders" 24="Social Circumstances" 25="Surgical And Medical Procedures" 26=""Vascular Disorders" "
01. Principal	ae_start_date	Start Date		SAS Date
01. Principal	ae_tac	Treatment Assignment Code (TAC)		0="TAC-0" 1="TAC1" 2="TAC2" 3="TAC3"
01. Principal	ae_toxcode	MedDRA Adverse Event Code (CTCAE V4.0)		Numeric
01. Principal	ae_verbatim	Adverse Event Verbatim Term		Char