

# 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
Sections	2
Entries	16
Document Filename	dictionary_ae.rtf

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## NWU2015-06-04 - Adverse Events: Data Dictionary

### Section 1: Identifiers

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Class	Variable	Label	Description	Format Text
01. Principal	<b>ptid</b>	Participant ID		Char

## Section 3: Adverse Events

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	Action		1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unknown" 6="Not Applicable" 7="Agent Interrupted"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

Class	Variable	Label	Description	Format Text
01. Principal	<b>ae_soc</b>	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	<b>ae_start_date</b>	Start Date		SAS Date
01. Principal	<b>ae_tac</b>	Treatment Assignment Code (TAC)		0="TAC-0" 1="TAC1" 2="TAC2" 3="TAC3"
01. Principal	<b>ae_toxcode</b>	MedDRA Adverse Event Code (CTCAE V4.0)		Numeric
01. Principal	<b>ae_verbatim</b>	Adverse Event Verbatim Term		Char