

NWU2016-08-02 - Adverse Events Data Dictionary

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Document Summary

Property	Value
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NWU2016-08-02 - Adverse Events: Data Dictionary

Section 1: Identifiers

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

Section 2: 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 Principal	ae_action	Action		1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unknown" 6="Not Applicable" 7="Agent Interrupted"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	Comments		Char
01. Principal	ae_ctcae	CTCAE Term		"113"="113" "134"="134" "138"="138" "141"="141" "157"="157" "16"="16" "172"="172" "175"="175" "190"="190" "232"="232" "239"="239" "246"="246" "273"="273" "288"="288" "3"="3" "314"="314" "321"="321" "357"="357" "476"="476" "478"="478" "506"="506" "616"="616" "62"="62" "638"="638" "736"="736" "755"="755" "779"="779" "784"="784" "88"="88"
01. Principal	ae_ctcae_other	Other (Specify)		Char
01. Principal	ae_dropped	Dropped Due To This AE?		0="No" 1="Yes"
01. Principal	ae_end_date	End Date		Char
01. Principal	ae_end_date_time	End Time		Char

Class	Variable	Label	Description	Format Text
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" 99="Unknown"
01. Principal	ae_sae	Reported As SAE?		0="No" 1="Yes"
01. Principal	ae_soc	MedDRA System Organ Class (SOC)		"1"="Blood and Lymphatic System 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 (Including Cysts and Polyps)" "17"="Nervous System Disorders" "18"="Pregnancy, Puerperium and Perinatal Conditions" "19"="Psychiatric Disorders" "2"="Cardiac 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" "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" "99"="No Toxicity Group Associated With CTCAE Term"
01. Principal	ae_start_date	Start Date		Char
01. Principal	ae_start_date_time	Start Time		Char

Class	Variable	Label	Description	Format Text
01. Principal	ae_tac	Treatment Assignment Code (TAC)		0="TAC-0" 1="TAC1" 2="TAC2" 3="TAC3" 4="TAC4" 5="TAC5"
01. Principal	ae_verbatim	Adverse Event Verbatim Term		Char