

MAY2013-02-01 - Toxicity Data Dictionary

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Document Summary

Property	Value
Document Title	MAY2013-02-01 - Toxicity: Data Dictionary
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Entries	35
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MAY2013-02-01 - Toxicity: Data Dictionary

Section 1: Identifiers

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

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	FOLDERINSTAN CENAME	Dataset Folder Name		"Adverse Events"="Adverse Events"
01. Principal	MAXUPDATED	Last Updated		SAS Datetime
01. Principal	MINCREATED	Created Time		SAS Datetime
01. Principal	PROJECT	Protocol		"MAY2013-02-01"="MAY2013-02-01"
01. Principal	RAVEID	Rave ID		Numeric
01. Principal	SITENUMBER	Site Number		"FL080"="FL080" "MN026"="MN026" "PA093"="PA093" "PR008"="PR008"

Section 3: Toxicity

Class	Variable	Label	Description	Format Text
01. Principal	ACTIONXX	Action		"Agent dose increased"="Agent dose increased" "Agent dose not changed"="Agent dose not changed" "Agent dose reduced"="Agent dose reduced" "Agent interrupted"="Agent interrupted" "Agent withdrawn"="Agent withdrawn" "Not applicable"="Not applicable" "Unknown"="Unknown"
01. Principal	AERXX	Reported As SAE?		1="Yes" 2="No"
01. Principal	AESI	Adverse Event Of Special Interest (AESI)?		1="Yes" 2="No"
01. Principal	COMTOXOTH	Comments		Char
01. Principal	DLT	Dose Limiting Toxicity		1="Yes" 2="No"
01. Principal	DROPPEDXX	Off Study Due To This Adverse Event?		1="Yes" 2="No"
01. Principal	ENDDTXX	Event End Date		SAS Date
01. Principal	EVALDTXX	Adverse Event Report Date		SAS Date
01. Principal	MEDRASOCXX	MedDRA Adverse Event Code (CTCAE V4.0)		Char
01. Principal	NOAE	Participant Experienced No Adverse Events		0="Unchecked" 1="Checked"
01. Principal	ONGOINGXX	Ongoing		0="Unchecked" 1="Checked"
01. Principal	ONSETDTXX	Onset Date		SAS Date
01. Principal	ONSETDTXX_DD	Onset Date (Day)		Numeric
01. Principal	ONSETDTXX_MM	Onset Date (Month)		Numeric
01. Principal	ONSETDTXX_YY YY	Onset Date (Year)		Numeric
01. Principal	OUTCOMEXX	Outcome		"Fatal"="Fatal" "Not Recovered Not Resolved"="Not Recovered Not Resolved" "Recovered Resolved with Sequelae"="Recovered Resolved with Sequelae" "Recovered Resolved"="Recovered Resolved" "Recovering Resolving"="Recovering Resolving" "Unknown"="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	PAGEREPEATNUMBER	Page Repeat Number		Numeric
01. Principal	RECORDPOSITION	Record Position		Numeric
01. Principal	SITE	Site		"Mayo Clinic in Florida"="Mayo Clinic in Florida" "Mayo Clinic"="Mayo Clinic" "Temple University Hospital"="Temple University Hospital" "University of Puerto Rico"="University of Puerto Rico"
01. Principal	SOCXX	MedDRA System Organ Class (V12.0)		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" 99="other not per protocol"
01. Principal	SOCXX_SP	MedDRA System Organ Class (V12.0) (Specify)		Char
01. Principal	TARGETDAYS	Target Days From Baseline		Numeric
01. Principal	TOX_RLXX	Adverse Event Attribution		1="Not Related" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	TOXXX	Adverse Event Term (CTCAE V4.0)		Numeric

Class	Variable	Label	Description	Format Text
01. Principal	TOXXX_SP	Adverse Event Term (CTCAE V4.0) (Specify)		Char
01. Principal	VALDESCXX	Adverse Event Grade Description		Char
01. Principal	VALXX	Grade		Numeric
01. Principal	VERBATIMXX	Symptom Description (Verbatim Term)		Char