

MAY2017-09-01 - TOXICITY/ADVERSE EVENTS: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	MAY2017-09-01 - Toxicity/Adverse Events: Data Dictionary
Date Created	02/26/2020
Sections	3
Entries	34
Document Filename	dictionary_toxicity.rtf

MAY2017-09-01 - Toxicity/Adverse Events: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
SUBJECT	Participant ID	Participant ID	Char

Section 2: Study-wide

Variable	Label	Description	Format Text
FOLDERINSTANCE NAME	Folder Name	Folder Name	"Adverse Events"="Adverse Events"
MAXUPDATED	Last Updated	Last Updated	Numeric
MINCREATED	Time Created	Time Created	Numeric
PAGEREPEATNUM BER	Page Repeat Number	Page Repeat Number	Numeric
PROJECT	Protocol	Protocol	"MAY2017-09-01"="MAY2017-09-01"
RAVEID	Rave ID	Rave ID	Numeric
RECORDPOSITION	Record Position	Record Position	Numeric
SITE	Study Institution	Study Institution	"Thomas Jefferson University Hospital"="Thomas Jefferson University Hospital"
SITENUMBER	Study Institution ID Number	Study Institution ID Number	"PA121"="PA121"
TARGETDAYS	Target Days From Randomization	Target Days From Randomization	Numeric

Section 3: Toxicity/Adverse Events

Variable	Label	Description	Format Text
ACTIONXX	Action	Action	"Agent dose not changed"="Agent dose not changed" "Agent withdrawn"="Agent withdrawn" "Not applicable"="Not applicable"
AERXX	Reported As SAE?	Reported As SAE?	2="No"
COMTOXOTH	Comments	Comments	Char
DROPPEDXX	Off Study Due To This AE	Off Study Due To This AE	"1"="Yes" "2"="No"
ENDDTXX	Event End Date	Event End Date	SAS Date
EVALDTXX	Adverse Event Reported Date	Adverse Event Reported Date	SAS Date
MEDRASOCXX	MedDRA AE Code (CTCAE v4.0)	MedDRA AE Code (CTCAE v4.0)	Char
NOAE	At End Of Study Only: Check This Box If Participant Experienced No Adverse Events	At End Of Study Only: Check This Box If Participant Experienced No Adverse Events	0="Unchecked" 1="Checked"
ONGOINGXX	Ongoing	Ongoing	0="Unchecked" 1="Checked"
ONSETDTXX	Event Onset Date	Event Onset Date	SAS Date
ONSETDTXX_DD	Event Onset Date Day	Event Onset Date Day	Numeric
ONSETDTXX_MM	Event Onset Date Month	Event Onset Date Month	Numeric
ONSETDTXX_YYYY	Event Onset Date Year	Event Onset Date Year	Numeric
OUTCOMEXX	Outcome	Outcome	"Not Recovered/not resolved"="Not Recovered/not resolved" "Recovered/resolved"="Recovered/resolved"
SOCXX	MedDRA System Organ Class (v12.0)	MedDRA System Organ Class (v12.0)	"12"="Injury, Poisoning and Procedural Complications" "14"="Metabolism and Nutrition Disorders" "15"="Musculoskeletal and Connective Tissue Disorders" "17"="Nervous System Disorders" "19"="Psychiatric Disorders" "22"="Respiratory, Thoracic and Mediastinal Disorders" "23"="Skin and Subcutaneous Tissue Disorders" "7"="Gastrointestinal Disorders" "8"="General Disorders and Administration Site Conditions"
SOCXX_SP	MedDRA System Organ Class (v12.0) Specify	MedDRA System Organ Class (v12.0) Specify	Char
STUDPROCRELXX	Ae Procedure Related?	Ae Procedure Related?	"1"="Yes" "2"="No"

Variable	Label	Description	Format Text
TOX_RLXX	AE Attribution	AE Attribution	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"
TOXXX	Adverse Event Term (v4.0)	Adverse Event Term (v4.0)	Numeric
TOXXX_SP	Adverse Event Term (v4.0) Specify	Adverse Event Term (v4.0) Specify	Char
VALDESCXX	Adverse Event Grade Description	Adverse Event Grade Description	Char
VALXX	AE Grade	AE Grade	1="Mildadverse event" 2="Moderate adverse event" 3="Severe adverse event"
VERBATIMXX	Adverse Event Verbatim Term	Adverse Event Verbatim Term	Char