

MAY2013-02-02 - Adverse Events Data Dictionary

TABLE OF CONTENTS

Document Summary.....	2
MAY2013-02-02 - Adverse Events: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Adverse Events	4

Document Summary

Property	Value
Document Title	MAY2013-02-02 - Adverse Events: Data Dictionary
Date Created	09/19/2025
Sections	2
Entries	31
Document Filename	dictionary_toxicity.rtf

MAY2013-02-02 - Adverse Events: Data Dictionary

Section 1: Identifiers

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

Section 2: Adverse Events

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Dose Not Changed" "Agent dose reduced"="Agent Dose Reduced" "Agent interrupted"="Agent Interrupted" "Agent withdrawn"="Agent Withdrawn" "Not applicable"="Not Applicable" "Unknown"="Unknown"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	COMTOXOTH	Comments		Char
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	FOLDERINSTAN CENAME	Dataset Folder Name		Char
01. Principal	MAXUPDATED	Last Updated		Numeric

Class	Variable	Label	Description	Format Text
01. Principal	MEDRASOCXX	MedDRA Adverse Event Code (CTCAE V4.0)		"10000081: Gastrointestinal disorders"="10000081: Gastrointestinal disorders" "10000486: Metabolism and nutrition disorders"="10000486: Metabolism and nutrition disorders" "10001723: Respiratory, thoracic and mediastinal disorders"="10001723: Respiratory, thoracic and mediastinal disorders" "10002272: Blood and lymphatic system disorders"="10002272: Blood and lymphatic system disorders" "10005364: Investigations"="10005364: Investigations" "10008481: Cardiac disorders"="10008481: Cardiac disorders" "10010300: Psychiatric disorders"="10010300: Psychiatric disorders" "10010774: Gastrointestinal disorders"="10010774: Gastrointestinal disorders" "10012727: Gastrointestinal disorders"="10012727: Gastrointestinal disorders" "10013442: Blood and lymphatic system disorders"="10013442: Blood and lymphatic system disorders" "10013946: Gastrointestinal disorders"="10013946: Gastrointestinal disorders" "10013963: Respiratory, thoracic and mediastinal disorders"="10013963: Respiratory, thoracic and mediastinal disorders" "10014625: Nervous system disorders"="10014625: Nervous system disorders" "10015090: Respiratory, thoracic and mediastinal disorders"="10015090: Respiratory, thoracic and mediastinal disorders" "10016173: Injury, poisoning and procedural complications"="10016173: Injury, poisoning and procedural complications" "10016256: General disorders and administration [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] MEDRASOCXX			[...continued] site conditions"="10016256: General disorders and administration site conditions" "10016791: General disorders and administration site conditions"="10016791: General disorders and administration site conditions" "10017947: Gastrointestinal disorders"="10017947: Gastrointestinal disorders" "10018065: General disorders and administration site conditions"="10018065: General disorders and administration site conditions" "10019211: Nervous system disorders"="10019211: Nervous system disorders" "10019663: Hepatobiliary disorders"="10019663: Hepatobiliary disorders" "10021038: Metabolism and nutrition disorders"="10021038: Metabolism and nutrition disorders" "10021097: Vascular disorders"="10021097: Vascular disorders" "10021113: General disorders and administration site conditions"="10021113: General disorders and administration site conditions" "10021881: Infections and infestations"="10021881: Infections and infestations" "10022891: Investigations"="10022891: Investigations" "10027433: Metabolism and nutrition disorders"="10027433: Metabolism and nutrition disorders" "10028130: Gastrointestinal disorders"="10028130: Gastrointestinal disorders" "10028395: Musculoskeletal and connective tissue disorders"="10028395: Musculoskeletal and connective tissue disorders" "10028813: Gastrointestinal disorders"="10028813: Gastrointestinal disorders" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] MEDRASOCXX			[...continued] "10037087: Skin and subcutaneous tissue disorders"="10037087: Skin and subcutaneous tissue disorders" "10037847: Skin and subcutaneous tissue disorders"="10037847: Skin and subcutaneous tissue disorders" "10038695: Respiratory, thoracic and mediastinal disorders"="10038695: Respiratory, thoracic and mediastinal disorders" "10040047: Infections and infestations"="10040047: Infections and infestations" "10040747: Nervous system disorders"="10040747: Nervous system disorders" "10040785: Skin and subcutaneous tissue disorders"="10040785: Skin and subcutaneous tissue disorders" "10040872: Infections and infestations"="10040872: Infections and infestations" "10041633: Blood and lymphatic system disorders"="10041633: Blood and lymphatic system disorders" "10042112: Gastrointestinal disorders"="10042112: Gastrointestinal disorders" "10046593: Renal and urinary disorders"="10046593: Renal and urinary disorders" "10047065: Vascular disorders"="10047065: Vascular disorders" "10048031: Injury, poisoning and procedural complications"="10048031: Injury, poisoning and procedural complications" "10048677: Musculoskeletal and connective tissue disorders"="10048677: Musculoskeletal and connective tissue disorders" "10051592: Cardiac disorders"="10051592: Cardiac disorders" "10055322: Injury, poisoning and procedural complications"="10055322: Injury, poisoning and procedural complications" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] MEDRASOCXX			[...continued] "10065776: Musculoskeletal and connective tissue disorders"="10065776: Musculoskeletal and connective tissue disorders" "10066874: Gastrointestinal disorders"="10066874: Gastrointestinal disorders" "10069339: Renal and urinary disorders"="10069339: Renal and urinary disorders"
01. Principal	MINCREATED	Created Time		Numeric
01. Principal	NOAE	Participant Experienced No Adverse Events		0="No" 1="Yes"
01. Principal	ONGOINGXX	Ongoing		Numeric
01. Principal	ONSETDTXX	Onset Date		SAS Date
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"
01. Principal	PAGEREPEATNUMBER	Page Repeat Number		Numeric
01. Principal	PROJECT	Protocol		"MAY2013-02-02"="MAY2013-02-02"
01. Principal	RAVEID	Rave ID		Numeric
01. Principal	RECORDPOSITION	Record Position		Numeric
01. Principal	SITE	Site		"Case Western Reserve University"="Case Western Reserve University" "Cleveland Clinic Foundation"="Cleveland Clinic Foundation" "Massachusetts General Hospital Cancer Center"="Massachusetts General Hospital Cancer Center" "Mayo Clinic in Florida"="Mayo Clinic in Florida" "Mayo Clinic"="Mayo Clinic" "Mount Sinai Hospital"="Mount Sinai Hospital"

Class	Variable	Label	Description	Format Text
01. Principal	SITENUMBER	Site Number		"FL080"="FL080" "MA034"="MA034" "MN026"="MN026" "NY021"="NY021" "OH027"="OH027" "OH029"="OH029"
01. Principal	SOCXX	MedDRA System Organ Class (V12.0)		"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"
01. Principal	SOCXX_SP	MedDRA System Organ Class (V12.0) (Specify)		Char
01. Principal	STUDPROCRELX	Study Procedure Related?		"1"="Yes" "2"="No"
01. Principal	TARGETDAYS	Target Days From Baseline		Numeric
01. Principal	TOX_RLXX	Adverse Event Attribution		1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"

Class	Variable	Label	Description	Format Text
01. Principal	TOXXX	Adverse Event Term (CTCAE V4.0)		10000081="Gastrointestinal disorders" 10000486="Metabolism and nutrition disorders" 10001723="Respiratory, thoracic and mediastinal disorders" 10002272="Blood and lymphatic system disorders" 10005364="Investigations" 10008481="Cardiac disorders" 10010300="Psychiatric disorders" 10010774="Gastrointestinal disorders" 10012727="Gastrointestinal disorders" 10013442="Blood and lymphatic system disorders" 10013946="Gastrointestinal disorders" 10013963="Respiratory, thoracic and mediastinal disorders" 10014625="Nervous system disorders" 10015090="Respiratory, thoracic and mediastinal disorders" 10016173="Injury, poisoning and procedural complications" 10016256="General disorders and administration site conditions" 10016791="General disorders and administration site conditions" 10017947="Gastrointestinal disorders" 10018065="General disorders and administration site conditions" 10019211="Nervous system disorders" 10019663="Hepatobiliary disorders" 10021038="Metabolism and nutrition disorders" 10021097="Vascular disorders" 10021113="General disorders and administration site conditions" 10021881="Infections and infestations" 10022891="Investigations" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] TOXXX			[...continued] 10027433="Metabolism and nutrition disorders" 10028130="Gastrointestinal disorders" 10028395="Musculoskeletal and connective tissue disorders" 10028813="Gastrointestinal disorders" 10037087="Skin and subcutaneous tissue disorders" 10037847="Skin and subcutaneous tissue disorders" 10038695="Respiratory, thoracic and mediastinal disorders" 10040047="Infections and infestations" 10040747="Nervous system disorders" 10040785="Skin and subcutaneous tissue disorders" 10040872="Infections and infestations" 10041633="Blood and lymphatic system disorders" 10042112="Gastrointestinal disorders" 10046593="Renal and urinary disorders" 10047065="Vascular disorders" 10048031="Injury, poisoning and procedural complications" 10048677="Musculoskeletal and connective tissue disorders" 10051592="Cardiac disorders" 10055322="Injury, poisoning and procedural complications" 10065776="Musculoskeletal and connective tissue disorders" 10066874="Gastrointestinal disorders" 10069339="Renal and urinary disorders"
01. Principal	TOXXX_SP	Adverse Event Term (CTCAE V4.0) (Specify)		Char
01. Principal	VALDESCXX	Adverse Event Grade Description		Char
01. Principal	VALXX	Grade		1="Mild" 2="Moderate" 3="Severe" 4="Life-Threatening" 5="Lethal"
01. Principal	VERBATIMXX	Symptom Description		Char