

MAY2013-02-02 - Expedited Reporting Data Dictionary

TABLE OF CONTENTS

Document Summary.....	2
MAY2013-02-02 - Expedited Reporting: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Expedited Reporting	4

Document Summary

Property	Value
Document Title	MAY2013-02-02 - Expedited Reporting: Data Dictionary
Date Created	09/19/2025
Sections	2
Entries	30
Document Filename	dictionary_nonaer_coord.rtf

MAY2013-02-02 - Expedited Reporting: Data Dictionary

Section 1: Identifiers

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

Section 2: Expedited Reporting

Class	Variable	Label	Description	Format Text
01. Principal	ADR_TYPE	Report Format		1="MedWatch" 2="AdEERs" 3="Other"
01. Principal	ADR_TYSP	Specify		Char
01. Principal	ADRFORM	Is This An AER Form?		1="Yes" 2="No"
01. Principal	AERATTACH	Attach Report Here		Char
01. Principal	AMENDNUM	Amendment Number(s)		Char
01. Principal	COMSAE	Comments		Char
01. Principal	CYCLE	Visit Number		Numeric
01. Principal	DEATH_DT	Date Of Death		SAS Date
01. Principal	FOLDERINSTAN CENAME	Dataset Folder Name		Char
01. Principal	HOSPITAL	Hospitalization		1="Yes" 2="No"
01. Principal	MAXUPDATED	Last Updated		Numeric
01. Principal	MEDRASOCXX	MedDRA Adverse Event Code (CTCAE V4.0)		Char
01. Principal	MINCREATED	Created Time		Numeric
01. Principal	NOTIFYDT	Date Made Aware Of Events		SAS Date
01. Principal	OCURDTXX	Date Of First Occurrence Of Adverse Event		SAS Date
01. Principal	PAGEREPEATNU MBER	Page Repeat Number		Numeric
01. Principal	PG_DZ	Was Death Due To Progression?		1="Yes" 2="No"
01. Principal	PROJECT	Protocol		"MAY2013-02-02"="MAY2013-02-02"
01. Principal	PT_DEAD	Has Patient Died?		1="Yes" 2="No"
01. Principal	RAVEID	Rave ID		Numeric
01. Principal	RECORDPOSITIO N	Record Position		Numeric
01. Principal	RLAERXX	What Is The Attribution To The Study Medication?		1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	SITE	Site		"Mayo Clinic in Florida"="Mayo Clinic in Florida"

Class	Variable	Label	Description	Format Text
01. Principal	SITENUMBER	Site Number		"FL080"="FL080"
01. Principal	TARGETDAYS	Target Days From Baseline		Numeric
01. Principal	TICNUM	Ticket Number		Char
01. Principal	TOXXX	Adverse Event Term (CTCAE V4.0)		Numeric
01. Principal	TOXXX_SP	Adverse Event Term (CTCAE V4.0) (Specify)		Char
01. Principal	VALXX	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"