

NWU2013-02-01 - Adverse Events Data Dictionary

TABLE OF CONTENTS

Document Summary.....	2
NWU2013-02-01 - Adverse Events: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Adverse Events	4

Document Summary

Property	Value
Document Title	NWU2013-02-01 - Adverse Events: Data Dictionary
Date Created	03/10/2021
Sections	2
Entries	25
Document Filename	dictionary_ae.rtf

NWU2013-02-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	Participant_Identifier	Participant Identifier	Participant Identifier	Char

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	Action	Action	Action	"1"="Agent Withdrawn" "4"="Agent Dose Not Changed" "6"="Not Applicable" "7"="Agent Interrupted"
01. Principal	Adverse_Event_Verbatim_Term	Adverse Event Verbatim Term	Adverse Event Verbatim Term	Char
01. Principal	AE_Attribution	AE Attribution	AE Attribution	"Definite"="Definite" "Possible"="Possible" "Probable"="Probable" "Unlikely"="Unlikely" "Unrelated"="Unrelated"
01. Principal	AE_Grade	AE Grade	AE Grade	1="Mild Adverse Event" 2="Moderate Adverse Event" 3="Severe Adverse Event" 4="Life-threatening Adverse Event"
01. Principal	Comments	Comments	Comments	Char
01. Principal	CTCAE_Term	CTCAE Term	CTCAE Term	Char
01. Principal	Dropped_due_to_AE_	Dropped due to AE?	Dropped due to AE?	1="Yes" 2="No"
01. Principal	End_Date	End Date	End Date	Char
01. Principal	F16	F16	Empty Variable	Char
01. Principal	F17	F17	Empty Variable	Char
01. Principal	F18	F18	Empty Variable	Char
01. Principal	F19	F19	Empty Variable	Char
01. Principal	F20	F20	Empty Variable	Char
01. Principal	F21	F21	Empty Variable	Char
01. Principal	F22	F22	Empty Variable	Char
01. Principal	F23	F23	Empty Variable	Char
01. Principal	F24	F24	Empty Variable	Char
01. Principal	F25	F25	Empty Variable	Char
01. Principal	MedDRA_System_Organ_Class_SOC_	MedDRA System Organ Class (SOC)	MedDRA System Organ Class (SOC)	Char
01. Principal	Other__Specify	Other, Specify	Other, Specify	Char
01. Principal	Outcome	Outcome	Outcome	"Not Recovered/Not Resolved"="Not Recovered/Not Resolved" "Recovered/Resolved with Sequelae"="Recovered/Resolved with Sequelae" "Recovered/Resolved"="Recovered/Resolved" "Unknown"="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	Reported_as_SAE_	Reported As SAE?	Reported As SAE?	1="Yes" 2="No"
01. Principal	Start_Date	Start Date	Start Date	Char
01. Principal	Treatment_Assignment_Code_TAC_	Treatment Assignment Code (TAC)	Treatment Assignment Code (TAC)	"TAC-0"="TAC-0" "TAC1"="TAC1" "TAC2"="TAC2"