

NWU2014-03-01 - ADVERSE EVENTS: DATA DICTIONARY

TABLE OF CONTENTS

Document Summary.....	2
NWU2014-03-01 - Adverse Events: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Study-wide	4
Section 3: Adverse Events	5

Document Summary

Property	Value
Document Title	NWU2014-03-01 - Adverse Events: Data Dictionary
Date Created	11/14/2019
Sections	3
Entries	16
Document Filename	dictionary_ae.rtf

NWU2014-03-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
Participant_Identifier	Participant Identifier		Char

Section 2: Study-wide

Variable	Label	Description	Format Text
Comments	Comments		Char
Sheet_Name	Sheet Name		Char

Section 3: Adverse Events

Variable	Label	Description	Format Text
Action	Change (If Any) in Agent Dose Due to Adverse Event		Numeric
Adverse_Event_Verbatim_Term	Adverse Event as Described Verbatim		Char
AE_Attribution	Likelihood Adverse Event Was Caused by Study Agent		"Possible"="Possible" "Probable"="Probable" "Unrelated"="Unrelated"
AE_Grade	Severity of Adverse Event		Numeric
CTCAE_Term	CTCAE Term v4.0		Char
Dropped_due_to_AE	Dropped Due to This Adverse Event?		Numeric
End_Date	End Date of Adverse Event		Char
MedDRA_System_Organ_Class_SOC	MedDRA v12.0 Code		"Gastrointestinal disorders"="Gastrointestinal disorders" "Infections and infestations"="Infections and infestations" "Investigations"="Investigations"
Other_Specify	Other		Char
Outcome	Outcome of Adverse Event		"Not Recovered/Not Resolved"="Not Recovered/Not Resolved" "Recovered/Resolved"="Recovered/Resolved"
Reported_as_SAE	Serious Adverse Event?		Numeric
Start_Date	Start Date of Adverse Event		Char
Treatment_Assignment_Code_TAC	TAC		"TAC1"="TAC1"