

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: Event Details	4

Document Summary

Property	Value
Document Title	NWU2014-03-01 - Adverse Events: Data Dictionary
Date Created	11/14/2019
Sections	2
Entries	14
Document Filename	dictionary_ae.rtf

NWU2014-03-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
build_dt	Build Date		SAS Date
Participant_Identifier	Participant Identifier		Char

Section 2: Event Details

Variable	Label	Description	Format Text
ae_action	Change (If Any) in Agent Dose Due to Adverse Event		4="Agent Dose Not Changed" 6="Not Applicable"
ae_attribution	Likelihood Adverse Event Was Caused by Study Agent		1="Unrelated" 3="Possible" 4="Probable"
ae_ctcae_term	CTCAE Term v4.0	Common Terminology Criteria for Adverse Events term v4.0.	"Alanine aminotransferase increased"="Alanine aminotransferase increased" "Aspartate aminotransferase increased"="Aspartate aminotransferase increased" "Diarrhea"="Diarrhea" "Nausea"="Nausea" "Pancreatitis"="Pancreatitis" "Upper respiratory infection"="Upper respiratory infection"
ae_dropped	Dropped Due to This Adverse Event?		0="No"
ae_end_dt	End Date of Adverse Event		SAS Date .M="Missing"
ae_event	Adverse Event as Described Verbatim		Char
ae_grade	Severity of Adverse Event		1="Mild" 2="Moderate" 3="Severe"
ae_meddra_v12	MedDRA v12.0 Code	Medical Dictionary for Regulatory Activities v12.0 code.	Numeric
ae_onset_dt	Onset Date of Adverse Event		SAS Date
ae_outcome	Outcome of Adverse Event		1="Recovered/Resolved" 3="Not Recovered/Not Resolved"
ae_sae	Serious Adverse Event?		0="No"
ae_tox_group	Toxicity Group		7="Gastrointestinal Disorders" 11="Infections and Infestations" 13="Investigations"