

# NWU2014-03-01 - ADVERSE EVENTS: DATA DICTIONARY

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## 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

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## NWU2014-03-01 - Adverse Events: Data Dictionary

### Section 1: Identifiers

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Variable	Label	Description	Format Text
<b>Participant_Identifier</b>	Participant Identifier		Char

## Section 2: Study-wide

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Variable	Label	Description	Format Text
<b>Comments</b>	Comments		Char
<b>Sheet_Name</b>	Sheet Name		Char

## Section 3: Adverse Events

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