NWU2013-01-03 - ADVERSE EVENTS

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Document Summary

Property	Value
Document Title	NWU2013-01-03 - Adverse Events
Date Created	01/17/2020
For Dataset	ae
Sections	2
Entries	16
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Section 1: Identifiers

Variable	Label	Description	Format Text
Participant_Identifier	Participant Identifier	Participant Identifier	Char
Sheet_Name	Sheet Name	Sheet Name	Char

Section 2: AE

Variable	Label	Description	Format Text
Action	Action	The code representing the action taken as the result of the adverse event.	Char
Adverse_Event_Verbatim_Term	Adverse Event Verbatim Term	The text that describes the adverse event word for word as described by the participant.	Char
AE_Attribution	Adverse Event Attribution	Relation of the causality between the treatment modality and the specific adverse event.	Char
AE_Grade	Adverse Event Grade	Numeric representation of the intensity/severity of an unfavorable and unintended sign (including an abnormal laboratory finding), symptom, syndrome, or disease, temporally associated with the use of a medical product or procedure, regardless of whether or not it is considered related to the product or procedure (attribution of unrelated, unlikely, possible, probable or definite).	Num 1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unkown" 6="Not Applicable" 7="Agent Interrupted"
Comments	Comments	The free text field for general notes.	Char
CTCAE_Term	CTCAE Term	Text that represents the Common Terminology Criteria for Adverse Events lowest level term name for an adverse event. Text term to represent the highest level of a terminology distinguished by anatomical or physiological system, etiology, or purpose, and referencing an international medical terminology (Medical Dictionary for Regulatory Activities) version 12.0, designed to support the classification, retrieval, presentation, and communication of medical information throughout the medical product regulatory cycle.	Char
Dropped_due_to_AE_	Dropped due to Adverse Events?	Did the participant stop participation due to AE?	Num 1="Yes" 2="No"
End_Date	End Date	The end or last date of an adverse event._The last or final date of an event, described using a date or a text response of 'ongoing'.	Char

Variable	Label	Description	Format Text
MedDRA_System_Organ_Class__SOC_	MedDRA System Organ Class (SOC)	Text term to represent the highest level of a terminology distinguished by anatomical or physiological system, etiology, or purpose, and referencing an international medical terminology (Medical Dictionary for Regulatory Activities) version 12.0, designed to support the classification, retrieval, presentation, and communication of medical information throughout the medical product regulatory cycle	Char
Other__Specify	Other, Specify	A description of an adverse event that is not stated explicitly in the CTCAE v4.0 adverse event vocabulary.	Char
Outcome	Outcome	The final status of the participant related to the adverse event.	Char
Reported_as_SAE_	Reported as Serious Adverse Event?	The code representing whether the event was reported as a Serious Adverse Event.	Num 1="Yes" 2="No"
Start_Date	Start Date	The date on which the adverse event was first evident.	Char
Treatment_Assignment_Code__TAC_	Treatment Assignment Code (TAC)	A coded value representing a treatment assigned to be uniformly administered to a group of study subjects for separate statistical analysis.	Char