NWU-2013-01-03 ADVERSE EVENTS

TABLE OF CONTENTS

Document Summary

Property	Value
Document Title	NWU-2013-01-03 Adverse Events
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For Dataset	adverse_events
Sections	2
Entries	16
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NWU-2013-01-03 Adverse Events

Section 1: Identifiers

Variable	Label	Description	Format Text
participant_identifier	Participant Identifier	Participant Identifier	Char

Section 2: Adverse Events

Variable	Label	Description	Format Text
ae_action	Change (If Any) In Agent Dose Due To Adverse Event	The code representing the action taken as the result of the adverse event.	1="Agent Withdrawn" 4="Agent Dose Not Changed" 6="Not Applicable" 7="Agent Interrupted"
ae_attribution	Likelihood Adverse Event Was Caused By Study Agent	Relation of the causality between the treatment modality and the specific adverse event.	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"
ae_comments	Adverse Events Comments	Comments	Char
ae_ctcae_term	CTCAE Term v4.0	Text that represents the Common Terminology Criteria for Adverse Events lowest level term name for an adverse event.	Char
ae_dropped	Dropped Due To This Adverse Event?	Did the participant stop participation due to AE?	0="No" 1="Yes"
ae_end_dt	End Date Of Adverse Event	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'.	SAS Date .M="Missing"
ae_event	Adverse Event As Described Verbatim	The text that describes the adverse event word for word as described by the participant.	Char
ae_grade	Severity Of Adverse Event	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 0="No Event" 1="Mildadverse event" 2="Moderate adverse event" 3="Severe adverse event" 4="Life threatening adverse event" 5=" Death Related to adverse event"
ae_meddra_v12	Meddra v12.0 Code	MedDRA v12.0 Code	Num
ae_onset_dt	Onset Date Of Adverse Event	The date on which the adverse event was first evident.	SAS Date
ae_other_specify	Adverse Events Other Specify Verbatim Text	A description of an adverse event that is not stated explicitly in the CTCAE v4.0 adverse event vocabulary.	Char
ae_outcome	Outcome Of Adverse Event	The final status of the participant related to the adverse event.	1="Recovered/Resolved" 3="Not Recovered/Not Resolved" 4="Recovered/Resolved with Sequelae" 6="Unknown"

Variable	Label	Description	Format Text
ae_sae	Serious Adverse Event?	The code representing whether the event was reported as a Serious Adverse Event.	0="No" 1="Yes"
ae_tox_group	Toxicity Group	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	2="Cardiac Disorders" 6="Eye Disorders" 7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 11="Infections and Infestations" 12="Injury, Poisoning and Procedural Complications" 14="Metabolism and Nutrition Disorders" 15="Musculoskeletal and Connective Tissue Disorders" 17="Nervous System Disorders" 19="Psychiatric Disorders" 21="Reproductive System and Breast Disorders" 22="Respiratory, Thoracic and Mediastinal Disorders" 23="Skin and Subcutaneous Tissue Disorders" 26="Vascular Disorders"
tactad_code	Treatment Assignment Code	A coded value representing a treatment assigned to be uniformly administered to a group of study subjects for separate statistical analysis.	0="TAC-0" 1="TAC1" 2="TAC2"