

MAY2017-09-01 - ADVERSE EVENTS: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	MAY2017-09-01 - Adverse Events: Data Dictionary
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MAY2017-09-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
SUBJECT	Participant ID	Participant ID	Char

Section 2: Adverse Events

Variable	Label	Description	Format Text
ae_action	Change (If Any) In Agent Dose Due To Adverse Event	Change (If Any) In Agent Dose Due To Adverse Event	.N="Not Applicable" 1="Agent withdrawn" 4="Agent dose not changed" 6="Not applicable"
ae_attribution	Likelihood Adverse Event Was Caused By Study Agent	Likelihood Adverse Event Was Caused By Study Agent	.M="Missing" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"
ae_comments	Adverse Events Comments	Adverse Events Comments	Char
ae_ctcae_term	CTCAE Term v4.0	CTCAE Term v4.0	"Anorexia"="Anorexia" "Anxiety"="Anxiety" "Back pain"="Back pain" "Bloating"="Bloating" "Constipation"="Constipation" "Cough"="Cough" "Diarrhea"="Diarrhea" "Dizziness"="Dizziness" "Dry mouth"="Dry mouth" "Dyspepsia"="Dyspepsia" "Fatigue"="Fatigue" "Flatulence"="Flatulence" "Flu like symptoms"="Flu like symptoms" "Fracture"="Fracture" "Generalized muscle w"="Generalized muscle w" "Headache"="Headache" "Rectal hemorrhage"="Rectal hemorrhage" "Skin and subcutaneous"="Skin and subcutaneous" "Stomach pain"="Stomach pain" "Voice alteration"="Voice alteration" "Vomiting"="Vomiting"
ae_dropped	Dropped Due To This Adverse Event?	Dropped Due To This Adverse Event?	.N="Not Applicable" 0="No" 1="Yes"
ae_end_dt	End Date Of Adverse Event	End Date Of Adverse Event	SAS Date .N="Not Applicable"
ae_event	Adverse Event As Described Verbatim	Adverse Event As Described Verbatim	Char
ae_grade	Severity Of Adverse Event	Severity Of Adverse Event	.M="Missing" 1="Mild adverse event" 2="Moderate adverse event" 3="Severe adverse event"
ae_grade_desc	Adverse Events Grade Description	Adverse Events Grade Description	Char
ae_meddra_v12	Meddra v12.0 Code	Meddra v12.0 Code	Numeric .N="Not Applicable"
ae_no_ae	No Adverse Events Reported	No Adverse Events Reported	0="No" 1="Yes"

Variable	Label	Description	Format Text
ae_ongoing	Adverse Event Ongoing	Adverse Event Ongoing	0="No" 1="Yes"
ae_onset_dt	Onset Date Of Adverse Event	Onset Date Of Adverse Event	SAS Date .N="Not Applicable"
ae_outcome	Outcome Of Adverse Event	Outcome Of Adverse Event	.N="Not Applicable" 1="Recovered/resolved" 3="Not recovered/not resolved"
ae_proc_related	Procedure Related?	Procedure Related?	.N="Not Applicable" 0="No" 1="Yes"
ae_report_dt	Reported Date Of Adverse Event	Reported Date Of Adverse Event	SAS Date .N="Not Applicable"
ae_sae	Serious Adverse Event?	Serious Adverse Event?	.N="Not Applicable" 0="No"
ae_tox_group	Toxicity Group	Toxicity Group	.N="Not Applicable" 7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 12="Injury, Poisoning and Procedural Complications" 14="Metabolism and Nutrition Disorders" 15="Musculoskeletal and Connective Tissue Disorders" 17="Nervous System Disorders" 19="Psychiatric Disorders" 22="Respiratory, Thoracic and Mediastinal Disorders" 23="Skin and Subcutaneous Tissue Disorders"