

MAY2012-00-01 - ADVERSE EVENTS FILE: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	May2012-00-01 - Adverse Events File: Data Dictionary
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For Dataset	mayo_adverse_events
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Entries	22
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May2012-00-01 - Adverse Events File: Data Dictionary
05/07/2019
Dataset: mayo_adverse_events

May2012-00-01 - Adverse Events File: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
DCNTR_ID	Data Center ID	Data Center ID	Char

Section 2: Toxicity

Variable	Label	Description	Format Text
action_taken	Action Taken	Action	Num .F="No Form" 2="Agent Dose Reduced" 4="Agent Dose Not Changed" 6="Not Applicable"
adverse_event	CTC Adverse Event Term	Adverse Event Verbatim Term (e.g. cough)	Num .F="No Form" 1="Abdominal Bubbling" 2="Diarrhea" 3="Tired" 4="Stomach Cramping" 5="Abdominal Cramping" 6="Threw Up" 7="My Butt is Raw" 8="Flatulence" 9="Increased Bowel Movements" 10="Runny Nose" 11="Bloating" 12="Slight Cramping" 13="Constipation" 14="Cough" 15="Loose Stool" 16="Bubble Guts" 17="Headache" 18="Sore Throat" 19="Cut on Left Thumb" 20="Stomach Bubbling" 21="Vomited" 22="Bump on Buttocks - Cystic Lesion" 23="Intermittant Headache" 24="Pain at Bump on Buttocks" 25="Gas" 26="Abdominal Distension" 27="Puritus" 28="Abdominal Pain" 29="Nauseous"
adverse_event_dt	Date of Adverse Event	Adverse Event Reported Date (mm/dd/yyyy)	SAS Date .F="No Form"
ae_end_dt	Toxicity Resolution	Event End Date (mm/dd/yyyy)	SAS Date .F="No Form"
ae_grade	Adverse Event Grade	Adverse Event Grade	Num .F="No Form" 1="Mildadverse event"
ae_onset_dt	Toxicity Onset	Event Onset Date (mm/dd/yyyy)	SAS Date .F="No Form"
ae_outcome	Outcome	Outcome	Num .F="No Form" 3="Recovered/Resolved"
ae_tox_code	Toxicity Code	MedDRA AE Code (CTCAE v4.0)	Num .F="No Form"

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Variable	Label	Description	Format Text
ae_tox_related	Toxicity Related to Study Agent	AE Attribution	Num .F="No Form" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
ae_verbatim	Adverse Event Raw Text	Adverse Event Verbatim Term (e.g. cough)	Char " "= " "
dropped_due_to_ae	Dropped Due to Adverse Event	Dropped due to this AE?	Num .F="No Form"
reported_as_sae	Reported as SAE	Reported as SAE?	Num .F="No Form" 2="No"

Section 3: Cyttox

Variable	Label	Description	Format Text
aer_submitted	AER Submitted	AER Submitted	Num .N="Not Applicable" 0="No"
body_system	Body System	General body system category from CTC/MeDra associated with the given adverse event.	Num .M="Missing" 6="Musculoskeletal" 7="Dermatologic" 9="Endocrine/Metabolic" 12="Neurologic"
end_treatment_date	End Active Treatment	End Active Treatment	SAS DATE .N="Not Applicable"
evaluation_date	Evaluation Date	Evaluation Date	SAS DATE .N="Not Applicable"
relationship_study_meds	Relationship Study Meds	Relationship Study Meds	Num .N="Not Applicable" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
sys_of_concern	System of Concern	System of Concern	7="Gastrointestinal disorders" 8="General disorders and administration site conditions" 11="Infections and infestations" 17="Nervous system disorders" 22="Respiratory, thoracic and mediastinal disorders" 23="Skin and subcutaneous tissue disorders"
toxicity	Toxicity	Toxicity	Num
treatment_cycle	Treatment Cycle	Treatment Cycle	Num
visit	Eval Visit	Eval Visit	Num 1="Pre-reg" 2="Rand"