

# MAY2013-01-01 - Adverse Events Data Dictionary

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## Document Summary

Property	Value
Document Title	MAY2013-01-01 - Adverse Events: Data Dictionary
Date Created	10/23/2020
Sections	2
Entries	13
Document Filename	dictionary_ae.rtf

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## MAY2013-01-01 - Adverse Events: Data Dictionary

### Section 1: Identifiers

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Variable	Label	Description	Format Text
<b>DCNTR_ID</b>	Data Center ID	Data Center ID	Char

## Section 2: Adverse Events

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Variable	Label	Description	Format Text
<b>ae_attribution</b>	Adverse Event Attribution	Likelihood Adverse Event Was Caused By Study Agent	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
<b>ae_ctcae_term</b>	CTCAE Verbatim	CTCAE Term v4.0	Char
<b>ae_dropped</b>	Dropped Due To Adverse Event	Dropped Due To This Adverse Event?	0="No" 1="Yes"
<b>ae_end_dt</b>	Adverse Event End Date	End Date Of Adverse Event	SAS Date .M="Missing"
<b>ae_grade</b>	Adverse Event Grade	Severity Of Adverse Event	1="Mild adverse event" 2="Moderate adverse event" 3="Severe adverse event" 4="Life threatening adverse event"
<b>ae_meddra_v12</b>	CTCAE Number	Meddra v12.0 Code	Numeric
<b>ae_onset_dt</b>	Adverse Event Onset Date	Onset Date Of Adverse Event	SAS Date
<b>ae_outcome</b>	Outcome	Outcome Of Adverse Event	1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not recovered/Not resolved" 4="Recovered/Resolved with Sequelae"
<b>ae_sae</b>	Reported As SAE?	Serious Adverse Event?	0="No" 1="Yes"
<b>ae_tac_code</b>	TAC Code	TAC Code	Numeric

Variable	Label	Description	Format Text
<b>ae_tox_group</b>	System Of Concern	System Of Concern	1="Blood and lymphatic system disorders" 2="Cardiac disorders" 4="Ear and labyrinth disorders" 5="Endocrine disorders" 6="Eye disorders" 7="Gastrointestinal disorders" 8="General disorders and administration site conditions" 9="Hepatobiliary disorders" 10="Immune system disorders" 11="Infections and infestations" 12="Injury, poisoning and procedural complications" 13="Investigations" 14="Metabolism and nutrition disorders" 15="Musculoskeletal and connective tissue disorders" 16="Neoplasms benign, malignant and unspecified (incl cysts and polyps)" 17="Nervous system disorders" 19="Psychiatric disorders" 20="Renal and urinary disorders" 21="Reproductive system and breast disorders" 22="Respiratory, thoracic and mediastinal disorders" 23="Skin and subcutaneous tissue disorders" 25="Surgical and medical procedures" 26="Vascular disorders"
<b>ae_verbatim</b>	Adverse Event Verbatim	Adverse Event Verbatim	Char