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
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MAY2013-01-01 - Adverse Events: Data Dictionary
Section 1: Identifiers

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

Section 2: Adverse Events

Variable	Label	Description	Format Text
attrib	Adverse Event Attribution	Adverse Event Attribution	"Definite"="Definite" "Possible"="Possible" "Probable"="Probable" "Unlikely"="Unlikely" "Unrelated"="Unrelated"
ctcae	CTCAE Number	CTCAE Number	Numeric
ctcaeterm	CTCAE Verbatim	CTCAE Verbatim	Char
drop	Dropped Due To Adverse Event	Dropped Due To Adverse Event	Numeric 1="Yes" 2="No"
end	Adverse Event End Date	Adverse Event End Date	SAS Date
grade	Adverse Event Grade	Adverse Event Grade	1="Mild" 2="Moderate" 3="Severe" 4="Life-Threatening"
onset	Adverse Event Onset Date	Adverse Event Onset Date	SAS Date
outcome	Outcome	Outcome	"Not recovered/Not resolved"="Not recovered/Not resolved" "Recovered/Resolved with Sequelae"="Recovered/Resolved with Sequelae" "Recovered/Resolved"="Recovered/Resolved" "Recovering/Resolving"="Recovering/Resolving"
sae	Reported As SAE?	Reported As SAE?	Numeric

Variable	Label	Description	Format Text
soc	System Of Concern	System Of Concern	"Blood and lymphatic system disorders"="Blood and lymphatic system disorders" "Cardiac disorders"="Cardiac disorders" "Ear and labyrinth disorders"="Ear and labyrinth disorders" "Endocrine disorders"="Endocrine disorders" "Eye disorders"="Eye disorders" "Gastrointestinal disorders"="Gastrointestinal disorders" "General disorders and administration site conditions"="General disorders and administration site conditions" "Hepatobiliary disorders"="Hepatobiliary disorders" "Immune system disorders"="Immune system disorders" "Infections and infestations"="Infections and infestations" "Injury, poisoning and procedural complications"="Injury, poisoning and procedural complications" "Investigations"="Investigations" "Metabolism and nutrition disorders"="Metabolism and nutrition disorders" "Musculoskeletal and connective tissue disorders"="Musculoskeletal and connective tissue disorders" "Neoplasms benign, malignant and unspecified (incl cysts and polyps)"="Neoplasms benign, malignant and unspecified (incl cysts and polyps)" "Nervous system disorders"="Nervous system disorders" "Psychiatric disorders"="Psychiatric disorders" "Renal and urinary disorders"="Renal and urinary disorders" "Reproductive system and breast disorders"="Reproductive system and breast disorders" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders" "Skin and subcutaneous tissue disorders"="Skin [continued...]

Variable	Label	Description	Format Text
[...continued] **soc**			[...continued] and subcutaneous tissue disorders" "Surgical and medical procedures"="Surgical and medical procedures" "Vascular disorders"="Vascular disorders"
table	Table	Table	"AE"="AE"
tac_code	TAC Code	TAC Code	"TAC1"="TAC1"
verbatim	Adverse Event Verbatim	Adverse Event Verbatim	Char