

MAY2013-01-01 - Adverse Events Maximum Grade Data Dictionary

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Document Summary

Property	Value
Document Title	MAY2013-01-01 - Adverse Events Maximum Grade: Data Dictionary
Date Created	10/23/2020
Sections	3
Entries	24
Document Filename	dictionary_crtox_reg.rtf

MAY2013-01-01 - Adverse Events Maximum Grade: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
DCNTR_ID	Data Center ID	DCNTR_ID	Char

Section 2: Study-wide

Variable	Label	Description	Format Text
ARM	Arm	Arm	"A"="MUC1" "B"="Placebo"
CASE	Case Number	Case Number	Numeric
CYCLE	Cycle	Cycle	Numeric
DC_NUM	Data Center Assigned Protocol Number	Data Center Assigned Protocol Number	"MAY2013-01-01"="MAY2013-01-01"
STUDY	Ingres Study Number	Ingres Study Number	Numeric

Section 3: Adverse Events Maximum Grade

Variable	Label	Description	Format Text
BODYSYS	Body System	General body system category from CTC/MeDra associated with the given adverse event.	****_**** "1"="Blood and lymphatic system 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" "18"="Pregnancy, puerperium and perinatal conditions" "19"="Psychiatric disorders" "2"="Cardiac disorders" "20"="Renal and urinary disorders" "23"="Other" "3"="Congenital, familial and genetic disorders" "4"="Ear and labyrinth disorders" "6"="Eye disorders" "7"="Gastrointestinal disorders" "8"="General disorders and administration site conditions" "9"="Hepatobiliary disorders"
COURSE	Course	Course	1="Yes"
CTC_V3	CTCAE V3	CTCAE V3	Char
CTC_V4	CTCAE V4	CTCAE V4	"Y"="Yes"
ENDAT_DT	End Active Treatment	End Active Treatment	SAS Date
EVAL_DT	Evaluation Date	Evaluation Date	SAS Date
EXCLUDED	Excluded	Excluded	Numeric
GRADE	Grade	Grade	1="Mildadverse event" 2="Moderate adverse event" 3="Severe adverse event" 4="Life threatening adverse event"
NADR_DAT	Nadir Date	Nadir Date	SAS Date
NADR_VAL	Nadir Value	Nadir Value	Numeric
PGRADE	Possible Grade	Possible Grade	1="Mildadverse event" 2="Moderate adverse event"
REL_SMED	Relationship Study Meds	Relationship Study Meds	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"

Variable	Label	Description	Format Text
SOC	System Of Concern	System Of Concern	"Blood and lymphatic sys disord"="Blood and lymphatic sys disord" "Cardiac disorders"="Cardiac disorders" "Ear and labyrinth disorders"="Ear and labyrinth disorders" "Endocrine disorders"="Endocrine disorders" "Eye disorders"="Eye disorders" "Gastrointestinal disorders"="Gastrointestinal disorders" "Gen disord and admin site cond"="Gen disord and admin site cond" "Hepatobiliary disorders"="Hepatobiliary disorders" "Immune system disorders"="Immune system disorders" "Infections and infestations"="Infections and infestations" "Inj, pois and proced complic"="Inj, pois and proced complic" "Investigations"="Investigations" "Metabol and nutrition disord"="Metabol and nutrition disord" "Musculosk and conn tiss disord"="Musculosk and conn tiss disord" "Neoplsn benign, mal and unspec"="Neoplsn benign, mal and unspec" "Nervous system disorders"="Nervous system disorders" "Psychiatric disorders"="Psychiatric disorders" "Renal and urinary disorders"="Renal and urinary disorders" "Reprod sys and breast disord"="Reprod sys and breast disord" "Respirat, thor, mediast disord"="Respirat, thor, mediast disord" "Skin and subcutan tiss disord"="Skin and subcutan tiss disord" "Surgical and medical proced"="Surgical and medical proced" "Vascular disorders"="Vascular disorders"
SUBJECT	Subject Number	Subject Number	Numeric
TOXCODE	Toxicity Code	Toxicity Code	Numeric
TOXICITY	Toxicity	Toxicity	Numeric
TRT_ARM	Treatment Arm	Treatment Arm	"A"="MUC1" "B"="Placebo"
TRTCYCLE	Treatment Cycle	Treatment Cycle	1="Treatment Cycle"