

MAY2013-01-01 - Toxicity Registration Data Dictionary

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Document Summary

Property	Value
Document Title	MAY2013-01-01 - Toxicity Registration: Data Dictionary
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Sections	3
Entries	31
Document Filename	dictionary_toxicity_reg.rtf

MAY2013-01-01 - Toxicity Registration: Data Dictionary

Section 1: Identifiers

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

Section 2: Study-wide

Variable	Label	Description	Format Text
ARM	Arm	Arm	"A"="MUC1" "B"="Placebo"
CASE	Case Number	Case Number	Numeric
CREATED	Created Date	Created Date	SAS Date
CYCLE	Cycle	Cycle	Numeric
DATE_MOD	Date Modified	Date Modified	SAS Date
DC_NUM	Data Center Assigned Protocol Number	Data Center Assigned Protocol Number	"MAY2013-01-01"="MAY2013-01-01"
FORMCOMP	Form Complete	Form Complete	Char
FORMNAME	Form Name	Form Name	"Adverse Events"="Adverse Events"
IGNORE	Nothing	Nothing	Numeric
NODE	Node	Node	Numeric
SEQUENCE	Sequence	Sequence	Numeric
STUDY	Ingres Study Number	Ingres Study Number	Numeric
VERSION	Version	Version	Numeric

Section 3: Toxicity Registration

Variable	Label	Description	Format Text
ACTION10	Action Taken	Action 1=Agent Withdrawn 2=Agent Dose Reduced 3=Agent Dose Increased 4=Agent Dose Not Changed 5=Unknown 6=Not Applicable	4="Agent dose not changed" 6="Not applicable"
ACTION35-44	Action Taken	Action 1=Agent Withdrawn 2=Agent Dose Reduced 3=Agent Dose Increased 4=Agent Dose Not Changed 5=Unknown 6=Not Applicable	1="Agent withdrawn" 4="Agent dose not changed" 6="Not applicable"
ADVEVENT	Adverse Event	At end of study only: Select if participant experienced no adverse events, otherwise leave blank	1="Yes"
AEDATE35-45	Adverse Event Reported Date	Adverse Event Reported Date (mm/dd/yyyy)	SAS Date
AEDROP35-45	Dropped Due To Adverse Event	Dropped due to this AE? 1=Yes 2=No	1="Yes" 2="No"
AER_35-45	AER Tox	Reported as SAE? 1=Yes 2=No	1="Yes" 2="No"
AETERM35-45	CTC Adverse Event Term	Symptom Description (Verbatim term) (33 available characters)	Char
FORM	Form	Form	Numeric
FORMTYPE	Form Type	Form Type	"ae"="ae"
ONSET35-45	Toxicity Onset Date	Onset Date (mm/dd/yyyy)	SAS Date
OUTCME35-45	Outcome	Outcome 1=Fatal 2=Not Recovered/Not Resolved 3=Recovered/Resolved 4=Unknown 5=Recovering/Resolving 6=Recovered/Resolved with Sequelae	2="Not recovered/Not resolved" 3="Recovered/Resolved" 5="Recovering/Resolving" 6="Recovered/Resolved with sequelae"
RESOL35-45	Toxicity Resolution Date	Event End Date (mm/dd/yyyy)	SAS Date
TOX35-45	Toxicity	Enter MedDRA Code v. 12.0 =	Numeric
TOX_R38	Toxicity Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"

Variable	Label	Description	Format Text
TOX_RL35-37	Toxicity Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
TOX_RL39-45	Toxicity Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
VAL35-45	Toxicity Value	Grade	Numeric