MAYO - RAND TOXICITY: DATA DICTIONARY

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11/27/2017
Dataset: toxicity

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Document Summary

Property	Value
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Date Created	11/27/2017
For Dataset	toxicity
Sections	3
Entries	117
Document Filename	dictionary_Toxicity.100617.rtf

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Section 1: Identifiers

Variable	Label	Description	Format Text
ARM	Arm		Char
DC_NUM	Data Center Assigned Prot Num		Char

Section 2: Form Data

Variable	Label	Description	Format Text
CASE	Case Number		Num
CREATED	Created Date		SAS Date
CYCLE	Cycle		Num
DATE_MOD	Date Modified		SAS Date
DCNTR_ID	Data Center ID		Char
EVAL_DT	Evaluation Date	Reporting Period End Date: (last date Adverse Events were assessed during this reporting period) (mm/dd/yyyy)	SAS Date
FORM	Form		Num 14="Adverse Events"
FORMCOMP	Form Complete		Char " "=" "
FORMNAME	Form Name		Char
FORMTYPE	Form Type		Char
IGNORE	Nothing		Num .="Missing"
STUDY	Ingres Study Number		Num
VERSION	Version		Num

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Section 3: Results

Variable	Label	Description	Format Text
ACTION35	Action Taken 35	Action 1=Agent Withdrawn 2=Agent Dose Reduced 3=Agent Dose Increased 4=Agent Dose Not Changed 5=Unknown 6=Not Applicable	Num .="Missing" 4="Agent Dose Not Changed" 6="Not Applicable"
ACTION36	Action Taken 36	Action 1=Agent Withdrawn 2=Agent Dose Reduced 3=Agent Dose Increased 4=Agent Dose Not Changed 5=Unknown 6=Not Applicable	Num .="Missing" 4="Agent Dose Not Changed" 6="Not Applicable"
ACTION37	Action Taken 37	Action 1=Agent Withdrawn 2=Agent Dose Reduced 3=Agent Dose Increased 4=Agent Dose Not Changed 5=Unknown 6=Not Applicable	Num .="Missing" 4="Agent Dose Not Changed" 6="Not Applicable"
ACTION38	Action Taken 38	Action 1=Agent Withdrawn 2=Agent Dose Reduced 3=Agent Dose Increased 4=Agent Dose Not Changed 5=Unknown 6=Not Applicable	Num .="Missing" 2="Agent Dose Reduced" 4="Agent Dose Not Changed"
ACTION39	Action Taken 39	Action 1=Agent Withdrawn 2=Agent Dose Reduced 3=Agent Dose Increased 4=Agent Dose Not Changed 5=Unknown 6=Not Applicable	Num .="Missing" 4="Agent Dose Not Changed" 6="Not Applicable"
ACTION40	Action Taken 40	Action 1=Agent Withdrawn 2=Agent Dose Reduced 3=Agent Dose Increased 4=Agent Dose Not Changed 5=Unknown 6=Not Applicable	Num .="Missing" 4="Agent Dose Not Changed"
ACTION41	Action Taken 41	Action 1=Agent Withdrawn 2=Agent Dose Reduced 3=Agent Dose Increased 4=Agent Dose Not Changed 5=Unknown 6=Not Applicable	Num .="Missing" 4="Agent Dose Not Changed" 6="Not Applicable"
ACTION42	Action Taken 42	Action 1=Agent Withdrawn 2=Agent Dose Reduced 3=Agent Dose Increased 4=Agent Dose Not Changed 5=Unknown 6=Not Applicable	Num .="Missing" 4="Agent Dose Not Changed"

Variable	Label	Description	Format Text
ACTION43	Action Taken 43	Action 1=Agent Withdrawn 2=Agent Dose Reduced 3=Agent Dose Increased 4=Agent Dose Not Changed 5=Unknown 6=Not Applicable	Num .="Missing" 4="Agent Dose Not Changed"
ADVEVENT	Adverse Event	Were adverse events assessed during most recent period? (select one) 1=Yes, and reportable adverse events occurred 2=Yes, but no reportable adverse events occurred - End form 3=No - End form	Num 1="Yes, and reportable adverse events occurred" 2="Yes, but no reportable adverse events occurred - End form"
AEDATE35	Date of AE 35	Adverse Event Reported Date (mm/dd/yyyy)	SAS Date .="Missing"
AEDATE36	Date of AE 36	Adverse Event Reported Date (mm/dd/yyyy)	SAS Date .="Missing"
AEDATE37	Date of AE 37	Adverse Event Reported Date (mm/dd/yyyy)	SAS Date .="Missing"
AEDATE38	Date of AE 38	Adverse Event Reported Date (mm/dd/yyyy)	SAS Date .="Missing"
AEDATE39	Date of AE 39	Adverse Event Reported Date (mm/dd/yyyy)	SAS Date .="Missing"
AEDATE40	Date of AE 40	Adverse Event Reported Date (mm/dd/yyyy)	SAS Date .="Missing"
AEDATE41	Date of AE 41	Adverse Event Reported Date (mm/dd/yyyy)	SAS Date .="Missing"
AEDATE42	Date of AE 42	Adverse Event Reported Date (mm/dd/yyyy)	SAS Date .="Missing"
AEDATE43	Date of AE 43	Adverse Event Reported Date (mm/dd/yyyy)	SAS Date .="Missing"
AEDROP35	Dropped Due to AE 35	Dropped due to this AE? 1=Yes 2=No	Num .="Missing" 2="No"
AEDROP36	Dropped Due to AE 36	Dropped due to this AE? 1=Yes 2=No	Num .="Missing" 2="No"
AEDROP37	Dropped Due to AE 37	Dropped due to this AE? 1=Yes 2=No	Num .="Missing" 2="No"
AEDROP38	Dropped Due to AE 38	Dropped due to this AE? 1=Yes 2=No	Num .="Missing" 2="No"
AEDROP39	Dropped Due to AE 39	Dropped due to this AE? 1=Yes 2=No	Num .="Missing" 2="No"
AEDROP40	Dropped Due to AE 40	Dropped due to this AE? 1=Yes 2=No	Num .="Missing" 2="No"

Variable	Label	Description	Format Text
AEDROP41	Dropped Due to AE 41	Dropped due to this AE? 1=Yes 2=No	Num .="Missing" 2="No"
AEDROP42	Dropped Due to AE 42	Dropped due to this AE? 1=Yes 2=No	Num .="Missing" 2="No"
AEDROP43	Dropped Due to AE 43	Dropped due to this AE? 1=Yes 2=No	Num .="Missing" 2="No"
AER_35	AER Tox 35	Reported as SAE? 1=Yes 2=No	Num .="Missing" 2="No"
AER_36	AER Tox 36	Reported as SAE? 1=Yes 2=No	Num .="Missing" 2="No"
AER_37	AER Tox 37	Reported as SAE? 1=Yes 2=No	Num .="Missing" 2="No"
AER_38	AER Tox 38	Reported as SAE? 1=Yes 2=No	Num .="Missing" 2="No"
AER_39	AER Tox 39	Reported as SAE? 1=Yes 2=No	Num .="Missing" 2="No"
AER_40	AER Tox 40	Reported as SAE? 1=Yes 2=No	Num .="Missing" 2="No"
AER_41	AER Tox 41	Reported as SAE? 1=Yes 2=No	Num .="Missing" 2="No"
AER_42	AER Tox 42	Reported as SAE? 1=Yes 2=No	Num .="Missing" 2="No"
AER_43	AER Tox 43	Reported as SAE? 1=Yes 2=No	Num .="Missing" 2="No"
AETERM35	CTC Adverse Event Term 35	Adverse Event Verbatim Term (33 available characters)	Char " "=" "
AETERM36	CTC Adverse Event Term 36	Adverse Event Verbatim Term (33 available characters)	Char " "=" "
AETERM37	CTC Adverse Event Term 37	Adverse Event Verbatim Term (33 available characters)	Char " "=" "
AETERM38	CTC Adverse Event Term 38	Adverse Event Verbatim Term (33 available characters)	Char " "=" "
AETERM39	CTC Adverse Event Term 39	Adverse Event Verbatim Term (33 available characters)	Char " "=" "

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Variable	Label	Description	Format Text
AETERM40	CTC Adverse Event Term 40	Adverse Event Verbatim Term (33 available characters)	Char " "=" "
AETERM41	CTC Adverse Event Term 41	Adverse Event Verbatim Term (33 available characters)	Char " "=" "
AETERM42	CTC Adverse Event Term 42	Adverse Event Verbatim Term (33 available characters)	Char " "=" "
AETERM43	CTC Adverse Event Term 43	Adverse Event Verbatim Term (33 available characters)	Char " "=" "
NODE	Node		Num
ONSET35	Toxicity Onset 35	Event Onset Date (mm/dd/yyyy)	SAS Date .="Missing"
ONSET36	Toxicity Onset 36	Event Onset Date (mm/dd/yyyy)	SAS Date .="Missing"
ONSET37	Toxicity Onset 37	Event Onset Date (mm/dd/yyyy)	SAS Date .="Missing"
ONSET38	Toxicity Onset 38	Event Onset Date (mm/dd/yyyy)	SAS Date .="Missing"
ONSET39	Toxicity Onset 39	Event Onset Date (mm/dd/yyyy)	SAS Date .="Missing"
ONSET40	Toxicity Onset 40	Event Onset Date (mm/dd/yyyy)	SAS Date .="Missing"
ONSET41	Toxicity Onset 41	Event Onset Date (mm/dd/yyyy)	SAS Date .="Missing"
ONSET42	Toxicity Onset 42	Event Onset Date (mm/dd/yyyy)	SAS Date .="Missing"
ONSET43	Toxicity Onset 43	Event Onset Date (mm/dd/yyyy)	SAS Date .="Missing"
OUTCME35	Outcome 35	Outcome 1=Fatal 2=Not Recovered/Not Resolved 3=Recovered/Resolved 4=Unknown 5=Recovering/Resolving 6=Recovered/Resolved with Sequelae	Num .="Missing" 3="Recovered/Resolved"
OUTCME36	Outcome 36	Outcome 1=Fatal 2=Not Recovered/Not Resolved 3=Recovered/Resolved 4=Unknown 5=Recovering/Resolving 6=Recovered/Resolved with Sequelae	Num .="Missing" 3="Recovered/Resolved"

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Variable	Label	Description	Format Text
OUTCME37	Outcome 37	Outcome 1=Fatal 2=Not Recovered/Not Resolved 3=Recovered/Resolved 4=Unknown 5=Recovering/Resolving 6=Recovered/Resolved with Sequelae	Num .="Missing" 3="Recovered/Resolved"
OUTCME38	Outcome 38	Outcome 1=Fatal 2=Not Recovered/Not Resolved 3=Recovered/Resolved 4=Unknown 5=Recovering/Resolving 6=Recovered/Resolved with Sequelae	Num .="Missing" 3="Recovered/Resolved"
OUTCME39	Outcome 39	Outcome 1=Fatal 2=Not Recovered/Not Resolved 3=Recovered/Resolved 4=Unknown 5=Recovering/Resolving 6=Recovered/Resolved with Sequelae	Num .="Missing" 3="Recovered/Resolved"
OUTCME40	Outcome 40	Outcome 1=Fatal 2=Not Recovered/Not Resolved 3=Recovered/Resolved 4=Unknown 5=Recovering/Resolving 6=Recovered/Resolved with Sequelae	Num .="Missing" 3="Recovered/Resolved"
OUTCME41	Outcome 41	Outcome 1=Fatal 2=Not Recovered/Not Resolved 3=Recovered/Resolved 4=Unknown 5=Recovering/Resolving 6=Recovered/Resolved with Sequelae	Num .="Missing" 3="Recovered/Resolved"
OUTCME42	Outcome 42	Outcome 1=Fatal 2=Not Recovered/Not Resolved 3=Recovered/Resolved 4=Unknown 5=Recovering/Resolving 6=Recovered/Resolved with Sequelae	Num .="Missing" 3="Recovered/Resolved"
OUTCME43	Outcome 43	Outcome 1=Fatal 2=Not Recovered/Not Resolved 3=Recovered/Resolved 4=Unknown 5=Recovering/Resolving 6=Recovered/Resolved with Sequelae	Num .="Missing" 3="Recovered/Resolved"
RESOL35	Toxicity Resolution 35	Event End Date (mm/dd/yyyy)	SAS Date .="Missing"
RESOL36	Toxicity Resolution 36	Event End Date (mm/dd/yyyy)	SAS Date .="Missing"
RESOL37	Toxicity Resolution 37	Event End Date (mm/dd/yyyy)	SAS Date .="Missing"

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Variable	Label	Description	Format Text
RESOL38	Toxicity Resolution 38	Event End Date (mm/dd/yyyy)	SAS Date .="Missing"
RESOL39	Toxicity Resolution 39	Event End Date (mm/dd/yyyy)	SAS Date .="Missing"
RESOL40	Toxicity Resolution 40	Event End Date (mm/dd/yyyy)	SAS Date .="Missing"
RESOL41	Toxicity Resolution 41	Event End Date (mm/dd/yyyy)	SAS Date .="Missing"
RESOL42	Toxicity Resolution 42	Event End Date (mm/dd/yyyy)	SAS Date .="Missing"
RESOL43	Toxicity Resolution 43	Event End Date (mm/dd/yyyy)	SAS Date .="Missing"
SEQUENCE	Sequence		Num
TOX35	Toxicity 35	MedDRA AE Code (CTCAE v4.0) =	Num .="Missing"
TOX36	Toxicity 36	MedDRA AE Code (CTCAE v4.0) =	Num .="Missing"
TOX37	Toxicity 37	MedDRA AE Code (CTCAE v4.0) =	Num .="Missing"
TOX38	Toxicity 38	MedDRA AE Code (CTCAE v4.0) =	Num .="Missing"
TOX39	Toxicity 39	MedDRA AE Code (CTCAE v4.0) =	Num .="Missing"
TOX40	Toxicity 40	MedDRA AE Code (CTCAE v4.0) =	Num .="Missing"
TOX41	Toxicity 41	MedDRA AE Code (CTCAE v4.0) =	Num .="Missing"
TOX42	Toxicity 42	MedDRA AE Code (CTCAE v4.0) =	Num .="Missing"
TOX43	Toxicity 43	MedDRA AE Code (CTCAE v4.0) =	Num .="Missing"
TOX_R38	Tox 38 Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	Num .="Missing" 1="Unrelated" 3="Possible" 4="Probable"
TOX_RL35	Tox 35 Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	Num .="Missing" 1="Unrelated" 3="Possible" 4="Probable"
TOX_RL36	Tox 36 Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	Num .="Missing" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"

Variable	Label	Description	Format Text
TOX_RL37	Tox 37 Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	Num .="Missing" 1="Unrelated" 2="Unlikely" 4="Probable"
TOX_RL39	Tox 39 Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	Num .="Missing" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
TOX_RL40	Tox 40 Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	Num .="Missing" 1="Unrelated" 4="Probable"
TOX_RL41	Tox 41 Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	Num .="Missing" 1="Unrelated"
TOX_RL42	Tox 40 Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	Num .="Missing" 4="Probable"
TOX_RL43	Tox 41 Related	AE Attribution: Relation to Study Agent 1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definite	Num .="Missing" 4="Probable"
VAL35	Toxicity Value 35	Adverse Event Grade	Num .="Missing" 1="Mildadverse event"
VAL36	Toxicity Value 36	Adverse Event Grade	Num .="Missing" 1="Mildadverse event"
VAL37	Toxicity Value 37	Adverse Event Grade	Num .="Missing" 1="Mildadverse event"
VAL38	Toxicity Value 38	Adverse Event Grade	Num .="Missing" 1="Mildadverse event"
VAL39	Toxicity Value 39	Adverse Event Grade	Num .="Missing" 1="Mildadverse event"
VAL40	Toxicity Value 40	Adverse Event Grade	Num .="Missing" 1="Mildadverse event"
VAL41	Toxicity Value 41	Adverse Event Grade	Num .="Missing" 1="Mildadverse event"
VAL42	Toxicity Value 42	Adverse Event Grade	Num .="Missing" 1="Mildadverse event"

Variable	Label	Description	Format Text
VAL43	Toxicity Value 43	Adverse Event Grade	Num .="Missing" 1="Mildadverse event"

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