

MDA2013-01-01 - ADVERSEEVENTS

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Document Summary

Property	Value
Document Title	MDA2013-01-01 - adverseevents
Date Created	09/18/2019
For Dataset	adverseevents
Sections	2
Entries	27
Document Filename	dictionary_adverseevents.07112019.rtf

MDA2013-01-01 - adverseevents
09/18/2019
Dataset: adverseevents

MDA2013-01-01 - adverseevents

Section 1: Identifiers

Variable	Label	Description	Format Text
accession	Accession	Accession	Num
form	Form	Form	Char
Institution	Institution	Institution	Char
mrno	Subject ID	Subject ID	Num
Reg_Date	Registration date	Registration Date	SAS Date
trial	Trial	Trial	Char

Section 2: Adverse Events

Variable	Label	Description	Format Text
_3489_10177_Event_End_Date	Event end date	Event End Date	Char
_3489_10178_Event_Onset_Date	Event onset date	Event Onset Date	SAS Date
_3489_10179_Adverse_Event_Report	Adverse event reported	Adverse Event Reported Date	Num .=."
_3489_10180_Outcome	Outcome	Outcome	1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not Recovered/Not Resolved" 4="Recovered/Resolved with sequelae" 5="Fatal" 6="Unkown"
_3489_10180_Outcome_Desc_	Outcome description	Outcome	Char
_3489_10181_Comments	Comments	Comments	Char
_3489_10182_Adverse_Event_Verbat	Adverse event verbatim	Adverse Event Verbatim Term	Char
_3489_10183_Dropped_due_to_this_	Dropped due to adverse event	Dropped due to this AE?	Char
_3489_10184_Reported_as_SAE	Reported as SAE	Reported as SAE?	1="Yes" 2="No"
_3489_10184_Reported_as_SAE_Des	Reported as SAE description	Reported as SAE?	Char
_3489_10185_CTCAE_Term	CTCAE term	CTCAE Term	Char
_3489_10187_Grade_Description	Grade description	Grade Description	Char
_3489_10188_Action	Action	Action	Char
_3489_10188_Action_Desc_	Action description	Action	Char
_3489_10511_MedDRA_System_Organ_	MedDra system organ	MedDRA System Organ Class (SOC v12)	Char
_3489_10512_AE_Grade	AE grade	AE Grade	1="Mild" 2="Moderate" 3="Severe" 4="Life Threatening" 5="Death Related to AE"
_3489_10512_AE_Grade_Desc_	AE grade description	AE Grade	Char
_3489_10513_AE_Attribution	AE attribution	AE Attribution	Char

Variable	Label	Description	Format Text
_3489_10513_AE_Attribution_Desc	AE attribution description	AE Attribution	Char
_3489_8377_CTC_AE_Version	CTC AE version	CTC AE Version	Num
VAR15	Dropped due to adverse event description	Dropped due to this AE?	Char