

MDA2016-08-02 - Adverse Events Data Dictionary

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Document Summary

Property	Value
Document Title	MDA2016-08-02 - Adverse Events: Data Dictionary
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MDA2016-08-02 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	MRNO	MRNO		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	Accession	Accession		Numeric
01. Principal	Form	Form		"Adverse Event"="Adverse Event"
01. Principal	Institution	Registering Institution		"M. D. Anderson Cancer Center"="M. D. Anderson Cancer Center"
01. Principal	Interval	Interval		"Event Interval not available"="Event Interval not available"
01. Principal	Interval_Date	Interval Date		SAS Date
01. Principal	Reg_Date	Registering Date		Char
01. Principal	Trial	Trial		"MDA2016-08-02"="MDA2016-08-02"

Section 3: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	_260_10177_Event_End_Date	Event End Date		Char
01. Principal	_260_10178_Event_Onset_Date	Event Onset Date		Char
01. Principal	_260_10179_Adverse_Event_Reporte	Adverse Event Reported Date		Char
01. Principal	_260_10180_Outcome	Outcome		"1"="Recovered/Resolved" "2"="Recovering/Resolving" "3"="Not Recovered/Not Resolved" "4"="Recovered/Resolved with sequelae" "5"="Fatal" "6"="Unknown"
01. Principal	_260_10180_Outcome_Desc	Outcome (Desc)		"1 = Recovered/Resolved"="Recovered/Resolved" "2 = Recovering/Resolving"="Recovering/Resolving" "3 = Not Recovered/Not Resolved"="Not Recovered/Not Resolved" "4 = Recovered/Resolved with sequelae"="Recovered/Resolved with sequelae" "6 = Unknown"="Unknown"
01. Principal	_260_10181_Comments	Comments		Char
01. Principal	_260_10182_Adverse_Event_Verbatim	Adverse Event Verbatim Term		Char
01. Principal	_260_10183_Dropped_due_to_this_0	Dropped Due To This Adverse Event (Desc)		"No"="No" "Yes"="Yes"
01. Principal	_260_10183_Dropped_due_to_this_A	Dropped Due To This Adverse Event		"No"="No" "Yes"="Yes"
01. Principal	_260_10184_Reported_as_SAE	Reported As Serious Adverse Event (SAE)		"1"="Yes" "2"="No"
01. Principal	_260_10184_Reported_as_SAE_Desc	Reported As Serious Adverse Event (SAE) (Desc)		"No"="No" "Yes"="Yes"
01. Principal	_260_10185_CTC_AE_Term	Common Terminology Criteria for Adverse Events (CTCAE) Term		Char
01. Principal	_260_10187_Grade_Description	Grade Description		Char

Class	Variable	Label	Description	Format Text
01. Principal	_260_10188_Acti on	Action		"1= Agent Withdrawn"="Agent Withdrawn" "4=Agent Dose Not Changed"="Agent Dose Not Changed" "6=Not Applicable"="Not Applicable" "7=Agent Interrupted"="Agent Interrupted"
01. Principal	_260_10188_Acti on__Desc_	Action (Desc)		"1= Agent Withdrawn"="Agent Withdrawn" "4=Agent Dose Not Changed"="Agent Dose Not Changed" "6=Not Applicable"="Not Applicable" "7=Agent Interrupted"="Agent Interrupted"
01. Principal	_260_10511_Med DRA_System_Or gan_C	MedDRA System Organ Class SOC V12		Char
01. Principal	_260_10513_AE_ Attribution	Adverse Event Attribution		"1 = Unrelated"="Unrelated" "2 = Unlikely"="Unlikely" "3 = Possible"="Possible" "4 = Probable"="Probable" "5 = Definite"="Definite"
01. Principal	_260_10513_AE_ Attribution__Des c_	Adverse Event Attribution (Desc)		"1 = Unrelated"="Unrelated" "2 = Unlikely"="Unlikely" "3 = Possible"="Possible" "4 = Probable"="Probable" "5 = Definite"="Definite"
01. Principal	_260_12604_AE_ Grade	Adverse Event Grade		"1"="Mild Adverse Event" "2"="Moderate Adverse Event" "3"="Severe Adverse Event"
01. Principal	_260_12604_AE_ Grade__Desc_	Adverse Event Grade (Desc)		"1 - Mild Adverse Event"="Mild Adverse Event" "2 - Moderate Adverse Event"="Moderate Adverse Event" "3- Severe Adverse Event"="Severe Adverse Event"
01. Principal	_260_14606_TAC _specify_TAC_at _t0	Treatment Assignment Code (TAC) (Specify TAC At Time Of Adverse Event Onset) (Desc)		Char
01. Principal	_260_14606_TAC _specify_TAC_at _ti	Treatment Assignment Code (TAC) (Specify TAC At Time Of Adverse Event Onset)		Char
01. Principal	_260_8377_CTC_ AE_Version	Common Terminology Criteria for Adverse Events (CTCAE) Version		"4.0"="4.0"