

MDA2014-04-01 - Adverse Events Data Dictionary

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Document Summary

Property	Value
Document Title	MDA2014-04-01 - Adverse Events: Data Dictionary
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Entries	29
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MDA2014-04-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	mrno	Participant Id		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	accession	Accession		Numeric
01. Principal	form	Form		"Adverse Events"="Adverse Events"
01. Principal	institution	Institution		"Columbia University Medical Center"="Columbia University Medical Center" "EUROPEAN INSTITUTE OF ONCOLOGY"="EUROPEAN INSTITUTE OF ONCOLOGY" "Galliera Hospital"="Galliera Hospital" "M. D. Anderson Cancer Center"="M. D. Anderson Cancer Center" "Moffitt Cancer Center"="Moffitt Cancer Center"
01. Principal	interval	Interval		"Baseline"="Baseline" "Event Interval not available"="Event Interval not available" "Follow-up 1"="Follow-up 1" "Month 1"="Month 1" "Month"="Month"
01. Principal	interval_date	Interval Date		SAS Date
01. Principal	reg_date	Registration Date		Char
01. Principal	trial	Trial		"MDA2014-04-01"="MDA2014-04-01"

Section 3: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	_489_10177_event_end_date	Event End Date		Char
01. Principal	_489_10178_event_onset_date	Event Onset Date		Char
01. Principal	_489_10179_adverse_event_report_e	Adverse Event Reported Date		Char
01. Principal	_489_10180_outcome	Outcome		"1"="Recovered/Resolved" "2"="Recovering/Resolving" "3"="Not Recovered/Not Resolved" "4"="Recovered/Resolved with sequelae" "6"="Unknown"
01. Principal	_489_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	_489_10181_comments	Comments		Char
01. Principal	_489_10182_adverse_event_verbat_i	Adverse Event Verbatim Term		Char
01. Principal	_489_10183_dropped_due_to_this_0	Dropped Due To This AE (Desc)		"No"="No" "Yes"="Yes"
01. Principal	_489_10183_dropped_due_to_this_a	Dropped Due To This AE		"No"="No" "Yes"="Yes"
01. Principal	_489_10184_reported_as_sae	Reported As Serious Adverse Event (SAE)		"1"="Yes" "2"="No"
01. Principal	_489_10184_reported_as_sae__desc	Reported As Serious Adverse Event (SAE) (Desc)		"No"="No" "Yes"="Yes"
01. Principal	_489_10185_ctcae_term	CTCAE Term		Char
01. Principal	_489_10187_grade_description	Grade Description		Char

Class	Variable	Label	Description	Format Text
01. Principal	_489_10188_action	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	_489_10188_action_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	_489_10511_meddra_system_organ_c	MedDRA System Organ Class SOC v12		Char
01. Principal	_489_10512_ae_grade	AE Grade		"1"="Mild" "2"="Moderate" "3"="Severe"
01. Principal	_489_10512_ae_grade_desc_	AE Grade (Desc)		"1 - Mild"="Mild" "2 - Moderate"="Moderate" "3- Severe"="Severe"
01. Principal	_489_10513_ae_attribution	AE Attribution		"1 = Unrelated"="Unrelated" "2 = Unlikely"="Unlikely" "3 = Possible"="Possible" "4 = Probable"="Probable" "5 = Definite"="Definite"
01. Principal	_489_10513_ae_attribution_desc_	AE Attribution (Desc)		"1 = Unrelated"="Unrelated" "2 = Unlikely"="Unlikely" "3 = Possible"="Possible" "4 = Probable"="Probable" "5 = Definite"="Definite"
01. Principal	_489_8377_ctc_ae_version	CTC AE Version		"4.0"="4.0"