ADVERSE EVENTS: DATA DICTIONARY

TABLE OF CONTENTS

Document Summary

Property	Value
Document Title	Adverse Events: Data Dictionary
Date Created	11/15/2019
Sections	2
Entries	27
Document Filename	dictionary_adverseevents.111519.rtf

Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	**Accession**	Participant Assignment	Participant Assignment	numeric
01. Principal	**Form**	Form	Form. CDE: 3008882 1.0 Released	"Adverse Events"="Adverse Events"
01. Principal	**Institution**	Institution	Institution. CDE: 2551737 1.0 Released	"Brigham and Women's Hospital"="Brigham and Women's Hospital" "M. D. Anderson Cancer Center"="M. D. Anderson Cancer Center" "University of Michigan Comprehensive Cancer Center"="University of Michigan Comprehensive Cancer Center" "University of Utah Health System - Huntsman Cancer Institute"="University of Utah Health System - Huntsman Cancer Institute"
01. Principal	**MRNO**	Participant ID (MRNO)	Participant ID (MRNO). CDE: 2003301 4.0 Released	numeric
01. Principal	**Reg_Date**	Registration Date	Registration Date. CDE: 2171 4.0 Released	sasdate
01. Principal	**Trial**	Trial	Trial. CDE: 977 3.0 Released	"MDA2013-01-02"="MDA2013-01-02"

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	**_3489_10177_Event_End_Date**	Event End Date (MM/DD/YYYY)	Event End Date (MM/DD/YYYY). CDE: 2189843 1.0 Released	char, 11 " "="Not Applicable"
01. Principal	**_3489_10178_Event_Onset_Date**	Event Onset Date (MM/DD/YYYY)	Event Onset Date (MM/DD/YYYY). CDE: 2744993 1.0 Released	char, 11
01. Principal	**_3489_10179_Adverse_Event_Report**	Adverse Event Reported Date (MM/DD/YYYY)	Adverse Event Reported Date (MM/DD/YYYY). CDE: 2182850 1.0 Released	numeric
01. Principal	**_3489_10180_Outcome**	Outcome	Outcome. CDE: 2746517 1.0 Released	1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not Recovered/Not Resolved" 4="Recovered/Resolved with sequelae" 6="Unknown"
01. Principal	**_3489_10180_Outcome__Desc_**	Outcome Description	Outcome Description	char, 36
01. Principal	**_3489_10181_Comments**	Comments	Comments. CDE: 797 5.0 Released	char, 141 " "="Not Applicable"
01. Principal	**_3489_10182_Adverse_Event_Verbat**	Adverse Event Verbatim Term	Adverse Event Verbatim Term. CDE: 2188132 1.0 Released	char, 73
01. Principal	**_3489_10183_Dropped_due_to_this_**	Dropped due to this AE?	Dropped due to this AE?. CDE: 2683534 1.0 Released	"No"="No" "Yes"="Yes"
01. Principal	**_3489_10184_Reported_as_SAE**	Reported as SAE?	Reported as SAE? CDE: 2182930 1.0 Released	1="Yes" 2="No"
01. Principal	**_3489_10184_Reported_as_SAE__Des**	Reported as SAE Description?	Reported as SAE Description? CDE: 2182930 1.0 Released	"No"="No" "Yes"="Yes"
01. Principal	**_3489_10185_CTCAE_Term**	CTCAE Term (v4.0)	CTCAE Term (v4.0). CDE: 3125302 1.1 Released	char, 86
01. Principal	**_3489_10187_Grade_Description**	Grade	Grade. CDE: 2944515 1.0 Released	char, 255 " "="Not Applicable"
01. Principal	**_3489_10188_Action**	Action	Action. CDE: 2182934 1.0 Released	"1= Agent Withdrawn"="1= Agent Withdrawn" "4=Agent Dose Not Changed"="4=Agent Dose Not Changed" "6=Not Applicable"="6=Not Applicable"
01. Principal	**_3489_10188_Action__Desc_**	Action Description	Action Description. CDE: 2182934 1.0 Released	"1= Agent Withdrawn"="1= Agent Withdrawn" "4=Agent Dose Not Changed"="4=Agent Dose Not Changed" "6=Not Applicable"="6=Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	**_3489_10511_MedDRA_System_Organ_**	MedDRA System Organ Class (SOC)	MedDRA System Organ Class (SOC). CDE: 2943864 1.0 Released	char, 69
01. Principal	**_3489_10512_AE_Grade**	AE Grade	AE Grade. CDE: 2944515 1.0 Released	numeric
01. Principal	**_3489_10512_AE_Grade__Desc_**	AE Grade Description	AE Grade Description. CDE: CDE: 2944515 1.0 Released	char, 12
01. Principal	**_3489_10513_AE_Attribution**	AE Attribution	AE Attribution. CDE: 1285 3.0 Released	"1 = Unrelated"="1 = Unrelated" "2 = Unlikely"="2 = Unlikely" "3 = Possible"="3 = Possible" "4 = Probable"="4 = Probable"
01. Principal	**_3489_10513_AE_Attribution__Desc**	AE Attribution Description	AE Attribution Description. CDE: 1285 3.0 Released	"1 = Unrelated"="1 = Unrelated" "2 = Unlikely"="2 = Unlikely" "3 = Possible"="3 = Possible" "4 = Probable"="4 = Probable"
01. Principal	**_3489_8377_CTC_AE_Version**	CTCAE Version	CTCAE Version	numeric
01. Principal	**VAR15**	Dropped due to this AE?	Dropped due to this AE?	"No"="No" "Yes"="Yes"

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