

# MDA2014-04-02 - Adverse Events Data Dictionary

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## Document Summary

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## MDA2014-04-02 - Adverse Events: Data Dictionary

### Section 1: Identifiers

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Class	Variable	Label	Description	Format Text
01. Principal	<b>MRNO</b>	MRNO		Char

## Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	<b>Accession</b>	Accession		Numeric
01. Principal	<b>Form</b>	Form		"Adverse Event"="Adverse Event"
01. Principal	<b>Institution</b>	Institution		"Dana Farber Cancer Institute"="Dana Farber Cancer Institute" "M. D. Anderson Cancer Center"="M. D. Anderson Cancer Center" "Thomas Jefferson University Hospital"="Thomas Jefferson University Hospital"
01. Principal	<b>Interval</b>	Interval		"Event Interval not available"="Event Interval not available"
01. Principal	<b>Interval_Date</b>	Interval Date		Numeric
01. Principal	<b>Reg_Date</b>	Registration Date		Char
01. Principal	<b>Registering_Physician</b>	Registering Physician		Char
01. Principal	<b>Trial</b>	Trial		"MDA2014-04-02"="MDA2014-04-02"

## Section 3: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	<b>_3489_10177_Event_End_Date</b>	Event End Date		Char
01. Principal	<b>_3489_10178_Event_Onset_Date</b>	Event Onset Date		Char
01. Principal	<b>_3489_10179_Adverse_Event_Report</b>	Adverse Event Reported Date		Char
01. Principal	<b>_3489_10180_Outcome</b>	Outcome		"1"="1" "2"="2" "3"="3" "4"="4" "6"="6"
01. Principal	<b>_3489_10180_Outcome_Desc_</b>	Outcome (Description)		"1 = Recovered/Resolved"="1 = Recovered/Resolved" "2 = Recovering/Resolving"="2 = Recovering/Resolving" "3 = Not Recovered/Not Resolved"="3 = Not Recovered/Not Resolved" "4 = Recovered/Resolved with sequelae"="4 = Recovered/Resolved with sequelae" "6 = Unknown"="6 = Unknown"
01. Principal	<b>_3489_10181_Comments</b>	Comments		Char
01. Principal	<b>_3489_10182_Adverse_Event_Verbat</b>	Adverse Event Verbatim Term		Char
01. Principal	<b>_3489_10183_Dropped_due_to_thi</b> <b>s</b>	Dropped Due To This AE		"No"="No"
01. Principal	<b>_3489_10183_Dropped_due_to_thi</b> <b>s1</b>	Dropped Due To This AE (Description)		"No"="No"
01. Principal	<b>_3489_10184_Reported_as_SAE</b>	Reported As SAE		"1"="1" "2"="2"
01. Principal	<b>_3489_10184_Reported_as_SAE_</b> <b>_Des</b>	Reported As SAE (Description)		"No"="No" "Yes"="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>_3489_10185_CT CAE_Term</b>	CTCAE Term		"Abdominal pain"="Abdominal pain" "Allergic reaction"="Allergic reaction" "Arthralgia"="Arthralgia" "Breast infection"="Breast infection" "Breast pain"="Breast pain" "Bruising"="Bruising" "Cardiac disorders - Other, specify"="Cardiac disorders - Other, specify" "Constipation"="Constipation" "Cough"="Cough" "Dermatitis radiation"="Dermatitis radiation" "Erythema multiforme"="Erythema multiforme" "Fatigue"="Fatigue" "Fever"="Fever" "Flu like symptoms"="Flu like symptoms" "Headache"="Headache" "Hot flashes"="Hot flashes" "Hypertension"="Hypertension" "Injection site reaction"="Injection site reaction" "Musculoskeletal and connective tissue disorder - Other, specify"="Musculoskeletal and connective tissue disorder - Other, specify" "Myalgia"="Myalgia" "Nasal congestion"="Nasal congestion" "Nausea"="Nausea" "Pain"="Pain" "Pruritus"="Pruritus" "Seroma"="Seroma" "Sinus tachycardia"="Sinus tachycardia" "Sinusitis"="Sinusitis" "Skin and subcutaneous tissue disorders - Other, specify"="Skin and subcutaneous tissue disorders - Other, specify" "Skin hyperpigmentation"="Skin hyperpigmentation"  [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	<b>[...continued]</b> <b>_3489_10185_CT</b> <b>CAE_Term</b>			[...continued] "Sore throat"="Sore throat" "Surgical and medical procedures - Other, specify"="Surgical and medical procedures - Other, specify" "Syncope"="Syncope" "Urinary tract infection"="Urinary tract infection" "Vaginal discharge"="Vaginal discharge" "Vasovagal reaction"="Vasovagal reaction" "Wound infection"="Wound infection"
01. Principal	<b>_3489_10187_Gra</b> <b>de_Description</b>	Grade Description		Char
01. Principal	<b>_3489_10188_Act</b> <b>ion</b>	Action		"4=Agent Dose Not Changed"="4=Agent Dose Not Changed" "6=Not Applicable"="6=Not Applicable"
01. Principal	<b>_3489_10188_Act</b> <b>ion_Desc_</b>	Action (Description)		"4=Agent Dose Not Changed"="4=Agent Dose Not Changed" "6=Not Applicable"="6=Not Applicable"
01. Principal	<b>_3489_10511_Me</b> <b>dDRA_System_O</b> <b>rgan</b>	MedDRA System Organ Class SOC v12		"Cardiac disorders"="Cardiac disorders" "Gastrointestinal disorders"="Gastrointestinal disorders" "General disorders and administration site conditions"="General disorders and administration site conditions" "Immune system disorders"="Immune system disorders" "Infections and infestations"="Infections and infestations" "Injury, poisoning and procedural complications"="Injury, poisoning and procedural complications" "Musculoskeletal and connective tissue disorders"="Musculoskeletal and connective tissue disorders" "Nervous system disorders"="Nervous system disorders" "Reproductive system and breast disorders"="Reproductive system and breast disorders" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders" "Skin and subcutaneous tissue disorders"="Skin and subcutaneous tissue disorders" "Surgical and medical procedures"="Surgical and medical procedures" "Vascular disorders"="Vascular disorders"
01. Principal	<b>_3489_10512_AE</b> <b>_Grade</b>	AE Grade		"1"="1" "2"="2" "3"="3"

Class	Variable	Label	Description	Format Text
01. Principal	<b>_3489_10512_AE_Grade_Desc_</b>	AE Grade (Description)		"1 - Mild"="1 - Mild" "2 - Moderate"="2 - Moderate" "3- Severe"="3- Severe"
01. Principal	<b>_3489_10513_AE_Attribution</b>	AE Attribution		"1 = Unrelated"="1 = Unrelated" "2 = Unlikely"="2 = Unlikely" "3 = Possible"="3 = Possible" "4 = Probable"="4 = Probable" "5 = Definite"="5 = Definite"
01. Principal	<b>_3489_10513_AE_Attribution_Desc</b>	AE Attribution (Description)		"1 = Unrelated"="1 = Unrelated" "2 = Unlikely"="2 = Unlikely" "3 = Possible"="3 = Possible" "4 = Probable"="4 = Probable" "5 = Definite"="5 = Definite"
01. Principal	<b>_3489_8377_CTC_AE_Version</b>	CTC AE Version		Char