

MAY2013-02-02 - [Adverse Events] Data Dictionary

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Document Summary

Property	Value
Document Title	MAY2013-02-02 - [Adverse Events]: Data Dictionary
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Entries	30
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MAY2013-02-02 - [Adverse Events]: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	SUBJECT	Participant ID		Char

Section 2: [Adverse Events]

Class	Variable	Label	Description	Format Text
01. Principal	ACTIONXX	Action		"Agent dose not changed"="Agent dose not changed" "Not applicable"="Not applicable"
01. Principal	AERXX	Reported As SAE?		"1"="1" "2"="2"
01. Principal	COMTOXOTH	Comments		Char
01. Principal	DROPPEDXX	Off Study Due To This Adverse Event?		"1"="1" "2"="2"
01. Principal	ENDDTXX	Event End Date		SAS Date
01. Principal	EVALDTXX	Adverse Event Report Date		SAS Date
01. Principal	MAXUPDATED	Last Updated		Numeric
01. Principal	MEDRASOCXX	MedDRA Adverse Event Code (CTCAE V4.0)		Char
01. Principal	MINCREATED	Created Time		Numeric
01. Principal	NOAE	Participant Experienced No Adverse Events		Numeric
01. Principal	ONGOINGXX	Ongoing		Numeric
01. Principal	ONSETDTXX	Onset Date		SAS Date
01. Principal	OUTCOMEXX	Outcome		"Fatal"="Fatal" "Not Recovered/not resolved"="Not Recovered/not resolved" "Recovered/resolved"="Recovered/resolved" "Recovering/resolving"="Recovering/resolving"
01. Principal	PAGEREPEATNUMBER	Page Repeat Number		Numeric
01. Principal	PROJECT	Protocol		"MAY2013-02-02"="MAY2013-02-02"
01. Principal	RAVEID	Rave ID		Numeric
01. Principal	RECORDPOSITION	Record Position		Numeric
01. Principal	SITE	Site		"Case Western Reserve University"="Case Western Reserve University" "Cleveland Clinic Foundation"="Cleveland Clinic Foundation" "Massachusetts General Hospital Cancer Center"="Massachusetts General Hospital Cancer Center" "Mayo Clinic in Florida"="Mayo Clinic in Florida" "Mayo Clinic"="Mayo Clinic" "Mount Sinai Hospital"="Mount Sinai Hospital"

Class	Variable	Label	Description	Format Text
01. Principal	SITENUMBER	Site Number		"FL080"="FL080" "MA034"="MA034" "MN026"="MN026" "NY021"="NY021" "OH027"="OH027" "OH029"="OH029"
01. Principal	SOCXX	MedDRA System Organ Class (V12.0)		"1"="1" "10"="10" "11"="11" "12"="12" "13"="13" "15"="15" "17"="17" "2"="2" "20"="20" "22"="22" "23"="23" "25"="25" "26"="26" "5"="5" "7"="7" "8"="8" "9"="9"
01. Principal	SOCXX_SP	MedDRA System Organ Class (V12.0) (Specify)		Char
01. Principal	STUDPROCRELX	Study Procedure Related?		"1"="1" "2"="2"
01. Principal	TARGETDAYS	Target Days From Baseline		Numeric
01. Principal	TOX_RLXX	Adverse Event Attribution		Numeric
01. Principal	TOXXX	Adverse Event Term (CTCAE V4.0)		Numeric
01. Principal	TOXXX_SP	Adverse Event Term (CTCAE V4.0) (Specify)		Char
01. Principal	VALDESCXX	Adverse Event Grade Description		Char
01. Principal	VALXX	Grade		Numeric

Class	Variable	Label	Description	Format Text
01. Principal	VERBATIMXX	Symptom Description		"Acne rash on face"="Acne rash on face" "Acute Coronary Syndrome"="Acute Coronary Syndrome" "Anemia Hgb <8 g/dL"="Anemia Hgb <8 g/dL" "Cellulitis"="Cellulitis" "Chest Pain"="Chest Pain" "Chest wall contusion due to fall"="Chest wall contusion due to fall" "Constipated"="Constipated" "Diverticulitis"="Diverticulitis" "Dysuria"="Dysuria" "Fatigue/Very Tired"="Fatigue/Very Tired" "Gastroesophageal reflux disease"="Gastroesophageal reflux disease" "Headache"="Headache" "Hyperbilirubinemia"="Hyperbilirubinemia" "Indigestion/Heartburn"="Indigestion/Heartburn" "Infection in Right Big Toe"="Infection in Right Big Toe" "Left Shoulder Pain"="Left Shoulder Pain" "Liver Failure"="Liver Failure" "Nausea"="Nausea" "Patchy areas of pruritic rash skin (back and upper arms)"="Patchy areas of pruritic rash skin (back and upper arms)" "Possible hernia"="Possible hernia" "Red spots on skin"="Red spots on skin" "Right buttock pain"="Right buttock pain" "Right groin pain"="Right groin pain" "Seaonal allergies"="Seaonal allergies" "Shortness of Breath"="Shortness of Breath" "Slightly tired"="Slightly tired" "Sores in Mouth"="Sores in Mouth" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] VERBATIMXX			<p>[...continued]</p> <p>"Stomach Pain"="Stomach Pain"</p> <p>"acute blood loss"="acute blood loss"</p> <p>"acute kidney injury"="acute kidney injury"</p> <p>"altered mental status"="altered mental status"</p> <p>"bactremia"="bactremia"</p> <p>"celiac stenosis"="celiac stenosis"</p> <p>"coagulopathy"="coagulopathy"</p> <p>"diarrhea"="diarrhea"</p> <p>"elevated ammonia level"="elevated ammonia level"</p> <p>"encephalopathy"="encephalopathy"</p> <p>"epistaxis"="epistaxis"</p> <p>"flu-like symptoms"="flu-like symptoms"</p> <p>"hyponatremia"="hyponatremia"</p> <p>"hypotension"="hypotension"</p> <p>"hypothermia"="hypothermia"</p> <p>"increased itching"="increased itching"</p> <p>"lactic acidosis"="lactic acidosis"</p> <p>"left upper quadrant pain"="left upper quadrant pain"</p> <p>"loss of appetite"="loss of appetite"</p> <p>"lower extremity weakness"="lower extremity weakness"</p> <p>"metabolic acidosis"="metabolic acidosis"</p> <p>"nausea"="nausea"</p> <p>"rash on torso, back and on scalp"="rash on torso, back and on scalp"</p> <p>"respiratory insufficiency"="respiratory insufficiency"</p> <p>"sinus pain"="sinus pain"</p> <p>"splenic infarct"="splenic infarct"</p> <p>"worsening GERD"="worsening GERD"</p> <p>"worsening pain at wound stie"="worsening pain at wound stie"</p> <p>"worsening wound infection"="worsening wound infection"</p> <p>[continued...]</p>

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] VERBATIMXX			[...continued] wound infection"