

# UWI2016-08-01 - Adverse Events Data Dictionary

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## Document Summary

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# UWI2016-08-01 - Adverse Events: Data Dictionary

## Section 1: Identifiers

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Class	Variable	Label	Description	Format Text
01. Principal	<b>Sequence_No_</b>	Participant ID		Char

## Section 2: Study-wide

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Class	Variable	Label	Description	Format Text
01. Principal	<b>DCP_Protocol_Number</b>	DCP Protocol Number		"UWI2016-08-01"="UWI2016-08-01"
01. Principal	<b>Registering_Institution</b>	Registering Institution		"AL002"="AL002" "MN022"="MN022" "WI020"="WI020"

## Section 3: Adverse Events

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Class	Variable	Label	Description	Format Text
01. Principal	<b>Action</b>	Action		"1 = Agent Withdrawn"="Agent Withdrawn" "2 = Agent Dose Reduced"="Agent Dose Reduced" "3 = Agent Dose Increased"="Agent Dose Increased" "4 = Agent Dose Not Changed"="Agent Dose Not Changed" "5 = Unknown"="Unknown" "6 = Not Applicable"="Not Applicable" "7 = Agent Interrupted"="Agent Interrupted"
01. Principal	<b>Adverse_Event_AE_Verbatim_Term</b>	Adverse Event Verbatim Term		Char
01. Principal	<b>Adverse_Event_Reported_Date</b>	Adverse Event Report Date		SAS Date
01. Principal	<b>AE_Attribution</b>	Attribution		"Definite"="Definite" "Possible"="Possible" "Probable"="Probable" "Unlikely"="Unlikely" "Unrelated"="Unrelated"
01. Principal	<b>AE_Grade</b>	Grade		"0"="Absent Adverse Event" "1"="Mild Adverse Event" "2"="Moderate Adverse Event" "3"="Severe Adverse Event" "4"="Life-Threatening Adverse Event" "5"="Death Related To Adverse Event"
01. Principal	<b>At_the_end_of_the_study_only_ch</b>	Participant Experienced No Adverse Events		"No Adverse Events"="No Adverse Events"
01. Principal	<b>Comments</b>	Comments		Char

Class	Variable	Label	Description	Format Text
01. Principal	CTCAE_Term	CTCAE Term (v4.0)		"Abdominal pain"="Abdominal pain" "Alanine aminotransferase increased"="Alanine aminotransferase increased" "Allergic rhinitis"="Allergic rhinitis" "Alopecia"="Alopecia" "Anxiety"="Anxiety" "Arthralgia"="Arthralgia" "Arthritis"="Arthritis" "Back pain"="Back pain" "Bloating"="Bloating" "Blood bilirubin increased"="Blood bilirubin increased" "Blurred vision"="Blurred vision" "Chest wall pain"="Chest wall pain" "Chills"="Chills" "Concentration impairment"="Concentration impairment" "Constipation"="Constipation" "Cough"="Cough" "Diarrhea"="Diarrhea" "Dizziness"="Dizziness" "Dysgeusia"="Dysgeusia" "Dyspepsia"="Dyspepsia" "Edema limbs"="Edema limbs" "Eye disorders - Other, specify"="Eye disorders - Other, specify" "Fatigue"="Fatigue" "Fever"="Fever" "Flu like symptoms"="Flu like symptoms" "Flushing"="Flushing" "Headache"="Headache" "Hot flashes"="Hot flashes" "Hyperhidrosis"="Hyperhidrosis" "Hypertension"="Hypertension" "Insomnia"="Insomnia" "Musculoskeletal and connective tissue disorder - Other, specify"="Musculoskeletal and connective tissue disorder - Other, specify" "Myalgia"="Myalgia" "Nasal congestion"="Nasal congestion"  [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	<b>[...continued]</b> <b>CTCAE_Term</b>			[...continued] "Nausea"="Nausea" "Pain in extremity"="Pain in extremity" "Paresthesia"="Paresthesia" "Pruritus"="Pruritus" "Skin and subcutaneous tissue disorders - Other, specify"="Skin and subcutaneous tissue disorders - Other, specify" "Sneezing"="Sneezing" "Stomach pain"="Stomach pain" "Urinary frequency"="Urinary frequency" "Urinary urgency"="Urinary urgency" "Urine discoloration"="Urine discoloration" "Vomiting"="Vomiting"
01. Principal	<b>Dropped_due_to_AE_</b>	Dropped Due To This AE?		"1"="Yes" "2"="No"
01. Principal	<b>Event_End_Date</b>	Event End Date		SAS Date
01. Principal	<b>Event_Onset_Date</b>	Event Onset Date		SAS Date
01. Principal	<b>MedDRA_System_Organ_Class_SOC_</b>	MedDRA System Organ Class (SOC) (V12.0)		"Eye disorders"="Eye disorders" "Gastrointestinal disorders"="Gastrointestinal disorders" "General disorders and administration site conditions"="General disorders and administration site conditions" "Investigations"="Investigations" "Musculoskeletal and connective tissue disorders"="Musculoskeletal and connective tissue disorders" "Nervous system disorders"="Nervous system disorders" "Psychiatric disorders"="Psychiatric disorders" "Renal and urinary disorders"="Renal and urinary disorders" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders" "Skin and subcutaneous tissue disorders"="Skin and subcutaneous tissue disorders" "Vascular disorders"="Vascular disorders"
01. Principal	<b>Outcome</b>	Outcome		"Fatal"="Fatal" "Not recovered/Not resolved"="Not recovered/Not resolved" "Recovered/Resolved with Sequelae"="Recovered/Resolved with Sequelae" "Recovered/Resolved"="Recovered/Resolved" "Recovering/Resolving"="Recovering/Resolving" "Sequelae"="Sequelae" "Unknown"="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	<b>Reported_as_SAE_</b>	Reported As SAE?		"1"="Yes" "2"="No"
01. Principal	<b>Treatment_Assignment_Code__TAC_</b>	Treatment Assignment Code (TAC)		"TAC-0"="TAC-0" "TAC1"="TAC1"