

# UWI2016-07-01 - ADVERSE EVENTS: DATA DICTIONARY

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## Document Summary

Property	Value
Document Title	UWI2016-07-01 - Adverse Events: Data Dictionary
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Sections	3
Entries	16
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## UWI2016-07-01 - Adverse Events: Data Dictionary

### Section 1: Identifiers

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Variable	Label	Description	Format Text
<b>SEQUENCE_NO_</b>	Patient ID		Numeric

## Section 2: Study-wide

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Variable	Label	Description	Format Text
<b>ae_tac</b>	Treatment Assignment Code		.N="N/A" 1="TAC1"
<b>visit_dt</b>	Visit Date		SAS Date

## Section 3: Event Details

Variable	Label	Description	Format Text
<b>ae_action</b>	Change (If Any) in Agent Dose Due to Adverse Event		.N="N/A" 4="Agent Dose Not Changed" 6="Not Applicable"
<b>ae_attribution</b>	Likelihood Adverse Event Was Caused by Treatment		.N="N/A" 1="Unrelated" 3="Possible" 4="Probable"
<b>ae_ctcae_term</b>	CTCAE Term v4.0	Common Terminology Criteria for Adverse Events term v4.0.	"Abdominal pain"="Abdominal pain" "Allergic rhinitis"="Allergic rhinitis" "Diarrhea"="Diarrhea" "Dizziness"="Dizziness" "Fatigue"="Fatigue" "Hypertension"="Hypertension" "Nausea"="Nausea" "Sore throat"="Sore throat"
<b>ae_dropped</b>	Dropped Due to this Adverse Event?		.N="N/A" 0="No"
<b>ae_end_dt</b>	End Date of Adverse Event		SAS Date .M="Missing" .N="N/A"
<b>ae_event</b>	Adverse Event as Described Verbatim		Char " "="Missing"
<b>ae_grade</b>	Severity of Adverse Event		.N="N/A" 1="Mild" 2="Moderate" 3="Severe"
<b>ae_meddra_v12</b>	MedDRA v12.0 Code	Medical Dictionary for Regulatory Activities v12.0 code.	Numeric .N="No Adverse Events Reported"
<b>ae_onset_dt</b>	Onset Date of Adverse Event		SAS Date .N="N/A"
<b>ae_outcome</b>	Outcome of Adverse Event		.N="N/A" 1="Recovered/Resolved" 6="Unknown"
<b>ae_rpt_dt</b>	Report Date of Adverse Event		SAS Date .N="N/A"
<b>ae_sae</b>	Serious Adverse Event?		.N="N/A" 0="No"
<b>ae_tox_group</b>	Toxicity Group		.N="N/A" 7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 17="Nervous System Disorders" 22="Respiratory, Thoracic and Mediastinal Disorders" 26="Vascular Disorders"