

# UWI10-16-01R - ADVERSE EVENTS: DATA DICTIONARY

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## Document Summary

Property	Value
Document Title	UWI10-16-01R - Adverse Events: Data Dictionary
Date Created	09/10/2019
Sections	2
Entries	14
Document Filename	dictionary_aeout.rtf

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## UWI10-16-01R - Adverse Events: Data Dictionary

### Section 1: Identifiers

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Variable	Label	Description	Format Text
PT	Participant ID	Participant ID	Char

## Section 2: Adverse Events

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Variable	Label	Description	Format Text
<b>actn</b>	Change (If Any) in Agent Dose Due to Adverse Event	Change (If Any) in Agent Dose Due to Adverse Event	Numeric
<b>aename</b>	CTCAE Term v4.0	CTCAE Term v4.0	Char
<b>bsys</b>	Body System Affected by Adverse Event	Body System Affected by Adverse Event	Char
<b>enddt</b>	End Date of Adverse Event	End Date of Adverse Event	SAS Date .= "Missing"
<b>graden</b>	Severity of Adverse Event	Severity of Adverse Event	Numeric
<b>onsdt</b>	Onset Date of Adverse Event	Onset Date of Adverse Event	SAS Date .= "Missing"
<b>outcm</b>	Outcome of Adverse Event	Outcome of Adverse Event	Numeric
<b>prot</b>	Protocol	Protocol	Char
<b>randt</b>	Date of Randomization	Date of Randomization	SAS Date
<b>relatn</b>	Likelihood Adverse Event was Caused by Treatment	Likelihood Adverse Event was Caused by Treatment	Numeric
<b>sae</b>	Serious Adverse Event?	Serious Adverse Event?	Numeric
<b>trtmnt</b>	Treatment	Treatment	Numeric
<b>verb</b>	Adverse Event as Described by the Participant	Adverse Event as Described by the Participant	Char