

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

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Document Summary

Property	Value
Document Title	UWI10-16-01R - Adverse Events: Data Dictionary
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UWI10-16-01R - Adverse Events: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
PT	Participant ID	Participant ID	Char

Section 2: Adverse Events

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