

UWI2016-07-01 - Maximum Adverse Events per Body System Data Dictionary

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Document Summary

Property	Value
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UWI2016-07-01 - Maximum Adverse Events per Body System: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	SEQUENCE_NO_	Patient ID	Number used to link participant with the study.	Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	treat	Treatment (Long)	Treatment that was assigned to participant- ACTOplus/Placebo	"ACTOplus"="ACTOplus" "Placebo"="Placebo"
01. Principal	trt	Treatment (Formatted)	Treatment (formatted) - arm that participant was assigned to.	"A"="ACTOplus" "B"="Placebo"

Section 3: Maximum Adverse Events per Body System

Class	Variable	Label	Description	Format Text
01. Principal	bsys	System Organ Class	System Organ Class	"Gastrointestinal disorders"="Gastrointestinal disorders" "Overall"="Overall" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders" "Vascular disorders"="Vascular disorders"
01. Principal	mxrlb	Maximum Attribution By Body System For Patient (Formatted)	Maximum Attribution by Body System for Patient (formatted)	0="None" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	mxsvb	Maximum Severity By Body System For Patient (Formatted)	Maximum Severity by Body System for Patient (formatted)	0="None" 1="Mild" 2="Moderate" 3="Severe" 4="Life-thr." 5="Lethal"
01. Principal	xrlb	Maximum Attribution By Body System For Patient (Text)	Maximum Attribution by Body System for Patient (text)	"No Event"="No Event" "Possible"="Possible" "Probable"="Probable" "Unrelated"="Unrelated"
01. Principal	xsvb	Maximum Severity By Body System For Patient (Text)	Maximum Severity by Body System for Patient (text)	"Mild"="Mild" "Moderate"="Moderate" "No Event"="No Event" "Severe"="Severe"