

UWI2016-07-01 - Maximum Adverse Events Data Dictionary

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Document Summary

Property	Value
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UWI2016-07-01 - Maximum Adverse Events: 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

Class	Variable	Label	Description	Format Text
01. Principal	ae	Patient Had AE	Whether Patient had any AEs	0="No" 1="Yes"
01. Principal	aem	Patient Had Multiple AEs	Whether Patient had Multiple AEs	0="No" 1="Yes"
01. Principal	aemx	Maximum Severity Of AE For Patient	Maximum Severity of AE for Patient	0="None" 1="Mild" 2="Moderate" 3="Severe" 4="Life-thr." 5="Lethal"
01. Principal	aen	Number Of AEs	Total Number of AEs for Patient	Numeric
01. Principal	aent	Categorized Number Of AEs	Number of AEs Patient Had	0="0" 1="1-2" 2="3-4" 3="5+"
01. Principal	aerl	Maximum Attribution Of AE For Patient	Maximum Attribution of AE for Patient	0="None" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	aesv	Patient Had Severe AE	Whether Patient Had Severe AE	0="No" 1="Yes"
01. Principal	sae	Patient Had SAE	Whether Patient had SAE	0="No" 1="Yes"