

MAY2013-02-02 - Adverse Events Data Dictionary

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Document Summary

Property	Value
Document Title	MAY2013-02-02 - Adverse Events: Data Dictionary
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MAY2013-02-02 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	subject	Participant ID		Char

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_attribution	Likelihood Adverse Event Was Caused By Study Agent		.M="Missing" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	ae_course	Course		Numeric
01. Principal	ae_ctcae_term	CTCAE Term v4.0		Char
01. Principal	ae_grade	Severity Of Adverse Event		.M="Missing" 1="Mild" 2="Moderate" 3="Severe" 4="Life-Threatening" 5="Lethal"
01. Principal	ae_meddra_v12	MedDRA v12.0 Code		Numeric .M="Missing" .N="No Adverse Events Reported" 99999999="No MedDRA Code Associated with CTCAE Term"
01. Principal	ae_off_study_dt	End Date Of Adverse Event		SAS Date
01. Principal	ae_report_dt	Report Date Of Adverse Event		SAS Date
01. Principal	ae_sae	Serious Adverse Event?		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	ae_trt_arm	Treatment Arm		Char
01. Principal	project	Protocol		Char