

MAY2013-02-02 - Analysis Adverse Events Data Dictionary

TABLE OF CONTENTS

Document Summary.....	2
MAY2013-02-02 - Analysis Adverse Events: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Study-wide	4
Section 3: Analysis Adverse Events	5

Document Summary

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

Section 1: Identifiers

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

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	ARM	Arm		"A"="A"
01. Principal	DC_NUM	Protocol Number		"MAY2013-02-02"="MAY2013-02-02"

Section 3: Analysis Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	AER_SUB	Reported As SAE?		"1"="Yes" "2"="No"
01. Principal	COURSE	Course		Numeric
01. Principal	CTC_V4	CTCAE Term (v4.0)		Char
01. Principal	ENDAT_DT	Off Study Date		SAS Date
01. Principal	EVAL_DT	Adverse Event Report Date		SAS Date
01. Principal	GRADE	Adverse Event Grade		0="Absent Adverse Event" 1="Mild Adverse Event" 2="Moderate Adverse Event" 3="Severe Adverse Event" 4="Life-threatening Adverse Event" 5="Death Related to Adverse Event"
01. Principal	REL_SMED	Adverse Event Attribution		1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	SOC	MedDRA System Organ Class (CTCAE V12.0)		"Blood and lymphatic system disorders"="Blood and lymphatic system disorders" "Cardiac disorders"="Cardiac disorders" "Gastrointestinal disorders"="Gastrointestinal disorders" "General disorders and administration site conditions"="General disorders and administration site conditions" "Infections and infestations"="Infections and infestations" "Injury, poisoning and procedural complications"="Injury, poisoning and procedural complications" "Investigations"="Investigations" "Metabolism and nutrition disorders"="Metabolism and nutrition disorders" "Musculoskeletal and connective tissue disorders"="Musculoskeletal and connective tissue disorders" "Nervous system disorders"="Nervous system disorders" "Renal and urinary disorders"="Renal and urinary disorders" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders" "Skin and subcutaneous tissue disorders"="Skin and subcutaneous tissue disorders"

Class	Variable	Label	Description	Format Text
01. Principal	TOXCODE	MedDRA Adverse Event Code (CTCAE V4.0)		Numeric
01. Principal	TOXICITY	Adverse Event Term (CTCAE V4.0)		Numeric
01. Principal	TRT_ARM	Treatment Arm		"A"="A"