

MAY2016-07-01 - Adverse Event Cytology Data Dictionary

TABLE OF CONTENTS

Document Summary.....	2
MAY2016-07-01 - Adverse Event Cytology: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Adverse Event Cytology	4

Document Summary

Property	Value
Document Title	MAY2016-07-01 - Adverse Event Cytology: Data Dictionary
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MAY2016-07-01 - Adverse Event Cytology: Data Dictionary

Section 1: Identifiers

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

Section 2: Adverse Event Cytology

Class	Variable	Label	Description	Format Text
01. Principal	aer_sub	Reported As Serious Adverse Event (SAE)?		1="Yes" 2="No"
01. Principal	arm	Arm		"A"="A"
01. Principal	course	Course		Numeric
01. Principal	ctc_v4	CTCAE V4.0		"Y"="Y"
01. Principal	dc_num	Protocol Number		"MAY2016-07-01"="MAY2016-07-01"
01. Principal	ENDAT_DT	Off Study Date		SAS Date
01. Principal	eval_dt	Adverse Event Reported Date		SAS Date
01. Principal	grade	Adverse Event Grade		Numeric
01. Principal	rel_smed	Adverse Event Attribution		1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"

Class	Variable	Label	Description	Format Text
01. Principal	soc	MedDRA System Organ Class (CTCAE V12.0)		"Blood and lymphatic system disorders"="Blood and lymphatic system disorders" "Cardiac disorders"="Cardiac disorders" "Ear and labyrinth disorders"="Ear and labyrinth disorders" "Eye disorders"="Eye disorders" "Gastrointestinal disorders"="Gastrointestinal disorders" "General disorders and administration site conditions"="General disorders and administration site conditions" "Immune system disorders"="Immune system disorders" "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" "Psychiatric disorders"="Psychiatric disorders" "Renal and urinary disorders"="Renal and urinary disorders" "Reproductive system and breast disorders"="Reproductive system and breast disorders" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders" "Skin and subcutaneous tissue disorders"="Skin and subcutaneous tissue disorders" "Vascular disorders"="Vascular disorders"
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"