

MAY2013-02-02 - [Adverse Events Report] Data Dictionary

TABLE OF CONTENTS

Document Summary.....	2
MAY2013-02-02 - [Adverse Events Report]: Data Dictionary.....	3
Section 1: Identifiers	3
Section 2: Study-wide	4
Section 3: Adverse Events Disregarding Grade	5

Document Summary

Property	Value
Document Title	MAY2013-02-02 - [Adverse Events Report]: Data Dictionary
Date Created	04/12/2024
Sections	3
Entries	14
Document Filename	dictionary_cytox.rtf

MAY2013-02-02 - [Adverse Events Report]: Data Dictionary

Section 1: Identifiers

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

Section 2: Study-wide

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

Section 3: Adverse Events Disregarding Grade

Class	Variable	Label	Description	Format Text
01. Principal	AER_SUB	Reported As SAE?	General body system category from CTC/MeDra associated with the given adverse event.	"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	Relationship Study Meds	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)	System Of Concern	"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"
01. Principal	TOXCODE	MedDRA Adverse Event Code (CTCAE V4.0)	Toxicity Code	Numeric
01. Principal	TOXICITY	Adverse Event Term (CTCAE V4.0)	Toxicity	Numeric
01. Principal	TRT_ARM	Treatment Arm	Treatment Arm	"A"="A"