

MAY2013-02-01 - Cyttox Data Dictionary

TABLE OF CONTENTS

Document Summary.....	2
MAY2013-02-01 - Cyttox: Data Dictionary.....	3
Section 1: Identifiers	3
Section 2: Final Adverse Events	4

Document Summary

Property	Value
Document Title	MAY2013-02-01 - Cytos: Data Dictionary
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MAY2013-02-01 - Cyttox: Data Dictionary

Section 1: Identifiers

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

Section 2: Final Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	action	Action		"Agent dose increased"="Agent dose increased" "Agent dose not changed"="Agent dose not changed" "Agent dose reduced"="Agent dose reduced" "Agent interrupted"="Agent interrupted" "Agent withdrawn"="Agent withdrawn" "Not applicable"="Not applicable" "Unknown"="Unknown"
01. Principal	aer_sub	Reported As SAE?		1="Yes" 2="No"
01. Principal	aesi	Adverse Event Of Special Interest (AESI)		1="Yes" 2="No"
01. Principal	arm	Treatment Arm		"A"="Dose Escalation" "B"="INO-8000" "C"="INO-8000 + INO-9012 (0.3 mg)" "D"="INO-8000 + INO-9012 (1 mg)" "E"="INO-8000 + INO-9012 (3 mg)"
01. Principal	course	Course		Numeric
01. Principal	ctc_v4	CTCAE Term (v4.0)		"N"="No" "Y"="Yes"
01. Principal	dc_num	Protocol Number		"MAY2013-02-01"="MAY2013-02-01"
01. Principal	dlt	Dose Limiting Toxicity		1="Yes" 2="No"
01. Principal	dose_level	Dose Level		0="Dose Level 1" 1="Dose Level 2" 2="Dose Level 3" 3="Dose Level 4"
01. Principal	endat_dt	Off Study Date		SAS Date
01. Principal	eval_dt	Adverse Event Report Date		SAS Date
01. Principal	grade	Grade		Numeric
01. Principal	outcome	Outcome		"Fatal"="Fatal" "Not Recovered Not Resolved"="Not Recovered Not Resolved" "Recovered Resolved with Sequelae"="Recovered Resolved with Sequelae" "Recovered Resolved"="Recovered Resolved" "Recovering Resolving"="Recovering Resolving" "Unknown"="Unknown"
01. Principal	rel_smed	Adverse Event Attribution		1="Not Related" 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" "Ear and labyrinth disorders"="Ear and labyrinth 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" "Neoplasms benign, malignant and unspecified (incl cysts and polyps)"="Neoplasms benign, malignant and unspecified (incl cysts and polyps)" "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" "Surgical and medical procedures"="Surgical and medical procedures" "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	toxicity_sp	Adverse Event Term (CTCAE V4.0) - Other, Specify		Char
01. Principal	trt_arm	Treatment Arm		"A"="Dose Escalation" "B"="INO-8000" "C"="INO-8000 + INO-9012 (0.3 mg)" "D"="INO-8000 + INO-9012 (1 mg)" "E"="INO-8000 + INO-9012 (3 mg)"
01. Principal	val3plus	Grade 3+ AE		0="No" 1="Yes"

