

# MAY2013-01-01 - Adverse Events Disregarding Grade Data Dictionary

## TABLE OF CONTENTS

---

---

Document Summary.....	2
MAY2013-01-01 - Adverse Events Disregarding Grade: 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	MAY2013-01-01 - Adverse Events Disregarding Grade: Data Dictionary
Date Created	11/06/2020
Sections	3
Entries	24
Document Filename	dictionary_cyttox_reg.rtf

---

# MAY2013-01-01 - Adverse Events Disregarding Grade: Data Dictionary

## Section 1: Identifiers

---

Variable	Label	Description	Format Text
<b>DCNTR_ID</b>	Data Center ID	DCNTR_ID	Char

## Section 2: Study-wide

---

Variable	Label	Description	Format Text
<b>ARM</b>	Arm	Arm	"A"="MUC1" "B"="Placebo"
<b>CASE</b>	Case Number	Case Number	Numeric
<b>CYCLE</b>	Cycle	Cycle	Numeric
<b>DC_NUM</b>	Data Center Assigned Protocol Number	Data Center Assigned Protocol Number	"MAY2013-01-01"="MAY2013-01-01"
<b>STUDY</b>	Ingres Study Number	Ingres Study Number	Numeric

## Section 3: Adverse Events Disregarding Grade

Variable	Label	Description	Format Text
<b>AER_SUB</b>	AER Submitted	General body system category from CTC/MeDra associated with the given adverse event.	1="Yes" 2="No"
<b>BODYSYS</b>	Body System	Course	"1"="Blood and lymphatic system disorders" "10"="Immune system disorders" "11"="Infections and infestations" "12"="Injury, poisoning and procedural complications" "13"="Investigations" "14"="Metabolism and nutrition disorders" "15"="Musculoskeletal and connective tissue disorders" "16"="Neoplasms benign, malignant and unspecified (incl cysts and polyps)" "17"="Nervous system disorders" "18"="Pregnancy, puerperium and perinatal conditions" "19"="Psychiatric disorders" "2"="Cardiac disorders" "20"="Renal and urinary disorders" "23"="Other" "3"="Congenital, familial and genetic disorders" "4"="Ear and labyrinth disorders" "6"="Eye disorders" "7"="Gastrointestinal disorders" "8"="General disorders and administration site conditions" "9"="Hepatobiliary disorders"
<b>COURSE</b>	Course	CTCAE V3	Numeric
<b>CTC_V3</b>	CTCAE V3	CTCAE V4	
<b>CTC_V4</b>	CTCAE V4	End Active Treatment	Char
<b>ENDAT_DT</b>	End Active Treatment	Evaluation Date	SAS Date
<b>EVAL_DT</b>	Evaluation Date	Excluded	Numeric
<b>EXCLUDED</b>	Excluded	Grade	
<b>GRADE</b>	Grade	Nadir Date	SAS Date
<b>NADR_DAT</b>	Nadir Date	Nadir Value	Numeric
<b>NADR_VAL</b>	Nadir Value	Possible Grade	
<b>REL_SMED</b>	Relationship Study Meds	Relationship Study Meds	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"

Variable	Label	Description	Format Text
<b>SOC</b>	System Of Concern	System Of Concern	"Blood and lymphatic sys disord"="Blood and lymphatic sys disord" "Cardiac disorders"="Cardiac disorders" "Ear and labyrinth disorders"="Ear and labyrinth disorders" "Endocrine disorders"="Endocrine disorders" "Eye disorders"="Eye disorders" "Gastrointestinal disorders"="Gastrointestinal disorders" "Gen disord and admin site cond"="Gen disord and admin site cond" "Hepatobiliary disorders"="Hepatobiliary disorders" "Immune system disorders"="Immune system disorders" "Infections and infestations"="Infections and infestations" "Inj, pois and proced complic"="Inj, pois and proced complic" "Investigations"="Investigations" "Metabol and nutrition disord"="Metabol and nutrition disord" "Musculosk and conn tiss disord"="Musculosk and conn tiss disord" "Neoplsn benign, mal and unspec"="Neoplsn benign, mal and unspec" "Nervous system disorders"="Nervous system disorders" "Psychiatric disorders"="Psychiatric disorders" "Renal and urinary disorders"="Renal and urinary disorders" "Reprod sys and breast disord"="Reprod sys and breast disord" "Respirat, thor, mediast disord"="Respirat, thor, mediast disord" "Skin and subcutan tiss disord"="Skin and subcutan tiss disord" "Surgical and medical proced"="Surgical and medical proced" "Vascular disorders"="Vascular disorders"
<b>SUBJECT</b>	Subject Number	Subject Number	Numeric
<b>TOXCODE</b>	Toxicity Code	Toxicity Code	Numeric
<b>TOXICITY</b>	Toxicity	Toxicity	Numeric
<b>TRT_ARM</b>	Treatment Arm	Treatment Arm	"A"="MUC1" "B"="Placebo"
<b>TRTCYCLE</b>	Treatment Cycle	Treatment Cycle	1="Treatment Cycle"