MAY2013-02-02 - Adverse Events Data Dictionary

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MAY2013-02-02 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	**build_dt**	Build Date		SAS Date
01. Principal	**SUBJECT**	Participant ID		Char

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	**ae_action**	Change (If Any) In Agent Dose Due To Adverse Event		.N="No Adverse Events Reported" 1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unknown" 6="Not Applicable" 7="Agent Interrupted"
01. Principal	**ae_attribution**	Likelihood Adverse Event Was Caused By Study Agent		1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	**ae_comments**	Comments		Char

Class	Variable	Label	Description	Format Text
01. Principal	**ae_ctcae_term**	CTCAE Term v4.0		"10000081: Gastrointestinal disorders"="10000081: Gastrointestinal disorders" "10000486: Metabolism and nutrition disorders"="10000486: Metabolism and nutrition disorders" "10001723: Respiratory, thoracic and mediastinal disorders"="10001723: Respiratory, thoracic and mediastinal disorders" "10002272: Blood and lymphatic system disorders"="10002272: Blood and lymphatic system disorders" "10005364: Investigations"="10005364: Investigations" "10008481: Cardiac disorders"="10008481: Cardiac disorders" "10010300: Psychiatric disorders"="10010300: Psychiatric disorders" "10010774: Gastrointestinal disorders"="10010774: Gastrointestinal disorders" "10012727: Gastrointestinal disorders"="10012727: Gastrointestinal disorders" "10013442: Blood and lymphatic system disorders"="10013442: Blood and lymphatic system disorders" "10013946: Gastrointestinal disorders"="10013946: Gastrointestinal disorders" "10013963: Respiratory, thoracic and mediastinal disorders"="10013963: Respiratory, thoracic and mediastinal disorders" "10014625: Nervous system disorders"="10014625: Nervous system disorders" "10015090: Respiratory, thoracic and mediastinal disorders"="10015090: Respiratory, thoracic and mediastinal disorders" "10016173: Injury, poisoning and procedural complications"="10016173: Injury, poisoning and procedural complications" "10016256: General disorders and administration [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] **ae_ctcae_term**			[...continued] site conditions"="10016256: General disorders and administration site conditions" "10016791: General disorders and administration site conditions"="10016791: General disorders and administration site conditions" "10017947: Gastrointestinal disorders"="10017947: Gastrointestinal disorders" "10018065: General disorders and administration site conditions"="10018065: General disorders and administration site conditions" "10019211: Nervous system disorders"="10019211: Nervous system disorders" "10019663: Hepatobiliary disorders"="10019663: Hepatobiliary disorders" "10021038: Metabolism and nutrition disorders"="10021038: Metabolism and nutrition disorders" "10021097: Vascular disorders"="10021097: Vascular disorders" "10021113: General disorders and administration site conditions"="10021113: General disorders and administration site conditions" "10021881: Infections and infestations"="10021881: Infections and infestations" "10022891: Investigations"="10022891: Investigations" "10027433: Metabolism and nutrition disorders"="10027433: Metabolism and nutrition disorders" "10028130: Gastrointestinal disorders"="10028130: Gastrointestinal disorders" "10028395: Musculoskeletal and connective tissue disorders"="10028395: Musculoskeletal and connective tissue disorders" "10028813: Gastrointestinal disorders"="10028813: Gastrointestinal disorders" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	**[...continued]** **ae_ctcae_term**			[...continued] "10037087: Skin and subcutaneous tissue disorders"="10037087: Skin and subcutaneous tissue disorders" "10037847: Skin and subcutaneous tissue disorders"="10037847: Skin and subcutaneous tissue disorders" "10038695: Respiratory, thoracic and mediastinal disorders"="10038695: Respiratory, thoracic and mediastinal disorders" "10040047: Infections and infestations"="10040047: Infections and infestations" "10040747: Nervous system disorders"="10040747: Nervous system disorders" "10040785: Skin and subcutaneous tissue disorders"="10040785: Skin and subcutaneous tissue disorders" "10040872: Infections and infestations"="10040872: Infections and infestations" "10041633: Blood and lymphatic system disorders"="10041633: Blood and lymphatic system disorders" "10042112: Gastrointestinal disorders"="10042112: Gastrointestinal disorders" "10046593: Renal and urinary disorders"="10046593: Renal and urinary disorders" "10047065: Vascular disorders"="10047065: Vascular disorders" "10048031: Injury, poisoning and procedural complications"="10048031: Injury, poisoning and procedural complications" "10048677: Musculoskeletal and connective tissue disorders"="10048677: Musculoskeletal and connective tissue disorders" "10051592: Cardiac disorders"="10051592: Cardiac disorders" "10055322: Injury, poisoning and procedural complications"="10055322: Injury, poisoning and procedural complications" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	**[...continued]** **ae_ctcae_term**			[...continued] "10065776: Musculoskeletal and connective tissue disorders"="10065776: Musculoskeletal and connective tissue disorders" "10066874: Gastrointestinal disorders"="10066874: Gastrointestinal disorders" "10069339: Renal and urinary disorders"="10069339: Renal and urinary disorders"
01. Principal	**ae_dropped**	Dropped Due To This Adverse Event?		0="No" 1="Yes"
01. Principal	**ae_end_dt**	End Date Of Adverse Event		SAS Date .C="Continuing" .M="Missing"
01. Principal	**ae_event**	Adverse Event As Described Verbatim		Char
01. Principal	**ae_grade**	Severity Of Adverse Event		1="Mild" 2="Moderate" 3="Severe" 4="Life-Threatening" 5="Lethal"
01. Principal	**ae_grade_desc**	Severity Of Adverse Event - Description		Char
01. Principal	**ae_in_cytox**	Final Adverse Event For Secondary Endpoint?		0="No" 1="Yes"
01. Principal	**ae_meddra_v12**	MedDRA v12.0 Code		Numeric .N="No Adverse Events Reported" 99999999="No MedDRA Code Associated with CTCAE Term"
01. Principal	**ae_onset_dt**	Onset Date Of Adverse Event		SAS Date
01. Principal	**ae_outcome**	Outcome Of Adverse Event		1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not recovering/Not Resolved" 4="Recovered/Resolved with sequelae" 5="Fatal" 6="Unknown"
01. Principal	**ae_report_dt**	Report Date Of Adverse Event		SAS Date
01. Principal	**ae_sae**	Serious Adverse Event?		0="No" 1="Yes"
01. Principal	**ae_study_proc_r elated**	Study Procedure Related?		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	**ae_tox_group**	Toxicity Group		.N="No Adverse Events Reported" 1="Blood and Lymphatic System Disorders" 2="Cardiac Disorders" 3="Congenital, Familial and Genetic Disorders" 4="Ear and Labyrinth Disorders" 5="Endocrine Disorders" 6="Eye Disorders" 7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 9="Hepatobiliary 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 (Including Cysts and Polyps)" 17="Nervous System Disorders" 18="Pregnancy, Puerperium and Perinatal Conditions" 19="Psychiatric Disorders" 20="Renal and Urinary Disorders" 21="Reproductive System and Breast Disorders" 22="Respiratory, Thoracic and Mediastinal Disorders" 23="Skin and Subcutaneous Tissue Disorders" 24="Social Circumstances" 25="Surgical and Medical Procedures" 26="Vascular Disorders" 99="No Toxicity Group Associated With CTCAE Term"