MAY2013-02-01 - Intervention Administration Data Dictionary

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MAY2013-02-01 - Intervention Administration: Data Dictionary
Section 1: Identifiers

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

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	**CYCLE**	Visit Number		0="Screening/Day -2" 1="Day 0/Week 2" 2="Weeks 4-8" 3="Weeks 12-14" 4="Weeks 24-26" 5="Week 36" 6="Week 48" 7="Week 76"
01. Principal	**FOLDERINSTANCENAME**	Dataset Folder Name		"Treatment (Intervention) Day 0 (1)"="Treatment (Intervention) Day 0 (1)" "Treatment (Intervention) Week 12 (1)"="Treatment (Intervention) Week 12 (1)" "Treatment (Intervention) Week 24 (1)"="Treatment (Intervention) Week 24 (1)" "Treatment (Intervention) Week 4 (1)"="Treatment (Intervention) Week 4 (1)"
01. Principal	**MAXUPDATED**	Last Updated		SAS Datetime
01. Principal	**MINCREATED**	Created Time		SAS Datetime
01. Principal	**PROJECT**	Protocol		"MAY2013-02-01"="MAY2013-02-01"
01. Principal	**RAVEID**	Rave ID		Numeric
01. Principal	**SITENUMBER**	Site Number		"FL080"="FL080" "MN026"="MN026" "PR008"="PR008"

Section 3: Intervention Administration

Class	Variable	Label	Description	Format Text
01. Principal	**AGENTXX**	Agent		"Study vaccine (INO-8000 +/- INO-9012)"="Study vaccine (INO-8000 +/- INO-9012)"
01. Principal	**ASSESS**	Time Point		"Day 0"="Day 0" "Week 12"="Week 12" "Week 24"="Week 24" "Week 4"="Week 4"
01. Principal	**COM**	Comments		Char
01. Principal	**DOSEDTXX**	Dose Date		SAS Date
01. Principal	**NOTXRSNXX**	Reason Agent Not Administered		Char
01. Principal	**PAGEREPEATNUMBER**	Page Repeat Number		Numeric
01. Principal	**PREEVAL**	Was Preinjection Evaluation Performed?		1="Yes" 2="No"
01. Principal	**RECORDPOSITION**	Record Position		Numeric
01. Principal	**RXADMINXX**	Was Agent Administered?		1="Yes" 2="No"
01. Principal	**RXDELAYRSNXX**	Dose Delay Reason		and genetic disorders 4=""ear and labyrinth disorders 5 = "endocrine disorders 6 = "eye" and infestations 12="injury poisoning and procedural complications" circumstances 25=""surgical and medical procedures 26 = "vascular disorders" conditions 9=""hepatobiliary disorders 10 = "immune system disorders 11 = "infections" connective tissue disorders 16="neoplasms benign malignant and unspecified (incl." cysts and polyps) 17=""nervous system disorders 18 = "pregnancy puerperium and" disorders 7=""gastrointestinal disorders 8 = "general disorders and administration site" mediastinal disorders 23=""skin and subcutaneous tissue disorders 24 = "social" perinatal conditions 19=""psychiatric disorders 20 = "renal and urinary disorders" 1=""blood and lymphatic system disorders 2 = "cardiac disorders 3 = "congenital familial" 13=""investigations 14 = "metabolism and nutrition disorders 15 = "musculoskeletal and" 21=""reproductive system and breast disorders 22 = "respiratory thoracic and" 99="other not per protocol"
01. Principal	**RXDELAYRSNXX _SP**	Dose Delay Reason, Specify		Char
01. Principal	**RXDELAYXX**	Was Protocol Intervention Delayed?		1="Yes" 2="No"

Class	Variable	Label	Description	Format Text
01. Principal	**SITE**	Site		"Mayo Clinic in Florida"="Mayo Clinic in Florida" "Mayo Clinic"="Mayo Clinic" "University of Puerto Rico"="University of Puerto Rico"
01. Principal	**TARGETDAYS**	Target Days From Baseline		Numeric
01. Principal	**TXSITEXX**	Site		"Left arm"="Left arm" "Left thigh"="Left thigh" "Right arm"="Right arm" "Right thigh"="Right thigh"
01. Principal	**TXTIMEXX**	Time		SAS Time