

MAY2013-02-01 - Investigational Device Information Data Dictionary

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Document Summary

Property	Value
Document Title	MAY2013-02-01 - Investigational Device Information: Data Dictionary
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Entries	25
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MAY2013-02-01 - Investigational Device Information: 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	FOLDERINSTAN CENAME	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: Investigational Device Information

Class	Variable	Label	Description	Format Text
01. Principal	ASSESS	Time Point		"Day 0"="Day 0" "Week 12"="Week 12" "Week 24"="Week 24" "Week 4"="Week 4"
01. Principal	ATTEMPTNUM	Total Number Of Attempts		Numeric
01. Principal	ATTEMPTNUMXX	Attempt		Numeric
01. Principal	COM	Comments		Char
01. Principal	DATASENTXX	Was The CELLECTRA Device Data Downloaded And Sent To Inovio?		1="Yes" 2="No"
01. Principal	ELECTRODT	Electroporation Date		SAS Date
01. Principal	HANDLENUMXX	CELLECTRA Applicator Serial Number		Char
01. Principal	LOTNUMXX	CELLECTRA Array Lot Numbers		Char
01. Principal	NOTSENTRSXXX	Provide Reason		Char
01. Principal	NUMARRAYXX	Number Of Arrays Used		Numeric
01. Principal	OTHERERRORXX	Were Any Other Errors Displayed That Were Not Reported		1="Yes" 2="No"
01. Principal	PAGEREPEATNUMBER	Page Repeat Number		Numeric
01. Principal	RECORDPOSITION	Record Position		Numeric
01. Principal	SENTDTXX	Date That The Data File Was Sent		SAS Date
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	UNITNUMXX	CELLECTRA Electroporation Unit Serial Number		Char