

MAY2013-01-01 - Colonoscopy Registration Data Dictionary

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Document Summary

Property	Value
Document Title	MAY2013-01-01 - Colonoscopy Registration: Data Dictionary
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MAY2013-01-01 - Colonoscopy Registration: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
DCNTR_ID	Data Center Id	Data Center Id	Char

Section 2: Study-wide

Variable	Label	Description	Format Text
ARM	Arm	Arm	"A"="MUC1" "B"="Placebo"
CASE	Case Number	Case Number	Numeric
CREATED	Created Date	Created Date	SAS Date
CYCLE	Cycle	Cycle	Numeric
DATE_MOD	Date Modified	Date Modified	SAS Date
DC_NUM	Data Center Assigned Protocol Number	Data Center Assigned Protocol Number	"MAY2013-01-01"="MAY2013-01-01"
FORMCOMP	Form Complete	Form Complete	Char
FORMNAME	Form Name	Form Name	"Colonoscopy Report"="Colonoscopy Report" "Continuation Colonoscopy Report"="Continuation Colonoscopy Report"
IGNORE	Nothing	Nothing	Numeric
NODE	Node	Node	Numeric
SEQUENCE	Sequence	Sequence	Numeric
STUDY	Ingres Study Number	Ingres Study Number	Numeric
VERSION	Version	Version	Numeric
VISIT	Evaluation Visit Number	Evaluation Visit Number	8="Week 156 or Early Termination" 99="Other, Specify"

Section 3: Colonoscopy Registration

Variable	Label	Description	Format Text
ADENOMT0-9	Type Of Adenoma	Type of adenoma: 1=Advanced* 2=Non-advanced 3=Not applicable *Advanced adenoma-One of the following characteristics must be present: (1) >=1 cm on colonoscopy report, (2) villous or tubulovillous, or (3) high grade (severe) dysplasia. Insert pathologist's conclusions, if any, into the comments section on the electronic CRF.	1="Advanced" 2="Non-Advanced" 3="Not Applicable"
ADVADENO	Number Of Advanced Adenomas	Total number advanced adenomas*: *Advanced adenoma-One of the following characteristics must be present: (1) greater than or equal to 1cm on colonoscopy report, (2) villous or tubulovillous, or (3) high grade (severe) dysplasia. Insert pathologist's conclusions, if any, into the comments section on the electronic CRF.	Numeric
BWLPREP	Was Bowl Prep Adequate	Was the overall bowel preparation adequate, good, or excellent (i.e., 90% of the rectal mucosa was well visualized. Note: preparation characterized as fair or poor is not adequate)? 1=Yes 2=No 3=Not reported	1="Yes" 2="No" 3="Not reported"
CECUMVIS	Was The Cecum Visualized?	Was the cecum visualized (including identification of cecal landmarks, i.e. ileocecal valve, appendiceal orifice, or terminal ileum)? 1=Yes 2=No 3=Not reported	1="Yes" 2="No" 3="Not reported"
COL_RSLT	Result Of Colonoscopy	Results of Colonoscopy: (select one) 1=Normal 2=Abnormal, specify 3=Other, specify	1="Normal" 2="Abnormal, specify" 3="Other, specify"
COLPSCPY	Colposcopy Done	Colonoscopy performed: 1=Yes 2=No	1="Yes" 2="No"
CONFIG1-10	Configuration	Configuration: 1=Pendunculated 2=Sessile 3=Not specified	1="Pendunculated" 2="Sessile" 3="Not specified"

Variable	Label	Description	Format Text
DYSPLAS0-9	Presence Of Dysplasia	Presence of dysplasia: 1=No dysplasia 2=Indefinite for dysplasia 3=Low grade dysplasia 4=High grade dysplasia 5=Not available	1="No dysplasia" 3="Low grade dysplasia" 5="Not available"
FORM	Form	Form	Numeric
FORMTYPE	Form Type	Form Type	"data"="data"
HISTOTP0-9	Histopathologic Type	Histopathologic type: 1=Hyperplastic polyps 2=Hamartomatous 3=Inflammatory polyps 4=Tubular adenoma 5=Tubulovillous adenoma 6=Adenoma 7=Villous adenoma 8=Serrated adenoma 9=Not specified 10=Juvenile 11=Other, specify	1="Hyperplastic polyps" 4="Tubular adenoma" 5="Tubulovillous adenoma" 7="Villous adenoma" 8="Serrated adenoma" 9="Not specified" 11="Other, specify"
LOCATN1-10	Location	Location: 1=Cecum 2=Ascending colon 3=Hepatic flexure 4=Transverse colon 5=Splenic flexure 6=Descending colon 7=Sigmoid colon 8=Rectosigmoid Junction 9=Rectum 10=Not specified	1="Cecum" 2="Ascending colon" 3="Hepatic flexure" 4="Transverse colon" 5="Splenic flexure" 6="Descending colon" 7="Sigmoid colon" 8="Rectosigmoid junction" 9="Rectum" 10="Not specified"
LOCCM1-10	Location If Identified By cm Only	If location only identified by cm: __.__.__	Numeric
MULTPOL0-9	Multiple Polyps Per Container	Were multiple polyps/fragments placed in one specimen container? 1=Yes 2=No	1="Yes" 2="No"
NAADENOM	Number Of Non-Advanced Adenomas	Total number non-advanced adenomas:	Numeric
OTH_SPEC	Other Specify	Colonoscopy Results: If Abnormal or Other, specify: (200 available characters)	Char
OTHSPEC	If Other, Specify:	Other, specify	Char
OTHSPEC0-9	Other Specify	Histopathologic Type: Other, specify (200 available characters)	Char
POLYP1-10	Polyp Number	Polyp #	Numeric
POLYPS	Any Polyps Found	Were all polyps excised? 1=Yes 2=No 3=Not reported	1="Yes" 2="No" 3="Not Reported"
PROC_DT	Procedure Date	Procedure Date: (mm/dd/yyyy)	SAS Date

Variable	Label	Description	Format Text
REPOLYP0-9	Is Recurrent Polyp In Same Location?	(Follow Up Only) Is this recurrent polyp in the same location as a polyp identified on the baseline colonoscopy? 1=Yes 2=No 3=Unknown 4=Not specified	1="Yes" 2="No" 3="Unkown" 4="Not specified"
RMPIECE0-9	Polyp Removed Piecemeal?	Polyp removed piecemeal? 1=Yes 2=No	1="Yes" 2="No"
SIZECX1-10	Size At Colonoscopy	Size at Colonoscopy: 1=Diminutive (less than 5 mm) 2=Medium (5-9 mm) 3=Large (greater than or equal to 1 cm)	1="Diminutive (< 5mm)" 2="Medium (5-9mm)" 3="Large (>= 1cm)"
SIZEPTH0-9	Size As Measured By Pathologist	Size as measured by Endoscopist (cm)	Numeric