

MAY2016-07-01 - Analysis Data Dictionary

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Document Summary

Property	Value
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MAY2016-07-01 - Analysis: 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	SITE	Site		"Cleveland Clinic Foundation"="Cleveland Clinic Foundation" "Huntsman Cancer Institute/University of Utah"="Huntsman Cancer Institute/University of Utah" "M D Anderson Cancer Center"="M D Anderson Cancer Center" "Mayo Clinic in Arizona"="Mayo Clinic in Arizona" "Mayo Clinic"="Mayo Clinic" "University of Michigan Comprehensive Cancer Center"="University of Michigan Comprehensive Cancer Center" "University of Pittsburgh Cancer Institute (UPCI)"="University of Pittsburgh Cancer Institute (UPCI)" "University of Puerto Rico"="University of Puerto Rico"
01. Principal	SITENUMBER	Site Number		"AZ020"="AZ020" "MI014"="MI014" "MN026"="MN026" "OH027"="OH027" "PA015"="PA015" "PR008"="PR008" "TX035"="TX035" "UT003"="UT003"

Section 3: Analysis

Class	Variable	Label	Description	Format Text
01. Principal	ae_gr2to3	Grade 2-3 Adverse Event		0="No" 1="Yes"
01. Principal	ae_rash	Rash Acneiform/Maculo-Papular		0="No" 1="Yes"
01. Principal	ae_rl3	Adverse Event, At Least Possibly Related		0="No" 1="Yes"
01. Principal	age	Age		Numeric
01. Principal	bmi	Bmi (kg/m^2)		Numeric
01. Principal	DF1	FAP		1="Classic" 2="Attenuated"
01. Principal	DF2	Aspirin Use		1="No Regular Use" 2="D81 mg Day"
01. Principal	DF3	Severity Of Duodenal Polyposis		1="Spigelman 2" 2="Spigelman 3"
01. Principal	DF4	APC Genetic Mutation		1="Yes" 2="No"
01. Principal	ENDATRSN	Off Study Reason		"Adverse Event"="Adverse Event" "Study Complete"="Study Complete"
01. Principal	ethnicity	Ethnicity		"Hispanic or Latino"="Hispanic or Latino" "Not Hispanic or Latino"="Not Hispanic or Latino"
01. Principal	eval	Evaluable For Primary Endpoint 1: Percent Change In Duodenal Polyp Burden (mm)		0="No" 1="Yes"
01. Principal	HEIGHT	Height (cm)		Numeric
01. Principal	intstart_dt	Intervention Start Date		SAS Date
01. Principal	LIFEDRINKS	In Your Entire Life, Have You Had At Least 12 Drinks Of Any Kind Of Alcoholic Beverage?		1="Yes" 2="No"
01. Principal	lowergi	Lower GI Status		Numeric
01. Principal	polypdiam_absdiff	Absolute Change In Lower GI Polyp Burden (mm)		Numeric
01. Principal	polypdiam_bsl	Baseline Lower GI Polyp Burden (mm)		Numeric
01. Principal	polypdiam_mo6	Month 6 Lower GI Polyp Burden (mm)		Numeric
01. Principal	polypdiam_pctdiff	Percent Change In Lower GI Polyp Burden (mm)		Numeric

Class	Variable	Label	Description	Format Text
01. Principal	polypnum_absdif	Absolute Change In Lower GI Polyp Number		Numeric
01. Principal	polypnum_bsl	Baseline Lower GI Polyp Number		Numeric
01. Principal	polypnum_mo6	Month 6 Lower GI Polyp Number		Numeric
01. Principal	polypnum_pctdiff	Percent Change In Lower GI Polyp Number		Numeric
01. Principal	race	Race		"Black or African American"="Black or African American" "Not Reported"="Not Reported" "White"="White"
01. Principal	reg_dt	Registration Date		SAS Date
01. Principal	sex	Sex		"Female"="Female" "Male"="Male"
01. Principal	SMOKE100	Have You Smoked At Least 100 Cigarettes (5 Packs = 100 Cigarettes) In Your Entire Life?		1="Yes" 2="No"
01. Principal	specprot_mo6	Month 6 Specimen Collection Protocol		"Spigelman 2"="Spigelman 2" "Spigelman 3"="Spigelman 3"
01. Principal	sschg	Change In Spigelman Stage		.="Not Applicable" 1="Downstaged" 2="Upstaged" 3="Unchanged"
01. Principal	totdia_absdiff	Absolute Change In Duodenal Polyp Burden (mm)		Numeric
01. Principal	totdia_bsl	Baseline Duodenal Polyp Burden (mm)		Numeric
01. Principal	totdia_mo6	Month 6 Duodenal Polyp Burden (mm)		Numeric
01. Principal	totdia_pctdiff	Percent Change In Duodenal Polyp Burden (mm)		Numeric
01. Principal	totduo_absdiff	Absolute Change In Duodenal Polyp Number		Numeric
01. Principal	totduo_bsl	Baseline Duodenal Polyp Number		Numeric
01. Principal	totduo_mo6	Month 6 Duodenal Polyp Number		Numeric
01. Principal	totduo_pctdiff	Percent Change In Duodenal Polyp Number		Numeric
01. Principal	WEIGHT	Weight (kg)		Numeric

