

MAY2017-09-01 - PRIMARY ENDPOINTS: DATA DICTIONARY

TABLE OF CONTENTS

Document Summary.....	2
MAY2017-09-01 - Primary Endpoints: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Study-wide	4
Section 3: Primary Endpoints	5

Document Summary

Property	Value
Document Title	MAY2017-09-01 - Primary Endpoints: Data Dictionary
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MAY2017-09-01 - Primary Endpoints: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
SUBJECT	Participant ID	Participant ID	Char

Section 2: Study-wide

Variable	Label	Description	Format Text
SITE	Site	Site	"Thomas Jefferson University Hospital"="Thomas Jefferson University Hospital"

Section 3: Primary Endpoints

Variable	Label	Description	Format Text
age	Age	Age	Numeric
ALLERGYHX	Does The Participant Have Any Allergies?	Does The Participant Have Any Allergies?	Numeric
arm	Arm	Arm	"A"="A" "B"="B"
bbpss_bsl	Baseline: Boston Bowel Preparation Scale Score	Baseline: Boston Bowel Preparation Scale Score	Numeric
bbpss_int	Post-Intervention: Boston Bowel Preparation Scale Score	Post-Intervention: Boston Bowel Preparation Scale Score	Numeric
biop1_diff	Difference In Mean cGMP Levels From Biopsy #1	Difference In Mean cGMP Levels From Biopsy #1	Numeric
biop2_diff	Difference In Mean cGMP Levels From Biopsy #2	Difference In Mean cGMP Levels From Biopsy #2	Numeric
BMI	BMI (Calculated At Baseline Only) (Kg/m^2)	BMI (Calculated At Baseline Only) (Kg/m^2)	Numeric
bwlprep_bsl	Baseline: Was Bowel Preparation Adequate?	Baseline: Was Bowel Preparation Adequate?	1="Yes"
bwlprep_int	Post-Intervention: Was Bowel Preparation Adequate?	Post-Intervention: Was Bowel Preparation Adequate?	1="Yes" 2="No"
day0_biop1	Mean cGMP Levels From Biopsy #1 At Day 0	Mean cGMP Levels From Biopsy #1 At Day 0	Numeric
day0_biop2	Mean cGMP Levels From Biopsy #2 At Day 0	Mean cGMP Levels From Biopsy #2 At Day 0	Numeric
day0_overall	Overall Mean cGMP Levels At Day 0	Overall Mean cGMP Levels At Day 0	Numeric
day7_biop1	Mean cGMP Levels From Biopsy #1 At Day 7	Mean cGMP Levels From Biopsy #1 At Day 7	Numeric
day7_biop2	Mean cGMP Levels From Biopsy #2 At Day 7	Mean cGMP Levels From Biopsy #2 At Day 7	Numeric
day7_overall	Overall Mean cGMP Levels At Day 7	Overall Mean cGMP Levels At Day 7	Numeric
dose1dt	Date Of First Dose	Date Of First Dose	SAS Date
ECGRES	ECG Result	ECG Result	1="Normal" 3="Abnormal, Not Clinically Significant"
ECOGPS	Performance Status (ECOG)	Performance Status (ECOG)	Numeric
ENDAT_DT	Off Study Date	Off Study Date	SAS Date
ENDATRSN	Off Study Reason	Off Study Reason	"Adverse Event"="Adverse Event" "Ineligible"="Ineligible" "Other"="Other" "Participant Withdrawal"="Participant Withdrawal" "Study Complete"="Study Complete"

Variable	Label	Description	Format Text
endocomp_bsl	Baseline: Endoscopy Completed	Baseline: Endoscopy Completed	1="Yes"
endocomp_int	Post-Intervention: Endoscopy Completed	Post-Intervention: Endoscopy Completed	1="Yes" 2="No"
endorslt_bsl	Baseline: Results Of Endoscopy	Baseline: Results Of Endoscopy	1="Normal" 2="Abnormal, Specify"
endorslt_int	Post-Intervention: Results Of Endoscopy	Post-Intervention: Results Of Endoscopy	1="Normal" 2="Abnormal, Specify"
ethnicity	Ethnicity	Ethnicity	"Hispanic or Latino"="Hispanic or Latino" "Not Hispanic or Latino"="Not Hispanic or Latino"
gender	Gender	Gender	"Female Gender"="Female Gender" "Male Gender"="Male Gender"
lastdosedt	Date Of Last Dose	Date Of Last Dose	SAS Date
num10p_bsl	Baseline: Number Of > 10 mm Polyps?	Baseline: Number Of > 10 mm Polyps?	Numeric
num10p_int	Post-Intervention: Number Of > 10 mm Polyps?	Post-Intervention: Number Of > 10 mm Polyps?	Numeric
num24p_bsl	Baseline: Number Of 2-4 mm Polyps?	Baseline: Number Of 2-4 mm Polyps?	Numeric
num24p_int	Post-Intervention: Number Of 2-4 mm Polyps?	Post-Intervention: Number Of 2-4 mm Polyps?	Numeric
num59p_bsl	Baseline: Number Of 5-9 mm Polyps?	Baseline: Number Of 5-9 mm Polyps?	Numeric
num59p_int	Post-Intervention: Number Of 5-9 mm Polyps?	Post-Intervention: Number Of 5-9 mm Polyps?	Numeric
overall_diff	Difference In Overall Mean Cgmp Levels	Difference In Overall Mean Cgmp Levels	Numeric
pe	Evaluable For Primary Endpoint	Evaluable For Primary Endpoint	Numeric
polyprem_bsl	Baseline: (If Any Polyps > 2 mm) Were All Rectal Polyps > 2mm Removed?	Baseline: (If Any Polyps > 2 mm) Were All Rectal Polyps > 2mm Removed?	2="No"
polyprem_int	Post-Intervention: (If Any Polyps > 2 mm) Were All Rectal Polyps > 2mm Removed?	Post-Intervention: (If Any Polyps > 2 mm) Were All Rectal Polyps > 2mm Removed?	1="Yes" 2="No" 3="N/A"
prereg_dt	Pre-Registration Date	Pre-Registration Date	SAS Date
race	Race	Race	"Asian"="Asian" "Black or African American"="Black or African American" "White"="White"
reg_dt	Registration Date	Registration Date	SAS Date
REG_STEP_NUM	Last Registration Step	Last Registration Step	"0"="Pre-Registration" "1"="Registration/Randomization"
SCRN	Does Participant Meet Screening Criteria?	Does Participant Meet Screening Criteria?	"No"="No" "Yes"="Yes"
SCRNDT	Screen Completion Date	Screen Completion Date	SAS Date

Variable	Label	Description	Format Text
SCRNRSN	If No, Which Screening Criteria Not Met?	If No, Which Screening Criteria Not Met?	"Did not meet other eligibility criteria specify"="Did not meet other eligibility criteria specify" "Other specify"="Other specify" "Participant decision specify"="Participant decision specify"
SCRNRSN_SP	If No, Which Screening Criteria Not Met? Specify	If No, Which Screening Criteria Not Met? Specify	"Subject cancelled due to funeral out of state"="Subject cancelled due to funeral out of state" "Subject did not meet lab criteria. Did not repeat."="Subject did not meet lab criteria. Did not repeat." "Trace leuko esterase in urine"="Trace leuko esterase in urine" "cancelled due to flu"="cancelled due to flu" "creatinine repeat elevated"="creatinine repeat elevated" "elevated RBC in urine"="elevated RBC in urine" "elevated bili and creatinine"="elevated bili and creatinine" "scheduling conflict - cancelled due to business trip"="scheduling conflict - cancelled due to business trip" "subject did not show up for screening 2"="subject did not show up for screening 2"