

MAY2012-00-01 - PERSON FILE: DATA DICTIONARY

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05/06/2019

Dataset: mayo_prsn

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Document Summary

Property	Value
Document Title	May2012-00-01 - Person File: Data Dictionary
Date Created	05/06/2019
For Dataset	mayo_prsn
Sections	23
Entries	551
Document Filename	dictionary_May2012-00-01PersonFile.05062019.rtf

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05/06/2019
Dataset: mayo_prsn

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Section 1: Identifiers

Variable	Label	Description	Format Text
arm	Intervention Arm		.N="Not Applicable" 1="Placebo" 2="Linaclotide"
dcntr_id	Data Center ID	Data Center ID	Char
stage	Trial Stage		.N="Not Applicable" 1="(Colonoscopy) Full colonoscopy prep, Linaclotide/Placebo 0.87mg Days 1-7" 2="(Sigmoidoscopy) Full colonoscopy prep, Linaclotide/Placebo 0.87mg Days 1-7" 3="(Sigmoidoscopy) Tap Water Enema prep, Linaclotide/Placebo 0.87mg Days 1-7" 4="(Sigmoidoscopy) Peg Enema prep, Linaclotide/Placebo 0.87mg Days 1-7"

Section 2: Demographics

Variable	Label	Description	Format Text
age	Age		Num
country	Country Code	Country Code _____ _____	Num 1="US" 99="Other"
ethnicity	Ethnicity	Ethnicity (check one)	Num 1="Hispanic" 2="Non-Hispanic" 8="Unknown"
race	Race	Race (check all that apply)	Num 1="White" 3="Black or African American"
sex	Gender	Gender (check one) ____ Male ____ Female ____ Unknown	Num 1="Male" 2="Female"

Section 3: Physical

Variable	Label	Description	Format Text
has_physical_1	Physical Exam Performed?	Overall Physical Exam Performed: (select one) 1=Yes 2=No	Num 1="Yes"
has_physical_2	Physical Exam Performed?	Pulse: __ __ __	Num .F="No Form" 1="Yes"
has_physical_2_2nd	Physical Exam Performed?	Pulse: __ __ __	Num .F="No Form" 0="No" 1="Yes"
physical_1_algspec	Specify Allergies	If Yes, specify (allergies): (200 available characters)	Num .N="Not Applicable" 1="ASA (results in difficulty breathing)" 2="Seafood/Shrimps"
physical_1_allergy	Does Patient have any Allergies?	Does the participant have any allergies? 1=Yes 2=No	Num 0="No" 1="Yes"
physical_1_date	Oral Exam Date	Evaluation Date: (mm/dd/yyyy)	SAS Date
physical_1_dia_press	Diastolic Pressure	Diastolic: __ __ __ (mm Hg)	Num
physical_1_ecg	ECG	ECG Result: (select one) 1=Normal 2=Abnormal - clinically significant 3=Abnormal - not clinically significant	Num 1="Normal" 3="Abnormal - not clinically significant"
physical_1_height	Height	Height (cm) __ __ __ __ __ __ The range for height is 135 to 210. If study participants height is not within this range and has been verified to be correct, Click on the validated button. If "Not Obtained" select the "Not Done" radio button.	Num
physical_1_pulse	Pulse	Pulse: __ __ __	Num
physical_1_sys_press	Systolic Pressure	Blood Pressure: Systolic: __ __ __ (mm Hg)	Num
physical_1_temperature	Temperature Celsius	Body temperature __ __ __. __ __ __ ^0C	Num

Variable	Label	Description	Format Text
physical_1_weight	Weight	Weight (kg) _____._____ The range for weight is 36.3 to 136.1. If study participants weight is not within this range and has been verified to be correct Click on the validated button.	Num .F="No Form" .N="Not Applicable"
physical_2_2nd_algyspec	Specify Allergies	Does the participant have any allergies? 1=Yes 2=No	Num .F="No Form" .N="Not Applicable"
physical_2_2nd_allergy	Does Patient have any Allergies?	Diastolic: ____ (mm Hg)	Num .F="No Form" .M="Missing" .N="Not Applicable" 0="No"
physical_2_2nd_date	Oral Exam Date	Overall Physical Exam Performed: (select one) 1=Yes 2=No	SAS Date .F="No Form" .N="Not Applicable"
physical_2_2nd_diapres	Diastolic Pressure	ECG Result: (select one) 1=Normal 2=Abnormal - clinically significant 3=Abnormal - not clinicallysignificant	Num .F="No Form" .N="Not Applicable"
physical_2_2nd_ecg	ECG	Evaluation Date: (mm/dd/yyyy)	Num .F="No Form" .M="Missing" .N="Not Applicable"
physical_2_2nd_pulse	Pulse	Blood Pressure: Systolic: ____ (mm Hg)	Num .F="No Form" .N="Not Applicable"
physical_2_2nd_syspres	Systolic Pressure	Body temperature ____ ^0C	Num .F="No Form" .N="Not Applicable"
physical_2_2nd_temperature	Temperature Celsius	Weight (kg) _____._____ The range for weight is 36.3 to 136.1. If study participants weight is not within this range and has been verified to be correct Click on the validated button.	Num .F="No Form" .N="Not Applicable"
physical_2_2nd_weight	Weight	Start Date (mm/dd/yyyy)	Num .F="No Form" .N="Not Applicable"
physical_2_algyspec	Specify Allergies	Does the participant have any allergies? 1=Yes 2=No	Num .F="No Form" .N="Not Applicable"
physical_2_allergy	Does Patient have any Allergies?	Diastolic: ____ (mm Hg)	Num .F="No Form" .M="Missing" 0="No"
physical_2_date	Oral Exam Date	Overall Physical Exam Performed: (select one) 1=Yes 2=No	SAS Date .F="No Form"

Variable	Label	Description	Format Text
physical_2_dia_press	Diastolic Pressure	ECG Result: (select one) 1=Normal 2=Abnormal - clinically significant 3=Abnormal - not clinicallysignificant	Num .F="No Form"
physical_2_ecg	ECG	Evaluation Date: (mm/dd/yyyy)	Num .F="No Form" .M="Missing"
physical_2_pulse	Pulse	Blood Pressure: Systolic: __ __ __ (mm Hg)	Num .F="No Form"
physical_2_sys_press	Systolic Pressure	Body temperature __ __ __.' __ __ ^0C	Num .F="No Form"
physical_2_temperature	Temperature Celsius	Weight (kg) __ __ __.' __ __ The range for weight is 36.3 to 136.1. If study participants weight is not within this range and has been verified to be correct Click on the validated button.	Num .F="No Form" .M="Missing"
physical_2_weight	Weight	If Yes, specify (allergies): (200 available characters)	Num .F="No Form"

Section 4: Colon

Variable	Label	Description	Format Text
colo_1_bowel_prep_adeq	Was Bowl Prep Adequate	Was the bowel preparation adequate (check one)	Num .F="No Form" .N="Not Applicable" 0="No" 1="Yes"
colo_1_last_meal_dt	Date of Last Meal	Last Meal: Meal date: (mm/dd/yyyy) __/__/____ ____/____/____	SAS Date .F="No Form" .M="Missing" .N="Not Applicable"
colo_1_last_meal_tm	Time of Last Meal	Last Meal: Meal time: (hh:mm) ____ : ____	Num .F="No Form" .M="Missing" .N="Not Applicable"
colo_1_num_polyps_1	Number of 2-4 mm Polyps	Number of 2-4 mm polyps? (If no polyps were seen enter _0_) ____	Num .F="No Form" .N="Not Applicable" 0="None"
colo_1_num_polyps_2	Number of 5-9 mm Polyps	Number of 5-9 mm polyps? (If no polyps were seen enter _0_) ____	Num .F="No Form" .N="Not Applicable" 0="None"
colo_1_num_polyps_3	Number of >10 mm Polyps	Number of polyps >10 mm? (If no polyps were seen enter _0_) ____	Num .F="No Form" .N="Not Applicable" 0="None"
colo_1_oth_spec	Other Specify	Results of Endoscopy: (check one) 3 Other, specify _____ _____	Char " _= " "
colo_1_remove_polyps	Polyps Removed	(If any polyps >2mm), Were all rectal polyps >2 mm removed? (check one)	Num .F="No Form" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
colo_1_start_tm	Start Time	Start time of endoscopy: (hh:mm) ____ : ____	Num .F="No Form" .M="Missing"
colo_1_stop_tm	Stop Time	Stop time of endoscopy: (hh:mm) ____ : ____	Num .F="No Form" .M="Missing"
colo_2_bowel_prep_adeq	Was Bowl Prep Adequate	Was the bowel preparation adequate (check one)	Num .F="No Form" 1="Yes"
colo_2_last_meal_dt	Date of Last Meal	Last Meal: Meal date: (mm/dd/yyyy) __/__/____ ____/____/____	SAS Date .F="No Form" .M="Missing"

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Variable	Label	Description	Format Text
colo_2_last_meal_tm	Time of Last Meal	Last Meal: Meal time: (hh:mm) ____ : ____	Num .F="No Form" .M="Missing"
colo_2_num_polyps_1	Number of 2-4 mm Polyps	Number of 2-4 mm polyps? (If no polyps were seen enter _0_) ____	Num .F="No Form" 0="None"
colo_2_num_polyps_2	Number of 5-9 mm Polyps	Number of 5-9 mm polyps? (If no polyps were seen enter _0_) ____	Num .F="No Form" 0="None"
colo_2_num_polyps_3	Number of >10 mm Polyps	Number of polyps >10 mm? (If no polyps were seen enter _0_) ____	Num .F="No Form" 0="None"
colo_2_oth_spec	Other Specify	Results of Endoscopy: (check one) 3 Other, specify _____ _____	Char " _ " "
colo_2_remove_polyps	Polyps Removed	(If any polyps >2mm), Were all rectal polyps >2 mm removed? (check one)	Num .F="No Form" .N="Not Applicable" 1="Yes"
colo_2_start_tm	Start Time	Start time of endoscopy: (hh:mm) ____ : ____	Num .F="No Form"
colo_2_stop_tm	Stop Time	Stop time of endoscopy: (hh:mm) ____ : ____	Num .F="No Form"
colonoscopy_1	Colposcopy Done	Endoscopyscopy completed: (check one)	Num .F="No Form" 0="No" 1="Yes"
colonoscopy_1_dt	Evaluation Date	Evaluation Date: (mm/dd/yyyy) ____ / ____ / ____	SAS Date .F="No Form" .N="Not Applicable"
colonoscopy_2	Colposcopy Done	Endoscopyscopy completed: (check one)	Num .F="No Form" 1="Yes"
colonoscopy_2_dt	Evaluation Date	Evaluation Date: (mm/dd/yyyy) ____ / ____ / ____	SAS Date .F="No Form"
colonoscopy_result_1	Result of Colonoscopy	Results of Endoscopy: (check one)	Num .F="No Form" .N="Not Applicable" 1="Normal" 2="Abnormal, specify" 3="Other, specify"
colonoscopy_result_2	Result of Colonoscopy	Results of Endoscopy: (check one)	Num .F="No Form" 1="Normal" 2="Abnormal, specify" 3="Other, specify"

Section 5: Colonbx

Variable	Label	Description	Format Text
colo_1_biop_sample_date_sent_1-3	Date Sent	Date Sent: (mm/dd/yyyy) __ __/_/_/____	SAS Date .F="No Form" .M="Missing"
colo_1_num_biop_sample_1-3	Number of Cecum Biopsy Samples Collected	Number of biopsy samples collected: _____	Num .F="No Form" .M="Missing"
colo_2_biop_sample_date_sent_1-3	Date Sent	Date Sent: (mm/dd/yyyy) __ __/_/_/____	SAS Date .F="No Form" .M="Missing"
colo_2_num_biop_sample_1-3	Number of Cecum Biopsy Samples Collected	Number of biopsy samples collected: _____	Num .F="No Form" .M="Missing"
colo_2_stored_tissue_cond	Tissue Stored Condition	Under what conditions were the specimens stored prior to shipment? (check one)	Num .F="No Form" 1="Stored per protocol"
colo_stored_tissue_cond_1	Tissue Stored Condition	Under what conditions were the specimens stored prior to shipment? (check one)	Num .F="No Form" .M="Missing" 1="Stored per protocol"

Section 6: Conmed

Variable	Label	Description	Format Text
conmed_1_1-5	Concomitant Medication 1	Concomitant agent name	Num .N="Not Applicable" 1="Movi Prep" 2="Movie Prep (PO)" 3="Timolol" 4="Timolol eye drops" 5="Lidocaine" 6="Lidocaine (iv)" 7="Propofol" 8="Propofol (iv)" 9="Propofol (iv) (mcg/kg/min)" 10="Propofol (titrated over case)" 11="Plasmalyte" 12="Plasmalyte (iv)"
conmed_1_cont_1-5	Concurrent Medication 1 continuing?	Continuing 1=Yes 2=No	Num .N="Not Applicable" 0="No" 1="Yes"
conmed_1_dose_1-5	Total Dose 1	Stop Date (mm/dd/yyyy)	SAS Date .N="Not Applicable"
conmed_1_proc_rel_1-5	Procedure related 1	Dose (Enter numeric value only.)	Num .N="Not Applicable" 0="No" 1="Yes"
conmed_1_reas_comment_1-5	Reason Comment 1	Frequency (24 available characters.)	Num .N="Not Applicable" 1="Bowel prep for sigmoidoscopy" 2="Prep for sigmoidoscopy" 3="Bowel prep for colonoscopy" 4="Prep for colonoscopy" 5="Sedation for colonoscopy" 6="Standard care during colonoscopy" 7="Glaucoma" 8="Glaucoma (left eye only)"
conmed_1_schedule_1-5	Drug Schedule 1	Frequency (24 available characters.)	Num .N="Not Applicable" 1="Titrated" 2="Titrated over case" 3="Infusion" 4="Once" 5="Twice" 6="Over Case" 7="BID"
conmed_1_start_dt_1-5	Concurrent Medication 1 start date	Start Date (mm/dd/yyyy)	SAS Date .N="Not Applicable"
conmed_1_stop_dt_1-5	Concurrent Medication 1 Stop Date	Concomitant agent name (1) (40 available characters.)	SAS Date .N="Not Applicable"

Variable	Label	Description	Format Text
conmed_1_units_1-5	Units of Measure 1	Frequency (24 available characters.)	Num .N="Not Applicable" 1="mg" 2="mL" 3="L" 4="Drop"
conmed_2_1-5	Concomitant Medication 1	Concomitant agent name	Num .F="No Form" .N="Not Applicable" 1="Movi Prep" 5="Lidocaine" 7="Propofol" 8="Propofol (iv)" 9="Propofol (iv) (mcg/kg/min)" 11="Plasmalyte" 12="Plasmalyte (iv)"
conmed_2_cont_1-5	Concurrent Medication 1 continuing?	Continuing 1=Yes 2=No	Num .F="No Form" .N="Not Applicable" 0="No"
conmed_2_dose_1-5	Total Dose 1	Stop Date (mm/dd/yyyy)	SAS Date .F="No Form" .N="Not Applicable"
conmed_2_proc_rel_1-5	Procedure related 1	Dose (Enter numeric value only.)	Num .F="No Form" .N="Not Applicable" 0="No" 1="Yes"
conmed_2_reas_comm_1-5	Reason Comment 1	Frequency (24 available characters.)	Num .F="No Form" .N="Not Applicable" 1="Bowel prep for sigmoidoscopy" 2="Prep for sigmoidoscopy" 3="Bowel prep for colonoscopy" 4="Prep for colonoscopy" 5="Sedation for colonoscopy" 6="Standard care during colonoscopy"
conmed_2_schedule_1-5	Drug Schedule 1	Frequency (24 available characters.)	Num .F="No Form" .N="Not Applicable" 1="Titrated" 2="Titrated over case" 3="Infusion" 4="Once" 5="Twice" 7="BID" 8="QD"
conmed_2_start_dt_1-5	Concurrent Medication 1 start date	Start Date (mm/dd/yyyy)	SAS Date .F="No Form" .N="Not Applicable"
conmed_2_stop_dt_1-5	Concurrent Medication 1 Stop Date	Concomitant agent name (1) (40 available characters.)	SAS Date .F="No Form" .N="Not Applicable"

Variable	Label	Description	Format Text
conmed_2_units_1-5	Units of Measure 1	Frequency (24 available characters.)	Num .F="No Form" .N="Not Applicable" 1="mg" 2="mL" 3="L"
conmed_eval_dt_1	Evaluation Date	Dose (Enter numeric value only.)	SAS Date .M="Missing"
conmed_eval_dt_2	Evaluation Date	Dose (Enter numeric value only.)	SAS Date .F="No Form"
conmed_prev_eval_dt_1	Previous Evaluation Date	Evaluation Date: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __	SAS Date .N="Not Applicable"
conmed_prev_eval_dt_2	Previous Evaluation Date	Evaluation Date: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __	SAS Date .F="No Form" .N="Not Applicable"
has_conmed_1	Concurrent Medication	Is the participant taking any concomitant medication? 1=Yes If Yes, enter all medications (including prescription, over-the-counter, alternative medications, vitamins, supplements, type of preparation, administration of sedation medications) 2=No	Num
has_conmed_2	Concurrent Medication	Is the participant taking any concomitant medication? 1=Yes If Yes, enter all medications (including prescription, over-the-counter, alternative medications, vitamins, supplements, type of preparation, administration of sedation medications) 2=No	Num .F="No Form"

Section 7: Crse

Variable	Label	Description	Format Text
progression_dt	Progression Date		SAS Date
registration_dt	Registration Date	Registration Date (date on) (mm/dd/yyyy) __ __/ __ __/ __ __ __ __	SAS Date

Section 8: Drgscrn

Variable	Label	Description	Format Text
drug_screen_1_barbituates_1-2	Barbituate Test Result 1	Barbiturate: (check one)	Num .F="No Form" 2="Negative"
drug_screen_1_benzodiazepine_1-2	Benzodiazepine Test Result 1	Benzodiazepine: (check one)	Num .F="No Form" 2="Negative"
drug_screen_1_cannabinoid_1-2	Cannabinoid Test Result 1	Cannabinoid: (check one)	Num .F="No Form" 1="Positive" 2="Negative"
drug_screen_1_cocaine_1-2	Cocaine Test Result 1	Cocaine: (check one)	Num .F="No Form" 2="Negative"
drug_screen_1_date_1-2	Date Urine Collected 1	Evaluation Date: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __	SAS Date .F="No Form"
drug_screen_1_opiate_1-2	Opiate Test Result 1	Opiate: (check one)	Num .F="No Form" 2="Negative"
drug_screen_2_barbituates	Barbituate Test Result 1	Barbiturate: (check one)	Num .F="No Form" .M="Missing"
drug_screen_2_benzodiazepine	Benzodiazepine Test Result 1	Benzodiazepine: (check one)	Num .F="No Form" .M="Missing"
drug_screen_2_cannabinoid	Cannabinoid Test Result 1	Cannabinoid: (check one)	Num .F="No Form" .M="Missing"
drug_screen_2_cocaine	Cocaine Test Result 1	Cocaine: (check one)	Num .F="No Form" .M="Missing"
drug_screen_2_date	Date Urine Collected 1	Evaluation Date: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __	SAS Date .F="No Form" .M="Missing"
drug_screen_2_opiate	Opiate Test Result 1	Opiate: (check one)	Num .F="No Form" .M="Missing"

Section 9: End_At

Variable	Label	Description	Format Text
end_treatment_dt_1	End Active Treatment	Off Study Date: (mm/dd/yyyy) __ __/__/____	SAS Date .F="No Form"
end_treatment_reason_1	Reason End Treatment	Off Study Reason: (check one)	Num .F="No Form" 8="Other" 22="Participant Withdrawal" 27="Physician Decision" 28="Protocol Violation"
last_dose_dt_1	Last Date Rx Dose	Last date protocol therapy was given: (mm/dd/yyyy) __ __/__/____	SAS Date .F="No Form"

Section 10: Intvlab

Variable	Label	Description	Format Text
blood_lab_1_anc	Absolute Neutrophil Count	Lab Value: Neutrophils (ANC), #, Blood B/L	Num .M="Missing"
blood_lab_1_basophils	Basophils	Lab Value: Basophils, #, Blood B/L	Num .M="Missing"
blood_lab_1_c_sig_anc	Clinically Significant Absolute Neutrophil Count	Clinically Significant: Neutrophils (ANC), #, Blood	Num .M="Missing"
blood_lab_1_c_sig_baso	Clinically Significant Basophils	Clinically Significant: Basophils, #, Blood	Num .M="Missing"
blood_lab_1_c_sig_eosi	Clinically Significant Eosinophils	Clinically Significant: Eosinophils, #, Blood	Num .M="Missing"
blood_lab_1_c_sig_hgb	Clinically Significant Hemoglobin	Clinically Significant: Hemoglobin, Blood	Num
blood_lab_1_c_sig_lymph	Clinically Significant Lymphocyte Count	Clinically Significant: Lymphocytes, #, Blood	Num .M="Missing"
blood_lab_1_c_sig_mono	Clinically Significant Monocytes	Clinically Significant: Monocytes, #, Blood	Num .M="Missing"
blood_lab_1_c_sig_plate	Clinically Significant Platelets	Clinically Significant: Platelets, Blood	Num
blood_lab_1_c_sig_rbc	Clinically Significant Red Blood Cells	Clinically Significant: Red Blood Cells (RBC), #, Blood	Num
blood_lab_1_c_sig_wbc	Clinically Significant White Blood Cells	Clinically Significant: White Blood Cells (WBC), #, Blood	Num
blood_lab_1_date	Hematology Date	Sample collection date: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __	SAS Date
blood_lab_1_eosinophils	Eosinophils	Lab Value: Eosinophils, #, Blood B/L	Num .M="Missing"
blood_lab_1_fasting	Fasting	Fasting(check one)	Num
blood_lab_1_hgb	Hemoglobin	Lab Value: Hemoglobin, Blood g/dL	Num
blood_lab_1_lymphocyte	Lymphocyte Count	Lab Value: Lymphocytes, #, Blood B/L	Num .M="Missing"
blood_lab_1_monocytes	Monocytes	Lab Value: Monocytes, #, Blood B/L	Num .M="Missing"
blood_lab_1_oor_anc	Out of Range Absolute Neutrophil Count	Out of Range: Neutrophils (ANC), #, Blood	Num .M="Missing"
blood_lab_1_oor_baso	Out of Range Basophils	Out of Range: Basophils, #, Blood	Num .M="Missing"
blood_lab_1_oor_eosi	Out of Range Eosinophils	Out of Range: Eosinophils, #, Blood	Num .M="Missing"
blood_lab_1_oor_hgb	Out of Range Hemoglobin	Out of Range: Hemoglobin, Blood	Num

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Variable	Label	Description	Format Text
blood_lab_1_oor_lymph	Out of Range Lymphocyte Count	Out of Range: Lymphocytes, #, Blood	Num .M="Missing"
blood_lab_1_oor_mono	Out of Range Monocytes	Out of Range: Monocytes, #, Blood	Num .M="Missing"
blood_lab_1_oor_plate	Out of Range Platelets	Out of Range: Platelets, Blood	Num
blood_lab_1_oor_rbc	Out of Range Red Blood Cells	Out of Range: Red Blood Cells (RBC), #, Blood	Num
blood_lab_1_oor_wbc	Out of Range White Blood Cells	Out of Range: White Blood Cells (WBC), #, Blood	Num
blood_lab_1_platelets	Platelets	Lab Value: Platelets, Blood B/L	Num
blood_lab_1_rbc	Red Blood Cells	Lab Value: Red Blood Cells (RBC), #, Blood T/L	Num
blood_lab_1_wbc	White Blood Cells	Lab Value: White Blood Cells (WBC), #, Blood B/L	Num
blood_lab_2_2nd ANC	Absolute Neutrophil Count	Lab Value: Neutrophils (ANC), #, Blood B/L	Num .F="No Form"
blood_lab_2_2nd_basophils	Basophils	Lab Value: Basophils, #, Blood B/L	Num .F="No Form"
blood_lab_2_2nd_c_sig ANC	Clinically Significant Absolute Neutrophil Count	Clinically Significant: Neutrophils (ANC), #, Blood	Num .F="No Form"
blood_lab_2_2nd_c_sig baso	Clinically Significant Basophils	Clinically Significant: Basophils, #, Blood	Num .F="No Form"
blood_lab_2_2nd_c_sig eosi	Clinically Significant Eosinophils	Clinically Significant: Eosinophils, #, Blood	Num .F="No Form"
blood_lab_2_2nd_c_sig hgb	Clinically Significant Hemoglobin	Clinically Significant: Hemoglobin, Blood	Num .F="No Form"
blood_lab_2_2nd_c_sig lymph	Clinically Significant Lymphocyte Count	Clinically Significant: Lymphocytes, #, Blood	Num .F="No Form"
blood_lab_2_2nd_c_sig mono	Clinically Significant Monocytes	Clinically Significant: Monocytes, #, Blood	Num .F="No Form"
blood_lab_2_2nd_c_sig plate	Clinically Significant Platelets	Clinically Significant: Platelets, Blood	Num .F="No Form"
blood_lab_2_2nd_c_sig rbc	Clinically Significant Red Blood Cells	Clinically Significant: Red Blood Cells (RBC), #, Blood	Num .F="No Form"
blood_lab_2_2nd_c_sig wbc	Clinically Significant White Blood Cells	Clinically Significant: White Blood Cells (WBC), #, Blood	Num .F="No Form"
blood_lab_2_2nd_date	Hematology Date	Sample collection date: (mm/dd/yyyy) ____ / ____ / ____	SAS Date .F="No Form"
blood_lab_2_2nd_eosinophils	Eosinophils	Lab Value: Eosinophils, #, Blood B/L	Num .F="No Form"
blood_lab_2_2nd_fasting	Fasting	Fasting(check one)	Num .F="No Form"
blood_lab_2_2nd_hgb	Hemoglobin	Lab Value: Hemoglobin, Blood g/dL	Num .F="No Form"

Variable	Label	Description	Format Text
blood_lab_2_2nd_lymphocyte	Lymphocyte Count	Lab Value: Lymphocytes, #, Blood B/L	Num .F="No Form"
blood_lab_2_2nd_monocytes	Monocytes	Lab Value: Monocytes, #, Blood B/L	Num .F="No Form"
blood_lab_2_2nd_or_anc	Out of Range Absolute Neutrophil Count	Out of Range: Neutrophils (ANC), #, Blood	Num .F="No Form"
blood_lab_2_2nd_or_baso	Out of Range Basophils	Out of Range: Basophils, #, Blood	Num .F="No Form"
blood_lab_2_2nd_or_eosi	Out of Range Eosinophils	Out of Range: Eosinophils, #, Blood	Num .F="No Form"
blood_lab_2_2nd_or_hgb	Out of Range Hemoglobin	Out of Range: Hemoglobin, Blood	Num .F="No Form"
blood_lab_2_2nd_or_lymph	Out of Range Lymphocyte Count	Out of Range: Lymphocytes, #, Blood	Num .F="No Form"
blood_lab_2_2nd_or_mono	Out of Range Monocytes	Out of Range: Monocytes, #, Blood	Num .F="No Form"
blood_lab_2_2nd_or_plate	Out of Range Platelets	Out of Range: Platelets, Blood	Num .F="No Form"
blood_lab_2_2nd_or_rbc	Out of Range Red Blood Cells	Out of Range: Red Blood Cells (RBC), #, Blood	Num .F="No Form"
blood_lab_2_2nd_or_wbc	Out of Range White Blood Cells	Out of Range: White Blood Cells (WBC), #, Blood	Num .F="No Form"
blood_lab_2_2nd_platelets	Platelets	Lab Value: Platelets, Blood B/L	Num .F="No Form"
blood_lab_2_2nd_rbc	Red Blood Cells	Lab Value: Red Blood Cells (RBC), #, Blood T/L	Num .F="No Form"
blood_lab_2_2nd_wbc	White Blood Cells	Lab Value: White Blood Cells (WBC), #, Blood B/L	Num .F="No Form"
blood_lab_2_anc	Absolute Neutrophil Count	Lab Value: Neutrophils (ANC), #, Blood B/L	Num .F="No Form" .M="Missing"
blood_lab_2_basophils	Basophils	Lab Value: Basophils, #, Blood B/L	Num .F="No Form" .M="Missing"
blood_lab_2_c_sig_anc	Clinically Significant Absolute Neutrophil Count	Clinically Significant: Neutrophils (ANC), #, Blood	Num .F="No Form" .M="Missing"
blood_lab_2_c_sig_baso	Clinically Significant Basophils	Clinically Significant: Basophils, #, Blood	Num .F="No Form" .M="Missing"
blood_lab_2_c_sig_eosi	Clinically Significant Eosinophils	Clinically Significant: Eosinophils, #, Blood	Num .F="No Form" .M="Missing"
blood_lab_2_c_sig_hgb	Clinically Significant Hemoglobin	Clinically Significant: Hemoglobin, Blood	Num .F="No Form"
blood_lab_2_c_sig_lymph	Clinically Significant Lymphocyte Count	Clinically Significant: Lymphocytes, #, Blood	Num .F="No Form" .M="Missing"

Variable	Label	Description	Format Text
blood_lab_2_c_sig_mono	Clinically Significant Monocytes	Clinically Significant: Monocytes, #, Blood	Num .F="No Form" .M="Missing"
blood_lab_2_c_sig_plate	Clinically Significant Platelets	Clinically Significant: Platelets, Blood	Num .F="No Form"
blood_lab_2_c_sig_rbc	Clinically Significant Red Blood Cells	Clinically Significant: Red Blood Cells (RBC), #, Blood	Num .F="No Form"
blood_lab_2_c_sig_wbc	Clinically Significant White Blood Cells	Clinically Significant: White Blood Cells (WBC), #, Blood	Num .F="No Form"
blood_lab_2_date	Hematology Date	Sample collection date: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __	SAS Date .F="No Form"
blood_lab_2_eosino phils	Eosinophils	Lab Value: Eosinophils, #, Blood B/L	Num .F="No Form" .M="Missing"
blood_lab_2_fasting	Fasting	Fasting(check one)	Num .F="No Form"
blood_lab_2_hgb	Hemoglobin	Lab Value: Hemoglobin, Blood g/dL	Num .F="No Form"
blood_lab_2_lymphocyte	Lymphocyte Count	Lab Value: Lymphocytes, #, Blood B/L	Num .F="No Form" .M="Missing"
blood_lab_2_monocytes	Monocytes	Lab Value: Monocytes, #, Blood B/L	Num .F="No Form" .M="Missing"
blood_lab_2_oor_anc	Out of Range Absolute Neutrophil Count	Out of Range: Neutrophils (ANC), #, Blood	Num .F="No Form" .M="Missing"
blood_lab_2_oor_baso	Out of Range Basophils	Out of Range: Basophils, #, Blood	Num .F="No Form" .M="Missing"
blood_lab_2_oor_eosi	Out of Range Eosinophils	Out of Range: Eosinophils, #, Blood	Num .F="No Form" .M="Missing"
blood_lab_2_oor_hgb	Out of Range Hemoglobin	Out of Range: Hemoglobin, Blood	Num .F="No Form"
blood_lab_2_oor_lymph	Out of Range Lymphocyte Count	Out of Range: Lymphocytes, #, Blood	Num .F="No Form" .M="Missing"
blood_lab_2_oor_mono	Out of Range Monocytes	Out of Range: Monocytes, #, Blood	Num .F="No Form" .M="Missing"
blood_lab_2_oor_plate	Out of Range Platelets	Out of Range: Platelets, Blood	Num .F="No Form"
blood_lab_2_oor_rbc	Out of Range Red Blood Cells	Out of Range: Red Blood Cells (RBC), #, Blood	Num .F="No Form"
blood_lab_2_oor_wbc	Out of Range White Blood Cells	Out of Range: White Blood Cells (WBC), #, Blood	Num .F="No Form"
blood_lab_2_platelets	Platelets	Lab Value: Platelets, Blood B/L	Num .F="No Form"

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Variable	Label	Description	Format Text
blood_lab_2_rbc	Red Blood Cells	Lab Value: Red Blood Cells (RBC), #, Blood T/L	Num .F="No Form"
blood_lab_2_wbc	White Blood Cells	Lab Value: White Blood Cells (WBC), #, Blood B/L	Num .F="No Form"

Section 11: Labform

Variable	Label	Description	Format Text
blood_chem_1_alkaline_phos	Alkaline Phosphatase	Lab Value: Alkaline Phosphatase, serum IU/L	Num
blood_chem_1_alt	Alanine Aminotransferase (ALT/SGPT)	Lab Value: Alanine Aminotransferase (ALT/SGPT), serum IU/L	Num
blood_chem_1_ast	Aspartate Aminotransferase (AST/SGOT)	Lab Value: Aspartate Aminotransferase (AST/SGOT), serum IU/L	Num
blood_chem_1_bilirubin	Bilirubin	Lab Value: Bilirubin, Total mg/dL	Num .M="Missing"
blood_chem_1_bun	Blood Urea Nitrogen (BUN)	Lab Value: Blood Urea Nitrogen (BUN), serum mg/dL	Num
blood_chem_1_c_sig_albumin	Clinically Significant Albumin	Clinically Significant: Albumin, serum	Num 0="No"
blood_chem_1_c_sig_alt	Clinically Significant Alanine Aminotransferase (ALT/SGPT)	Clinically Significant: Alanine Aminotransferase (ALT/SGPT), serum	Num 0="No"
blood_chem_1_c_sig_ast	Clinically Significant Aspartate Aminotransferase (AST/SGOT)	Clinically Significant: Aspartate Aminotransferase (AST/SGOT), serum	Num 0="No"
blood_chem_1_c_sig_bilir	Clinically Significant Bilirubin	Clinically Significant: Bilirubin, Total	Num 0="No"
blood_chem_1_c_sig_bun	Clinically Significant Blood Urea Nitrogen (BUN)	Clinically Significant: Blood Urea Nitrogen (BUN), serum	Num 0="No"
blood_chem_1_c_sig_calc	Clinically Significant Calcium	Clinically Significant: Calcium, serum	Num 0="No"
blood_chem_1_c_sig_chloride	Clinically Significant Chloride	Clinically Significant: Chloride, serum	Num 0="No"
blood_chem_1_c_sig_creat	Clinically Significant Creatinine	Clinically Significant: Creatinine, serum	Num 0="No"
blood_chem_1_c_sig_fsh	Clinically Significant FSH _SCG/FSH	Clinically Significant: FSH _SCG/FSH (if subjects male select NA)	Num .M="Missing" 0="No"
blood_chem_1_c_sig_glucose	Clinically Significant Glucose	Clinically Significant: Glucose, plasma	Num 0="No"
blood_chem_1_c_sig_hcg	Clinically Significant Human Chorionic Gonadotropin (HCG)	Clinically Significant: Human Chorionic Gonadotropin (HCG) (if applicable)	Num .M="Missing" 0="No"
blood_chem_1_c_sig_inr	Clinically Significant INR	Clinically Significant: INR	Num 0="No"

Variable	Label	Description	Format Text
blood_chem_1_c_sig_phos	Clinically Significant Alkaline Phosphatase	Clinically Significant: Alkaline Phosphatase, serum	Num 0="No"
blood_chem_1_c_sig_potass	Clinically Significant Potassium	Clinically Significant: Potassium, serum	Num 0="No"
blood_chem_1_c_sig_proth	Clinically Significant Prothrombin Time	Clinically Significant: Prothrombin Time, Blood	Num 0="No"
blood_chem_1_c_sig_ptt	Clinically Significant Partial Prothromboplastin Time (PTT)	Clinically Significant: Partial Prothromboplastin Time (PTT), Blood	Num 0="No"
blood_chem_1_c_sig_sodium	Clinically Significant Sodium	Clinically Significant: Sodium, serum	Num 0="No"
blood_chem_1_calcium	Calcium	Lab Value: Calcium, serum mg/dL	Num
blood_chem_1_chloride	Chloride	Lab Value: Chloride, serum mmol/L	Num
blood_chem_1_creatinine	Creatinine Value	Lab Value: Creatinine, serum mg/dL	Num
blood_chem_1_date	Blood Chem Date	Sample collection date: (mm/dd/yyyy) __/__/__ __/__/__	SAS Date
blood_chem_1_fasting	Fasting	Fasting: (check one)	Num 1="Yes"
blood_chem_1_fsh	FSH _ SCG/FSH	Lab Value: FSH _ SCG/FSH (if subjects male select NA) IU/L	Num .M="Missing"
blood_chem_1_glucose	Glucose	Lab Value: Glucose, plasma mg/dL	Num
blood_chem_1_hcg	Human Chorionic Gonadotropin (HCG)	Lab Value: Human Chorionic Gonadotropin (HCG) (if applicable) IU/L	Num .M="Missing"
blood_chem_1_inr	INR	Lab Value: INR seconds	Num
blood_chem_1_lab_ptt	Partial Prothromboplastin Time (PTT)	Lab Value: Partial Prothromboplastin Time (PTT), Blood Seconds	Num
blood_chem_1_nav1	Navigational Question 1		Num .M="Missing"
blood_chem_1_oor_albumin	Out of Range Albumin	Out of Range: Albumin, serum	Num 0="No" 1="Yes"
blood_chem_1_oor_alt	Out of Range Alanine Aminotransferase (ALT/SGPT)	Out of Range: Alanine Aminotransferase (ALT/SGPT), serum	Num 0="No" 1="Yes"
blood_chem_1_oor_ast	Out of Range Aspartate Aminotransferase (AST/SGOT)	Out of Range: Aspartate Aminotransferase (AST/SGOT), serum	Num 0="No" 1="Yes"
blood_chem_1_oor_bilir	Out of Range Bilirubin	Out of Range: Bilirubin, Total	Num 0="No" 1="Yes"

Variable	Label	Description	Format Text
blood_chem_1_oor_bun	Out of Range Blood Urea Nitrogen (BUN)	Out of Range: Blood Urea Nitrogen (BUN), serum	Num 0="No" 1="Yes"
blood_chem_1_oor_calc	Out of Range Calcium	Out of Range: Calcium, serum	Num 0="No" 1="Yes"
blood_chem_1_oor_chloride	Out of Range Chloride	Out of Range: Chloride, serum	Num 0="No"
blood_chem_1_oor_creat	Out of Range Creatinine	Out of Range: Creatinine, serum	Num 0="No" 1="Yes"
blood_chem_1_oor_fsh	Out of Range FSH _SCG/FSH	Out of Range: FSH _SCG/FSH (if subjects male select NA)	Num .M="Missing" 0="No"
blood_chem_1_oor_glucose	Out of Range Glucose	Out of Range: Glucose, plasma	Num 0="No" 1="Yes"
blood_chem_1_oor_hcg	Out of Range Human Chorionic Gonadotropin (HCG)	Out of Range: Human Chorionic Gonadotropin (HCG) (if applicable)	Num .M="Missing" 0="No"
blood_chem_1_oor_inr	Out of Range INR	Out of Range: INR	Num 0="No"
blood_chem_1_oor_phos	Out of Range Alkaline Phosphatase	Out of Range: Alkaline Phosphatase, serum	Num 0="No" 1="Yes"
blood_chem_1_oor_potass	Out of Range Potassium	Out of Range: Potassium, serum	Num 0="No" 1="Yes"
blood_chem_1_oor_proth	Out of Range Prothrombin Time	Out of Range: Prothrombin Time, Blood	Num 0="No"
blood_chem_1_oor_ptt	Out of Range Partial Prothromboplastin Time (PTT)	Out of Range: Partial Prothromboplastin Time (PTT), Blood	Num 0="No" 1="Yes"
blood_chem_1_oor_sodium	Out of Range Sodium	Out of Range: Sodium, serum	Num 0="No" 1="Yes"
blood_chem_1_potassium	Potassium	Lab Value: Potassium, serum mmol/L	Num
blood_chem_1_prothrombin	Prothrombin Time	Lab Value: Prothrombin Time, Blood Seconds	Num
blood_chem_1_serum_albumin	Albumin	Lab Value: Albumin, serum g/dL	Num
blood_chem_1_sodium	Sodium	Lab Value: Sodium, serum mmol/L	Num
blood_chem_2_2nd_alkaline_phos	Alkaline Phosphatase	Lab Value: Alkaline Phosphatase, serum IU/L	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_alt	Alanine Aminotransferase (ALT/SGPT)	Lab Value: Alanine Aminotransferase (ALT/SGPT), serum IU/L	Num .F="No Form" .N="Not Applicable"

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Variable	Label	Description	Format Text
blood_chem_2_2nd_ast	Aspartate Aminotransferase (AST/SGOT)	Lab Value: Aspartate Aminotransferase (AST/SGOT), serum IU/L	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_bilirubin	Bilirubin	Lab Value: Bilirubin, Total mg/dL	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_bun	Blood Urea Nitrogen (BUN)	Lab Value: Blood Urea Nitrogen (BUN), serum mg/dL	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_c_sig_albumin	Clinically Significant Albumin	Clinically Significant: Albumin, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_alt	Clinically Significant Alanine Aminotransferase (ALT/SGPT)	Clinically Significant: Alanine Aminotransferase (ALT/SGPT), serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_ast	Clinically Significant Aspartate Aminotransferase (AST/SGOT)	Clinically Significant: Aspartate Aminotransferase (AST/SGOT), serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_bilir	Clinically Significant Bilirubin	Clinically Significant: Bilirubin, Total	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_bun	Clinically Significant Blood Urea Nitrogen (BUN)	Clinically Significant: Blood Urea Nitrogen (BUN), serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_calc	Clinically Significant Calcium	Clinically Significant: Calcium, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_chloride	Clinically Significant Chloride	Clinically Significant: Chloride, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_creat	Clinically Significant Creatinine	Clinically Significant: Creatinine, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_fsh	Clinically Significant FSH _SCG/FSH	Clinically Significant: FSH _SCG/FSH (if subjects male select NA)	Num .F="No Form" .M="Missing" .N="Not Applicable"
blood_chem_2_2nd_c_sig_glucose	Clinically Significant Glucose	Clinically Significant: Glucose, plasma	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_hcg	Clinically Significant Human Chorionic Gonadotropin (HCG)	Clinically Significant: Human Chorionic Gonadotropin (HCG) (if applicable)	Num .F="No Form" .M="Missing" .N="Not Applicable"

Variable	Label	Description	Format Text
blood_chem_2_2nd_c_sig_inr	Clinically Significant INR	Clinically Significant: INR	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_phos	Clinically Significant Alkaline Phosphatase	Clinically Significant: Alkaline Phosphatase, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_potass	Clinically Significant Potassium	Clinically Significant: Potassium, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_proth	Clinically Significant Prothrombin Time	Clinically Significant: Prothrombin Time, Blood	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_ptt	Clinically Significant Partial Prothromboplastin Time (PTT)	Clinically Significant: Partial Prothromboplastin Time (PTT), Blood	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_c_sig_sodium	Clinically Significant Sodium	Clinically Significant: Sodium, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_calcium	Calcium	Lab Value: Calcium, serum mg/dL	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_chloride	Chloride	Lab Value: Chloride, serum mmol/L	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_creatinine	Creatinine Value	Lab Value: Creatinine, serum mg/dL	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_date	Blood Chem Date	Sample collection date: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __	SAS Date .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_fasting	Fasting	Fasting: (check one)	Num .F="No Form" .N="Not Applicable" 1="Yes"
blood_chem_2_2nd_fsh	FSH _ SCG/FSH	Lab Value: FSH _ SCG/FSH (if subjects male select NA) IU/L	Num .F="No Form" .M="Missing" .N="Not Applicable"
blood_chem_2_2nd_glucose	Glucose	Lab Value: Glucose, plasma mg/dL	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_hcg	Human Chorionic Gonadotropin (HCG)	Lab Value: Human Chorionic Gonadotropin (HCG) (if applicable) IU/L	Num .F="No Form" .M="Missing" .N="Not Applicable"

Variable	Label	Description	Format Text
blood_chem_2_2nd_inr	INR	Lab Value: INR seconds	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_lab_ptt	Partial Prothromboplastin Time (PTT)	Lab Value: Partial Prothromboplastin Time (PTT), Blood Seconds	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_nav1	Navigational Question 1		Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_oor_albumin	Out of Range Albumin	Out of Range: Albumin, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_alt	Out of Range Alanine Aminotransferase (ALT/SGPT)	Out of Range: Alanine Aminotransferase (ALT/SGPT), serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_ast	Out of Range Aspartate Aminotransferase (AST/SGOT)	Out of Range: Aspartate Aminotransferase (AST/SGOT), serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_bilir	Out of Range Bilirubin	Out of Range: Bilirubin, Total	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_bun	Out of Range Blood Urea Nitrogen (BUN)	Out of Range: Blood Urea Nitrogen (BUN), serum	Num .F="No Form" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_2_2nd_oor_calc	Out of Range Calcium	Out of Range: Calcium, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_chloride	Out of Range Chloride	Out of Range: Chloride, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_creat	Out of Range Creatinine	Out of Range: Creatinine, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_fsh	Out of Range FSH _ SCG/FSH	Out of Range: FSH _ SCG/FSH (if subjects male select NA)	Num .F="No Form" .M="Missing" .N="Not Applicable"
blood_chem_2_2nd_oor_glucose	Out of Range Glucose	Out of Range: Glucose, plasma	Num .F="No Form" .N="Not Applicable" 0="No"

Variable	Label	Description	Format Text
blood_chem_2_2nd_oor_hcg	Out of Range Human Chorionic Gonadotropin (HCG)	Out of Range: Human Chorionic Gonadotropin (HCG) (if applicable)	Num .F="No Form" .M="Missing" .N="Not Applicable"
blood_chem_2_2nd_oor_inr	Out of Range INR	Out of Range: INR	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_phos	Out of Range Alkaline Phosphatase	Out of Range: Alkaline Phosphatase, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_potass	Out of Range Potassium	Out of Range: Potassium, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_proth	Out of Range Prothrombin Time	Out of Range: Prothrombin Time, Blood	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_ptt	Out of Range Partial Prothromboplastin Time (PTT)	Out of Range: Partial Prothromboplastin Time (PTT), Blood	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_oor_sodium	Out of Range Sodium	Out of Range: Sodium, serum	Num .F="No Form" .N="Not Applicable" 0="No"
blood_chem_2_2nd_potassium	Potassium	Lab Value: Potassium, serum mmol/L	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_prothrombin	Prothrombin Time	Lab Value: Prothrombin Time, Blood Seconds	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_serum_albumin	Albumin	Lab Value: Albumin, serum g/dL	Num .F="No Form" .N="Not Applicable"
blood_chem_2_2nd_sodium	Sodium	Lab Value: Sodium, serum mmol/L	Num .F="No Form" .N="Not Applicable"
blood_chem_2_alkaline_phos	Alkaline Phosphatase	Lab Value: Alkaline Phosphatase, serum IU/L	Num .F="No Form"
blood_chem_2_alt	Alanine Aminotransferase (ALT/SGPT)	Lab Value: Alanine Aminotransferase (ALT/SGPT), serum IU/L	Num .F="No Form"
blood_chem_2_ast	Aspartate Aminotransferase (AST/SGOT)	Lab Value: Aspartate Aminotransferase (AST/SGOT), serum IU/L	Num .F="No Form"
blood_chem_2_bilirubin	Bilirubin	Lab Value: Bilirubin, Total mg/dL	Num .F="No Form"

Variable	Label	Description	Format Text
blood_chem_2_bun	Blood Urea Nitrogen (BUN)	Lab Value: Blood Urea Nitrogen (BUN), serum mg/dL	Num .F="No Form" 0="No"
blood_chem_2_c_sig_albumin	Clinically Significant Albumin	Clinically Significant: Albumin, serum	Num .F="No Form" 0="No"
blood_chem_2_c_sig_alt	Clinically Significant Alanine Aminotransferase (ALT/SGPT)	Clinically Significant: Alanine Aminotransferase (ALT/SGPT), serum	Num .F="No Form" 0="No"
blood_chem_2_c_sig_ast	Clinically Significant Aspartate Aminotransferase (AST/SGOT)	Clinically Significant: Aspartate Aminotransferase (AST/SGOT), serum	Num .F="No Form" 0="No"
blood_chem_2_c_sig_bilir	Clinically Significant Bilirubin	Clinically Significant: Bilirubin, Total	Num .F="No Form" 0="No"
blood_chem_2_c_sig_bun	Clinically Significant Blood Urea Nitrogen (BUN)	Clinically Significant: Blood Urea Nitrogen (BUN), serum	Num .F="No Form" 0="No"
blood_chem_2_c_sig_calc	Clinically Significant Calcium	Clinically Significant: Calcium, serum	Num .F="No Form" 0="No"
blood_chem_2_c_sig_chloride	Clinically Significant Chloride	Clinically Significant: Chloride, serum	Num .F="No Form" 0="No"
blood_chem_2_c_sig_creat	Clinically Significant Creatinine	Clinically Significant: Creatinine, serum	Num .F="No Form" 0="No"
blood_chem_2_c_sig_fsh	Clinically Significant FSH _ SCG/FSH	Clinically Significant: FSH _ SCG/FSH (if subjects male select NA)	Num .F="No Form" .M="Missing"
blood_chem_2_c_sig_glucose	Clinically Significant Glucose	Clinically Significant: Glucose, plasma	Num .F="No Form" 0="No"
blood_chem_2_c_sig_hcg	Clinically Significant Human Chorionic Gonadotropin (HCG)	Clinically Significant: Human Chorionic Gonadotropin (HCG) (if applicable)	Num .F="No Form" .M="Missing"
blood_chem_2_c_sig_inr	Clinically Significant INR	Clinically Significant: INR	Num .F="No Form" 0="No"
blood_chem_2_c_sig_phos	Clinically Significant Alkaline Phosphatase	Clinically Significant: Alkaline Phosphatase, serum	Num .F="No Form" 0="No"
blood_chem_2_c_sig_potass	Clinically Significant Potassium	Clinically Significant: Potassium, serum	Num .F="No Form" 0="No"
blood_chem_2_c_sig_proth	Clinically Significant Prothrombin Time	Clinically Significant: Prothrombin Time, Blood	Num .F="No Form" 0="No"

Variable	Label	Description	Format Text
blood_chem_2_c_sig_ptt	Clinically Significant Partial Prothromboplastin Time (PTT)	Clinically Significant: Partial Prothromboplastin Time (PTT), Blood	Num .F="No Form" 0="No"
blood_chem_2_c_sig_sodium	Clinically Significant Sodium	Clinically Significant: Sodium, serum	Num .F="No Form" 0="No"
blood_chem_2_calcium	Calcium	Lab Value: Calcium, serum mg/dL	Num .F="No Form"
blood_chem_2_chloride	Chloride	Lab Value: Chloride, serum mmol/L	Num .F="No Form"
blood_chem_2_creatinine	Creatinine Value	Lab Value: Creatinine, serum mg/dL	Num .F="No Form"
blood_chem_2_date	Blood Chem Date	Sample collection date: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __	SAS Date .F="No Form"
blood_chem_2_fasting	Fasting	Fasting: (check one)	Num .F="No Form" 0="No" 1="Yes"
blood_chem_2_fsh	FSH _ SCG/FSH	Lab Value: FSH _ SCG/FSH (if subjects male select NA) IU/L	Num .F="No Form" .M="Missing"
blood_chem_2_glucose	Glucose	Lab Value: Glucose, plasma mg/dL	Num .F="No Form"
blood_chem_2_hcg	Human Chorionic Gonadotropin (HCG)	Lab Value: Human Chorionic Gonadotropin (HCG) (if applicable) IU/L	Num .F="No Form" .M="Missing"
blood_chem_2_inr	INR	Lab Value: INR seconds	Num .F="No Form"
blood_chem_2_lab_ptt	Partial Prothromboplastin Time (PTT)	Lab Value: Partial Prothromboplastin Time (PTT), Blood Seconds	Num .F="No Form"
blood_chem_2_nav1	Navigational Question 1		Num .F="No Form" .M="Missing"
blood_chem_2_oor_albumin	Out of Range Albumin	Out of Range: Albumin, serum	Num .F="No Form" 0="No"
blood_chem_2_oor_alt	Out of Range Alanine Aminotransferase (ALT/SGPT)	Out of Range: Alanine Aminotransferase (ALT/SGPT), serum	Num .F="No Form" 0="No"
blood_chem_2_oor_ast	Out of Range Aspartate Aminotransferase (AST/SGOT)	Out of Range: Aspartate Aminotransferase (AST/SGOT), serum	Num .F="No Form" 0="No"
blood_chem_2_oor_bilir	Out of Range Bilirubin	Out of Range: Bilirubin, Total	Num .F="No Form" 0="No"
blood_chem_2_oor_bun	Out of Range Blood Urea Nitrogen (BUN)	Out of Range: Blood Urea Nitrogen (BUN), serum	Num .F="No Form" 0="No" 1="Yes"

May2012-00-01 - Person File: Data Dictionary

05/06/2019

Dataset: mayo_prsn

Variable	Label	Description	Format Text
blood_chem_2_oor_calc	Out of Range Calcium	Out of Range: Calcium, serum	Num .F="No Form" 0="No"
blood_chem_2_oor_chloride	Out of Range Chloride	Out of Range: Chloride, serum	Num .F="No Form" 0="No"
blood_chem_2_oor_creat	Out of Range Creatinine	Out of Range: Creatinine, serum	Num .F="No Form" 0="No" 1="Yes"
blood_chem_2_oor_fsh	Out of Range FSH _ SCG/FSH	Out of Range: FSH _ SCG/FSH (if subjects male select NA)	Num .F="No Form" .M="Missing"
blood_chem_2_oor_glucose	Out of Range Glucose	Out of Range: Glucose, plasma	Num .F="No Form" 0="No" 1="Yes"
blood_chem_2_oor_hcg	Out of Range Human Chorionic Gonadotropin (HCG)	Out of Range: Human Chorionic Gonadotropin (HCG) (if applicable)	Num .F="No Form" .M="Missing"
blood_chem_2_oor_inr	Out of Range INR	Out of Range: INR	Num .F="No Form" 0="No"
blood_chem_2_oor_phos	Out of Range Alkaline Phosphatase	Out of Range: Alkaline Phosphatase, serum	Num .F="No Form" 0="No"
blood_chem_2_oor_potass	Out of Range Potassium	Out of Range: Potassium, serum	Num .F="No Form" 0="No"
blood_chem_2_oor_proth	Out of Range Prothrombin Time	Out of Range: Prothrombin Time, Blood	Num .F="No Form" 0="No"
blood_chem_2_oor_ptt	Out of Range Partial Prothromboplastin Time (PTT)	Out of Range: Partial Prothromboplastin Time (PTT), Blood	Num .F="No Form" 0="No"
blood_chem_2_oor_sodium	Out of Range Sodium	Out of Range: Sodium, serum	Num .F="No Form" 0="No" 1="Yes"
blood_chem_2_potassium	Potassium	Lab Value: Potassium, serum mmol/L	Num .F="No Form"
blood_chem_2_prothrombin	Prothrombin Time	Lab Value: Prothrombin Time, Blood Seconds	Num .F="No Form"
blood_chem_2_serum_albumin	Albumin	Lab Value: Albumin, serum g/dL	Num .F="No Form"
blood_chem_2_sodium	Sodium	Lab Value: Sodium, serum mmol/L	Num .F="No Form"

Section 12: Laburine

Variable	Label	Description	Format Text
lab_urine_1_date	Date Urine Collected	Sample collection date: (mm/dd/yyyy) __ __/__ __/____	SAS Date
lab_urine_1_glucose	Glucose Spot Urine	Glucose, spot urine	Num 2="Negative"
lab_urine_1_ketones	Ketones Spot Urine	Ketones, spot urine	Num 1="Positive" 2="Negative"
lab_urine_1_pH	pH Spot Urine	pH, spot urine	Num .M="Missing"
lab_urine_1_protein	Protein Qualitative Urine	Protein, qualitative, urine	Num 1="Positive" 2="Negative"
lab_urine_1_redbc	Red Blood Cells	Red Blood Cells (RBC)	Num 2="Negative"
lab_urine_1_specific_gravity	Specific Gravity, Spot Urine	Specific gravity, spot urine	Num .M="Missing"
lab_urine_2_2nd_date	Date Urine Collected	Sample collection date: (mm/dd/yyyy) __ __/__ __/____	SAS Date .F="No Form" .N="Not Applicable"
lab_urine_2_2nd_glucose	Glucose Spot Urine	Glucose, spot urine	Num .F="No Form" .N="Not Applicable" 2="Negative"
lab_urine_2_2nd_ketones	Ketones Spot Urine	Ketones, spot urine	Num .F="No Form" .N="Not Applicable" 1="Positive" 2="Negative"
lab_urine_2_2nd_pH	pH Spot Urine	pH, spot urine	Num .F="No Form" .M="Missing" .N="Not Applicable"
lab_urine_2_2nd_protein	Protein Qualitative Urine	Protein, qualitative, urine	Num .F="No Form" .M="Missing" .N="Not Applicable" 1="Positive" 2="Negative"
lab_urine_2_2nd_redbc	Red Blood Cells	Red Blood Cells (RBC)	Num .F="No Form" .N="Not Applicable" 1="Positive" 2="Negative"

Variable	Label	Description	Format Text
lab_urine_2_2nd_specific_gravity	Specific Gravity, Spot Urine	Specific gravity, spot urine	Num .F="No Form" .M="Missing" .N="Not Applicable"
lab_urine_2_date	Date Urine Collected	Sample collection date: (mm/dd/yyyy) __ __/__/____	SAS Date .F="No Form"
lab_urine_2_glucose	Glucose Spot Urine	Glucose, spot urine	Num .F="No Form" 2="Negative"
lab_urine_2_ketones	Ketones Spot Urine	Ketones, spot urine	Num .F="No Form" 1="Positive" 2="Negative"
lab_urine_2_pH	pH Spot Urine	pH, spot urine	Num .F="No Form" .M="Missing"
lab_urine_2_protein	Protein Qualitative Urine	Protein, qualitative, urine	Num .F="No Form" .M="Missing" 1="Positive" 2="Negative"
lab_urine_2_redbc	Red Blood Cells	Red Blood Cells (RBC)	Num .F="No Form" 1="Positive" 2="Negative"
lab_urine_2_specific_gravity	Specific Gravity, Spot Urine	Specific gravity, spot urine	Num .F="No Form" .M="Missing"

Section 13: Checklist

Variable	Label	Description	Format Text
ability_to_consent	Ability to understand and willingness to sign a written informed consent document and follow study procedures."	Ability to understand and willingness to sign a written informed consent document and follow study procedures.	Num 1="Yes"
abstain_concomitant_med	Willingness to abstain from grapefruit juice, alcohol and concomitant medications during study."	Willingness to abstain from grapefruit juice, alcohol and concomitant medications during study.	Num 1="Yes"
all_base_symptoms_doc	All baseline symptoms must be documented and graded.	All baseline symptoms must be documented and graded.	Num 1="Yes"
all_participants_auto_reg	All Participants will automatically be registered to the correlative components of this study (see Section 9.0).	All Participants will automatically be registered to the correlative components of this study (see Section 9.0).	Num 1="Yes"
allergic_similar_linacotide	History of allergic reactions attributed to compounds of similar chemical or biologic composition to linacotide.	History of allergic reactions attributed to compounds of similar chemical or biologic composition to linacotide.	Num 0="No"
anti_coagulants	Use of anti-coagulants within two weeks of anticipated colonoscopy.	Use of anti-coagulants within two weeks of anticipated colonoscopy.	Num 0="No"
anti_platelet_agent	Use anti-platelet agents within two weeks of anticipated colonoscopy.	Use anti-platelet agents within two weeks of anticipated colonoscopy.	Num 0="No"
any_malignancy	Any malignancy within 3 years of baseline. Participants with a history of basal cell or squamous cell skin cancer may be enrolled at the discretion of the investigator.	Any malignancy within 3 years of baseline. Participants with a history of basal cell or squamous cell skin cancer may be enrolled at the discretion of the investigator.	Num 0="No"
auth_disc_health_info	Authorization for use and disclosure of protected health information (USA Institutions only) signed and dated. If not a USA Institution (select NA)	Authorization for use and disclosure of protected health information (USA Institutions only) signed and dated. If not a USA Institution (select NA)	Num 1="Yes"
authorized_sample_1	Authorized Sample	The following will also be recorded: Participant has given permission to collect and store blood and tissue for at least 5 years for future use in research to learn about, prevent, treat, or cure cancer.	Num 1="Yes"

Variable	Label	Description	Format Text
authorized_sample_oth_1	Authorized Sample Other	Participant has given permission to collect and store blood and tissue for at least 5 years for future use in research about other health problems (for example: causes of diabetes, Alzheimer's disease, and heart disease).	Num 1="Yes"
authorized_sample_out_1	Authorized Sample OUT	Participant has given permission to send blood and/or tissue sample(s) to researchers at an outside institution.	Num 0="No" 1="Yes"
bowel_disorders	Irritable bowel syndrome, chronic constipation, functional bowel disorders, or colonic motility disorder.	Irritable bowel syndrome, chronic constipation, functional bowel disorders, or colonic motility disorder.	Num 0="No"
colonoscopy_req_int	Colonoscopic finding requiring clinical intervention.	Colonoscopic finding requiring clinical intervention.	Num .F="No Form" 0="No"
consent_date_1	Consent Date	Date informed consent signed: (mm/dd/yyyy)	SAS Date
consent_form_signed	Consent form signed and dated.	Consent form signed and dated.	Num 1="Yes"
eval_in_guidelines	Evaluations must be completed within the guidelines specified on the Schedule of Events.	Evaluations must be completed within the guidelines specified on the Schedule of Events.	Num 1="Yes"
fam_hist_polyposis	Family history of polyposis syndrome (e.g., FAP, HNPCC) or colorectal cancer (first degree relatives younger than 60 years old).	Family history of polyposis syndrome (e.g., FAP, HNPCC) or colorectal cancer (first degree relatives younger than 60 years old).	Num 0="No"
hipaa_dt_1	Date of Authorization For HIPAA	If a USA Institution - Date of authorization (mm/dd/yyyy)	SAS Date
hist_bleeding_coagulation	History of bleeding/coagulation problems.	History of bleeding/coagulation problems.	Num 0="No"
hist_celiac_disease	History of celiac disease.	History of celiac disease.	Num 0="No"
hist_diff_colonoscopy_abn_colo	History of difficulty with colonoscopy or abnormal colorectal anatomy.	History of difficulty with colonoscopy or abnormal colorectal anatomy.	Num 0="No"
hist_gastroparesis	History of gastroparesis.	History of gastroparesis.	Num 0="No"
hist_surgery_gi_tract	History of surgery involving the luminal GI tract, including bariatric surgery.	History of surgery involving the luminal GI tract, including bariatric surgery.	Num 0="No"

Variable	Label	Description	Format Text
in_age_range	Male and female participants with an age between 18 years and 65 years."	Male and female participants with an age between 18 years and 65 years.	Num 1="Yes"
in_bmi_range	Body Mass Index <35 kg/m^2."	Body Mass Index <35 kg/m^2.	Num 1="Yes"
inadeq_pre_int_bowel_prep	Inadequate pre-intervention bowel preparation, as determined by the study physician.	Inadequate pre-intervention bowel preparation, as determined by the study physician.	Num .F="No Form" .M="Missing" 0="No"
infl_bowel_disease	Inflammatory bowel disease (Crohn's disease, ulcerative colitis).	Inflammatory bowel disease (Crohn's disease, ulcerative colitis).	Num 0="No"
intestinal_motility_agents	Intestinal motility agents, histamine-2 inverse agonists (H-2 blockers), or proton pump inhibitors.	Intestinal motility agents, histamine-2 inverse agonists (H-2 blockers), or proton pump inhibitors.	Num 0="No"
intolerance_of_sedation	Prior intolerance of or contraindications for the use of sedation anesthetic agents, which would prevent the safe use of sedation for colonoscopy. This includes allergies to eggs and soy products.	Prior intolerance of or contraindications for the use of sedation anesthetic agents, which would prevent the safe use of sedation for colonoscopy. This includes allergies to eggs and soy products.	Num .M="Missing" 0="No"
no_intervention_before_reg	Intervention cannot begin prior to Registration.	Intervention cannot begin prior to Registration.	Num .F="No Form" 1="Yes"
normal_organ_and_lab	Participants must have normal organ function and have normal laboratory findings without clinically significant findings (see Appendix B).	Participants must have normal organ function and have normal laboratory findings without clinically significant findings (see Appendix B).	Num .F="No Form" 1="Yes"
othr_investigat_agents	Participants may not be receiving any other investigational agents.	Participants may not be receiving any other investigational agents.	Num 0="No"
participant_eligible_1	Participant Eligible for Study?	Is the patient eligible for inclusion on this study?	Num 1="Yes"
participant_eligible_2	Participant Eligible for Study?	Is the patient eligible for inclusion on this study?	Num .F="No Form" 1="Yes"
preg_or_lactating	Pregnant or lactating women.	Pregnant or lactating women.	Num 0="No"
prsn_hist_adenoma	Previous personal history of advanced adenomas (≥ 1 cm in maximal diameter, ≥ 3 in total number, villous morphology, or high-grade dysplasia) or colorectal cancer).	Previous personal history of advanced adenomas (≥ 1 cm in maximal diameter, ≥ 3 in total number, villous morphology, or high-grade dysplasia) or colorectal cancer).	Num 0="No"

Variable	Label	Description	Format Text
satisfactory_prep	Satisfactory anesthesia and intestinal preparation, with no findings of advanced adenoma, chronic inflammation, or cancer.	Satisfactory anesthesia and intestinal preparation, with no findings of advanced adenoma, chronic inflammation, or cancer.	Num .F="No Form" 1="Yes"
uncontrolled_curr_ill	Uncontrolled current illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance	Uncontrolled current illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.	Num 0="No"
unsafe_medical_cond	Any medical condition judged by the investigator to constitute a risk to safe participation.	Any medical condition judged by the investigator to constitute a risk to safe participation.	Num 0="No"
use_alcohol_3_per_day	Current use of >= 3 alcoholic drinks/day.	Current use of >= 3 alcoholic drinks/day.	Num 0="No"
use_cigarettes_5_per_day	Current use of >= 5 cigarettes/day.	Current use of >= 5 cigarettes/day.	Num 0="No"
use_laxative_3_per_wk	Use of laxatives more than 3 times per week.	Use of laxatives more than 3 times per week.	Num 0="No"
use_of_illicit_substances	Use of any illicit or illegal substances detected by urinary drug screen.	Use of any illicit or illegal substances detected by urinary drug screen.	Num .F="No Form" 0="No"
willing_to_provide_samples	Willingness to provide blood and tissue specimens for research purposes."	Willingness to provide blood and tissue specimens for research purposes.	Num 1="Yes"
willing_to_use_contraception	Willingness to employ adequate contraception for men and women of childbearing potential. Acceptable methods include double barrier methods, intrauterine device (IUD), postmenopausal status documented by serum FSH, and/or documentation"	Willingness to employ adequate contraception for men and women of childbearing potential. Acceptable methods include double barrier methods, intrauterine device (IUD), postmenopausal status documented by serum FSH, and/or documentation of surgical sterilization. If not of childbearing potential (select N/A)	Num 1="Yes"

Section 14: Protdata

Variable	Label	Description	Format Text
agent_administered_1-7	Agent Administered 1	Start time: (hh:mm) DO NOT use colon (:) with entry	Num .F="No Form" 1="Yes"
agent_start_date_1-7	Agent 1 Start Date	Fasting 1=Yes 2=No	SAS Date .F="No Form"
agent_start_time_1-7	Start Time 1	Start time: (hh:mm) DO NOT use colon (:) with entry	Num .F="No Form"
hours_since_last_meal_1-7	Number of Hours Since Last Meal 1	Was agent administered? (enter one) 1=Yes, 2=No	Num .F="No Form"
last_meal_date_1-7	Date of Last Meal 1	(Last) Meal time: (hh:mm) DO NOT use colon (:) with entry	SAS Date .F="No Form"
last_meal_time_1-7	Time of Last Meal 1	Number of hours since last meal ____ (round to the nearest hour)	Num .F="No Form"
total_dose_agent_1-7	Total Dose Agent 1	Dose* ____ mg *If any dose was missed, enter 0.000.	Num .F="No Form"
was_pt_fasting_1-7	Was Patient 1 Fasting?	(Last) Meal date: (mm/dd/yyyy)	Num .F="No Form" 0="No" 1="Yes"

Section 15: QoI

Variable	Label	Description	Format Text
was_it_worth_q1	Quality Life 1	Was it worthwhile for you to participate in this research study? 1=Y 2=N 3=U	Num .F="No Form" 1="Yes"
was_it_worth_q2	Quality Life 2	If you had to do it over, would you participate in this research study again? 1=Y 2=N 3=U	Num .F="No Form" 0="No" 1="Yes" 9="Unknown"
was_it_worth_q3	Quality Life 3	Would you recommend participating in this research study to others? 1=Y 2=N 3=U	Num .F="No Form" 0="No" 1="Yes" 9="Unknown"
was_it_worth_q4	Quality Life 4	Directions: Select one response: Overall, did your quality of life change by participating in this research study? 1=It improved 2=It stayed the same 3=It got worse	Num .F="No Form" 1="It improved" 2="The same as I expected"
was_it_worth_q5	Quality Life 5	Overall, how was your experience of participating in this research study? 1=Better than I expected 2=The same as I expected 3=Worse than I expected	Num .F="No Form" 1="Better than I expected" 2="The same as I expected"
was_it_worth_q6	Quality Life 6	If there was one thing that could have been done to improve your experience in this research study, what would it be? (200 available characters)	Num .F="No Form" .M="Missing"
was_it_worth_q7	Quality Life 7	Would you like to talk to someone about your concerns (select one response)? 1=Yes 2=No	Num .F="No Form"

Section 16: ScrFail

Variable	Label	Description	Format Text
scr_fail_reason	Screen Failure Reason, Other Specified	Screen Failure Reason, Other Specified	Num .M="Missing" .N="Not Applicable" 1="Subject was an alternate, not needed" 2="Subject was a no-show for screening" 3="Proctitis or Sigmoid Diverticulosis" 4="Polyps" 5="Failed sigmoidoscopy, did not clear" 6="Drug screen positive for cannabinoid"
screen_completion_dt_1	Completion Date	Screen completion date: (mm/dd/yyyy)	SAS Date
screen_fail_1	Screen Failure	Does the participant meet all screening criteria? 1=Yes 2=No	Num 0="No" 1="Yes"
screen_fail_reason_1	Reason Screen Failure	If no, which screening criteria not met: 1=Investigator decision 2=Participant decision 3=Did not meet eligibility criteria, specify 6=Other, specify	Num .N="Not Applicable" 1="Investigator decision" 2="Participant decision" 3="Did not meet eligibility criteria, specify" 6="Other, specify"
screen_other_spec_1	Other Specify1	If Other, specify (40 available characters.)	Char " _=" "

Section 17: Toxicity

Variable	Label	Description	Format Text
adverse_events_1	Adverse Event	Were adverse events assessed during most recent period? (check one)	Num 1="Yes, and reportable adverse events occurred" 2="Yes, but no reportable adverse events occurred - End form" 3="No - End form"
adverse_events_2	Adverse Event	Were adverse events assessed during most recent period? (check one)	Num .F="No Form" 1="Yes, and reportable adverse events occurred" 2="Yes, but no reportable adverse events occurred - End form"
stool_per_day_1	Stools/Day Per Cycle	Number of stools per day _____	Num
tox_visit_dt_1	Post-Treatment Follow-up Visit Date	Visit Date: (mm/dd/yyyy) __ __/__/____	SAS Date

Section 18: Casecrse

Variable	Label	Description	Format Text
date_off_1	Date off		SAS Date .M="Missing"
date_off_2	Date off		SAS Date .F="No Form"
date_on_1	Date on		SAS Date
date_on_2	Date on		SAS Date .F="No Form"
date_on_current_arm_1	Date On Current Arm		SAS Date
date_on_current_arm_2	Date On Current Arm		SAS Date .F="No Form"
end_active_treatment_dt_1	End Active Treatment		SAS Date .M="Missing"
end_active_treatment_dt_2	End Active Treatment		SAS Date .F="No Form"
followup_dt_1	Follow-up Date		SAS Date
followup_dt_2	Follow-up Date		SAS Date .F="No Form"
followup_stat_1	Follow-up Status		Num
followup_stat_2	Follow-up Status		Num .F="No Form"
last_alive_dt_1	Date Last Known Alive		SAS Date
last_alive_dt_2	Date Last Known Alive		SAS Date .F="No Form"
reason_end_treatment_1	Reason End Treatment		Num .N="Not Applicable"
reason_end_treatment_2	Reason End Treatment		Num .F="No Form"
registered_1	Pre-reg Study		Num 1="Yes"
registered_2	Pre-reg Study	Registration Date (date on) (mm/dd/yyyy) __ __ / __ __ / __ __ __ __	Num .F="No Form" .M="Missing"
status_1	Status		Num .M="Missing"
status_2	Status		Num .F="No Form" .M="Missing"

Section 19: Stage 3

Variable	Label	Description	Format Text
stage_3_day1_biopsy_site_1_1	Biopsy Site 1, Stage 3, Day 1, Number 1	Biopsy Site 1, Stage 3, Day 1, Number 1	Num .F="No Form"
stage_3_day1_biopsy_site_1_2	Biopsy Site 1, Stage 3, Day 1, Number 2	Biopsy Site 1, Stage 3, Day 1, Number 2	Num .F="No Form"
stage_3_day1_biopsy_site_1_3	Biopsy Site 1, Stage 3, Day 1, Number 3	Biopsy Site 1, Stage 3, Day 1, Number 3	Num .F="No Form"
stage_3_day1_biopsy_site_2_1	Biopsy Site 2, Stage 3, Day 1, Number 1	Biopsy Site 2, Stage 3, Day 1, Number 1	Num .F="No Form"
stage_3_day1_biopsy_site_2_2	Biopsy Site 2, Stage 3, Day 1, Number 2	Biopsy Site 2, Stage 3, Day 1, Number 2	Num .F="No Form"
stage_3_day1_biopsy_site_2_3	Biopsy Site 2, Stage 3, Day 1, Number 3	Biopsy Site 2, Stage 3, Day 1, Number 3	Num .F="No Form"
stage_3_day7_biopsy_site_1_1	Biopsy Site 1, Stage 3, Day 7, Number 1	Biopsy Site 1, Stage 3, Day 7, Number 1	Num .F="No Form"
stage_3_day7_biopsy_site_1_2	Biopsy Site 1, Stage 3, Day 7, Number 2	Biopsy Site 1, Stage 3, Day 7, Number 2	Num .F="No Form"
stage_3_day7_biopsy_site_1_3	Biopsy Site 1, Stage 3, Day 7, Number 3	Biopsy Site 1, Stage 3, Day 7, Number 3	Num .F="No Form"
stage_3_day7_biopsy_site_2_1	Biopsy Site 2, Stage 3, Day 7, Number 1	Biopsy Site 2, Stage 3, Day 7, Number 1	Num .F="No Form"
stage_3_day7_biopsy_site_2_2	Biopsy Site 2, Stage 3, Day 7, Number 2	Biopsy Site 2, Stage 3, Day 7, Number 2	Num .F="No Form"
stage_3_day7_biopsy_site_2_3	Biopsy Site 2, Stage 3, Day 7, Number 3	Biopsy Site 2, Stage 3, Day 7, Number 3	Num .F="No Form"

Section 20: Stage 4

Variable	Label	Description	Format Text
stage_4_day1_biopsy_site_1_1	Biopsy Site 1, Stage 4, Day 1, Number 1	Biopsy Site 1, Stage 4, Day 1, Number 1	Num .F="No Form"
stage_4_day1_biopsy_site_1_2	Biopsy Site 1, Stage 4, Day 1, Number 2	Biopsy Site 1, Stage 4, Day 1, Number 2	Num .F="No Form"
stage_4_day1_biopsy_site_1_3	Biopsy Site 1, Stage 4, Day 1, Number 3	Biopsy Site 1, Stage 4, Day 1, Number 3	Num .F="No Form"
stage_4_day1_biopsy_site_2_1	Biopsy Site 2, Stage 4, Day 1, Number 1	Biopsy Site 2, Stage 4, Day 1, Number 1	Num .F="No Form"
stage_4_day1_biopsy_site_2_2	Biopsy Site 2, Stage 4, Day 1, Number 2	Biopsy Site 2, Stage 4, Day 1, Number 2	Num .F="No Form"
stage_4_day1_biopsy_site_2_3	Biopsy Site 2, Stage 4, Day 1, Number 3	Biopsy Site 2, Stage 4, Day 1, Number 3	Num .F="No Form"
stage_4_day7_biopsy_site_1_1	Biopsy Site 1, Stage 4, Day 7, Number 1	Biopsy Site 1, Stage 4, Day 7, Number 1	Num .F="No Form"
stage_4_day7_biopsy_site_1_2	Biopsy Site 1, Stage 4, Day 7, Number 2	Biopsy Site 1, Stage 4, Day 7, Number 2	Num .F="No Form"
stage_4_day7_biopsy_site_1_3	Biopsy Site 1, Stage 4, Day 7, Number 3	Biopsy Site 1, Stage 4, Day 7, Number 3	Num .F="No Form"
stage_4_day7_biopsy_site_2_1	Biopsy Site 2, Stage 4, Day 7, Number 1	Biopsy Site 2, Stage 4, Day 7, Number 1	Num .F="No Form"
stage_4_day7_biopsy_site_2_2	Biopsy Site 2, Stage 4, Day 7, Number 2	Biopsy Site 2, Stage 4, Day 7, Number 2	Num .F="No Form"
stage_4_day7_biopsy_site_2_3	Biopsy Site 2, Stage 4, Day 7, Number 3	Biopsy Site 2, Stage 4, Day 7, Number 3	Num .F="No Form"

Section 21: Levels_All

Variable	Label	Description	Format Text
levels_all_day1_bio psy_site_1_1	Biopsy Site 1, Levels All, Day 1, Number 1	Biopsy Site 1, Levels All, Day 1, Number 1	Num .F="No Form"
levels_all_day1_bio psy_site_1_2	Biopsy Site 1, Levels All, Day 1, Number 2	Biopsy Site 1, Levels All, Day 1, Number 2	Num .F="No Form"
levels_all_day1_bio psy_site_1_3	Biopsy Site 1, Levels All, Day 1, Number 3	Biopsy Site 1, Levels All, Day 1, Number 3	Num .F="No Form"
levels_all_day1_bio psy_site_2_1	Biopsy Site 2, Levels All, Day 1, Number 1	Biopsy Site 2, Levels All, Day 1, Number 1	Num .F="No Form"
levels_all_day1_bio psy_site_2_2	Biopsy Site 2, Levels All, Day 1, Number 2	Biopsy Site 2, Levels All, Day 1, Number 2	Num .F="No Form"
levels_all_day1_bio psy_site_2_3	Biopsy Site 2, Levels All, Day 1, Number 3	Biopsy Site 2, Levels All, Day 1, Number 3	Num .F="No Form"
levels_all_day7_bio psy_site_1_1	Biopsy Site 1, Levels All, Day 7, Number 1	Biopsy Site 1, Levels All, Day 7, Number 1	Num .F="No Form"
levels_all_day7_bio psy_site_1_2	Biopsy Site 1, Levels All, Day 7, Number 2	Biopsy Site 1, Levels All, Day 7, Number 2	Num .F="No Form"
levels_all_day7_bio psy_site_1_3	Biopsy Site 1, Levels All, Day 7, Number 3	Biopsy Site 1, Levels All, Day 7, Number 3	Num .F="No Form"
levels_all_day7_bio psy_site_2_1	Biopsy Site 2, Levels All, Day 7, Number 1	Biopsy Site 2, Levels All, Day 7, Number 1	Num .F="No Form"
levels_all_day7_bio psy_site_2_2	Biopsy Site 2, Levels All, Day 7, Number 2	Biopsy Site 2, Levels All, Day 7, Number 2	Num .F="No Form"
levels_all_day7_bio psy_site_2_3	Biopsy Site 2, Levels All, Day 7, Number 3	Biopsy Site 2, Levels All, Day 7, Number 3	Num .F="No Form"

Section 22: Levels_4

Variable	Label	Description	Format Text
levels_4_day1_biopsy_site_1_1	Biopsy Site 1, Levels Stage 4, Day 1, Number 1	Biopsy Site 1, Levels Stage 4, Day 1, Number 1	Num .F="No Form"
levels_4_day1_biopsy_site_1_2	Biopsy Site 1, Levels Stage 4, Day 1, Number 2	Biopsy Site 1, Levels Stage 4, Day 1, Number 2	Num .F="No Form"
levels_4_day1_biopsy_site_1_3	Biopsy Site 1, Levels Stage 4, Day 1, Number 3	Biopsy Site 1, Levels Stage 4, Day 1, Number 3	Num .F="No Form"
levels_4_day1_biopsy_site_2_1	Biopsy Site 2, Levels Stage 4, Day 1, Number 1	Biopsy Site 2, Levels Stage 4, Day 1, Number 1	Num .F="No Form"
levels_4_day1_biopsy_site_2_2	Biopsy Site 2, Levels Stage 4, Day 1, Number 2	Biopsy Site 2, Levels Stage 4, Day 1, Number 2	Num .F="No Form"
levels_4_day1_biopsy_site_2_3	Biopsy Site 2, Levels Stage 4, Day 1, Number 3	Biopsy Site 2, Levels Stage 4, Day 1, Number 3	Num .F="No Form"
levels_4_day7_biopsy_site_1_1	Biopsy Site 1, Levels Stage 4, Day 7, Number 1	Biopsy Site 1, Levels Stage 4, Day 7, Number 1	Num .F="No Form"
levels_4_day7_biopsy_site_1_2	Biopsy Site 1, Levels Stage 4, Day 7, Number 2	Biopsy Site 1, Levels Stage 4, Day 7, Number 2	Num .F="No Form"
levels_4_day7_biopsy_site_1_3	Biopsy Site 1, Levels Stage 4, Day 7, Number 3	Biopsy Site 1, Levels Stage 4, Day 7, Number 3	Num .F="No Form"
levels_4_day7_biopsy_site_2_1	Biopsy Site 2, Levels Stage 4, Day 7, Number 1	Biopsy Site 2, Levels Stage 4, Day 7, Number 1	Num .F="No Form"
levels_4_day7_biopsy_site_2_2	Biopsy Site 2, Levels Stage 4, Day 7, Number 2	Biopsy Site 2, Levels Stage 4, Day 7, Number 2	Num .F="No Form"
levels_4_day7_biopsy_site_2_3	Biopsy Site 2, Levels Stage 4, Day 7, Number 3	Biopsy Site 2, Levels Stage 4, Day 7, Number 3	Num .F="No Form"

Section 23: Form Accounting

Variable	Label	Description	Format Text
has_casecrse_1	Has Prereg Casecrse Dataset	Has Prereg Casecrse Dataset	Num 1="In Dataset"
has_casecrse_2	Has Rand Casecrse Dataset	Has Rand Casecrse Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_chklist_1	Has Prereg Chklist Dataset	Has Prereg Chklist Dataset	Num 1="In Dataset"
has_chklist_2	Has Rand Chklist Dataset	Has Rand Chklist Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_colon_1	Has Prereg Colon Dataset	Has Prereg Colon Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_colon_2	Has Rand Colon Dataset	Has Rand Colon Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_colonbx_1	Has Prereg Colonbx Dataset	Has Prereg Colonbx Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_colonbx_2	Has Rand Colonbx Dataset	Has Rand Colonbx Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_conmed_1	Has Prereg Conmed Dataset	Has Prereg Conmed Dataset	Num 1="In Dataset"
has_conmed_2	Has Rand Conmed Dataset	Has Rand Conmed Dataset	Num .F="No Form" 1="In Dataset"
has_crse_1	Has Prereg Crse Dataset	Has Prereg Crse Dataset	Num 1="In Dataset"
has_drgscrn_1	Has Prereg Drgscrn Dataset	Has Prereg Drgscrn Dataset	Num 1="In Dataset"
has_drgscrn_2	Has Rand Drgscrn Dataset	Has Rand Drgscrn Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_end_at_1	Has Prereg End_at Dataset	Has Prereg End_at Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_intvlab_1	Has Prereg Intvlab Dataset	Has Prereg Intvlab Dataset	Num 1="In Dataset"
has_intvlab_2	Has Rand Intvlab Dataset	Has Rand Intvlab Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_labform_1	Has Prereg Labform Dataset	Has Prereg Labform Dataset	Num 1="In Dataset"

Variable	Label	Description	Format Text
has_labform_2	Has Rand Labform Dataset	Has Rand Labform Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_laburine_1	Has Prereg Laburine Dataset	Has Prereg Laburine Dataset	Num 1="In Dataset"
has_laburine_2	Has Rand Laburine Dataset	Has Rand Laburine Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_physexam_1	Has Prereg Physexam Dataset	Has Prereg Physexam Dataset	Num 1="In Dataset"
has_physexam_2	Has Rand Physexam Dataset	Has Rand Physexam Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_protdata_2	Has Rand Protdata Dataset	Has Rand Protdata Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_qol_2	Has Rand Qol Dataset	Has Rand Qol Dataset	Num 0="Not in Dataset" 1="In Dataset"
has_scrfail_1	Has Prereg Scrfail Dataset	Has Prereg Scrfail Dataset	Num 1="In Dataset"
has_toxprsn_1	Has Prereg Toxprsn Dataset	Has Prereg Toxprsn Dataset	Num 1="In Dataset"
has_toxprsn_2	Has Rand Toxprsn Dataset	Has Rand Toxprsn Dataset	Num 0="Not in Dataset" 1="In Dataset"
results_has_level_4	Has Results Levels 4 Dataset	Has Results Levels 4 Dataset	Num 0="Not in Dataset" 1="In Dataset"
results_has_level_all	Has Results Levels All Dataset	Has Results Levels All Dataset	Num 0="Not in Dataset" 1="In Dataset"
results_has_stage_3	Has Results Stage 3 Dataset	Has Results Stage 3 Dataset	Num 0="Not in Dataset" 1="In Dataset"
results_has_stage_4	Has Results Stage 4 Dataset	Has Results Stage 4 Dataset	Num 0="Not in Dataset" 1="In Dataset"