

NWU2014-03-01 - ENHANCED PERSON: DATA DICTIONARY

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NWU2014-03-01 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
build_dt	Build Date	Build Date	SAS Date
participant_identifier	Participant Identifier	Participant Identifier	Char
pid	Participant Identifier (Abbreviated)	Participant Identifier (Abbreviated)	Numeric
screening_identification_number	Screening Identification Number	Screening Identification Number	Char

Section 2: Study-wide

Variable	Label	Description	Format Text
ag_start_dt	Agent Start Date	Start date of agent	SAS Date .R="Not Randomized"
eligible	Eligible for Study?	Indicates if participant is eligible for the study	0="No" 1="Yes"
randomized	Randomized?	Indicates if the participant was randomized	0="No" 1="Yes"
reg_dt	Date of Registration	Date of registration	SAS Date .R="Not Randomized"
rnd_dt	Date of Randomization	Date of randomization	SAS Date .R="Not Randomized"
tac_dt	TAC Date	TAC date	SAS Date .N="N/A"
treatment	Treatment	Treatment	.R="Not Randomized" 1="Placebo" 2="Berberine"
visit_dt_v1-5	Date of Visit	Date of the specified visit	SAS Date .M="Missing" .R="Not Randomized"

Section 3: Contact

Variable	Label	Description	Format Text
contact_ae1-7	Any Adverse Events? - Contact - [Contact]	Indicates if any adverse events were reported at the specified contact	.F="No Record for This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="Too Early to Evaluate"
contact_compliant1-7	Compliant With Protocol Intervention? - Contact # - [Contact]	Indicates if the participant was compliant with the protocol intervention before the specified contact	.F="No Record for This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
contact_conmed1-7	Any Changes in Concomitant Medications? - Contact # - [Contact]	Indicates if any changes in concomitant medications were reported at the specified contact	.F="No Record for This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="Not Applicable"
contact_dt1-7	Date of Contact - [Contact]	Date of the specified contact	SAS Date .F="No Record for This Visit" .R="Not Randomized"
timept_end_dt1-7	End Date - Time Point	End date of the specified time point	SAS Date .M="Missing" .N="N/A"
timept_start_dt1-7	Start Date - Time Point	Start date of the specified time point	SAS Date .M="Missing" .N="N/A"

Section 4: Consent

Variable	Label	Description	Format Text
consent_biobank	My Samples and Related Information May Be Kept in A Biobank For Use in Future Health Research - [Consent]	Selection to the option: "My samples and related information may be kept in a biobank for use in future health research"	1="Yes"
consent_dt	Date of Consent	Date of consent	SAS Date
consent_future	I Agree That My Study Doctor, or Their Representative, May Contact Me or My Physician to See if I Wish to Participate in Other Research in The Future - [Consent]	Selection to the option: "I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future"	1="Yes"
consent_result	I Agree That My Study Doctor, or Their Representative, May Contact Me or My Physician to See if I Wish to Learn About Results From This(ese) Study(ies) - [Consent]	Selection to the option: "I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to learn about results from this(ese) study(ies)"	1="Yes"
consent_specimen	I Agree to Have My Specimen Collected and I Agree That My Specimen Sample(s) and Related Information May Be Used For The Laboratory Study(ies) Described Above - [Consent]	Selection to the option: "I agree to have my specimen collected and I agree that my specimen sample(s) and related information may be used for the laboratory study(ies) described above"	1="Yes"

Section 5: Demographics

Variable	Label	Description	Format Text
demo_age	Age at Screening - [Demographics]	Age at screening	Numeric
demo_ethnicity	Ethnicity - [Demographics]	Ethnicity of the participant	2="Not Hispanic or Latino"
demo_gender	Gender - [Demographics]	Gender of the participant	1="Female" 2="Male"
demo_race	Race - [Demographics]	Race of the participant	3="Asian"
demo_race_eth	Race + Ethnicity - [Demographics]	Combination of the Race and Ethnicity variables. Participants can only be considered white or black when they are not Hispanic. If the participant is white or black and Hispanic, then they are considered Hispanic. If the participant is Asian, Pacific Islander, or American Indian then they are considered that race.	4="Asian"

Section 6: Screening

Variable	Label	Description	Format Text
screen_failure	Is Participant a Screen Failure? - [Demographics]	Indicates if the participant is a screen failure in the Demographics dataset	0="No" 1="Yes"
screen_failure_rsn	Reason For Screen Failure - [Demographics]	Indicates the reason for screen failure (if participant failed)	Char

Section 7: Baseline Symptoms

Variable	Label	Description	Format Text
bsymp_description1-2	Description - Symptom # - [Baseline Symptoms]	Type of baseline sympom	Char
bsymp_grade1-2	Severity - Symptom # - [Baseline Symptoms]	Severity of the baseline symptom	.F="No Record for This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Mild (Hardly Noticeable)"
bsymp_num	Number of Baseline Symptoms - [Baseline Symptoms]	Number of baseline symptoms	Numeric .F="No Record for This Visit" .R="Not Randomized"
bsymp_onset_dt1-2	Onset Date - Symptom # - [Baseline Symptoms]	Onset date of the baseline symptom	SAS Date .F="No Record for This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Section 8: Medical History

Variable	Label	Description	Format Text
medhist_breast_comments	Breast Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's breasts (All missing values in dataset)	Char
medhist_cardio_comments	Cardiovascular System Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's cardiovascular system	Char
medhist_derma_comments	Dermatologic System Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's dermatologic system (All missing values in dataset)	Char
medhist_endometa_comments	Endometrial System Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's endometrial system (All missing values in dataset)	Char
medhist_gastro_abn	Gastrointestinal System - Abnormal? - [Medical History]	Indicates if the participant has a medical history of an abnormal gastrointestinal system	.R="Not Randomized" 1="Yes"
medhist_gastro_comments	Gastrointestinal System Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's gastrointestinal system	Char
medhist_genit_comments	Genitourinary System Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's genitourinary system (All missing values in dataset)	Char
medhist_heent_comments	H/E/E/N/T System Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's H/E/E/N/T system (All missing values in dataset)	Char
medhist_hemalymph_comments	Hematopoietic/Lymph System Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's hematopoietic system (All missing values in dataset)	Char
medhist_muscskel_comments	Musculoskeletal System Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's musculoskeletal system (All missing values in dataset)	Char
medhist_neck_comments	Neck Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's neck (All missing values in dataset)	Char
medhist_neuro_comments	Neurological System Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's neurological system (All missing values in dataset)	Char

Variable	Label	Description	Format Text
medhist_oth_abn	Any Other Body Systems Abnormal? - [Medical History]	Indicates if the participant has a medical history of any other abnormal body systems	.R="Not Randomized" 0="No" 1="Yes"
medhist_resp_comments	Respiratory System Abnormality - Comments - [Medical History]	Comments on the medical history of the participant's respiratory system (All missing values in dataset)	Char

Section 9: Concomitant Medications

Variable	Label	Description	Format Text
conmed_dose1-7	Medication Dosage - Medication # - [Concomitant Medications]	Dosage taken of the specified medication	Numeric .N="N/A"
conmed_end_dt1-7	Date Medication Was Ended - Medication # - [Concomitant Medications]	Date the specified medication was ended	SAS Date .C="Continuous" .N="N/A"
conmed_freq1-7	Frequency of Medication Use - Medication # - [Concomitant Medications]	Frequency that the specified medication was used	Char
conmed_name1-7	Medication Name - Medication # - [Concomitant Medications]	Name of the specified medication	Char
conmed_num	Number of Concomitant Medications Taken	Number of concomitant medications that were taken during the study	Numeric
conmed_rpt_dt1-7	Date Medication Was Reported - Medication # - [Concomitant Medications]	Date the specified medication was reported	SAS Date .N="N/A"
conmed_start_dt1-7	Date Medication Was Started - Medication # - [Concomitant Medications]	Date the specified medication was started	SAS Date .N="N/A"
conmed_timing1-7	Timing of Medication Use - Medication # - [Concomitant Medications]	Timing of the specified medication	.M="Missing" .N="N/A" 1="Before Colonoscopy" 2="Before Enteroscopy" 3="During Colonoscopy" 4="During Enteroscopy"
conmed_units1-7	Units of Measure for Medication Dosage - Medication # - [Concomitant Medications]	Units of measure used for the specified medication	Char

Section 10: Agent Interruption

Variable	Label	Description	Format Text
agent_num	Number of Interruptions - [Agent Interruption]	Number of agent interruptions during the study	Numeric
agent_restart_dt	Date Agent Regimen Was Restarted - [Agent Interruption]	Date the agent regimen was restarted (if restarted) after being interrupted	SAS Date .N="N/A"
agent_restarted	Was Agent Restarted? - [Agent Interruption]	Indicates if the agent was restarted after being interrupted.	.N="N/A" 1="Yes"
agent_stop_dt	Date Agent Regimen Was Stopped - [Agent Interruption]	Date the agent was interrupted	SAS Date .N="N/A"
agent_stop_rsn	Reason Agent Was Stopped - [Agent Interruption]	Indicates the reason the agent was interrupted	.N="N/A" 4="Other, Specify"
agent_stop_spec	Specific Reason Agent Was Stopped - [Agent Interruption]	The specific reason the agent was interrupted	Char

Section 11: Pregnancy Tests

Variable	Label	Description	Format Text
pregtest_dt1	Date of Test - Test 1 - [Pregnancy Tests]	Date of the first pregnancy test taken during the study. Males will always be N/A.	SAS Date .N="N/A"
pregtest_dt2	Date of Test - Test 2 - [Pregnancy Tests]	Date of the first pregnancy test taken during the study. Males will always be N/A.	SAS Date .N="N/A"
pregtest_num	Number of Pregnancy Tests Taken - [Pregnancy Tests]	Number of pregnancy tests that the participant took throughout the study. Males will always have 0.	Numeric
pregtest_result1	Result of Test - Test 1 - [Pregnancy Tests]	Result of the first pregnancy test taken during the study. Males will always be N/A.	.N="N/A" 0="Negative" 9="Not Applicable, Not Female of Child-Bearing Potential"
pregtest_result2	Result of Test - Test 2 - [Pregnancy Tests]	Result of the second pregnancy test taken during the study. Males will always be N/A.	.N="N/A" 0="Negative"

Section 12: Agent Return

Variable	Label	Description	Format Text
agent_amt_missing_v2-4	Amount of Study Agent Missing - Visit # - [Agent Returned]	Amount of study agent missing at the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"
agent_amt_provided_v2-4	Amount of Study Agent Provided - Visit # - [Agent Returned]	Amount of study agent provided at the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"
agent_amt_returned_v2-4	Amount of Study Agent Returned - Visit # - [Agent Returned]	Amount of study agent returned at the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"
agent_amt_taken_v2-4	Amount of Study Agent Taken - Visit # - [Agent Returned]	Amount of study agent taken before the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"
agent_comments_v2-4	Comments - Visit # - [Agent Returned]	Comments for the specified visit	Char

Section 13: Reason Off Study

Variable	Label	Description	Format Text
off_last_agent_dt	Date Study Agent Was Taken for Last Time - [Off Study]	Date that the study agent was taken for the last time	SAS Date .M="Missing"
off_last_contact_dt	Date of Last Contact - [Off Study]	Date of the last contact between the study and the participant	SAS Date
off_rsn	Reason Off Study - [Off Study]	Reason the participant went off of the study	1="Study Complete" 2="Ineligible" 4="Lost to Follow-up" 5="Participant Withdrawal"
off_rsn_exp	Reason Off Study (Explanation) - [Off Study]	Explanation for the reason the participant went off of the study	Char
off_study_dt	Date Off Study - [Off Study]	Date the participant went off of the study	SAS Date

Section 14: Vitals

Variable	Label	Description	Format Text
vit_bmi_v1-5	BMI - Visit # - [Vitals]	BMI at the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"
vit_diastolic_v1-5	Diastolic Blood Pressure - Visit # - [Vitals]	Diastolic blood pressure at the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"
vit_ecog_v1-5	ECOG Performance Status - Visit # - [Vitals]	ECOG performance status at the specified visit	.F="No Record for This Visit" .M="Missing" .R="Not Randomized" 0="Normal activity. Fully active, able to carry on all pre-disease performance without restriction."
vit_height_v1-5	Height (in) - Visit # - [Vitals]	Height (in) at the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"
vit_pulse_v1-5	Pulse Rate - Visit # - [Vitals]	Pulse rate at the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"
vit_resp_v1-5	Respiration Rate - Visit # - [Vitals]	Respiration rate at the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"
vit_systolic_v1-5	Systolic Blood Pressure - Visit # - [Vitals]	Systolic blood pressure at the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"
vit_temp_v1-5	Temperature (C) - Visit # - [Vitals]	Temperature (C) at the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"
vit_weight_v1-5	Weight (kg) - Visit # - [Vitals]	Weight (kg) at the specified visit	Numeric .F="No Record for This Visit" .R="Not Randomized"

Section 15: Adverse Events

Variable	Label	Description	Format Text
ae_num	Number of Adverse Events the Participant Experienced During the Study - [Adverse Events]	Number of adverse events the participant experienced during the study	Numeric

Section 16: Physical Examination

Variable	Label	Description	Format Text
pe_abdom_abn_v1-5	Abdomen Found Abnormal? - Visit # - [Physical Examination]	Indicates if the participant's abdomen was found abnormal at the specified visit	.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
pe_abdom_comments_v1-5	Abdomen Abnormality - Comments - [Physical Examination]	Comments on the participant's abdomen (if found abnormal) at the specified visit	Char
pe_appearance_comments_v1-5	Appearance Abnormality - Comments - [Physical Examination]	Comments on the participant's appearance (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_breast_comments_v1-5	Breast Abnormality - Comments - [Physical Examination]	Comments on the participant's breasts (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_chest_comments_v1-5	Chest Abnormality - Comments - [Physical Examination]	Comments on the participant's chest (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_genitalia_comments_v1-5	Genitalia Abnormality - Comments - [Physical Examination]	Comments on the participant's genitalia (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_heart_comments_v1-5	Heart Abnormality - Comments - [Physical Examination]	Comments on the participant's heart (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_heent_comments_v1-5	H/E/E/N/T System Abnormality - Comments - [Physical Examination]	Comments on the participant's H/E/E/N/T system (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_lung_comments_v1-5	Lung Abnormality - Comments - [Physical Examination]	Comments on the participant's lung (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_lymph_comments_v1-5	Lymph Node Abnormality - Comments - [Physical Examination]	Comments on the participant's lymph node (if found abnormal) at the specified visit (All missing values in dataset)	Char

Variable	Label	Description	Format Text
pe_muscskel_comments_v1-5	Musculoskeletal System Abnormality - Comments - [Physical Examination]	Comments on the participant's musculoskeletal system (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_neuro_comments_v1-5	Neurological System Abnormality - Comments - [Physical Examination]	Comments on the participant's neurological system (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_oth_abn_v1-5	Any Other Abnormalities? - Visit # - [Physical Examination]	Indicates if the participant had any other sites found abnormal at the specified visit	.M="Missing" .R="Not Randomized" 0="No"
pe_pelvis_comments_v1-5	Pelvis Abnormality - Comments - [Physical Examination]	Comments on the participant's pelvis (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_prostate_comments_v1-5	Prostate Abnormality - Comments - [Physical Examination]	Comments on the participant's prostate (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_rectal_abn_v1-5	Rectum Found Abnormal? - Visit # - [Physical Examination]	Indicates if the participant's rectum was found abnormal at the specified visit	.M="Missing" .R="Not Randomized" 0="No"
pe_rectal_comments_v1-5	Rectal Abnormality - Comments - [Physical Examination]	Comments on the participant's rectum (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_skin_comments_v1-5	Skin Abnormality - Comments - [Physical Examination]	Comments on the participant's skin (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_thyroid_comments_v1-5	Thyroid Abnormality - Comments - [Physical Examination]	Comments on the participant's thyroid (if found abnormal) at the specified visit (All missing values in dataset)	Char
pe_vascular_comments_v1-5	Vascular System Abnormality - Comments - [Physical Examination]	Comments on the participant's vascular system (if found abnormal) at the specified visit (All missing values in dataset)	Char

Section 17: Blood Chemistry

Variable	Label	Description	Format Text
bldchem_albumin_clin_v1	Albumin (g/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the albumin blood test (g/L) at visit 1 was clinically significant	.F="No Record for This Visit"
bldchem_albumin_clin_v4	Albumin (g/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the albumin blood test (g/L) at visit 4 was clinically significant	.F="No Record for This Visit"
bldchem_albumin_out_v1	Albumin (g/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the albumin blood test (g/L) at visit 1 was out of range	.F="No Record for This Visit"
bldchem_albumin_out_v4	Albumin (g/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the albumin blood test (g/L) at visit 4 was out of range	.F="No Record for This Visit"
bldchem_albumin_v1	Albumin (g/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the albumin blood test (g/L) at visit 1	Numeric .F="No Record for This Visit"
bldchem_albumin_v4	Albumin (g/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the albumin blood test (g/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_alk_phos_clin_v1	Alkaline Phosphatase (IU/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the alkaline phosphatase blood test (IU/L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_alk_phos_clin_v4	Alkaline Phosphatase (IU/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the alkaline phosphatase blood test (IU/L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_alk_phos_out_v1	Alkaline Phosphatase (IU/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the alkaline phosphatase blood test (IU/L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_alk_phos_out_v4	Alkaline Phosphatase (IU/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the alkaline phosphatase blood test (IU/L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_alk_phos_v1	Alkaline Phosphatase (IU/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the alkaline phosphatase blood test (IU/L) at visit 1	Numeric .F="No Record for This Visit"
bldchem_alk_phos_v4	Alkaline Phosphatase (IU/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the alkaline phosphatase blood test (IU/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_any_other_out_v1	Any Other Tests Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if any other blood tests were out of range at visit 1	0="No" 1="Yes"
bldchem_any_other_out_v4	Any Other Tests Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if any other blood tests were out of range at visit 4	.F="No Record for This Visit" 0="No" 1="Yes"

Variable	Label	Description	Format Text
bldchem_bilirubin_c lin_v1	Bilirubin (umol/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the bilirubin blood test (umol/L) at visit 1 was clinically significant	.M="Missing" 0="No"
bldchem_bilirubin_c lin_v4	Bilirubin (umol/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the bilirubin blood test (umol/L) at visit 4 was clinically significant	.F="No Record for This Visit" .M="Missing" 0="No"
bldchem_bilirubin_ out_v1	Bilirubin (umol/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the bilirubin blood test (umol/L) at visit 1 was out of range	0="No" 1="Yes"
bldchem_bilirubin_ out_v4	Bilirubin (umol/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the bilirubin blood test (umol/L) at visit 4 was out of range	.F="No Record for This Visit" 0="No" 1="Yes"
bldchem_bilirubin_v 1	Bilirubin (umol/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the bilirubin blood test (umol/L) at visit 1	Numeric
bldchem_bilirubin_v 4	Bilirubin (umol/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the bilirubin blood test (umol/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_bun_clin_ v1	BUN (mmol/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the BUN blood test (mmol/L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_bun_clin_ v4	BUN (mmol/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the BUN blood test (mmol/L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_bun_out_v 1	BUN (mmol/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the BUN blood test (mmol/L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_bun_out_v 4	BUN (mmol/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the BUN blood test (mmol/L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_bun_v1	BUN (mmol/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the BUN blood test (mmol/L) at visit 1	Numeric .F="No Record for This Visit"
bldchem_bun_v4	BUN (mmol/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the BUN blood test (mmol/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_calcium_c lin_v1	Calcium (mmol/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the calcium blood test (mmol/L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_calcium_c lin_v4	Calcium (mmol/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the calcium blood test (mmol/L) at visit 4 was clinically significant	.F="No Record for This Visit"
bldchem_calcium_o ut_v1	Calcium (mmol/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the calcium blood test (mmol/L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_calcium_o ut_v4	Calcium (mmol/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the calcium blood test (mmol/L) at visit 4 was out of range	.F="No Record for This Visit"

Variable	Label	Description	Format Text
bldchem_calcium_v1	Calcium (mmol/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the calcium blood test (mmol/L) at visit 1	Numeric .F="No Record for This Visit"
bldchem_calcium_v4	Calcium (mmol/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the calcium blood test (mmol/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_chloride_clin_v1	Chloride (mmol/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the chloride blood test (mmol/L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_chloride_clin_v4	Chloride (mmol/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the chloride blood test (mmol/L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_chloride_out_v1	Chloride (mmol/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the chloride blood test (mmol/L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_chloride_out_v4	Chloride (mmol/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the chloride blood test (mmol/L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_chloride_v1	Chloride (mmol/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the chloride blood test (mmol/L) at visit 1	Numeric .F="No Record for This Visit"
bldchem_chloride_v4	Chloride (mmol/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the chloride blood test (mmol/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_creatinine_clin_v1	Creatinine (umol/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the creatinine blood test (umol/L) at visit 1 was clinically significant	.M="Missing"
bldchem_creatinine_clin_v4	Creatinine (umol/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the creatinine blood test (umol/L) at visit 4 was clinically significant	.F="No Record for This Visit" .M="Missing"
bldchem_creatinine_out_v1	Creatinine (umol/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the creatinine blood test (umol/L) at visit 1 was out of range	0="No"
bldchem_creatinine_out_v4	Creatinine (umol/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the creatinine blood test (umol/L) at visit 4 was out of range	.F="No Record for This Visit" 0="No"
bldchem_creatinine_v1	Creatinine (umol/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the creatinine blood test (umol/L) at visit 1	Numeric
bldchem_creatinine_v4	Creatinine (umol/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the creatinine blood test (umol/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_glucose_clin_v1	Glucose Serum (mmol/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the glucose serum blood test (mmol/L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"

Variable	Label	Description	Format Text
bldchem_glucose_c lin_v4	Glucose Serum (mmol/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the glucose serum blood test (mmol/L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_glucose_o ut_v1	Glucose Serum (mmol/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the glucose serum blood test (mmol/L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_glucose_o ut_v4	Glucose Serum (mmol/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the glucose serum blood test (mmol/L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_glucose_v 1	Glucose Serum (mmol/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the glucose serum blood test (mmol/L) at visit 1	Numeric .F="No Record for This Visit"
bldchem_glucose_v 4	Glucose Serum (mmol/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the glucose serum blood test (mmol/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_ind_bili_cl in_v1	Indirect Bilirubin (umol/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the indirect bilirubin blood test (umol/L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_ind_bili_cl in_v4	Indirect Bilirubin (umol/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the indirect bilirubin blood test (umol/L) at visit 4 was clinically significant	.F="No Record for This Visit"
bldchem_ind_bili_o ut_v1	Indirect Bilirubin (umol/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the indirect bilirubin blood test (umol/L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_ind_bili_o ut_v4	Indirect Bilirubin (umol/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the indirect bilirubin blood test (umol/L) at visit 4 was out of range	.F="No Record for This Visit"
bldchem_ind_bili_v 1	Indirect Bilirubin (umol/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the indirect bilirubin blood test (umol/L) at visit 1	Numeric .F="No Record for This Visit"
bldchem_ind_bili_v 4	Indirect Bilirubin (umol/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the indirect bilirubin blood test (umol/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_ldh_clin_v 1	LDH (IU/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the LDH blood test (IU/L) at visit 1 was clinically significant	.F="No Record for This Visit"
bldchem_ldh_clin_v 4	LDH (IU/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the LDH blood test (IU/L) at visit 4 was clinically significant	.F="No Record for This Visit"
bldchem_ldh_out_v 1	LDH (IU/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the LDH blood test (IU/L) at visit 1 was out of range	.F="No Record for This Visit"
bldchem_ldh_out_v 4	LDH (IU/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the LDH blood test (IU/L) at visit 4 was out of range	.F="No Record for This Visit"

Variable	Label	Description	Format Text
bldchem_ldh_v1	LDH (IU/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the LDH blood test (IU/L) at visit 1	Numeric .F="No Record for This Visit"
bldchem_ldh_v4	LDH (IU/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the LDH blood test (IU/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_potassium_clin_v1	Potassium (mmol/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the potassium blood test (mmol/L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_potassium_clin_v4	Potassium (mmol/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the potassium blood test (mmol/L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_potassium_out_v1	Potassium (mmol/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the potassium blood test (mmol/L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_potassium_out_v4	Potassium (mmol/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the potassium blood test (mmol/L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_potassium_v1	Potassium (mmol/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the potassium blood test (mmol/L) at visit 1	Numeric .F="No Record for This Visit"
bldchem_potassium_v4	Potassium (mmol/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the potassium blood test (mmol/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_protein_clin_v1	Total Protein (g/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the total protein blood test (g/L) at visit 1 was clinically significant	.F="No Record for This Visit"
bldchem_protein_clin_v4	Total Protein (g/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the total protein blood test (g/L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_protein_out_v1	Total Protein (g/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the total protein blood test (g/L) at visit 1 was out of range	.F="No Record for This Visit"
bldchem_protein_out_v4	Total Protein (g/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the total protein blood test (g/L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_protein_v1	Total Protein (g/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the total protein blood test (g/L) at visit 1	Numeric .F="No Record for This Visit"
bldchem_protein_v4	Total Protein (g/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the total protein blood test (g/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_sgot_ast_clin_v1	SGOT/AST (IU/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the SGOT/AST blood test (IU/L) at visit 1 was clinically significant	.M="Missing"

Variable	Label	Description	Format Text
bldchem_sgot_ast_clin_v4	SGOT/AST (IU/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the SGOT/AST blood test (IU/L) at visit 4 was clinically significant	.F="No Record for This Visit" .M="Missing" 1="Yes"
bldchem_sgot_ast_out_v1	SGOT/AST (IU/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the SGOT/AST blood test (IU/L) at visit 1 was out of range	0="No"
bldchem_sgot_ast_out_v4	SGOT/AST (IU/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the SGOT/AST blood test (IU/L) at visit 4 was out of range	.F="No Record for This Visit" 0="No" 1="Yes"
bldchem_sgot_ast_v1	SGOT/AST (IU/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the SGOT/AST blood test (IU/L) at visit 1	Numeric
bldchem_sgot_ast_v4	SGOT/AST (IU/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the SGOT/AST blood test (IU/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_sgpt_alt_clin_v1	SGPT/ALT (IU/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the SGPT/ALT blood test (IU/L) at visit 1 was clinically significant	.M="Missing" 0="No"
bldchem_sgpt_alt_clin_v4	SGPT/ALT (IU/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the SGPT/ALT blood test (IU/L) at visit 4 was clinically significant	.F="No Record for This Visit" .M="Missing" 0="No" 1="Yes"
bldchem_sgpt_alt_out_v1	SGPT/ALT (IU/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the SGPT/ALT blood test (IU/L) at visit 1 was out of range	0="No" 1="Yes"
bldchem_sgpt_alt_out_v4	SGPT/ALT (IU/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the SGPT/ALT blood test (IU/L) at visit 4 was out of range	.F="No Record for This Visit" 0="No" 1="Yes"
bldchem_sgpt_alt_v1	SGPT/ALT (IU/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the SGPT/ALT blood test (IU/L) at visit 1	Numeric
bldchem_sgpt_alt_v4	SGPT/ALT (IU/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the SGPT/ALT blood test (IU/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_sodium_clin_v1	Sodium (mmol/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the sodium blood test (mmol/L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_sodium_clin_v4	Sodium (mmol/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the sodium blood test (mmol/L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_sodium_out_v1	Sodium (mmol/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the sodium blood test (mmol/L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_sodium_out_v4	Sodium (mmol/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the sodium blood test (mmol/L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_sodium_v1	Sodium (mmol/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the sodium blood test (mmol/L) at visit 1	Numeric .F="No Record for This Visit"

Variable	Label	Description	Format Text
bldchem_sodium_v4	Sodium (mmol/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the sodium blood test (mmol/L) at visit 4	Numeric .F="No Record for This Visit"
bldchem_uric_acid_clin_v1	Uric Acid (umol/L) Test Results Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the result of the uric acid blood test (mmol/L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_uric_acid_clin_v4	Uric Acid (umol/L) Test Results Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the result of the uric acid blood test (mmol/L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
bldchem_uric_acid_out_v1	Uric Acid (umol/L) Test Results Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the result of the uric acid blood test (mmol/L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_uric_acid_out_v4	Uric Acid (umol/L) Test Results Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the result of the uric acid blood test (mmol/L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
bldchem_uric_acid_v1	Uric Acid (umol/L) Test Results - Visit 1 - [Blood Chemistry]	Result of the uric acid blood test (mmol/L) at visit 1	Numeric .F="No Record for This Visit"
bldchem_uric_acid_v4	Uric Acid (umol/L) Test Results - Visit 4 - [Blood Chemistry]	Result of the uric acid blood test (mmol/L) at visit 4	Numeric .F="No Record for This Visit"

Section 18: Hematology

Variable	Label	Description	Format Text
hema_anc_clin_v1	Absolute Neutrophil Count (x10 ⁹ /L) Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the absolute neutrophil count hematology test (mmol/L) at visit 1 was clinically significant	.M="Missing" 0="No"
hema_anc_clin_v4	Absolute Neutrophil Count (x10 ⁹ /L) Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the absolute neutrophil count hematology test (mmol/L) at visit 4 was clinically significant	.F="No Record for This Visit" .M="Missing"
hema_anc_out_v1	Absolute Neutrophil Count (x10 ⁹ /L) Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the absolute neutrophil count hematology test (mmol/L) at visit 1 was out of range	0="No" 1="Yes"
hema_anc_out_v4	Absolute Neutrophil Count (x10 ⁹ /L) Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the absolute neutrophil count hematology test (mmol/L) at visit 4 was out of range	.F="No Record for This Visit" 0="No"
hema_anc_v1	Absolute Neutrophil Count (x10 ⁹ /L) Test Results - Visit 1 - [Hematology]	Result of the absolute neutrophil count hematology test (mmol/L) at visit 1	Numeric
hema_anc_v4	Absolute Neutrophil Count (x10 ⁹ /L) Test Results - Visit 4 - [Hematology]	Result of the absolute neutrophil count hematology test (mmol/L) at visit 4	Numeric .F="No Record for This Visit"
hema_any_other_out_v1	Any Other Tests Out of Range? - Visit 1 - [Hematology]	Indicates if any other hematology tests were out of range at visit 1	0="No" 1="Yes"
hema_any_other_out_v4	Any Other Tests Out of Range? - Visit 4 - [Hematology]	Indicates if any other hematology tests were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
hema_basophils_clin_v1	Basophils (x10 ⁹ /L) Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the basophils hematology test (x10 ⁹ /L) at visit 1 was clinically significant	.F="No Record for This Visit"
hema_basophils_clin_v4	Basophils (x10 ⁹ /L) Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the basophils hematology test (x10 ⁹ /L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
hema_basophils_out_v1	Basophils (x10 ⁹ /L) Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the basophils hematology test (x10 ⁹ /L) at visit 1 was out of range	.F="No Record for This Visit"
hema_basophils_out_v4	Basophils (x10 ⁹ /L) Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the basophils hematology test (x10 ⁹ /L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"

Variable	Label	Description	Format Text
hema_basophils_v1	Basophils (x10 ⁹ /L) Test Results - Visit 1 - [Hematology]	Result of the basophils hematology test (x10 ⁹ /L) at visit 1	Numeric .F="No Record for This Visit"
hema_basophils_v4	Basophils (x10 ⁹ /L) Test Results - Visit 4 - [Hematology]	Result of the basophils hematology test (x10 ⁹ /L) at visit 4	Numeric .F="No Record for This Visit"
hema_eosinophils_clin_v1	Eosinophils (x10 ⁹ /L) Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the eosinophils hematology test (x10 ⁹ /L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
hema_eosinophils_clin_v4	Eosinophils (x10 ⁹ /L) Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the eosinophils hematology test (x10 ⁹ /L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
hema_eosinophils_out_v1	Eosinophils (x10 ⁹ /L) Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the eosinophils hematology test (x10 ⁹ /L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
hema_eosinophils_out_v4	Eosinophils (x10 ⁹ /L) Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the eosinophils hematology test (x10 ⁹ /L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
hema_eosinophils_v1	Eosinophils (x10 ⁹ /L) Test Results - Visit 1 - [Hematology]	Result of the eosinophils hematology test (x10 ⁹ /L) at visit 1	Numeric .F="No Record for This Visit"
hema_eosinophils_v4	Eosinophils (x10 ⁹ /L) Test Results - Visit 4 - [Hematology]	Result of the eosinophils hematology test (x10 ⁹ /L) at visit 4	Numeric .F="No Record for This Visit"
hema_hematocrit_clin_v1	Hematocrit Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the hematocrit hematology test at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
hema_hematocrit_clin_v4	Hematocrit Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the hematocrit hematology test at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
hema_hematocrit_out_v1	Hematocrit Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the hematocrit hematology test at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
hema_hematocrit_out_v4	Hematocrit Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the hematocrit hematology test at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
hema_hematocrit_v1	Hematocrit Test Results - Visit 1 - [Hematology]	Result of the hematocrit hematology test at visit 1	Numeric .F="No Record for This Visit"
hema_hematocrit_v4	Hematocrit Test Results - Visit 4 - [Hematology]	Result of the hematocrit hematology test at visit 4	Numeric .F="No Record for This Visit"
hema_hemoglobin_clin_v1	Hemoglobin (g/L) Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the hemoglobin hematology test (g/L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"

Variable	Label	Description	Format Text
hema_hemoglobin_clin_v4	Hemoglobin (g/L) Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the hemoglobin hematology test (g/L) at visit 4 was clinically significant	.F="No Record for This Visit"
hema_hemoglobin_out_v1	Hemoglobin (g/L) Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the hemoglobin hematology test (g/L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
hema_hemoglobin_out_v4	Hemoglobin (g/L) Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the hemoglobin hematology test (g/L) at visit 4 was out of range	.F="No Record for This Visit"
hema_hemoglobin_v1	Hemoglobin (g/L) Test Results - Visit 1 - [Hematology]	Result of the hemoglobin hematology test (g/L) at visit 1	Numeric .F="No Record for This Visit"
hema_hemoglobin_v4	Hemoglobin (g/L) Test Results - Visit 4 - [Hematology]	Result of the hemoglobin hematology test (g/L) at visit 4	Numeric .F="No Record for This Visit"
hema_inr_clin_v1	INR Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the INR hematology test at visit 1 was clinically significant	.F="No Record for This Visit"
hema_inr_clin_v4	INR Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the INR hematology test at visit 4 was clinically significant	.F="No Record for This Visit"
hema_inr_out_v1	INR Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the INR hematology test at visit 1 was out of range	.F="No Record for This Visit"
hema_inr_out_v4	INR Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the INR hematology test at visit 4 was out of range	.F="No Record for This Visit"
hema_inr_v1	INR Test Results - Visit 1 - [Hematology]	Result of the INR hematology test at visit 1	Numeric .F="No Record for This Visit"
hema_inr_v4	INR Test Results - Visit 4 - [Hematology]	Result of the INR hematology test at visit 4	Numeric .F="No Record for This Visit"
hema_lymphocytes_clin_v1	Lymphocytes (x10 ⁹ /L) Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the lymphocytes hematology test (x10 ⁹ /L) at visit 1 was clinically significant	.F="No Record for This Visit"
hema_lymphocytes_clin_v4	Lymphocytes (x10 ⁹ /L) Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the lymphocytes hematology test (x10 ⁹ /L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
hema_lymphocytes_out_v1	Lymphocytes (x10 ⁹ /L) Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the lymphocytes hematology test (x10 ⁹ /L) at visit 1 was out of range	.F="No Record for This Visit"
hema_lymphocytes_out_v4	Lymphocytes (x10 ⁹ /L) Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the lymphocytes hematology test (x10 ⁹ /L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
hema_lymphocytes_v1	Lymphocytes (x10 ⁹ /L) Test Results - Visit 1 - [Hematology]	Result of the lymphocytes hematology test (x10 ⁹ /L) at visit 1	Numeric .F="No Record for This Visit"

Variable	Label	Description	Format Text
hema_lymphocytes_v4	Lymphocytes (x10 ⁹ /L) Test Results - Visit 4 - [Hematology]	Result of the lymphocytes hematology test (x10 ⁹ /L) at visit 4	Numeric .F="No Record for This Visit"
hema_monocytes_clin_v1	Monocytes (x10 ⁹ /L) Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the monocytes hematology test (x10 ⁹ /L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
hema_monocytes_clin_v4	Monocytes (x10 ⁹ /L) Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the monocytes hematology test (x10 ⁹ /L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
hema_monocytes_out_v1	Monocytes (x10 ⁹ /L) Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the monocytes hematology test (x10 ⁹ /L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
hema_monocytes_out_v4	Monocytes (x10 ⁹ /L) Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the monocytes hematology test (x10 ⁹ /L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
hema_monocytes_v1	Monocytes (x10 ⁹ /L) Test Results - Visit 1 - [Hematology]	Result of the monocytes hematology test (x10 ⁹ /L) at visit 1	Numeric .F="No Record for This Visit"
hema_monocytes_v4	Monocytes (x10 ⁹ /L) Test Results - Visit 4 - [Hematology]	Result of the monocytes hematology test (x10 ⁹ /L) at visit 4	Numeric .F="No Record for This Visit"
hema_neutrophils_clin_v1	Neutrophils (x10 ⁹ /L) Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the neutrophils hematology test (x10 ⁹ /L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"
hema_neutrophils_clin_v4	Neutrophils (x10 ⁹ /L) Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the neutrophils hematology test (x10 ⁹ /L) at visit 4 was clinically significant	.F="No Record for This Visit"
hema_neutrophils_out_v1	Neutrophils (x10 ⁹ /L) Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the neutrophils hematology test (x10 ⁹ /L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
hema_neutrophils_out_v4	Neutrophils (x10 ⁹ /L) Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the neutrophils hematology test (x10 ⁹ /L) at visit 4 was out of range	.F="No Record for This Visit"
hema_neutrophils_v1	Neutrophils (x10 ⁹ /L) Test Results - Visit 1 - [Hematology]	Result of the neutrophils hematology test (x10 ⁹ /L) at visit 1	Numeric .F="No Record for This Visit"
hema_neutrophils_v4	Neutrophils (x10 ⁹ /L) Test Results - Visit 4 - [Hematology]	Result of the neutrophils hematology test (x10 ⁹ /L) at visit 4	Numeric .F="No Record for This Visit"
hema_other1_clin_v1	Other Test (1) Results Clinically Significant - Visit 1 - [Hematology]	Indicates if the result of the other hematology test (1) at visit 1 was clinically significant	.N="N/A"

Variable	Label	Description	Format Text
hema_other1_clin_v4	Other Test (1) Results Clinically Significant - Visit 4 - [Hematology]	Indicates if the result of the other hematology test (1) at visit 4 was clinically significant	.N="N/A" 0="No"
hema_other1_name_v1	Other Test (1) Name - Visit 1 - [Hematology]	Name of other hematology test (1) at visit 1	Char
hema_other1_name_v4	Other Test (1) Name - Visit 4 - [Hematology]	Name of other hematology test (1) at visit 4	Char
hema_other1_out_v1	Other Test (1) Results Out of Range - Visit 1 - [Hematology]	Indicates if the result of the other hematology test (1) at visit 1 was out of range	.N="N/A"
hema_other1_out_v4	Other Test (1) Results Out of Range - Visit 4 - [Hematology]	Indicates if the result of the other hematology test (1) at visit 4 was out of range	.N="N/A" 1="Yes"
hema_other1_units_v1	Other Test (1) Units - Visit 1 - [Hematology]	Units used in other hematology test (1) at visit 1	Char
hema_other1_units_v4	Other Test (1) Units - Visit 4 - [Hematology]	Units used in other hematology test (1) at visit 4	Char
hema_other1_v1	Other Test (1) Results - Visit 1 - [Hematology]	Result of other hematology test (1) at visit 1	Numeric .N="N/A"
hema_other1_v4	Other Test (1) Results - Visit 4 - [Hematology]	Result of other hematology test (1) test at visit 4	Numeric .N="N/A"
hema_other2_clin_v1	Other Test (2) Results Clinically Significant - Visit 1 - [Hematology]	Indicates if the result of the other hematology test (2) at visit 1 was clinically significant	.N="N/A"
hema_other2_clin_v4	Other Test (2) Results Clinically Significant - Visit 4 - [Hematology]	Indicates if the result of the other hematology test (2) at visit 4 was clinically significant	.N="N/A" 0="No"
hema_other2_name_v1	Other Test (2) Name - Visit 1 - [Hematology]	Name of other hematology test (2) at visit 1	Char
hema_other2_name_v4	Other Test (2) Name - Visit 4 - [Hematology]	Name of other hematology test (2) at visit 4	Char
hema_other2_out_v1	Other Test (2) Results Out of Range - Visit 1 - [Hematology]	Indicates if the result of the other hematology test (2) at visit 1 was out of range	.N="N/A"
hema_other2_out_v4	Other Test (2) Results Out of Range - Visit 4 - [Hematology]	Indicates if the result of the other hematology test (2) at visit 4 was out of range	.N="N/A" 1="Yes"
hema_other2_units_v1	Other Test (2) Units - Visit 1 - [Hematology]	Units used in other hematology test (2) at visit 1	Char
hema_other2_units_v4	Other Test (2) Units - Visit 4 - [Hematology]	Units used in other hematology test (2) at visit 4	Char
hema_other2_v1	Other Test (2) Results - Visit 1 - [Hematology]	Result of other hematology test (2) at visit 1	Numeric .N="N/A"
hema_other2_v4	Other Test (2) Results - Visit 4 - [Hematology]	Result of other hematology test (2) test at visit 4	Numeric .N="N/A"

Variable	Label	Description	Format Text
hema_other3_clin_v1	Other Test (3) Results Clinically Significant - Visit 1 - [Hematology]	Indicates if the result of the other hematology test (3) at visit 1 was clinically significant	.N="N/A"
hema_other3_clin_v4	Other Test (3) Results Clinically Significant - Visit 4 - [Hematology]	Indicates if the result of the other hematology test (3) at visit 4 was clinically significant	.N="N/A" 0="No"
hema_other3_name_v1	Other Test (3) Name - Visit 1 - [Hematology]	Name of other hematology test (3) at visit 1	Char
hema_other3_name_v4	Other Test (3) Name - Visit 4 - [Hematology]	Name of other hematology test (3) at visit 4	Char
hema_other3_out_v1	Other Test (3) Results Out of Range - Visit 1 - [Hematology]	Indicates if the result of the other hematology test (3) at visit 1 was out of range	.N="N/A"
hema_other3_out_v4	Other Test (3) Results Out of Range - Visit 4 - [Hematology]	Indicates if the result of the other hematology test (3) at visit 4 was out of range	.N="N/A" 1="Yes"
hema_other3_units_v1	Other Test (3) Units - Visit 1 - [Hematology]	Units used in other hematology test (3) at visit 1	Char
hema_other3_units_v4	Other Test (3) Units - Visit 4 - [Hematology]	Units used in other hematology test (3) at visit 4	Char
hema_other3_v1	Other Test (3) Results - Visit 1 - [Hematology]	Result of other hematology test (3) at visit 1	Numeric .N="N/A"
hema_other3_v4	Other Test (3) Results - Visit 4 - [Hematology]	Result of other hematology test (3) test at visit 4	Numeric .N="N/A"
hema_platelets_clin_v1	Platelets (x10 ⁹ /L) Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the platelets hematology test (mmol/L) at visit 1 was clinically significant	.M="Missing" 0="No"
hema_platelets_clin_v4	Platelets (x10 ⁹ /L) Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the platelets hematology test (mmol/L) at visit 4 was clinically significant	.F="No Record for This Visit" .M="Missing" 0="No"
hema_platelets_out_v1	Platelets (x10 ⁹ /L) Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the platelets hematology test (mmol/L) at visit 1 was out of range	0="No" 1="Yes"
hema_platelets_out_v4	Platelets (x10 ⁹ /L) Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the platelets hematology test (mmol/L) at visit 4 was out of range	.F="No Record for This Visit" 0="No" 1="Yes"
hema_platelets_v1	Platelets (x10 ⁹ /L) Test Results - Visit 1 - [Hematology]	Result of the platelets hematology test (mmol/L) at visit 1	Numeric
hema_platelets_v4	Platelets (x10 ⁹ /L) Test Results - Visit 4 - [Hematology]	Result of the platelets hematology test (mmol/L) at visit 4	Numeric .F="No Record for This Visit"
hema_rbc_clin_v1	Red Blood Cells (x10 ¹² /L) Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the red blood cells hematology test (x10 ¹² /L) at visit 1 was clinically significant	.F="No Record for This Visit" 0="No"

Variable	Label	Description	Format Text
hema_rbc_clin_v4	Red Blood Cells (x10 ¹² /L) Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the red blood cells hematology test (x10 ¹² /L) at visit 4 was clinically significant	.F="No Record for This Visit" 0="No"
hema_rbc_out_v1	Red Blood Cells (x10 ¹² /L) Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the red blood cells hematology test (x10 ¹² /L) at visit 1 was out of range	.F="No Record for This Visit" 1="Yes"
hema_rbc_out_v4	Red Blood Cells (x10 ¹² /L) Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the red blood cells hematology test (x10 ¹² /L) at visit 4 was out of range	.F="No Record for This Visit" 1="Yes"
hema_rbc_v1	Red Blood Cells (x10 ¹² /L) Test Results - Visit 1 - [Hematology]	Result of the red blood cells hematology test (x10 ¹² /L) at visit 1	Numeric .F="No Record for This Visit"
hema_rbc_v4	Red Blood Cells (x10 ¹² /L) Test Results - Visit 4 - [Hematology]	Result of the red blood cells hematology test (x10 ¹² /L) at visit 4	Numeric .F="No Record for This Visit"
hema_wbc_clin_v1	White Blood Cells (x10 ⁹ /L) Test Results Clinically Significant? - Visit 1 - [Hematology]	Indicates if the result of the white blood cells hematology test (x10 ⁹ /L) at visit 1 was clinically significant	.M="Missing" 0="No"
hema_wbc_clin_v4	White Blood Cells (x10 ⁹ /L) Test Results Clinically Significant? - Visit 4 - [Hematology]	Indicates if the result of the white blood cells hematology test (x10 ⁹ /L) at visit 4 was clinically significant	.F="No Record for This Visit" .M="Missing"
hema_wbc_out_v1	White Blood Cells (x10 ⁹ /L) Test Results Out of Range? - Visit 1 - [Hematology]	Indicates if the result of the white blood cells hematology test (x10 ⁹ /L) at visit 1 was out of range	0="No" 1="Yes"
hema_wbc_out_v4	White Blood Cells (x10 ⁹ /L) Test Results Out of Range? - Visit 4 - [Hematology]	Indicates if the result of the white blood cells hematology test (x10 ⁹ /L) at visit 4 was out of range	.F="No Record for This Visit" 0="No"
hema_wbc_v1	White Blood Cells (x10 ⁹ /L) Test Results - Visit 1 - [Hematology]	Result of the white blood cells hematology test (x10 ⁹ /L) at visit 1	Numeric
hema_wbc_v4	White Blood Cells (x10 ⁹ /L) Test Results - Visit 4 - [Hematology]	Result of the white blood cells hematology test (x10 ⁹ /L) at visit 4	Numeric .F="No Record for This Visit"

Section 19: Specimens

Variable	Label	Description	Format Text
spec_bld_v1_dt1-3	Date of Collection - Blood Specimen # - Visit 1 - [Specimens]	Date that the specified blood specimen was collected	SAS Date .R="Not Randomized"
spec_bld_v1_temp1-3	Storage Temperature - Blood Specimen # - Visit 1 - [Specimens]	Storage temperature of the specified blood specimen	Numeric .R="Not Randomized"
spec_bld_v1_time1-3	Time of Collection - Blood Specimen # - Visit 1 - [Specimens]	Time that the specified blood specimen was collected	Numeric .M="Missing" .R="Not Randomized"
spec_bld_v4_dt1-3	Date of Collection - Blood Specimen # - Visit 4 - [Specimens]	Date that the specified blood specimen was collected	SAS Date .F="No Record for This Visit" .R="Not Randomized"
spec_bld_v4_temp1-3	Storage Temperature - Blood Specimen # - Visit 4 - [Specimens]	Storage temperature of the specified blood specimen	Numeric .F="No Record for This Visit" .R="Not Randomized"
spec_bld_v4_time1-3	Time of Collection - Blood Specimen # - Visit 4 - [Specimens]	Time that the specified blood specimen was collected	Numeric .F="No Record for This Visit" .R="Not Randomized"
spec_last_berb_dt_v4	Date of Last Berberine Dose - Visit 4 - [Specimens]	Date that the last dose of Berberine was taken before Visit 4 specimens	SAS Date .F="No Record for This Visit" .R="Not Randomized"
spec_last_berb_time_v4	Time of Last Berberine Dose - Visit 4 - [Specimens]	Time that the last dose of Berberine was taken before Visit 4 specimens	Numeric .F="No Record for This Visit" .R="Not Randomized"
spec_position_v1	Position of Participant During Colonoscopy - Visit 1 - [Specimens]	Position of the participant during Visit 1 colonoscopy	Char
spec_position_v4	Position of Participant During Colonoscopy - Visit 4 - [Specimens]	Position of the participant during Visit 4 colonoscopy	Char
spec_tis_v1_dt1-7	Date of Collection - Tissue Specimen # - Visit 1 - [Specimens]	Date that the specified tissue specimen was collected	SAS Date .R="Not Randomized"
spec_tis_v1_loc1-7	Tissue Location (cm from Anal Verge) - Tissue Specimen # - Visit 1 - [Specimens]	Location (cm from anal verge) of the specified tissue sample	Numeric .R="Not Randomized"
spec_tis_v1_temp1-7	Storage Temperature - Tissue Specimen # - Visit 1 - [Specimens]	Storage temperature of the specified tissue specimen	Numeric .R="Not Randomized"
spec_tis_v1_time1-7	Time of Collection - Tissue Specimen # - Visit 1 - [Specimens]	Time that the specified tissue specimen was collected	Numeric .R="Not Randomized"
spec_tis_v4_dt1-7	Date of Collection - Tissue Specimen # - Visit 4 - [Specimens]	Date that the specified tissue specimen was collected	SAS Date .F="No Record for This Visit" .R="Not Randomized"

Variable	Label	Description	Format Text
spec_tis_v4_loc1-7	Tissue Location (cm from Anal Verge) - Tissue Specimen # - Visit 4 - [Specimens]	Location (cm from anal verge) of the specified tissue sample	Numeric .F="No Record for This Visit" .M="Missing" .R="Not Randomized"
spec_tis_v4_temp1-7	Storage Temperature - Tissue Specimen # - Visit 4 - [Specimens]	Storage temperature of the specified tissue specimen	Numeric .F="No Record for This Visit" .R="Not Randomized"
spec_tis_v4_time1-7	Time of Collection - Tissue Specimen # - Visit 4 - [Specimens]	Time that the specified tissue specimen was collected	Numeric .F="No Record for This Visit" .R="Not Randomized"

Section 20: Ulcerative Colitis Disease Activity Index

Variable	Label	Description	Format Text
ucdai_bleed_score_v1	Daily Bleeding Score - Visit 1 - [UCDAI]	Daily bleeding score at visit 1	.R="Not Randomized" 0="No Blood Seen"
ucdai_bleed_score_v4	Daily Bleeding Score - Visit 4 - [UCDAI]	Daily bleeding score at visit 4	.N="N/A" .R="Not Randomized" 0="No Blood Seen"
ucdai_endo_v1	Endoscopic Findings - Visit 1 - [UCDAI]	Endoscopic findings at visit 1	.R="Not Randomized" 0="Normal or Inactive Disease" 1="Mild Disease (Erythema, Decreased Vascular Pattern, Mild Friability)"
ucdai_endo_v4	Endoscopic Findings - Visit 4 - [UCDAI]	Endoscopic findings at visit 4	.N="N/A" .R="Not Randomized" 0="Normal or Inactive Disease" 1="Mild Disease (Erythema, Decreased Vascular Pattern, Mild Friability)"
ucdai_global_asses_s_v1	Physician's Global Assessment - Visit 1 - [UCDAI]	Physician's global assessment at visit 1	.R="Not Randomized" 0="Normal"
ucdai_global_asses_s_v4	Physician's Global Assessment - Visit 4 - [UCDAI]	Physician's global assessment at visit 4	.N="N/A" .R="Not Randomized" 0="Normal"
ucdai_score_v1	UCDAI Score - Visit 1 - [UCDAI]	UCDAI score at visit 1	Numeric .R="Not Randomized"
ucdai_score_v4	UCDAI Score - Visit 4 - [UCDAI]	UCDAI score at visit 4	Numeric .N="N/A" .R="Not Randomized"
ucdai_stool_freq_v1	Stool Frequency Score - Visit 1 - [UCDAI]	Stool frequency score at visit 1	.R="Not Randomized" 0="Normal Number of Stools/Day for This Patient"
ucdai_stool_freq_v4	Stool Frequency Score - Visit 4 - [UCDAI]	Stool frequency score at visit 4	.N="N/A" .R="Not Randomized" 0="Normal Number of Stools/Day for This Patient"

Section 21: Berberine Concentration

Variable	Label	Description	Format Text
conc_berberine_v1	Berberine Concentration (ng/mL) - Visit 1 - [Concentration]	Berberine concentration (ng/mL) at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
conc_berberine_v4	Berberine Concentration (ng/mL) - Visit 4 - [Concentration]	Berberine concentration (ng/mL) at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"

Section 22: Cytokines

Variable	Label	Description	Format Text
cyto_il10_50llq_v1	IL-10 (pg/mL) with 50% LLQ added as 0#55 pg/mL - Visit 1 - [Cytokines]	IL-10 (pg/mL) with 50% LLQ added as 0#55 pg/mL at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
cyto_il10_50llq_v4	IL-10 (pg/mL) with 50% LLQ added as 0#55 pg/mL - Visit 4 - [Cytokines]	IL-10 (pg/mL) with 50% LLQ added as 0#55 pg/mL at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"
cyto_il10_v1	IL-10 - Visit 1 - [Cytokines]	IL-10 at Visit 1	Numeric -1="Out of Range <" .F="No Record for This Visit" .R="Not Randomized"
cyto_il10_v4	IL-10 - Visit 4 - [Cytokines]	IL-10 at Visit 4	Numeric -1="Out of Range <" .F="No Record for This Visit" .R="Not Randomized"
cyto_il2_50llq_v1	IL-2 (pg/mL) with 50% LLQ as #5 pg/mL - Visit 1 - [Cytokines]	IL-2 (pg/mL) with 50% LLQ as #5 pg/mL at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
cyto_il2_50llq_v4	IL-2 (pg/mL) with 50% LLQ as #5 pg/mL - Visit 4 - [Cytokines]	IL-2 (pg/mL) with 50% LLQ as #5 pg/mL at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"
cyto_il2_v1	IL-2 - Visit 1 - [Cytokines]	IL-2 at Visit 1	Numeric -1="Out of Range <" .F="No Record for This Visit" .R="Not Randomized"
cyto_il2_v4	IL-2 - Visit 4 - [Cytokines]	IL-2 at Visit 4	Numeric -1="Out of Range <" .F="No Record for This Visit" .R="Not Randomized"
cyto_il4_50llq_v1	IL-4 (pg/mL) with 50% LLQ as 2#25 pg/mL - Visit 1 - [Cytokines]	IL-4 (pg/mL) with 50% LLQ as 2#25 pg/mL at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
cyto_il4_50llq_v4	IL-4 (pg/mL) with 50% LLQ as 2#25 pg/mL - Visit 4 - [Cytokines]	IL-4 (pg/mL) with 50% LLQ as 2#25 pg/mL at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"
cyto_il4_v1	IL-4 - Visit 1 - [Cytokines]	IL-4 at Visit 1	Numeric -1="Out of Range <" .F="No Record for This Visit" .R="Not Randomized"
cyto_il4_v4	IL-4 - Visit 4 - [Cytokines]	IL-4 at Visit 4	Numeric -1="Out of Range <" .F="No Record for This Visit" .R="Not Randomized"
cyto_il6_50llq_v1	IL-6 (pg/mL) with 50% LLQ added as 0#75 pg/mL - Visit 1 - [Cytokines]	IL-6 (pg/mL) with 50% LLQ added as 0#75 pg/mL at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
cyto_il6_50llq_v4	IL-6 (pg/mL) with 50% LLQ added as 0#75 pg/mL - Visit 4 - [Cytokines]	IL-6 (pg/mL) with 50% LLQ added as 0#75 pg/mL at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"

Variable	Label	Description	Format Text
cyto_il6_v1	IL-6 - Visit 1 - [Cytokines]	IL-6 at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
cyto_il6_v4	IL-6 - Visit 4 - [Cytokines]	IL-6 at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized" 1.499="<1.5"
cyto_il8_50llq_v1	IL-8 (pg/mL) with 50% LLQ added as 0#2 pg/mL, and ULQ added as 30 - Visit 1 - [Cytokines]	IL-8 (pg/mL) with 50% LLQ added as 0#2 pg/mL, and ULQ added as 30 at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
cyto_il8_50llq_v4	IL-8 (pg/mL) with 50% LLQ added as 0#2 pg/mL, and ULQ added as 30 - Visit 4 - [Cytokines]	IL-8 (pg/mL) with 50% LLQ added as 0#2 pg/mL, and ULQ added as 30 at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"
cyto_il8_v1	IL-8 - Visit 1 - [Cytokines]	IL-8 at Visit 1	Numeric -1="Out of Range <" .F="No Record for This Visit" .R="Not Randomized" 1="Out of Range >"
cyto_il8_v4	IL-8 - Visit 4 - [Cytokines]	IL-8 at Visit 4	Numeric -1="Out of Range <" .F="No Record for This Visit" .R="Not Randomized"
cyto_spec_dt_v1	Specimen Collection Date - Visit 1 - [Cytokines]	Specimen collection date at Visit 1	SAS Date .F="No Record for This Visit" .R="Not Randomized"
cyto_spec_dt_v4	Specimen Collection Date - Visit 4 - [Cytokines]	Specimen collection date at Visit 4	SAS Date .F="No Record for This Visit" .R="Not Randomized"
cyto_tnfa_v1	TNF-Alpha - Visit 1 - [Cytokines]	TNF-Alpha at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
cyto_tnfa_v4	TNF-Alpha - Visit 4 - [Cytokines]	TNF-Alpha at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"

Section 23: Pathology

Variable	Label	Description	Format Text
path_diagnosis_v1	Diagnosis - Visit 1 - [Pathology]	Diagnosis at Visit 1	Char
path_diagnosis_v4	Diagnosis - Visit 4 - [Pathology]	Diagnosis at Visit 4	Char
path_geboes_cii_v1	Chronic Inflammatory Infiltrate - Geboes Score - Visit 1 - [Pathology]	Chronic Inflammatory Infiltrate Geboes score at Visit 1	.F="No Record for This Visit" .R="Not Randomized" 1.1="1.1 - Mild but Unequivocal Increase" 1.2="1.2 - Moderate Increase" 1.3="1.3 - Marked Increase"
path_geboes_cii_v4	Chronic Inflammatory Infiltrate - Geboes Score - Visit 4 - [Pathology]	Chronic Inflammatory Infiltrate Geboes score at Visit 4	.F="No Record for This Visit" .R="Not Randomized" 1="1.0 - No Increase" 1.1="1.1 - Mild but Unequivocal Increase" 1.2="1.2 - Moderate Increase" 1.3="1.3 - Marked Increase"
path_geboes_crypt_des_v1	Crypt Destruction - Geboes Score - Visit 1 - [Pathology]	Crypt Destruction Geboes score at Visit 1	.F="No Record for This Visit" .R="Not Randomized" 4="4.0 - None" 4.1="4.1 - Probable: Local Excess of Neutrophils in Part of the Crypts" 4.3="4.3 - Unequivocal Crypt Destruction"
path_geboes_crypt_des_v4	Crypt Destruction - Geboes Score - Visit 4 - [Pathology]	Crypt Destruction Geboes score at Visit 4	.F="No Record for This Visit" .R="Not Randomized" 4="4.0 - None" 4.1="4.1 - Probable: Local Excess of Neutrophils in Part of the Crypts" 4.2="4.2 - Probable: Marked Attenuation" 4.3="4.3 - Unequivocal Crypt Destruction"
path_geboes_eosin_v1	Eosinophils - Geboes Score - Visit 1 - [Pathology]	Eosinophils Geboes score at Visit 1	.F="No Record for This Visit" .R="Not Randomized" 0="2A.0 - No Increase" 1="2A.1 - Mild but Unequivocal Increase" 2="2A.2 - Moderate Increase"
path_geboes_eosin_v4	Eosinophils - Geboes Score - Visit 4 - [Pathology]	Eosinophils Geboes score at Visit 4	.F="No Record for This Visit" .R="Not Randomized" 0="2A.0 - No Increase" 1="2A.1 - Mild but Unequivocal Increase" 2="2A.2 - Moderate Increase" 3="2A.3 - Marked Increase"
path_geboes_erosin_ulc_v1	Erosin or Ulceration - Geboes Score - Visit 1 - [Pathology]	Erosin or Ulceration Geboes score at Visit 1	.F="No Record for This Visit" .R="Not Randomized" 5="5.0 - No Erosion, Ulceration or Granulation Tissue" 5.1="5.1 - Recovering Epithelium + Adjacent Inflammation" 5.2="5.2 - Probable Erosion: Focally Stripped" 5.4="5.4 - Ulcer or Granulation Tissue"

Variable	Label	Description	Format Text
path_geboes_erosin_ulc_v4	Erosin or Ulceration - Geboes Score - Visit 4 - [Pathology]	Erosin or Ulceration Geboes score at Visit 4	.F="No Record for This Visit" .R="Not Randomized" 5="5.0 - No Erosion, Ulceration or Granulation Tissue" 5.1="5.1 - Recovering Epithelium + Adjacent Inflammation" 5.2="5.2 - Probable Erosion: Focally Stripped" 5.3="5.3 - Unequivocal Erosion" 5.4="5.4 - Ulcer or Granulation Tissue"
path_geboes_final_v1	Geboes Final Score - Visit 1 - [Pathology]	Geboes final score at Visit 1	Numeric .F="No Record for This Visit" .M="Missing" .R="Not Randomized"
path_geboes_final_v4	Geboes Final Score - Visit 4 - [Pathology]	Geboes final score at Visit 4	Numeric .F="No Record for This Visit" .M="Missing" .R="Not Randomized"
path_geboes_neutr_o_epi_v1	Neutrophils in Epithelium - Geboes Score - Visit 1 - [Pathology]	Neutrophils in Epithelium Geboes score at Visit 1	.F="No Record for This Visit" .R="Not Randomized" 3="3.0 - None" 3.1="3.1 - <5% Crypts Involved" 3.2="3.2 - <50% Crypts Involved" 3.3="3.3 - >50% Crypts Involved"
path_geboes_neutr_o_epi_v4	Neutrophils in Epithelium - Geboes Score - Visit 4 - [Pathology]	Neutrophils in Epithelium Geboes score at Visit 4	.F="No Record for This Visit" .R="Not Randomized" 3="3.0 - None" 3.1="3.1 - <5% Crypts Involved" 3.2="3.2 - <50% Crypts Involved" 3.3="3.3 - >50% Crypts Involved"
path_geboes_neutr_o_v1	Neutrophils - Geboes Score - Visit 1 - [Pathology]	Neutrophils Geboes score at Visit 1	.F="No Record for This Visit" .R="Not Randomized" 0="2B.0 - No Increase" 1="2B.1 - Mild but Unequivocal Increase" 2="2B.2 - Moderate Increase" 3="2B.3 - Marked Increase"
path_geboes_neutr_o_v4	Neutrophils - Geboes Score - Visit 4 - [Pathology]	Neutrophils Geboes score at Visit 4	.F="No Record for This Visit" .R="Not Randomized" 0="2B.0 - No Increase" 1="2B.1 - Mild but Unequivocal Increase" 2="2B.2 - Moderate Increase" 3="2B.3 - Marked Increase"
path_geboes_struct_v1	Structural - Geboes Score - Visit 1 - [Pathology]	Structural Geboes score at Visit 1	.F="No Record for This Visit" .R="Not Randomized" 0="0.0 - No Abnormality" 0.1="0.1 - Mild Abnormality" 0.2="0.2 - Mild/Moderate Diffuse or Multifocal Abnormalities" 0.3="0.3 - Severe Diffuse or Multifocal Abnormalities"
path_geboes_struct_v4	Structural - Geboes Score - Visit 4 - [Pathology]	Structural Geboes score at Visit 4	.F="No Record for This Visit" .R="Not Randomized" 0="0.0 - No Abnormality" 0.1="0.1 - Mild Abnormality" 0.2="0.2 - Mild/Moderate Diffuse or Multifocal Abnormalities" 0.3="0.3 - Severe Diffuse or Multifocal Abnormalities"

Variable	Label	Description	Format Text
path_ihc_caspase3_v1	Caspase-3 - Immunohistochemistry - Visit 1 - [Pathology]	Caspase-3 immunohistochemistry at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
path_ihc_caspase3_v4	Caspase-3 - Immunohistochemistry - Visit 4 - [Pathology]	Caspase-3 immunohistochemistry at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"
path_ihc_cox2_v1	COX-2 - Immunohistochemistry - Visit 1 - [Pathology]	COX-2 immunohistochemistry at Visit 1	.F="No Record for This Visit" .R="Not Randomized" 0="0" 1="1+" 2="2+" 3="3+"
path_ihc_cox2_v4	COX-2 - Immunohistochemistry - Visit 4 - [Pathology]	COX-2 immunohistochemistry at Visit 4	.F="No Record for This Visit" .R="Not Randomized" 1="1+" 2="2+" 3="3+"
path_ihc_ki67_v1	Ki-67 - Immunohistochemistry - Visit 1 - [Pathology]	Ki-67 immunohistochemistry at Visit 1	Char
path_ihc_ki67_v4	Ki-67 - Immunohistochemistry - Visit 4 - [Pathology]	Ki-67 immunohistochemistry at Visit 4	Char
path_ihc_nfkb_v1	NF-KB - Immunohistochemistry - Visit 1 - [Pathology]	NF-KB immunohistochemistry at Visit 1	.F="No Record for This Visit" .R="Not Randomized" 0="0" 1="1%" 2="2%" 3="3%" 5="5%"
path_ihc_nfkb_v4	NF-KB - Immunohistochemistry - Visit 4 - [Pathology]	NF-KB immunohistochemistry at Visit 4	.F="No Record for This Visit" .R="Not Randomized" 1="1%" 2="2%" 3="3%" 5="5%" 8="8%"
path_ihc_tnfa_v1	TNF-Alpha - Immunohistochemistry - Visit 1 - [Pathology]	TNF-Alpha immunohistochemistry at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
path_ihc_tnfa_v4	TNF-Alpha - Immunohistochemistry - Visit 4 - [Pathology]	TNF-Alpha immunohistochemistry at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"
path_ki67_where_v1	Ki-67 Where 1/3=1, 1/2=2, 2/3=3 - Visit 1 - [Pathology]	Ki-67 where 1/3=1, 1/2=2, 2/3=3 at Visit 1	.F="No Record for This Visit" .R="Not Randomized" 1="ki-67 positive cells located in the lower 1/3 of the crypt" 2="ki-67 positive cells located in the lower 1/2 of the crypt" 3="ki-67 positive cells located in the lower 2/3 of the crypt"

Variable	Label	Description	Format Text
path_ki67_where_v4	Ki-67 Where 1/3=1, 1/2=2, 2/3=3 - Visit 4 - [Pathology]	Ki-67 where 1/3=1, 1/2=2, 2/3=3 at Visit 4	.F="No Record for This Visit" .R="Not Randomized" 1="ki-67 positive cells located in the lower 1/3 of the crypt" 2="ki-67 positive cells located in the lower 1/2 of the crypt" 3="ki-67 positive cells located in the lower 2/3 of the crypt"
path_pos_cm_v1	Position or cm From Dentate Line - Visit 1 - [Pathology]	Position or cm from dentate line at Visit 1	Char
path_pos_cm_v4	Position or cm From Dentate Line - Visit 4 - [Pathology]	Position or cm from dentate line at Visit 4	Char
path_rpt_dt_v1	Report Date - Visit 1 - [Pathology]	Report date at Visit 1	SAS Date .F="No Record for This Visit" .R="Not Randomized"
path_rpt_dt_v4	Report Date - Visit 4 - [Pathology]	Report date at Visit 4	SAS Date .F="No Record for This Visit" .R="Not Randomized"
path_spec_dt_v1	Specimen Date - Visit 1 - [Pathology]	Specimen date at Visit 1	SAS Date .F="No Record for This Visit" .R="Not Randomized"
path_spec_dt_v4	Specimen Date - Visit 4 - [Pathology]	Specimen date at Visit 4	SAS Date .F="No Record for This Visit" .R="Not Randomized"
path_stromal_cox2_calc_v1	COX-2 in Stromal Cells Calculated - Visit 1 - [Pathology]	COX-2 in stromal cells calculated at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
path_stromal_cox2_calc_v4	COX-2 in Stromal Cells Calculated - Visit 4 - [Pathology]	COX-2 in stromal cells calculated at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"
path_stromal_cox2_exp_pct_v1	Stromal Cell COX-2 Expression (%) - Visit 1 - [Pathology]	Stromal cell COX-2 expression (%) at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
path_stromal_cox2_exp_pct_v4	Stromal Cell COX-2 Expression (%) - Visit 4 - [Pathology]	Stromal cell COX-2 expression (%) at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"
path_stromal_cox2_exp_v1	Stromal Cell COX-2 Expression - Visit 1 - [Pathology]	Stromal cell COX-2 expression at Visit 1	Numeric .F="No Record for This Visit" .R="Not Randomized"
path_stromal_cox2_exp_v4	Stromal Cell COX-2 Expression - Visit 4 - [Pathology]	Stromal cell COX-2 expression at Visit 4	Numeric .F="No Record for This Visit" .R="Not Randomized"