

UAZ2013-01-01 - ENHANCED PERSON: DATA DICTIONARY

TABLE OF CONTENTS

Document Summary	2
UAZ2013-01-01 - Enhanced Person: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Study-wide	4
Section 3: Demographics	5
Section 4: Registration	6
Section 5: Randomization	7
Section 6: Tobacco/Alcohol Assessment	8
Section 7: Medical/Surgical History	9
Section 8: Anthropometry	12
Section 9: Adverse Events	13
Section 10: Concomitant Medications	14
Section 11: Physical Examination	15
Section 12: Agent Interruption	16
Section 13: Compliance	17
Section 14: Off Study	19
Section 15: Genes	20
Section 16: Urine Results	21
Section 17: Blood Chemistry	22
Section 18: Hematology	29
Section 19: Other Lab Tests	34

Document Summary

Property	Value
Document Title	UAZ2013-01-01 - Enhanced Person: Data Dictionary
Date Created	09/11/2019
Sections	19
Entries	368
Document Filename	dictionary_enhanced_prsn.rtf

UAZ2013-01-01 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
build_dt	Build Date	Build Date	SAS Date
ParticipantID	Participant ID	Participant ID	Char

Section 2: Study-wide

Variable	Label	Description	Format Text
ag_prov_dt	Date Study Agent was Provided - [Intervention Administration]	Date that the study agent was provided to the participant.	SAS Date
ag_start_dt	Date Study Agent was Started - [Intervention Administration]	Date that the study agent was started by the participant.	SAS Date
arm	Arm	Indicates whether the participant was to intermittently or continuously use the study agent	1="Intermittent" 2="Continuous"
visit_dt_v1	Date of Visit 1 - Screening	Date of Visit 1 - Screening	SAS Date
visit_dt_v2	Date of Visit 2 - Baseline	Date of Visit 2 - Baseline	SAS Date
visit_dt_v3	Date of Visit 3 - Mid-Study	Date of Visit 3 - Mid-Study	SAS Date .M="Missing"
visit_dt_v4	Date of Visit 4 - End of Intervention	Date of Visit 4 - End of Intervention	SAS Date .M="Missing"
visit_dt_v5	Date of Visit 5 - Post-Intervention	Date of Visit 5 - Post-Intervention	SAS Date .M="Missing"

Section 3: Demographics

Variable	Label	Description	Format Text
reg_age	Age at Registration - [Registration]	Age of Participant at Registration	Numeric
reg_ethnicity	Ethnicity - [Registration]	Ethnicity of the participant.	1="Hispanic or Latino" 2="Not Hispanic or Latino"
reg_gender	Gender - [Registration]	Gender of the participant.	1="Female" 2="Male"
reg_race_1-3	Race - [Registration]	Race of the participant.	.N="N/A" 1="White" 2="Black or African American" 3="Asian" 5="American Indian or Alaska Native"
reg_race_eth	Race + Ethnicity - [Registration]	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.	1="White, Non-Hispanic" 2="Black, Non-Hispanic" 3="Hispanic" 4="Asian" 6="American Indian"

Section 4: Registration

Variable	Label	Description	Format Text
reg_consent_dt	Consent Date - [Registration]	Date that the participant consented to the study.	SAS Date
reg_dt	Registration Date - [Registration]	Date that the participant registered for the study.	SAS Date
reg_eligible	Satisfies all Eligibility Criteria? - [Registration]	Indicates whether or not the participant satisfied all study eligibility.	1="Yes"

Section 5: Randomization

Variable	Label	Description	Format Text
rnd_dt	Randomization Date - [Randomization]	Date that the participant was randomized.	SAS Date
rnd_wash_end_dt	Washout End Date - [Randomization]	End date of washout period (if washout was needed)	SAS Date .N="N/A"
rnd_wash_start_dt	Washout Start Date - [Randomization]	Start date of washout period (if washout was needed)	SAS Date .N="N/A"

Section 6: Tobacco/Alcohol Assessment

Variable	Label	Description	Format Text
tobalc_habitual_alc	Habitual Alcohol Intake - [Tobacco/Alcohol Assessment]	Indicates the habitual alcohol intake of the participant.	2="Former Drinker" 3="Consumes One to Two Alcoholic Drinks Per Day or Less"
tobalc_pack_years	Pack Years (((Average # Cigarettes Smoked Per Day) * (# of Years Smoking)) / 20) - [Tobacco/Alcohol Assessment]	Number of "pack years" the participant has, calculated by (((Average # cigarettes smoked per day) * (# of years smoking)) / 20)	Numeric

Section 7: Medical/Surgical History

Variable	Label	Description	Format Text
medhist_all_normal	All Body Systems Normal? - [Medical/Surgical History]	Indicates if all body systems were found normal in the participant's medical and surgical history.	0="No" 1="Yes"
medhist_aller	Participant has Any Allergies? - [Medical/Surgical History]	Indicates if the participant has any allergies.	0="No" 1="Yes"
medhist_breast_abn	History of Breast Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of breast abnormality.	0="No"
medhist_breast_det	Details of Breast Abnormality - [Medical/Surgical History]	Details of breast medical/surgical history.	Char
medhist_cardio_abn	History of Cardiovascular System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of cardiovascular abnormality.	0="No" 1="Yes"
medhist_cardio_det	Details of Cardiovascular System Abnormality - [Medical/Surgical History]	Details of cardiovascular system medical/surgical history.	Char
medhist_derma_abn	History of Dermatologic System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of dermatologic abnormality.	0="No" 1="Yes"
medhist_derma_det	Details of Dermatologic System Abnormality - [Medical/Surgical History]	Details of dermatologic system medical/surgical history.	Char
medhist_endometa_abn	History of Endocrine/Metabolic System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of endocrine/metabolic abnormality.	0="No" 1="Yes"
medhist_endometa_det	Details of Endocrine/Metabolic System Abnormality - [Medical/Surgical History]	Details of endocrine/metabolic system medical/surgical history.	Char
medhist_gastro_abn	History of Gastrointestinal System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of gastrointestinal abnormality.	0="No" 1="Yes"
medhist_gastro_det	Details of Gastrointestinal System Abnormality - [Medical/Surgical History]	Details of gastrointestinal system medical/surgical history.	Char
medhist_general_abn	History of General Disorders? - [Medical History (Continued)]	Indicates whether or not the participant has a history of general disorders.	.F="Participant Missing from Dataset" 0="No" 1="Yes"
medhist_general_det	Details of General Disorders - [Medical History (Continued)]	Details of general disorders.	Char

Variable	Label	Description	Format Text
medhist_genit_abn	History of Genitourinary System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of genitourinary abnormality.	0="No" 1="Yes"
medhist_genit_det	Details of Genitourinary System Abnormality - [Medical/Surgical History]	Details of genitourinary system medical/surgical history.	Char
medhist_heent_abn	History of H/E/E/N/T System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of H/E/E/N/T abnormality.	0="No" 1="Yes"
medhist_heent_det	Details of H/E/E/N/T System Abnormality - [Medical/Surgical History]	Details of H/E/E/N/T system medical/surgical history.	Char
medhist_hemalymph_h_abn	History of Hematopoietic/Lymph System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of hematopoietic/lymph abnormality.	0="No" 1="Yes"
medhist_hemalymph_h_det	Details of Hematopoietic/Lymph System Abnormality - [Medical/Surgical History]	Details of hematopoietic/lymph system medical/surgical history.	Char
medhist_infect_infest_abn	History of Infections/Infestations? - [Medical History (Continued)]	Indicates whether or not the participant has a history of infections/infestations.	.F="Participant Missing from Dataset" 0="No" 1="Yes"
medhist_infect_infest_det	Details of Infections/Infestations - [Medical History (Continued)]	Details of infections/infestations.	Char
medhist_inj_psn_proc_abn	History of Injury, Poisoning & Procedural Complications? - [Medical History (Continued)]	Indicates whether or not the participant has a history of Injury, Poisoning & Procedural Complications.	.F="Participant Missing from Dataset" 0="No" 1="Yes"
medhist_inj_psn_proc_det	Details of Injury, Poisoning & Procedural Complications - [Medical History (Continued)]	Details of Injury, Poisoning & Procedural Complications.	Char
medhist_muscskel_abn	History of Musculoskeletal System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of musculoskeletal system abnormality.	0="No" 1="Yes"
medhist_muscskel_det	Details of Musculoskeletal System Abnormality - [Medical/Surgical History]	Details of musculoskeletal system medical/surgical history.	Char
medhist_neck_abn	History of Neck Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of neck abnormality.	0="No" 1="Yes"
medhist_neck_det	Details of Neck Abnormality - [Medical/Surgical History]	Details of neck medical/surgical history.	Char
medhist_neuro_abn	History of Neurologic System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of neurologic abnormality.	0="No" 1="Yes"

Variable	Label	Description	Format Text
medhist_neuro_det	Details of Neurologic System Abnormality - [Medical/Surgical History]	Details of neurologic system medical/surgical history.	Char
medhist_psych_abn	History of Psychiatric Disorders? - [Medical History (Continued)]	Indicates whether or not the participant has a history of Psychiatric Disorders.	.F="Participant Missing from Dataset" 0="No" 1="Yes"
medhist_psych_det	Details of Psychiatric Disorders - [Medical History (Continued)]	Details of Psychiatric Disorders.	Char
medhist_repro_abn	History of Reproductive System Abnormality? - [Medical History (Continued)]	Indicates whether or not the participant has a history of Reproductive System Abnormality.	.F="Participant Missing from Dataset" 0="No" 1="Yes"
medhist_repro_det	Details of Reproductive System Abnormality - [Medical History (Continued)]	Details of Reproductive System Abnormality.	Char
medhist_resp_abn	History of Respiratory System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of respiratory abnormality.	0="No" 1="Yes"
medhist_resp_det	Details of Respiratory System Abnormality - [Medical/Surgical History]	Details of respiratory system medical/surgical history.	Char
medhist_spec_aller	Allergies Participant has - [Medical/Surgical History]	Specific allergies participant has (if any).	Char

Section 8: Anthropometry

Variable	Label	Description	Format Text
pe_diastolic_v1-4	Diastolic Blood Pressure (mmhg) - [Physical Examination]	Diastolic blood pressure (mmhg) recorded at the specified visit.	Numeric .M="Missing"
pe_height_v1	Height (in) - Visit 1 - [Physical Examination]	Height (in) of the participant at visit 1.	Numeric
pe_karnofsky_v1	Karnofsky Performance Status - Visit 1 - [Physical Examination]	Karnofsky Performance Status of the participant at visit 1.	Numeric
pe_pulse_v1-4	Pulse Rate - [Physical Examination]	Pulse rate of the participant at the specified visit.	Numeric .M="Missing"
pe_systolic_v1-4	Systolic Blood Pressure (mmhg) - [Physical Examination]	Systolic blood pressure (mmhg) recorded at the specified visit.	Numeric .M="Missing"
pe_temp_v1-4	Temperature (F) - [Physical Examination]	Body temperature (F) of the participant at the specified visit.	Numeric .M="Missing"
pe_weight_v1-4	Weight (lb) - [Physical Examination]	Weight (lb) of the participant at the specified visit.	Numeric .M="Missing"

Section 9: Adverse Events

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

Section 10: Concomitant Medications

Variable	Label	Description	Format Text
conmed_dose_1-17	Medication Dosage - [Concomitant Medications]	Dosage of the specified concomitant medication.	Numeric .M="Missing" .N="N/A"
conmed_end_dt_1-17	Date Medication was Ended - [Concomitant Medications]	Date that the specified concomitant medication was ended.	SAS Date .C="Medication Taken Continuously" .M="Missing" .N="N/A"
conmed_freq_1-17	Frequency of Medication Use - [Concomitant Medications]	Frequency of the specified concomitant medication.	.M="Missing" .N="No Concomitant Medications Taken" 1="As Needed (PRN)" 2="At Bedtime (HS)" 5="Every Day (QD)" 8="Every Other Day (QOD)" 9="Every Week (QW)" 10="Four Times Daily (QID)" 13="Three Times Daily (TID)" 14="Twice Daily (BID)" 18="Other"
conmed_name_1-17	Medication Name - [Concomitant Medications]	Name of the concomitant medication being used by the participant.	Char
conmed_num	Number of Concomitant Medications taken	Number of concomitant medications taken by the participant.	Numeric
conmed_reason_1-17	Reason Medication Taken - [Concomitant Medications]	Reason that the specified concomitant medication is being taken.	Char
conmed_rpt_dt_1-17	Date Medication was Reported - [Concomitant Medications]	Date that the specified concomitant medication was reported.	SAS Date .M="Missing" .N="N/A"
conmed_start_dt_1-17	Date Medication was Started - [Concomitant Medications]	Date that the specified concomitant medication was started.	SAS Date .M="Missing" .N="N/A"
conmed_units_1-17	Units of Measure for Medication Dosage - [Concomitant Medications]	Units of measure for the dosage of the specified concomitant medication.	.M="Missing" .N="N/A" .U="Unknown" 2="Capsule (Cap)" 4="Milliliter (mL)" 9="Tablet (Tab)" 12="International Unit (IU)" 13="Microgram (µg)" 14="Milligram (mg)" 18="1000/uL" 19="IU/L" 20="U/mL"

Section 11: Physical Examination

Variable	Label	Description	Format Text
pe_abdom_abn_v1	Abdomen Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the abdomen was found abnormal at visit 1.	.N="N/A" 0="No"
pe_avg_10_v2-5	Smoked an Average of 10 Cigarettes / Day Since Last Visit? - [Physical Examination]	Indicates if the participant smoked an average of 10 cigarettes / day since the last visit.	.M="Missing" 1="Yes"
pe_chest_abn_v1	Chest Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the chest was found abnormal at visit 1.	.N="N/A" 0="No"
pe_heart_abn_v1	Heart Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the heart was found abnormal at visit 1.	.N="N/A" 0="No"
pe_lungs_abn_v1	Lungs Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the lungs were found abnormal at visit 1.	.N="N/A" 0="No" 1="Yes"

Section 12: Agent Interruption

Variable	Label	Description	Format Text
agint_num	Number of Interruptions - [Agent Interruption]	Number of times the study agent was interrupted throughout the study.	Numeric .F="Participant Missing from Dataset"
agint_restart_dt	Date Agent Regimen was Restarted - [Agent Interruption]	Date that the agent regimen was restarted (if restarted) after interruption.	SAS Date .F="Participant Missing from Dataset" .M="Missing"
agint_restart_rsn	Reason Agent was Restarted - [Agent Interruption]	Indicates the reason that the study agent was restarted after being interrupted.	.F="Participant Missing from Dataset" .M="Missing" 1="Participant Decision"
agint_restarted	Was Agent Restarted? - [Agent Interruption]	Indicates whether or not the agent was restarted after an interruption.	.F="Participant Missing from Dataset" 0="No" 1="Yes"
agint_stop_dt	Date Agent Regimen was Stopped - [Agent Interruption]	Date that the study agent regimen was stopped (if stopped).	SAS Date .F="Participant Missing from Dataset"
agint_stop_rsn	Reason Agent was Stopped - [Agent Interruption]	Indicates the reason that the study agent was stopped (if stopped)	.F="Participant Missing from Dataset" 1="Participant Decision" 3="Adverse Event"
agint_stop_spec	Specific Reason Agent was Stopped - [Agent Interruption]	Details why the study agent was interrupted (if interrupted).	Char

Section 13: Compliance

Variable	Label	Description	Format Text
comp_amt_miss_thi s_v3	Amount of Agent Missing/not Accounted for this period - Visit 3 - [Compliance]	Amount of study agent missing/not accounted for at visit 3.	Numeric .F="Participant Missing from Dataset"
comp_amt_miss_thi s_v4	Amount of Agent Missing/not Accounted for this period - Visit 4 - [Compliance]	Amount of study agent missing/not accounted for at visit 4.	Numeric .F="Participant Missing from Dataset" .M="Missing"
comp_amt_prov_las t_v3	Amount of Agent Provided at Last Visit - Visit 3 - [Compliance]	Amount of study agent provided at visit 2	Numeric .F="Participant Missing from Dataset"
comp_amt_prov_las t_v4	Amount of Agent Provided at Last Visit - Visit 4 - [Compliance]	Amount of study agent provided at visit 3.	Numeric .F="Participant Missing from Dataset" .M="Missing"
comp_amt_prov_thi s_v3	Amount of Agent Provided at This Visit - Visit 3 - [Compliance]	Amount of study agent provided at visit 3.	Numeric .F="Participant Missing from Dataset"
comp_amt_prov_thi s_v4	Amount of Agent Provided at This Visit - Visit 4 - [Compliance]	Amount of study agent provided at visit 4.	Numeric .F="Participant Missing from Dataset" .M="Missing"
comp_amt_rtn_this _v3	Amount of Agent Returned This Visit - Visit 3 - [Compliance]	Amount of study agent returned at visit 3.	Numeric .F="Participant Missing from Dataset"
comp_amt_rtn_this _v4	Amount of Agent Returned This Visit - Visit 4 - [Compliance]	Amount of study agent returned at visit 3.	Numeric .F="Participant Missing from Dataset" .M="Missing"
comp_amt_tkn_this _v3	Amount of Agent Taken During this period - Visit 3 - [Compliance]	Amount of study agent taken from visit 2 to visit 3.	Numeric .F="Participant Missing from Dataset"
comp_amt_tkn_this _v4	Amount of Agent Taken During this period - Visit 4 - [Compliance]	Amount of study agent taken from visit 3 to visit 4.	Numeric .F="Participant Missing from Dataset" .M="Missing"
comp_compliant_v3	Is the participant compliant with protocol intervention? - Visit 3 - [Compliance]	Indicates if the participant was compliant with the study protocol up to visit 3.	.F="Participant Missing from Dataset" 1="Yes"
comp_compliant_v4	Is the participant compliant with protocol intervention? - Visit 4 - [Compliance]	Indicates if the participant was compliant with the study protocol up to visit 4.	.F="Participant Missing from Dataset" .M="Missing" 0="No" 1="Yes"
comp_first_dose_dt _v3	Date of First Dose Taken This Period - Visit 3 - [Compliance]	Date of first dose taken from visit 2 to visit 3.	SAS Date .F="Participant Missing from Dataset"
comp_first_dose_dt _v4	Date of First Dose Taken This Period - Visit 4 - [Compliance]	Date of first dose taken from visit 3 to visit 4.	SAS Date .F="Participant Missing from Dataset" .M="Missing"

Variable	Label	Description	Format Text
comp_interrupted_v3	Was Agent Interrupted During This Period? - Visit 3 - [Compliance]	Indicates if the study agent was interrupted from visit 2 to visit 3.	.F="Participant Missing from Dataset" 0="No"
comp_interrupted_v4	Was Agent Interrupted During This Period? - Visit 4 - [Compliance]	Indicates if the study agent was interrupted from visit 3 to visit 4.	.F="Participant Missing from Dataset" .M="Missing" 0="No" 1="Yes"
comp_last_dose_dt_v3	Date of Last Dose Taken This Period - Visit 3 - [Compliance]	Date of last dose taken from visit 2 to visit 3	SAS Date .F="Participant Missing from Dataset"
comp_last_dose_dt_v4	Date of Last Dose Taken This Period - Visit 4 - [Compliance]	Date of last dose taken from visit 3 to visit 4	SAS Date .F="Participant Missing from Dataset" .M="Missing"
comp_num_ints_v3	Number of Interruptions This Period - Visit 3 - [Compliance]	Number of interruptions from visit 2 to visit 3.	Numeric .F="Participant Missing from Dataset"
comp_num_ints_v4	Number of Interruptions This Period - Visit 4 - [Compliance]	Number of interruptions from visit 3 to visit 4.	Numeric .F="Participant Missing from Dataset" .M="Missing"
comp_prov_this_v3	Was Agent Provided at This Visit? - Visit 3 - [Compliance]	Indicates if the study agent was provided at visit 3.	.F="Participant Missing from Dataset" 1="Yes"
comp_prov_this_v4	Was Agent Provided at This Visit? - Visit 4 - [Compliance]	Indicates if the study agent was provided at visit 4.	.F="Participant Missing from Dataset" .M="Missing" 0="No"
comp_reg_mod_v3	Was Agent Regimen Modified During This Period? - Visit 3 - [Compliance]	Indicates if the agent regimen was modified from visit 2 to visit 3.	.F="Participant Missing from Dataset" .N="N/A" 0="No"
comp_reg_mod_v4	Was Agent Regimen Modified During This Period? - Visit 4 - [Compliance]	Indicates if the agent regimen was modified from visit 3 to visit 4.	.F="Participant Missing from Dataset" .M="Missing" 0="No"

Section 14: Off Study

Variable	Label	Description	Format Text
off_followup_off_dt	Date off Follow-up - [Off Study]	Date off follow-up.	SAS Date .M="Missing"
off_followup_on_dt	Date on Follow-up - [Off Study]	Date on follow-up.	SAS Date .M="Missing"
off_last_agent_dt	Date Last Study Agent was Taken - [Off Study]	Date last study agent was taken.	SAS Date
off_last_contact_dt	Date of Last Contact - [Off Study]	Date of last contact.	SAS Date
off_rsn	Reason off Study - [Off Study]	Reason the participant went off of the study.	1="Study Complete" 4="Lost to Follow-up" 5="Participant Withdrawal" 7="Protocol Violation"
off_rsn_exp	Reason off Study (Explanation) - [Off Study]	Explanation for reason the participant went off of the study.	Char
off_study_dt	Date off Study - [Off Study]	Date off study.	SAS Date

Section 15: Genes

Variable	Label	Description	Format Text
genes_beane2007_t1-3	Beane 2007 - Gene Value - Timepoint - [Genetics]	Value of the Beane 2007 gene.	Numeric .F="Participant Missing from Dataset" .M="Missing"
genes_gustafson2010_t1-3	Gustafson 2010 - Gene Value - Timepoint - [Genetics]	Value of the Gustafson 2010 gene.	Numeric .F="Participant Missing from Dataset" .M="Missing"
genes_perezrogers30_t1-3	Perez Rogers 30 - Gene Value - Timepoint - [Genetics]	Value of the Perez Rogers 30 gene.	Numeric .F="Participant Missing from Dataset" .M="Missing"
genes_perezrogers535_t1-3	Perez Rogers 535 - Gene Value - Timepoint - [Genetics]	Value of the Perez Rogers 535 gene.	Numeric .F="Participant Missing from Dataset" .M="Missing"
genes_steiling2013_t1-3	Steiling 2013 - Gene Value - Timepoint - [Genetics]	Value of the Steiling 2013 gene.	Numeric .F="Participant Missing from Dataset" .M="Missing"
genes_whitney2015_t1-3	Cancer Whitney BMCMedGen 2015 - Gene Value - Timepoint - [Genetics]	Value of the Cancer Whitney BMCMedGen 2015 gene.	Numeric .F="Participant Missing from Dataset" .M="Missing"
genes_zhang2010_t1-3	Zhang 2010 - Gene Value - Timepoint - [Genetics]	Value of the Zhang 2010 gene.	Numeric .F="Participant Missing from Dataset" .M="Missing"

Section 16: Urine Results

Variable	Label	Description	Format Text
cotinine_2	Cotinine 2 - [Cotinine]	Value of Cotinine 2.	Numeric
cotinine_4	Cotinine 4 - [Cotinine]	Value of Cotinine 4.	Numeric .M="Missing"
cotinine_5	Cotinine 5 - [Cotinine]	Value of Cotinine 5.	Numeric .M="Missing"
lte_42	LTE 4 2 - [LTE4]	Value of LTE (4) 2.	Numeric .F="Participant Missing from Dataset"
lte_44	LTE 4 4 - [LTE4]	Value of LTE (4) 4.	Numeric .F="Participant Missing from Dataset"
lte_45	LTE 4 5 - [LTE4]	Value of LTE (4) 5.	Numeric .F="Participant Missing from Dataset"
pgem_2	PGEM 2 - [PGEM]	Value of PGEM 2.	Numeric .F="Participant Missing from Dataset"
pgem_4	PGEM 4 - [PGEM]	Value of PGEM 4.	Numeric .F="Participant Missing from Dataset"
pgem_5	PGEM 5 - [PGEM]	Value of PGEM 5.	Numeric .F="Participant Missing from Dataset"

Section 17: Blood Chemistry

Variable	Label	Description	Format Text
bld_alb_glob_clin_v1	Albumin/Globulin Ratio Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Alb/Glob ratio test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_alb_glob_clin_v4	Albumin/Globulin Ratio Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Alb/Glob ratio test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_alb_glob_out_v1	Albumin/Globulin Ratio Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Alb/Glob ratio test results were out of range at visit 1	0="No" 1="Yes"
bld_alb_glob_out_v4	Albumin/Globulin Ratio Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Alb/Glob ratio test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_alb_glob_v1	Albumin/Globulin Ratio Test - Results - Visit 1 - [Blood Chemistry]	Alb/Glob ratio test results at visit 1.	Numeric
bld_alb_glob_v4	Albumin/Globulin Ratio Test - Results - Visit 4 - [Blood Chemistry]	Alb/Glob ratio test results at visit 4.	Numeric .M="Missing"
bld_albumin_clin_v1	Albumin (g/dL) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Albumin (g/dL) test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_albumin_clin_v4	Albumin (g/dL) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Albumin (g/dL) test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_albumin_out_v1	Albumin (g/dL) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Albumin (g/dL) test results were out of range at visit 1	0="No" 1="Yes"
bld_albumin_out_v4	Albumin (g/dL) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Albumin (g/dL) test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_albumin_v1	Albumin (g/dL) Test - Results - Visit 1 - [Blood Chemistry]	Albumin (g/dL) test results at visit 1.	Numeric
bld_albumin_v4	Albumin (g/dL) Test - Results - Visit 4 - [Blood Chemistry]	Albumin (g/dL) test results at visit 4.	Numeric .M="Missing"
bld_alk_phos_clin_v1	Alkaline Phosphatase (IU/L) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Alkaline Phosphatase (IU/L) test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_alk_phos_clin_v4	Alkaline Phosphatase (IU/L) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Alkaline Phosphatase (IU/L) test results were clinically significant at visit 4.	.M="Missing" 0="No"

Variable	Label	Description	Format Text
bld_alk_phos_out_v1	Alkaline Phosphatase (IU/L) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Alkaline Phosphatase (IU/L) test results were out of range at visit 1	0="No" 1="Yes"
bld_alk_phos_out_v4	Alkaline Phosphatase (IU/L) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Alkaline Phosphatase (IU/L) test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_alk_phos_v1	Alkaline Phosphatase (IU/L) Test - Results - Visit 1 - [Blood Chemistry]	Alkaline Phosphatase (IU/L) test results at visit 1.	Numeric
bld_alk_phos_v4	Alkaline Phosphatase (IU/L) Test - Results - Visit 4 - [Blood Chemistry]	Alkaline Phosphatase (IU/L) test results at visit 4.	Numeric .M="Missing"
bld_anion_gap_clin_v1	Anion Gap Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Anion Gap test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_anion_gap_clin_v4	Anion Gap Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Anion Gap test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_anion_gap_out_v1	Anion Gap Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Anion Gap test results were out of range at visit 1	0="No" 1="Yes"
bld_anion_gap_out_v4	Anion Gap Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Anion Gap test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_anion_gap_v1	Anion Gap Test - Results - Visit 1 - [Blood Chemistry]	Anion Gap test results at visit 1.	Numeric
bld_anion_gap_v4	Anion Gap Test - Results - Visit 4 - [Blood Chemistry]	Anion Gap test results at visit 4.	Numeric .M="Missing"
bld_bicarbonate_clin_v1	Bicarbonate (mmol/l) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Bicarbonate (mmol/l) test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_bicarbonate_clin_v4	Bicarbonate (mmol/l) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Bicarbonate (mmol/l) test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_bicarbonate_out_v1	Bicarbonate (mmol/l) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Bicarbonate (mmol/l) test results were out of range at visit 1	0="No"
bld_bicarbonate_out_v4	Bicarbonate (mmol/l) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Bicarbonate (mmol/l) test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_bicarbonate_v1	Bicarbonate (mmol/l) Test - Results - Visit 1 - [Blood Chemistry]	Bicarbonate (mmol/l) test results at visit 1.	Numeric
bld_bicarbonate_v4	Bicarbonate (mmol/l) Test - Results - Visit 4 - [Blood Chemistry]	Bicarbonate (mmol/l) test results at visit 4.	Numeric .M="Missing"
bld_bilirubin_clin_v1	Bilirubin (mg/dl) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Bilirubin (mg/dl) test results were clinically significant at visit 1.	.M="Missing" 0="No"

Variable	Label	Description	Format Text
bld_bilirubin_clin_v4	Bilirubin (mg/dl) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Bilirubin (mg/dl) test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_bilirubin_out_v1	Bilirubin (mg/dl) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Bilirubin (mg/dl) test results were out of range at visit 1	0="No" 1="Yes"
bld_bilirubin_out_v4	Bilirubin (mg/dl) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Bilirubin (mg/dl) test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_bilirubin_v1	Bilirubin (mg/dl) Test - Results - Visit 1 - [Blood Chemistry]	Bilirubin (mg/dl) test results at visit 1.	Numeric .P="< .2"
bld_bilirubin_v4	Bilirubin (mg/dl) Test - Results - Visit 4 - [Blood Chemistry]	Bilirubin (mg/dl) test results at visit 4.	Numeric .M="Missing" .P="< .2"
bld_bun_clin_v1	BUN (mg/dl) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the BUN (mg/dl) test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_bun_clin_v4	BUN (mg/dl) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the BUN (mg/dl) test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_bun_creat_clin_v1	BUN/Creatinine Ratio Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Bun/Creat ratio test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_bun_creat_clin_v4	BUN/Creatinine Ratio Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Bun/Creat ratio test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_bun_creat_out_v1	BUN/Creatinine Ratio Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Bun/Creat ratio test results were out of range at visit 1	0="No" 1="Yes"
bld_bun_creat_out_v4	BUN/Creatinine Ratio Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Bun/Creat ratio test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_bun_creat_v1	BUN/Creatinine Ratio Test - Results - Visit 1 - [Blood Chemistry]	Bun/Creat ratio test results at visit 1.	Numeric
bld_bun_creat_v4	BUN/Creatinine Ratio Test - Results - Visit 4 - [Blood Chemistry]	Bun/Creat ratio test results at visit 4.	Numeric .M="Missing"
bld_bun_out_v1	BUN (mg/dl) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the BUN (mg/dl) test results were out of range at visit 1	0="No" 1="Yes"
bld_bun_out_v4	BUN (mg/dl) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the BUN (mg/dl) test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_bun_v1	BUN (mg/dl) Test - Results - Visit 1 - [Blood Chemistry]	BUN (mg/dl) test results at visit 1.	Numeric
bld_bun_v4	BUN (mg/dl) Test - Results - Visit 4 - [Blood Chemistry]	BUN (mg/dl) test results at visit 4.	Numeric .M="Missing"
bld_calcium_clin_v1	Calcium (mg/dl) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Calcium (mg/dl) test results were clinically significant at visit 1.	.M="Missing" 0="No"

Variable	Label	Description	Format Text
bld_calcium_clin_v4	Calcium (mg/dl) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Calcium (mg/dl) test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_calcium_out_v1	Calcium (mg/dl) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Calcium (mg/dl) test results were out of range at visit 1	0="No" 1="Yes"
bld_calcium_out_v4	Calcium (mg/dl) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Calcium (mg/dl) test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_calcium_v1	Calcium (mg/dl) Test - Results - Visit 1 - [Blood Chemistry]	Calcium (mg/dl) test results at visit 1.	Numeric
bld_calcium_v4	Calcium (mg/dl) Test - Results - Visit 4 - [Blood Chemistry]	Calcium (mg/dl) test results at visit 4.	Numeric .M="Missing"
bld_chloride_clin_v1	Chloride (mmol/l) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Chloride (mmol/l) test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_chloride_clin_v4	Chloride (mmol/l) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Chloride (mmol/l) test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_chloride_out_v1	Chloride (mmol/l) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Chloride (mmol/l) test results were out of range at visit 1	0="No" 1="Yes"
bld_chloride_out_v4	Chloride (mmol/l) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Chloride (mmol/l) test results were out of range at visit 4	.M="Missing" 0="No"
bld_chloride_v1	Chloride (mmol/l) Test - Results - Visit 1 - [Blood Chemistry]	Chloride (mmol/l) test results at visit 1.	Numeric
bld_chloride_v4	Chloride (mmol/l) Test - Results - Visit 4 - [Blood Chemistry]	Chloride (mmol/l) test results at visit 4.	Numeric .M="Missing"
bld_collection_dt_v1	Date Specimen Collected - Visit 1 - [Blood Chemistry]	Date blood specimen was collected - visit 1.	SAS Date
bld_collection_dt_v4	Date Specimen Collected - Visit 4 - [Blood Chemistry]	Date blood specimen was collected - visit 4.	SAS Date .M="Missing"
bld_creatinine_clin_v1	Creatinine (mg/dl) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Creatinine (mg/dl) test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_creatinine_clin_v4	Creatinine (mg/dl) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Creatinine (mg/dl) test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_creatinine_out_v1	Creatinine (mg/dl) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Creatinine (mg/dl) test results were out of range at visit 1	0="No" 1="Yes"
bld_creatinine_out_v4	Creatinine (mg/dl) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Creatinine (mg/dl) test results were out of range at visit 4	.M="Missing" 0="No"
bld_creatinine_v1	Creatinine (mg/dl) Test - Results - Visit 1 - [Blood Chemistry]	Creatinine (mg/dl) test results at visit 1.	Numeric

Variable	Label	Description	Format Text
bld_creatinine_v4	Creatinine (mg/dl) Test - Results - Visit 4 - [Blood Chemistry]	Creatinine (mg/dl) test results at visit 4.	Numeric .M="Missing"
bld_fasting_v1	Was Participant Fasting before Sample was Taken? - Visit 1 - [Blood Chemistry]	Indicates if participant was fasting before sample was taken at visit 1.	.U="Unknown" 0="No" 1="Yes"
bld_fasting_v4	Was Participant Fasting before Sample was Taken? - Visit 4 - [Blood Chemistry]	Indicates if participant was fasting before sample was taken at visit 4.	.M="Missing" 0="No" 1="Yes"
bld_globulin_clin_v1	Globulin (g/dL) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Globulin (g/dL) test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_globulin_clin_v4	Globulin (g/dL) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Globulin (g/dL) test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_globulin_out_v1	Globulin (g/dL) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Globulin (g/dL) test results were out of range at visit 1	0="No" 1="Yes"
bld_globulin_out_v4	Globulin (g/dL) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Globulin (g/dL) test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_globulin_v1	Globulin (g/dL) Test - Results - Visit 1 - [Blood Chemistry]	Globulin (g/dL) test results - Visit 1	Numeric
bld_globulin_v4	Globulin (g/dL) Test - Results - Visit 4 - [Blood Chemistry]	Globulin (g/dL) test results - Visit 4	Numeric .M="Missing"
bld_glucose_clin_v1	Glucose Serum (mg/dl) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Glucose Serum (mg/dl) test results were clinically significant at visit 1.	.M="Missing" 0="No" 1="Yes"
bld_glucose_clin_v4	Glucose Serum (mg/dl) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Glucose Serum (mg/dl) test results were clinically significant at visit 4.	.M="Missing" 0="No" 1="Yes"
bld_glucose_out_v1	Glucose Serum (mg/dl) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Glucose Serum (mg/dl) test results were out of range at visit 1	0="No" 1="Yes"
bld_glucose_out_v4	Glucose Serum (mg/dl) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Glucose Serum (mg/dl) test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_glucose_v1	Glucose Serum (mg/dl) Test - Results - Visit 1 - [Blood Chemistry]	Glucose Serum (mg/dl) test results - Visit 1	Numeric
bld_glucose_v4	Glucose Serum (mg/dl) Test - Results - Visit 4 - [Blood Chemistry]	Glucose Serum (mg/dl) test results - Visit 4	Numeric .M="Missing"
bld_potassium_clin_v1	Potassium (mmol/l) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Potassium (mmol/l) test results were clinically significant at visit 1.	.M="Missing" 0="No" 1="Yes"
bld_potassium_clin_v4	Potassium (mmol/l) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Potassium (mmol/l) test results were clinically significant at visit 4.	.M="Missing" 0="No"

Variable	Label	Description	Format Text
bld_potassium_out_v1	Potassium (mmol/l) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Potassium (mmol/l) test results were out of range at visit 1	.M="Missing" 0="No" 1="Yes"
bld_potassium_out_v4	Potassium (mmol/l) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Potassium (mmol/l) test results were out of range at visit 4	.M="Missing" 0="No"
bld_potassium_v1	Potassium (mmol/l) Test - Results - Visit 1 - [Blood Chemistry]	Potassium (mmol/l) test results at visit 1	Numeric
bld_potassium_v4	Potassium (mmol/l) Test - Results - Visit 4 - [Blood Chemistry]	Potassium (mmol/l) test results at visit 4	Numeric .M="Missing"
bld_protein_clin_v1	Total Protein (g/dL) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Total Protein (g/dL) test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_protein_clin_v4	Total Protein (g/dL) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Total Protein (g/dL) test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_protein_out_v1	Total Protein (g/dL) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Total Protein (g/dL) test results were out of range at visit 1	0="No" 1="Yes"
bld_protein_out_v4	Total Protein (g/dL) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Total Protein (g/dL) test results were out of range at visit 4	.M="Missing" 0="No" 1="Yes"
bld_protein_v1	Total Protein (g/dL) Test - Results - Visit 1 - [Blood Chemistry]	Total Protein (g/dL) test results at visit 1	Numeric
bld_protein_v4	Total Protein (g/dL) Test - Results - Visit 4 - [Blood Chemistry]	Total Protein (g/dL) test results at visit 4	Numeric .M="Missing"
bld_sgop_ast_clin_v1	SGOP/AST (IU/L) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the SGOP/AST (IU/L) test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_sgop_ast_clin_v4	SGOP/AST (IU/L) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the SGOP/AST (IU/L) test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_sgop_ast_out_v1	SGOP/AST (IU/L) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the SGOP/AST (IU/L) test results were out of range at visit 1.	0="No"
bld_sgop_ast_out_v4	SGOP/AST (IU/L) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the SGOP/AST (IU/L) test results were out of range at visit 4.	.M="Missing" 0="No"
bld_sgop_ast_v1	SGOP/AST (IU/L) Test - Results - Visit 1 - [Blood Chemistry]	SGOP/AST (IU/L) test results at visit 1	Numeric
bld_sgop_ast_v4	SGOP/AST (IU/L) Test - Results - Visit 4 - [Blood Chemistry]	SGOP/AST (IU/L) test results at visit 4	Numeric .M="Missing"
bld_sgpt_alt_clin_v1	SGPT/ALT (IU/L) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the SGPT/ALT (IU/L) test results were clinically significant at visit 1.	.M="Missing" 0="No"

Variable	Label	Description	Format Text
bld_sgpt_alt_clin_v4	SGPT/ALT (IU/L) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the SGPT/ALT (IU/L) test results were clinically significant at visit 4.	.M="Missing" 0="No" 1="Yes"
bld_sgpt_alt_out_v1	SGPT/ALT (IU/L) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the SGPT/ALT (IU/L) test results were out of range at visit 1.	0="No" 1="Yes"
bld_sgpt_alt_out_v4	SGPT/ALT (IU/L) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the SGPT/ALT (IU/L) test results were out of range at visit 4.	.M="Missing" 0="No" 1="Yes"
bld_sgpt_alt_v1	SGPT/ALT (IU/L) Test - Results - Visit 1 - [Blood Chemistry]	SGPT/ALT (IU/L) test results at visit 1.	Numeric
bld_sgpt_alt_v4	SGPT/ALT (IU/L) Test - Results - Visit 4 - [Blood Chemistry]	SGPT/ALT (IU/L) test results at visit 4.	Numeric .M="Missing"
bld_sodium_clin_v1	Sodium (mmol/l) Test - Clinically Significant? - Visit 1 - [Blood Chemistry]	Indicates if the Sodium (mmol/l) test results were clinically significant at visit 1.	.M="Missing" 0="No"
bld_sodium_clin_v4	Sodium (mmol/l) Test - Clinically Significant? - Visit 4 - [Blood Chemistry]	Indicates if the Sodium (mmol/l) test results were clinically significant at visit 4.	.M="Missing" 0="No"
bld_sodium_out_v1	Sodium (mmol/l) Test - Out of Range? - Visit 1 - [Blood Chemistry]	Indicates if the Sodium (mmol/l) test results were out of range at visit 1.	0="No" 1="Yes"
bld_sodium_out_v4	Sodium (mmol/l) Test - Out of Range? - Visit 4 - [Blood Chemistry]	Indicates if the Sodium (mmol/l) test results were out of range at visit 4.	.M="Missing" 0="No" 1="Yes"
bld_sodium_v1	Sodium (mmol/l) Test - Results - Visit 1 - [Blood Chemistry]	Sodium (mmol/l) test results at visit 1.	Numeric
bld_sodium_v4	Sodium (mmol/l) Test - Results - Visit 4 - [Blood Chemistry]	Sodium (mmol/l) test results at visit 4.	Numeric .M="Missing"

Section 18: Hematology

Variable	Label	Description	Format Text
hema_anc_clin_v1	ANC Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the ANC test results were clinically significant at visit 1.	.M="Missing"
hema_anc_clin_v4	ANC Test - Clinically Significant? - Visit 4 - [Hematology]	Indicates if the ANC test results were clinically significant at visit 4.	.M="Missing"
hema_anc_out_v1	ANC Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the ANC test results were out of range at visit 1.	.M="Missing"
hema_anc_out_v4	ANC Test - Out of Range? - Visit 4 - [Hematology]	Indicates if the ANC test results were out of range at visit 4.	.M="Missing"
hema_anc_v1	ANC Test - Results (k/uL) - Visit 1 - [Hematology]	ANC test results (k/uL) at visit 1.	Numeric .M="Missing"
hema_anc_v4	ANC Test - Results (k/uL) - Visit 4 - [Hematology]	ANC test results (k/uL) at visit 4.	Numeric .M="Missing"
hema_basophils_clin_v1	Basophils Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the Basophils % test results were clinically significant at visit 1.	.M="Missing" 0="No"
hema_basophils_clin_v4	Basophils Test - Clinically Significant? - Visit 4 - [Hematology]	Indicates if the Basophils % test results were clinically significant at visit 4.	.M="Missing" 0="No"
hema_basophils_out_v1	Basophils Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the Basophils % test results were out of range at visit 1.	0="No"
hema_basophils_out_v4	Basophils Test - Out of Range? - Visit 4 - [Hematology]	Indicates if the Basophils % test results were out of range at visit 4.	.M="Missing" 0="No"
hema_basophils_v1	Basophils Test - Results (%) - Visit 1 - [Hematology]	Basophils % test results at visit 1.	Numeric
hema_basophils_v4	Basophils Test - Results (%) - Visit 4 - [Hematology]	Basophils % test results at visit 4.	Numeric .M="Missing"
hema_collection_dt_v1	Date Specimen Collected - Visit 1 - [Hematology]	Date hematology specimen was collected - visit 1.	SAS Date .F="Participant Missing from Dataset"
hema_collection_dt_v4	Date Specimen Collected - Visit 4 - [Hematology]	Date hematology specimen was collected - visit 4.	SAS Date .M="Missing"
hema_eosinophils_clin_v1	Eosinophils Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the Eosinophils % test results were clinically significant at visit 1.	.M="Missing" 0="No"
hema_eosinophils_clin_v4	Eosinophils Test - Clinically Significant? - Visit 4 - [Hematology]	Indicates if the Eosinophils % test results were clinically significant at visit 4.	.M="Missing" 0="No"
hema_eosinophils_out_v1	Eosinophils Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the Eosinophils % test results were out of range at visit 1.	0="No"

Variable	Label	Description	Format Text
hema_eosinophils_out_v4	Eosinophils Test - Out of Range? - Visit 4 - [Hematology]	Indicates if the Eosinophils % test results were out of range at visit 4.	.M="Missing" 0="No"
hema_eosinophils_v1	Eosinophils Test - Results (%) - Visit 1 - [Hematology]	Eosinophils % test results at visit 1.	Numeric
hema_eosinophils_v4	Eosinophils Test - Results (%) - Visit 4 - [Hematology]	Eosinophils % test results at visit 4.	Numeric .M="Missing"
hema_hematocrit_clin_v1	Hemoglobin Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the Hemoglobin test results were clinically significant at visit 1.	.M="Missing" 0="No"
hema_hematocrit_clin_v4	Hemoglobin Test - Clinically Significant? - Visit 4 - [Hematology]	Indicates if the Hemoglobin test results were clinically significant at visit 4.	.M="Missing" 0="No"
hema_hematocrit_out_v1	Hemoglobin Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the Hemoglobin test results were out of range at visit 1.	0="No" 1="Yes"
hema_hematocrit_out_v4	Hemoglobin Test - Out of Range? - Visit 4 - [Hematology]	Indicates if the Hemoglobin test results were out of range at visit 4.	.M="Missing" 0="No" 1="Yes"
hema_hematocrit_v1	Hemoglobin Test - Results (g/dL) - Visit 1 - [Hematology]	Hemoglobin test results (g/dL) at visit 1.	Numeric
hema_hematocrit_v4	Hemoglobin Test - Results (g/dL) - Visit 4 - [Hematology]	Hemoglobin test results (g/dL) at visit 4.	Numeric .M="Missing"
hema_hemoglobin_clin_v1	Lymphocytes Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the Lymphocytes % test results were clinically significant at visit 1.	.M="Missing" 0="No"
hema_hemoglobin_clin_v4	Lymphocytes Test - Clinically Significant? - Visit 4 - [Hematology]	Indicates if the Lymphocytes % test results were clinically significant at visit 4.	.M="Missing" 0="No"
hema_hemoglobin_out_v1	Lymphocytes Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the Lymphocytes % test results were out of range at visit 1.	0="No" 1="Yes"
hema_hemoglobin_out_v4	Lymphocytes Test - Out of Range? - Visit 4 - [Hematology]	Indicates if the Lymphocytes % test results were out of range at visit 4.	.M="Missing" 0="No"
hema_hemoglobin_v1	Lymphocytes Test - Results (%) - Visit 1 - [Hematology]	Lymphocytes % test results at visit 1.	Numeric
hema_hemoglobin_v4	Lymphocytes Test - Results (%) - Visit 4 - [Hematology]	Lymphocytes % test results at visit 4.	Numeric .M="Missing"
hema_lymphocytes_clin_v1	Hematocrit Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the Hematocrit test results were clinically significant at visit 1.	.M="Missing" 0="No"
hema_lymphocytes_clin_v4	Hematocrit Test - Clinically Significant? - Visit 4 - [Hematology]	Indicates if the Hematocrit test results were clinically significant at visit 4.	.M="Missing" 0="No" 1="Yes"
hema_lymphocytes_out_v1	Hematocrit Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the Hematocrit test results were out of range at visit 1.	0="No"

Variable	Label	Description	Format Text
hema_lymphocytes_out_v4	Hematocrit Test - Out of Range? - Visit 4 - [Hematology]	Indicates if the Hematocrit test results were out of range at visit 4.	.M="Missing" 0="No" 1="Yes"
hema_lymphocytes_v1	Hematocrit Test - Results (%) - Visit 1 - [Hematology]	Hematocrit test results (%) at visit 1.	Numeric
hema_lymphocytes_v4	Hematocrit Test - Results (%) - Visit 4 - [Hematology]	Hematocrit test results (%) at visit 4.	Numeric .M="Missing"
hema_monocytes_clin_v1	Monocytes Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the Monocytes % test results were clinically significant at visit 1.	.M="Missing" 0="No"
hema_monocytes_clin_v4	Monocytes Test - Clinically Significant? - Visit 4 - [Hematology]	Indicates if the Monocytes % test results were clinically significant at visit 4.	.M="Missing" 0="No"
hema_monocytes_out_v1	Monocytes Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the Monocytes % test results were out of range at visit 1.	0="No"
hema_monocytes_out_v4	Monocytes Test - Out of Range? - Visit 4 - [Hematology]	Indicates if the Monocytes % test results were out of range at visit 4.	.M="Missing" 0="No"
hema_monocytes_v1	Monocytes Test - Results (%) - Visit 1 - [Hematology]	Monocytes % test results at visit 1.	Numeric
hema_monocytes_v4	Monocytes Test - Results (%) - Visit 4 - [Hematology]	Monocytes % test results at visit 4.	Numeric .M="Missing"
hema_neutrophils_clin_v1	Neutrophils Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the Neutrophils % test results were clinically significant at visit 1.	.M="Missing" 0="No" 1="Yes"
hema_neutrophils_clin_v4	Neutrophils Test - Clinically Significant? - Visit 4 - [Hematology]	Indicates if the Neutrophils % test results were clinically significant at visit 4.	.M="Missing" 0="No"
hema_neutrophils_out_v1	Neutrophils Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the Neutrophils % test results were out of range at visit 1.	0="No" 1="Yes"
hema_neutrophils_out_v4	Neutrophils Test - Out of Range? - Visit 4 - [Hematology]	Indicates if the Neutrophils % test results were out of range at visit 4.	.M="Missing" 0="No"
hema_neutrophils_v1	Neutrophils Test - Results (%) - Visit 1 - [Hematology]	Neutrophils % test results at visit 1.	Numeric
hema_neutrophils_v4	Neutrophils Test - Results (%) - Visit 4 - [Hematology]	Neutrophils % test results at visit 4.	Numeric .M="Missing"
hema_platelets_clin_v1	Platelets Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the Platelets test results were clinically significant at visit 1.	.M="Missing" 0="No"
hema_platelets_clin_v4	Platelets Test - Clinically Significant? - Visit 4 - [Hematology]	Indicates if the Platelets test results were clinically significant at visit 4.	.M="Missing" 0="No"
hema_platelets_out_v1	Platelets Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the Platelets test results were out of range at visit 1.	0="No"
hema_platelets_out_v4	Platelets Test - Out of Range? - Visit 4 - [Hematology]	Indicates if the Platelets test results were out of range at visit 4.	.M="Missing" 0="No"

Variable	Label	Description	Format Text
hema_platelets_v1	Platelets Test - Results (k/mm3) - Visit 1 - [Hematology]	Platelets test results (k/mm3) at visit 1.	Numeric
hema_platelets_v4	Platelets Test - Results (k/mm3) - Visit 4 - [Hematology]	Platelets test results (k/mm3) at visit 4.	Numeric .M="Missing"
hema_pt_clin_v1	PT Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the PT test results were clinically significant at visit 1.	.M="Missing"
hema_pt_out_v1	PT Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the PT test results were out of range at visit 1.	.M="Missing"
hema_pt_v1	PT Test - Results (sec) - Visit 1 - [Hematology]	PT test results (sec) at visit 1.	Numeric .M="Missing"
hema_ptt_clin_v1	PTT Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the PTT test results were clinically significant at visit 1.	.M="Missing"
hema_ptt_out_v1	PTT Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the PTT test results were out of range at visit 1.	.M="Missing"
hema_ptt_v1	PTT Test - Results (sec) - Visit 1 - [Hematology]	PTT test results (sec) at visit 1.	Numeric .M="Missing"
hema_rbc_clin_v1	Red Blood Cell Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the RBC test results were clinically significant at visit 1.	.M="Missing" 0="No"
hema_rbc_clin_v4	Red Blood Cell Test - Clinically Significant? - Visit 4 - [Hematology]	Indicates if the RBC test results were clinically significant at visit 4.	.M="Missing" 0="No" 1="Yes"
hema_rbc_out_v1	Red Blood Cell Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the RBC test results were out of range at visit 1.	0="No" 1="Yes"
hema_rbc_out_v4	Red Blood Cell Test - Out of Range? - Visit 4 - [Hematology]	Indicates if the RBC test results were out of range at visit 4.	.M="Missing" 0="No" 1="Yes"
hema_rbc_v1	Red Blood Cell Test - Results (m/mm3) - Visit 1 - [Hematology]	RBC test results (m/mm3) at visit 1.	Numeric
hema_rbc_v4	Red Blood Cell Test - Results (m/mm3) - Visit 4 - [Hematology]	RBC test results (m/mm3) at visit 4.	Numeric .M="Missing"
hema_wbc_clin_v1	White Blood Cell Test - Clinically Significant? - Visit 1 - [Hematology]	Indicates if the WBC test results were clinically significant at visit 1.	.M="Missing" 0="No" 1="Yes"
hema_wbc_clin_v4	White Blood Cell Test - Clinically Significant? - Visit 4 - [Hematology]	Indicates if the WBC test results were clinically significant at visit 4.	.M="Missing" 0="No"
hema_wbc_out_v1	White Blood Cell Test - Out of Range? - Visit 1 - [Hematology]	Indicates if the WBC test results were out of range at visit 1.	0="No" 1="Yes"
hema_wbc_out_v4	White Blood Cell Test - Out of Range? - Visit 4 - [Hematology]	Indicates if the WBC test results were out of range at visit 4.	.M="Missing" 0="No" 1="Yes"

Variable	Label	Description	Format Text
hema_wbc_v1	White Blood Cell Test - Results (k/mm3) - Visit 1 - [Hematology]	WBC test results (k/mm3) at visit 1.	Numeric
hema_wbc_v4	White Blood Cell Test - Results (k/mm3) - Visit 4 - [Hematology]	WBC test results (k/mm3) at visit 4.	Numeric .M="Missing"

Section 19: Other Lab Tests

Variable	Label	Description	Format Text
othlab_collection_dt_v1	Date Specimen Collected - Visit 1 - [Other Lab Tests]	Date specimen was collected at visit 1.	SAS Date .F="Participant Missing from Dataset" .N="N/A"
othlab_collection_dt_v4	Date Specimen Collected - Visit 4 - [Other Lab Tests]	Date specimen was collected at visit 4.	SAS Date .F="Participant Missing from Dataset" .N="N/A"
othlab_fasting_v1	Was Participant Fasting before Sample was Taken? - Visit 1 - [Other Lab Tests]	Indicates if the participant was fasting before sample was taken at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"
othlab_fasting_v4	Was Participant Fasting before Sample was Taken? - Visit 4 - [Other Lab Tests]	Indicates if the participant was fasting before sample was taken at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"
othlab_gfr_est_clin_v1	GFR Estimated (mL/min/1.73m2) Test - Clinically Significant? - Visit 1 - [Other Lab Tests]	Indicates if the GFR Estimated (mL/min/1.73m2) test results were clinically significant at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"
othlab_gfr_est_clin_v4	GFR Estimated (mL/min/1.73m2) Test - Clinically Significant? - Visit 4 - [Other Lab Tests]	Indicates if the GFR Estimated (mL/min/1.73m2) test results were clinically significant at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"
othlab_gfr_est_out_v1	GFR Estimated (mL/min/1.73m2) Test - Out of Range? - Visit 1 - [Other Lab Tests]	Indicates if the GFR Estimated (mL/min/1.73m2) test results were out of range at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"
othlab_gfr_est_out_v4	GFR Estimated (mL/min/1.73m2) Test - Out of Range? - Visit 4 - [Other Lab Tests]	Indicates if the GFR Estimated (mL/min/1.73m2) test results were out of range at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"
othlab_gfr_est_v1	GFR Estimated (mL/min/1.73m2) Test - Results - Visit 1 - [Other Lab Tests]	GFR Estimated (mL/min/1.73m2) test results at visit 1.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_gfr_est_v4	GFR Estimated (mL/min/1.73m2) Test - Results - Visit 4 - [Other Lab Tests]	GFR Estimated (mL/min/1.73m2) test results at visit 4.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_glucose_clin_v1	Glucose (mg/dL) Test - Clinically Significant? - Visit 1 - [Other Lab Tests]	Indicates if the Glucose (mg/dL) test results were clinically significant at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 0="No"
othlab_glucose_clin_v4	Glucose (mg/dL) Test - Clinically Significant? - Visit 4 - [Other Lab Tests]	Indicates if the Glucose (mg/dL) test results were clinically significant at visit 4.	.F="Participant Missing from Dataset" .N="N/A"
othlab_glucose_out_v1	Glucose (mg/dL) Test - Out of Range? - Visit 1 - [Other Lab Tests]	Indicates if the Glucose (mg/dL) test results were out of range at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"

Variable	Label	Description	Format Text
othlab_glucose_out_v4	Glucose (mg/dL) Test - Out of Range? - Visit 4 - [Other Lab Tests]	Indicates if the Glucose (mg/dL) test results were out of range at visit 4.	.F="Participant Missing from Dataset" .N="N/A"
othlab_glucose_v1	Glucose (mg/dL) Test - Results - Visit 1 - [Other Lab Tests]	Glucose (mg/dL) test results at visit 1.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_glucose_v4	Glucose (mg/dL) Test - Results - Visit 4 - [Other Lab Tests]	Glucose (mg/dL) test results at visit 4.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_mch_clin_v1	MCH (pg) Test - Clinically Significant? - Visit 1 - [Other Lab Tests]	Indicates if the MCH (pg) test results were clinically significant at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"
othlab_mch_clin_v4	MCH (pg) Test - Clinically Significant? - Visit 4 - [Other Lab Tests]	Indicates if the MCH (pg) test results were clinically significant at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"
othlab_mch_out_v1	MCH (pg) Test - Out of Range? - Visit 1 - [Other Lab Tests]	Indicates if the MCH (pg) test results were out of range at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"
othlab_mch_out_v4	MCH (pg) Test - Out of Range? - Visit 4 - [Other Lab Tests]	Indicates if the MCH (pg) test results were out of range at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"
othlab_mch_v1	MCH (pg) Test - Results - Visit 1 - [Other Lab Tests]	MCH (pg) test results at visit 1.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_mch_v4	MCH (pg) Test - Results - Visit 4 - [Other Lab Tests]	MCH (pg) test results at visit 4.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_mchc_clin_v1	MCHC (g/dL) Test - Clinically Significant? - Visit 1 - [Other Lab Tests]	Indicates if the MCHC (g/dL) test results were clinically significant at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"
othlab_mchc_clin_v4	MCHC (g/dL) Test - Clinically Significant? - Visit 4 - [Other Lab Tests]	Indicates if the MCHC (g/dL) test results were clinically significant at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"
othlab_mchc_out_v1	MCHC (g/dL) Test - Out of Range? - Visit 1 - [Other Lab Tests]	Indicates if the MCHC (g/dL) test results were out of range at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"
othlab_mchc_out_v4	MCHC (g/dL) Test - Out of Range? - Visit 4 - [Other Lab Tests]	Indicates if the MCHC (g/dL) test results were out of range at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"
othlab_mchc_v1	MCHC (g/dL) Test - Results - Visit 1 - [Other Lab Tests]	MCHC (g/dL) test results at visit 1.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_mchc_v4	MCHC (g/dL) Test - Results - Visit 4 - [Other Lab Tests]	MCHC (g/dL) test results at visit 4.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_mcv_clin_v1	MCV (fL) Test - Clinically Significant? - Visit 1 - [Other Lab Tests]	Indicates if the MCV (fL) test results were clinically significant at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"

Variable	Label	Description	Format Text
othlab_mcv_clin_v4	MCV (fL) Test - Clinically Significant? - Visit 4 - [Other Lab Tests]	Indicates if the MCV (fL) test results were clinically significant at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"
othlab_mcv_out_v1	MCV (fL) Test - Out of Range? - Visit 1 - [Other Lab Tests]	Indicates if the MCV (fL) test results were out of range at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"
othlab_mcv_out_v4	MCV (fL) Test - Out of Range? - Visit 4 - [Other Lab Tests]	Indicates if the MCV (fL) test results were out of range at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"
othlab_mcv_v1	MCV (fL) Test - Results - Visit 1 - [Other Lab Tests]	MCV (fL) test results at visit 1.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_mcv_v4	MCV (fL) Test - Results - Visit 4 - [Other Lab Tests]	MCV (fL) test results at visit 4.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_rdw_cv_clin_v1	RDW (cv) (%) Test - Clinically Significant? - Visit 1 - [Other Lab Tests]	Indicates if the RDW (cv) (%) test results were clinically significant at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"
othlab_rdw_cv_clin_v4	RDW (cv) (%) Test - Clinically Significant? - Visit 4 - [Other Lab Tests]	Indicates if the RDW (cv) (%) test results were clinically significant at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"
othlab_rdw_cv_out_v1	RDW (cv) (%) Test - Out of Range? - Visit 1 - [Other Lab Tests]	Indicates if the RDW (cv) (%) test results were out of range at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"
othlab_rdw_cv_out_v4	RDW (cv) (%) Test - Out of Range? - Visit 4 - [Other Lab Tests]	Indicates if the RDW (cv) (%) test results were out of range at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 1="Yes"
othlab_rdw_cv_v1	RDW (cv) (%) Test - Results - Visit 1 - [Other Lab Tests]	RDW (cv) (%) test results at visit 1.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_rdw_cv_v4	RDW (cv) (%) Test - Results - Visit 4 - [Other Lab Tests]	RDW (cv) (%) test results at visit 4.	Numeric .F="Participant Missing from Dataset" .N="N/A"
othlab_rdw_sd_clin_v1	RDW (sd) (fL) Test - Clinically Significant? - Visit 1 - [Other Lab Tests]	Indicates if the RDW (sd) (fL) test results were clinically significant at visit 1.	.F="Participant Missing from Dataset" .N="N/A" 0="No" 1="Yes"
othlab_rdw_sd_clin_v4	RDW (sd) (fL) Test - Clinically Significant? - Visit 4 - [Other Lab Tests]	Indicates if the RDW (sd) (fL) test results were clinically significant at visit 4.	.F="Participant Missing from Dataset" .N="N/A" 0="No"
othlab_rdw_sd_out_v1	RDW (sd) (fL) Test - Out of Range? - Visit 1 - [Other Lab Tests]	Indicates if the RDW (sd) (fL) test results were out of range at visit 1.	.F="Participant Missing from Dataset" .N="N/A"
othlab_rdw_sd_out_v4	RDW (sd) (fL) Test - Out of Range? - Visit 4 - [Other Lab Tests]	Indicates if the RDW (sd) (fL) test results were out of range at visit 4.	.F="Participant Missing from Dataset" .N="N/A"
othlab_rdw_sd_v1	RDW (sd) (fL) Test - Results - Visit 1 - [Other Lab Tests]	RDW (sd) (fL) test results at visit 1.	Numeric .F="Participant Missing from Dataset" .N="N/A"

Variable	Label	Description	Format Text
othlab_rdw_sd_v4	RDW (sd) (fL) Test - Results - Visit 4 - [Other Lab Tests]	RDW (sd) (fL) test results at visit 4.	Numeric .F="Participant Missing from Dataset" .N="N/A"