

UAZ2013-02-01 - Enhanced Person Data Dictionary

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Document Summary

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UAZ2013-02-01 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	build_dt	Build Date		SAS Date
01. Principal	ParticipantID	Participant ID		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	rnd_dt	Randomization Date		SAS Date .E="Not Eligible For Study"
01. Principal	rnd_num	Randomization Number		Numeric .E="Not Eligible For Study"
01. Principal	rnd_washout_end_dt	Washout End Date		SAS Date .E="Not Eligible For Study" .N="N/A"
01. Principal	rnd_washout_start_dt	Washout Start Date		SAS Date .E="Not Eligible For Study" .N="N/A"
01. Principal	site	Site		.E="Not Eligible For Study" .M="Missing" 1="Phoenix" 2="Tucson"
01. Principal	treatment	Treatment		.E="Not Eligible For Study" 1="Aspirin + Zileuton" 2="Placebo"
01. Principal	visit_dt_v1	Date of Visit 1 (Screening)		SAS Date .F="No Record For This Visit"
01. Principal	visit_dt_v2	Date of Visit 2 (Baseline)		SAS Date .F="No Record For This Visit"
01. Principal	visit_dt_v3	Date of Visit 3 (Week 4 Interim Study)		SAS Date .F="No Record For This Visit"
01. Principal	visit_dt_v4	Date of Visit 4 (Week 8 Interim Study)		SAS Date .F="No Record For This Visit"
01. Principal	visit_dt_v5	Date of Visit 5 (End of Intervention)		SAS Date .F="No Record For This Visit"
01. Principal	visit_dt_v6	Date of Visit 6 (Follow-up)		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Section 3: Registration

Class	Variable	Label	Description	Format Text
01. Principal	reg_age	Age at Registration - [Registration]		Numeric
01. Principal	reg_consent_dt	Date Informed Consent Signed - [Registration]		SAS Date
01. Principal	reg_dt	Date of Registration - [Registration]		SAS Date
01. Principal	reg_eligible	Participant Satisfies All Eligibility Criteria? - [Registration]		0="No" 1="Yes"
01. Principal	reg_ethnicity	Ethnicity - [Registration]		1="Hispanic or Latino" 2="Not Hispanic or Latino"
01. Principal	reg_gender	Gender - [Registration]		1="Male" 2="Female"
01. Principal	reg_oth_pay_method	Other Method of Payment - [Registration]		Char
01. Principal	reg_pay_method	Method of Payment - [Registration]		Char
01. Principal	reg_race1-2	Race # - [Registration]		.N="N/A" 1="White" 2="Black or African American" 4="Asian" 5="American Indian or Alaska Native" 7="Not Reported"
01. Principal	reg_race_eth	Race + Ethnicity - [Registration]		1="White, Non-Hispanic" 2="Black, Non-Hispanic" 3="Hispanic" 4="Asian" 5="Pacific Islander" 7="Not Reported"
01. Principal	reg_screen_dt1-2	Screen Date # - [Registration]		SAS Date .M="Missing" .N="N/A"

Section 4: Demographics

Class	Variable	Label	Description	Format Text
01. Principal	demo_10cig_v2	Smoked an Average of 10 Cigarettes Per Day Since Last Visit - Visit 2 (Baseline) - [Demographics]		.E="Not Eligible For Study" 1="Yes"
01. Principal	demo_10cig_v3	Smoked an Average of 10 Cigarettes Per Day Since Last Visit - Visit 3 (Week 4 Interim Study) - [Demographics]		.E="Not Eligible For Study" .M="Missing" 1="Yes"
01. Principal	demo_10cig_v4	Smoked an Average of 10 Cigarettes Per Day Since Last Visit - Visit 4 (Week 8 Interim Study) - [Demographics]		.E="Not Eligible For Study" .M="Missing" 1="Yes"
01. Principal	demo_10cig_v5	Smoked an Average of 10 Cigarettes Per Day Since Last Visit - Visit 5 (End of Intervention) - [Demographics]		.E="Not Eligible For Study" .M="Missing" 1="Yes"
01. Principal	demo_bmi	BMI - [Demographics]		Numeric .E="Not Eligible For Study"
01. Principal	demo_cig_hist	Cigarette History - [Demographics]		.E="Not Eligible For Study" 1="Current Smoker"
01. Principal	demo_cotinine_v2	Cotinine - Visit 2 (Baseline) - [Demographics]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	demo_cotinine_v5	Cotinine - Visit 5 (End of Intervention) - [Demographics]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	demo_cotinine_v5_v2	Difference Between Cotinine at Visit 5 and 2 - [Demographics]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	demo_cotinine_v6	Cotinine - Visit 6 (Follow-up) - [Demographics]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	demo_cotinine_v6_v2	Difference Between Cotinine at Visit 6 and 2 - [Demographics]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	demo_pack_years	Pack Years - [Demographics]		Numeric .E="Not Eligible For Study"

Section 5: Medical History

Class	Variable	Label	Description	Format Text
01. Principal	medhist_all_normal	All Body Systems Normal? - [Medical History]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	medhist_breast_cmnt	Comments - Breasts - [Medical History]		Char
01. Principal	medhist_breast_finding	Finding - Breasts - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal"
01. Principal	medhist_cardio_cmnt	Comments - Cardiovascular System - [Medical History]		Char
01. Principal	medhist_cardio_finding	Finding - Cardiovascular System - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal" 2="Abnormal"
01. Principal	medhist_derma_cmnt	Comments - Dermatologic System - [Medical History]		Char
01. Principal	medhist_derma_finding	Finding - Dermatologic System - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal" 2="Abnormal"
01. Principal	medhist_endome ta_cmnt	Comments - Endocrine/Metabolic System - [Medical History]		Char
01. Principal	medhist_endome ta_finding	Finding - Endocrine/Metabolic System - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal" 2="Abnormal"
01. Principal	medhist_gastro_cmnt	Comments - Gastrointestinal System - [Medical History]		Char
01. Principal	medhist_gastro_finding	Finding - Gastrointestinal System - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal" 2="Abnormal"
01. Principal	medhist_genit_cmnt	Comments - Genitourinary System - [Medical History]		Char
01. Principal	medhist_genit_finding	Finding - Genitourinary System - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal" 2="Abnormal"
01. Principal	medhist_has_allergies	Any Allergies? - [Medical History]		.E="Not Eligible For Study" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	medhist_heent_cmnt	Comments - H/E/E/N/T System - [Medical History]		Char
01. Principal	medhist_heent_finding	Finding - H/E/E/N/T System - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal" 2="Abnormal"
01. Principal	medhist_hemalymph_cmnt	Comments - Hematopoietic/Lymph System - [Medical History]		Char
01. Principal	medhist_hemalymph_finding	Finding - Hematopoietic/Lymph System - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal" 2="Abnormal"
01. Principal	medhist_musculoskeletal_cmnt	Comments - Musculoskeletal System - [Medical History]		Char
01. Principal	medhist_musculoskeletal_finding	Finding - Musculoskeletal System - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal" 2="Abnormal"
01. Principal	medhist_neck_cmnt	Comments - Neck - [Medical History]		Char
01. Principal	medhist_neck_finding	Finding - Neck - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal" 2="Abnormal"
01. Principal	medhist_neuro_cmnt	Comments - Neurologic System - [Medical History]		Char
01. Principal	medhist_neuro_finding	Finding - Neurologic System - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal" 2="Abnormal"
01. Principal	medhist_oth_cmnt1-5	Comments - Other Body System # - [Medical History]		Char
01. Principal	medhist_oth_finding1-5	Finding - Other Body System # - [Medical History]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 2="Abnormal"
01. Principal	medhist_oth_num	Number of Other Body Systems Reported - [Medical History]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	medhist_oth_sys1-5	Type - Other Body System # - [Medical History]		Char
01. Principal	medhist_resp_cmnt	Comments - Respiratory System - [Medical History]		Char

Class	Variable	Label	Description	Format Text
01. Principal	medhist_resp_finding	Finding - Respiratory System - [Medical History]		.E="Not Eligible For Study" .M="Missing" 1="Normal" 2="Abnormal"
01. Principal	medhist_spec_allergies	Specific Allergies - [Medical History]		Char

Section 6: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	conmed_dose1-10	Dose - Medication # - [Concomitant Medications]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	conmed_freq1-10	Frequency - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_name1-10	Name - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_num	Number of Concomitant Medications Taken - [Concomitant Medications]		Numeric .E="Not Eligible For Study"
01. Principal	conmed_reason1-10	Reason for Taking - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_report_dt1-10	Report Date - Medication # - [Concomitant Medications]		SAS Date .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	conmed_resolved_dt1-10	Resolved Date - Medication # - [Concomitant Medications]		SAS Date .C="Continuing" .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	conmed_start_dt1-10	Start Date - Medication # - [Concomitant Medications]		SAS Date .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	conmed_units1-10	Units - Medication # - [Concomitant Medications]		Char

Section 7: Pregnancy Specimen Data

Class	Variable	Label	Description	Format Text
01. Principal	preg_result_v1	Test Result - Urine Test - Visit 1 (Screening) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .N="N/A" 3="Negative"
01. Principal	preg_result_v2	Test Result - Urine Test - Visit 2 (Baseline) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 3="Negative"
01. Principal	preg_result_v3	Test Result - Urine Test - Visit 3 (Week 4 Interim Study) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 3="Negative"
01. Principal	preg_result_v4	Test Result - Urine Test - Visit 4 (Week 8 Interim Study) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 3="Negative"
01. Principal	preg_result_v5	Test Result - Urine Test - Visit 5 (End of Intervention) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 1="Not Obtained" 3="Negative"
01. Principal	preg_rsn_not_col_v1	Reason Test Was Not Collected - Urine Test - Visit 1 (Screening) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .N="N/A" 1="Participant Is Male" 2="Participant Is Female And Not Of Childbearing Potential"
01. Principal	preg_rsn_not_col_v2	Reason Test Was Not Collected - Urine Test - Visit 2 (Baseline) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 1="Participant Is Male" 2="Participant Is Female And Not Of Childbearing Potential"
01. Principal	preg_rsn_not_col_v3	Reason Test Was Not Collected - Urine Test - Visit 3 (Week 4 Interim Study) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 1="Participant Is Male" 2="Participant Is Female And Not Of Childbearing Potential"
01. Principal	preg_rsn_not_col_v4	Reason Test Was Not Collected - Urine Test - Visit 4 (Week 8 Interim Study) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 1="Participant Is Male" 2="Participant Is Female And Not Of Childbearing Potential"

Class	Variable	Label	Description	Format Text
01. Principal	preg_rsn_not_col_v5	Reason Test Was Not Collected - Urine Test - Visit 5 (End of Intervention) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 1="Participant Is Male" 2="Participant Is Female And Not Of Childbearing Potential"
01. Principal	preg_spec_dt_v1	Specimen Collection Date - Urine Test - Visit 1 (Screening) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .M="Missing"
01. Principal	preg_spec_dt_v2	Specimen Collection Date - Urine Test - Visit 2 (Baseline) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	preg_spec_dt_v3	Specimen Collection Date - Urine Test - Visit 3 (Week 4 Interim Study) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	preg_spec_dt_v4	Specimen Collection Date - Urine Test - Visit 4 (Week 8 Interim Study) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	preg_spec_dt_v5	Specimen Collection Date - Urine Test - Visit 5 (End of Intervention) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"

Section 8: Tobacco/Alcohol Assessment

Class	Variable	Label	Description	Format Text
01. Principal	tobalc_cig_hist	Cigarette History - [Tobacco/Alcohol Assessment]		.E="Not Eligible For Study" 1="Current Smoker"
01. Principal	tobalc_hab_alc_in	Habitual Alcohol Intake - [Tobacco/Alcohol Assessment]		.E="Not Eligible For Study" 0="Never Drank" 1="Former Drinker" 2="Consumes One to Two Per Day"
01. Principal	tobalc_pack_years	Pack Years - [Tobacco/Alcohol Assessment]		Numeric .E="Not Eligible For Study"

Section 9: Intervention Administration

Class	Variable	Label	Description	Format Text
01. Principal	intadm_agent_prov_dt	Date Agent Provided - [Intervention Administration]		SAS Date .E="Not Eligible For Study"
01. Principal	intadm_agent_start_dt	Date Agent Started - [Intervention Administration]		SAS Date .E="Not Eligible For Study" .M="Missing"

Section 10: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_num	Number of Adverse Events the Participant Experienced During the Study - [Adverse Events]		Numeric .E="Not Eligible For Study"

Section 11: Agent Interruption

Class	Variable	Label	Description	Format Text
01. Principal	agent_restart_dt1-2	Date Restarted - Interruption # - [Agent Interruption]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	agent_restart_rsn1-2	Reason Restarted - Interruption # - [Agent Interruption]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 2="Participant Decision"
01. Principal	agent_restarted1-2	Was Agent Restarted? - Interruption # - [Agent Interruption]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	agent_stop_dt1-2	Date Stopped - Interruption # - [Agent Interruption]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	agent_stop_rsn1-2	Reason Stopped - Interruption # - [Agent Interruption]		.E="Not Eligible For Study" .F="No Record For This Visit" 4="Other"
01. Principal	agent_stop_rsn_spec1-2	Specific Reason Stopped - Interruption # - [Agent Interruption]		Char

Section 12: Compliance

Class	Variable	Label	Description	Format Text
01. Principal	comp_asp_amt_agent_missing_v3	Amount of Agent Missing - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_missing_v4	Amount of Agent Missing - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_missing_v5	Amount of Agent Missing - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_prov_last_v3	Amount of Agent Provided at Last Visit - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_prov_last_v4	Amount of Agent Provided at Last Visit - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_prov_last_v5	Amount of Agent Provided at Last Visit - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_prov_this_v3	Amount of Agent Provided at This Visit - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	comp_asp_amt_agent_prov_this_v4	Amount of Agent Provided at This Visit - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_prov_this_v5	Amount of Agent Provided at This Visit - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_rtn_v3	Amount of Agent Returned - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	comp_asp_amt_agent_rtn_v4	Amount of Agent Returned - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_rtn_v5	Amount of Agent Returned - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_tkn_v3	Amount of Agent Taken - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_tkn_v4	Amount of Agent Taken - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_amt_agent_tkn_v5	Amount of Agent Taken - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_compliant_v3	Compliant? - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	comp_asp_compliant_v4	Compliant? - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	comp_asp_compliant_v5	Compliant? - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	comp_asp_first_dose_dt_v3	First Dose Date - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_first_dose_dt_v4	First Dose Date - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_first_dose_dt_v5	First Dose Date - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_interrupted_v3	Agent Interrupted? - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	comp_asp_interrupted_v4	Agent Interrupted? - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	comp_asp_interrupted_v5	Agent Interrupted? - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	comp_asp_last_dose_dt_v3	Last Dose Date - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_last_dose_dt_v4	Last Dose Date - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_last_dose_dt_v5	Last Dose Date - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_noncompliance_rsn_v3	Reason For Noncompliance - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Char
01. Principal	comp_asp_noncompliance_rsn_v4	Reason For Noncompliance - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Char
01. Principal	comp_asp_noncompliance_rsn_v5	Reason For Noncompliance - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		Char
01. Principal	comp_asp_number_of_interruptions_v3	Number of Interruptions - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_number_of_interruptions_v4	Number of Interruptions - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_number_of_interruptions_v5	Number of Interruptions - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_asp_provided_v3	Agent Provided at This Visit? - Aspirin/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	comp_asp_provided_v4	Agent Provided at This Visit? - Aspirin/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	comp_asp_provided_v5	Agent Provided at This Visit? - Aspirin/Placebo - Visit 5 (End of Intervention) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	comp_zil_amt_agent_missing_v3	Amount of Agent Missing - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_missing_v4	Amount of Agent Missing - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_missing_v5	Amount of Agent Missing - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_prov_last_v3	Amount of Agent Provided at Last Visit - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_prov_last_v4	Amount of Agent Provided at Last Visit - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_prov_last_v5	Amount of Agent Provided at Last Visit - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_prov_this_v3	Amount of Agent Provided at This Visit - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	comp_zil_amt_agent_prov_this_v4	Amount of Agent Provided at This Visit - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_prov_this_v5	Amount of Agent Provided at This Visit - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_rtn_v3	Amount of Agent Returned - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	comp_zil_amt_agent_rtn_v4	Amount of Agent Returned - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_rtn_v5	Amount of Agent Returned - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_tkn_v3	Amount of Agent Taken - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_tkn_v4	Amount of Agent Taken - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_amt_agent_tkn_v5	Amount of Agent Taken - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_compliant_v3	Compliant? - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	comp_zil_compliant_v4	Compliant? - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	comp_zil_compliant_v5	Compliant? - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	comp_zil_first_dose_dt_v3	First Dose Date - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_first_dose_dt_v4	First Dose Date - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_first_dose_dt_v5	First Dose Date - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_interrupted_v3	Agent Interrupted? - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	comp_zil_interrupted_v4	Agent Interrupted? - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	comp_zil_interrupted_v5	Agent Interrupted? - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	comp_zil_last_dose_dt_v3	Last Dose Date - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_last_dose_dt_v4	Last Dose Date - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_last_dose_dt_v5	Last Dose Date - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_noncompliance_rsn_v3	Reason For Noncompliance - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Char
01. Principal	comp_zil_noncompliance_rsn_v4	Reason For Noncompliance - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Char
01. Principal	comp_zil_noncompliance_rsn_v5	Reason For Noncompliance - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		Char
01. Principal	comp_zil_num_interruptions_v3	Number of Interruptions - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_num_interruptions_v4	Number of Interruptions - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_num_interruptions_v5	Number of Interruptions - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_zil_provided_v3	Agent Provided at This Visit? - Zileuton/Placebo - Visit 3 (Week 4 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	comp_zil_provided_v4	Agent Provided at This Visit? - Zileuton/Placebo - Visit 4 (Week 8 Interim Study) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	comp_zil_provided_v5	Agent Provided at This Visit? - Zileuton/Placebo - Visit 5 (End of Intervention) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Section 13: Off Study

Class	Variable	Label	Description	Format Text
01. Principal	offstudy_dt	Date Off Study - [Off Study]		SAS Date .E="Not Eligible For Study"
01. Principal	offstudy_form_dt	Form Date - [Off Study]		SAS Date .E="Not Eligible For Study"
01. Principal	offstudy_last_agent_dt	Date Last Agent Taken - [Off Study]		SAS Date .E="Not Eligible For Study" .N="N/A"
01. Principal	offstudy_last_contact_dt	Date of Last Contact - [Off Study]		SAS Date .E="Not Eligible For Study"
01. Principal	offstudy_off_followup_dt	Date Off Follow-up - [Off Study]		SAS Date .E="Not Eligible For Study" .N="N/A"
01. Principal	offstudy_on_followup_dt	Date On Follow-up - [Off Study]		SAS Date .E="Not Eligible For Study" .N="N/A"
01. Principal	offstudy_oth_explanation	Other Reason Explanation - [Off Study]		Char
01. Principal	offstudy_reason	Reason Off Study - [Off Study]		.E="Not Eligible For Study" 1="Study Complete" 3="Adverse Event" 4="Lost to Follow-up" 5="Participant Withdrawal" 8="Other, Specify"

Section 14: Comments

Class	Variable	Label	Description	Format Text
01. Principal	cmnt_comments	Comments - [Comments]		Char
01. Principal	cmnt_field_name	Field Name - [Comments]		Char
01. Principal	cmnt_visit	Visit - [Comments]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Section 15: Physical Examination

Class	Variable	Label	Description	Format Text
01. Principal	phys_abdomen_cmnt_v1	Abdomen - Comments - Visit 1 (Screening) - [Physical Examination]		Char
01. Principal	phys_abdomen_cmnt_v2	Abdomen - Comments - Visit 2 (Baseline) - [Physical Examination]		Char
01. Principal	phys_abdomen_cmnt_v3	Abdomen - Comments - Visit 3 (Week 4 Interim Study) - [Physical Examination]		Char
01. Principal	phys_abdomen_cmnt_v4	Abdomen - Comments - Visit 4 (Week 8 Interim Study) - [Physical Examination]		Char
01. Principal	phys_abdomen_cmnt_v5	Abdomen - Comments - Visit 5 (End of Intervention) - [Physical Examination]		Char
01. Principal	phys_abdomen_finding_v1	Abdomen - Finding - Visit 1 (Screening) - [Physical Examination]		.E="Not Eligible For Study" 1="Normal"
01. Principal	phys_abdomen_finding_v2	Abdomen - Finding - Visit 2 (Baseline) - [Physical Examination]		.E="Not Eligible For Study" .M="Missing"
01. Principal	phys_abdomen_finding_v3	Abdomen - Finding - Visit 3 (Week 4 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_abdomen_finding_v4	Abdomen - Finding - Visit 4 (Week 8 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_abdomen_finding_v5	Abdomen - Finding - Visit 5 (End of Intervention) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_avg_10cigs_v1	Smoked an Average of 10 Cigarettes Per Day Since Last Visit - Visit 1 (Screening) - [Physical Examination]		.E="Not Eligible For Study" .M="Missing"
01. Principal	phys_avg_10cigs_v2	Smoked an Average of 10 Cigarettes Per Day Since Last Visit - Visit 2 (Baseline) - [Physical Examination]		.E="Not Eligible For Study" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	phys_avg_10cigs_v3	Smoked an Average of 10 Cigarettes Per Day Since Last Visit - Visit 3 (Week 4 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	phys_avg_10cigs_v4	Smoked an Average of 10 Cigarettes Per Day Since Last Visit - Visit 4 (Week 8 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	phys_avg_10cigs_v5	Smoked an Average of 10 Cigarettes Per Day Since Last Visit - Visit 5 (End of Intervention) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	phys_bp_diastolic_v1	Diastolic Blood Pressure (mm Hg) - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_bp_diastolic_v2	Diastolic Blood Pressure (mm Hg) - Visit 2 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_bp_diastolic_v3	Diastolic Blood Pressure (mm Hg) - Visit 3 (Week 4 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_bp_diastolic_v4	Diastolic Blood Pressure (mm Hg) - Visit 4 (Week 8 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_bp_diastolic_v5	Diastolic Blood Pressure (mm Hg) - Visit 5 (End of Intervention) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_bp_systolic_v1	Systolic Blood Pressure (mm Hg) - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_bp_systolic_v2	Systolic Blood Pressure (mm Hg) - Visit 2 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_bp_systolic_v3	Systolic Blood Pressure (mm Hg) - Visit 3 (Week 4 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	phys_bp_systolic_v4	Systolic Blood Pressure (mm Hg) - Visit 4 (Week 8 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_bp_systolic_v5	Systolic Blood Pressure (mm Hg) - Visit 5 (End of Intervention) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_chest_cmnt_v1	Chest - Comments - Visit 1 (Screening) - [Physical Examination]		Char
01. Principal	phys_chest_cmnt_v2	Chest - Comments - Visit 2 (Baseline) - [Physical Examination]		Char
01. Principal	phys_chest_cmnt_v3	Chest - Comments - Visit 3 (Week 4 Interim Study) - [Physical Examination]		Char
01. Principal	phys_chest_cmnt_v4	Chest - Comments - Visit 4 (Week 8 Interim Study) - [Physical Examination]		Char
01. Principal	phys_chest_cmnt_v5	Chest - Comments - Visit 5 (End of Intervention) - [Physical Examination]		Char
01. Principal	phys_chest_finding_v1	Chest - Finding - Visit 1 (Screening) - [Physical Examination]		.E="Not Eligible For Study" 1="Normal"
01. Principal	phys_chest_finding_v2	Chest - Finding - Visit 2 (Baseline) - [Physical Examination]		.E="Not Eligible For Study" .M="Missing"
01. Principal	phys_chest_finding_v3	Chest - Finding - Visit 3 (Week 4 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_chest_finding_v4	Chest - Finding - Visit 4 (Week 8 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_chest_finding_v5	Chest - Finding - Visit 5 (End of Intervention) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_examination_dt_v1	Examination Date - Visit 1 (Screening) - [Physical Examination]		SAS Date .E="Not Eligible For Study"
01. Principal	phys_examination_dt_v2	Examination Date - Visit 2 (Baseline) - [Physical Examination]		SAS Date .E="Not Eligible For Study"
01. Principal	phys_examination_dt_v3	Examination Date - Visit 3 (Week 4 Interim Study) - [Physical Examination]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	phys_examination_dt_v4	Examination Date - Visit 4 (Week 8 Interim Study) - [Physical Examination]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_examination_dt_v5	Examination Date - Visit 5 (End of Intervention) - [Physical Examination]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_heart_cmnt_v1	Heart - Comments - Visit 1 (Screening) - [Physical Examination]		Char
01. Principal	phys_heart_cmnt_v2	Heart - Comments - Visit 2 (Baseline) - [Physical Examination]		Char
01. Principal	phys_heart_cmnt_v3	Heart - Comments - Visit 3 (Week 4 Interim Study) - [Physical Examination]		Char
01. Principal	phys_heart_cmnt_v4	Heart - Comments - Visit 4 (Week 8 Interim Study) - [Physical Examination]		Char
01. Principal	phys_heart_cmnt_v5	Heart - Comments - Visit 5 (End of Intervention) - [Physical Examination]		Char
01. Principal	phys_heart_finding_v1	Heart - Finding - Visit 1 (Screening) - [Physical Examination]		.E="Not Eligible For Study" 1="Normal"
01. Principal	phys_heart_finding_v2	Heart - Finding - Visit 2 (Baseline) - [Physical Examination]		.E="Not Eligible For Study" .M="Missing"
01. Principal	phys_heart_finding_v3	Heart - Finding - Visit 3 (Week 4 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_heart_finding_v4	Heart - Finding - Visit 4 (Week 8 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_heart_finding_v5	Heart - Finding - Visit 5 (End of Intervention) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_height_v1	Height (in) - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_height_v2	Height (in) - Visit 2 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	phys_height_v3	Height (in) - Visit 3 (Week 4 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	phys_height_v4	Height (in) - Visit 4 (Week 8 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_height_v5	Height (in) - Visit 5 (End of Intervention) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_karnofsky_v1	Karnofsky Performance Status - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_karnofsky_v2	Karnofsky Performance Status - Visit 2 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	phys_karnofsky_v3	Karnofsky Performance Status - Visit 3 (Week 4 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_karnofsky_v4	Karnofsky Performance Status - Visit 4 (Week 8 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_karnofsky_v5	Karnofsky Performance Status - Visit 5 (End of Intervention) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_lung_cmnt_v1	Lungs - Comments - Visit 1 (Screening) - [Physical Examination]		Char
01. Principal	phys_lung_cmnt_v2	Lungs - Comments - Visit 2 (Baseline) - [Physical Examination]		Char
01. Principal	phys_lung_cmnt_v3	Lungs - Comments - Visit 3 (Week 4 Interim Study) - [Physical Examination]		Char
01. Principal	phys_lung_cmnt_v4	Lungs - Comments - Visit 4 (Week 8 Interim Study) - [Physical Examination]		Char
01. Principal	phys_lung_cmnt_v5	Lungs - Comments - Visit 5 (End of Intervention) - [Physical Examination]		Char
01. Principal	phys_lung_findin g_v1	Lungs - Finding - Visit 1 (Screening) - [Physical Examination]		.E="Not Eligible For Study" 1="Normal"
01. Principal	phys_lung_findin g_v2	Lungs - Finding - Visit 2 (Baseline) - [Physical Examination]		.E="Not Eligible For Study" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	phys_lung_finding_v3	Lungs - Finding - Visit 3 (Week 4 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_lung_finding_v4	Lungs - Finding - Visit 4 (Week 8 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_lung_finding_v5	Lungs - Finding - Visit 5 (End of Intervention) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_pulse_rate_v1	Pulse Rate - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_pulse_rate_v2	Pulse Rate - Visit 2 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_pulse_rate_v3	Pulse Rate - Visit 3 (Week 4 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_pulse_rate_v4	Pulse Rate - Visit 4 (Week 8 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_pulse_rate_v5	Pulse Rate - Visit 5 (End of Intervention) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_temperature_v1	Temperature (F) - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_temperature_v2	Temperature (F) - Visit 2 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_temperature_v3	Temperature (F) - Visit 3 (Week 4 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_temperature_v4	Temperature (F) - Visit 4 (Week 8 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_temperature_v5	Temperature (F) - Visit 5 (End of Intervention) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_urine_cotinine_v1	Urine Cotinine Collected at Screening to Determine Smoking Status - Visit 1 (Screening) - [Physical Examination]		.E="Not Eligible For Study" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	phys_urine_cotinine_v2	Urine Cotinine Collected at Screening to Determine Smoking Status - Visit 2 (Baseline) - [Physical Examination]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	phys_urine_cotinine_v3	Urine Cotinine Collected at Screening to Determine Smoking Status - Visit 3 (Week 4 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_urine_cotinine_v4	Urine Cotinine Collected at Screening to Determine Smoking Status - Visit 4 (Week 8 Interim Study) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_urine_cotinine_v5	Urine Cotinine Collected at Screening to Determine Smoking Status - Visit 5 (End of Intervention) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_weight_v1	Weight (lb) - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_weight_v2	Weight (lb) - Visit 2 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study"
01. Principal	phys_weight_v3	Weight (lb) - Visit 3 (Week 4 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_weight_v4	Weight (lb) - Visit 4 (Week 8 Interim Study) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_weight_v5	Weight (lb) - Visit 5 (End of Intervention) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Section 16: Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alb_glob_clin_v1	Albumin/Globulin (Ratio) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_alb_glob_clin_v3	Albumin/Globulin (Ratio) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No"
01. Principal	bldchem_alb_glob_clin_v4	Albumin/Globulin (Ratio) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_alb_glob_clin_v5	Albumin/Globulin (Ratio) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_alb_glob_clin_v6	Albumin/Globulin (Ratio) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_alb_glob_cmnt_v1	Albumin/Globulin (Ratio) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_alb_glob_cmnt_v3	Albumin/Globulin (Ratio) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_alb_glob_cmnt_v4	Albumin/Globulin (Ratio) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_alb_glob_cmnt_v5	Albumin/Globulin (Ratio) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_alb_glob_cmnt_v6	Albumin/Globulin (Ratio) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alb_glob_fasting_v1	Albumin/Globulin (Ratio) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_alb_glob_fasting_v3	Albumin/Globulin (Ratio) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_alb_glob_fasting_v4	Albumin/Globulin (Ratio) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_alb_glob_fasting_v5	Albumin/Globulin (Ratio) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_alb_glob_fasting_v6	Albumin/Globulin (Ratio) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_alb_glob_out_v1	Albumin/Globulin (Ratio) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_alb_glob_out_v3	Albumin/Globulin (Ratio) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_alb_glob_out_v4	Albumin/Globulin (Ratio) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_alb_glob_out_v5	Albumin/Globulin (Ratio) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_alb_glob_out_v6	Albumin/Globulin (Ratio) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_alb_glob_res_v1	Albumin/Globulin (Ratio) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_alb_glob_res_v3	Albumin/Globulin (Ratio) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alb_glob_res_v4	Albumin/Globulin (Ratio) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alb_glob_res_v5	Albumin/Globulin (Ratio) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alb_glob_res_v6	Albumin/Globulin (Ratio) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alb_glob_spec_dt_v1	Albumin/Globulin (Ratio) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_alb_glob_spec_dt_v3	Albumin/Globulin (Ratio) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alb_glob_spec_dt_v4	Albumin/Globulin (Ratio) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alb_glob_spec_dt_v5	Albumin/Globulin (Ratio) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alb_glob_spec_dt_v6	Albumin/Globulin (Ratio) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_albumin_clin_v1	Albumin (g/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_albumin_clin_v3	Albumin (g/dL) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_albumin_clin_v4	Albumin (g/dL) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_albumin_clin_v5	Albumin (g/dL) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_albumin_clin_v6	Albumin (g/dL) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_albumin_cmnt_v1	Albumin (g/dL) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_albumin_cmnt_v3	Albumin (g/dL) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_albumin_cmnt_v4	Albumin (g/dL) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_albumin_cmnt_v5	Albumin (g/dL) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_albumin_cmnt_v6	Albumin (g/dL) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_albumin_fasting_v1	Albumin (g/dL) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_albumin_fasting_v3	Albumin (g/dL) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_albumin_fasting_v4	Albumin (g/dL) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_albumin_fasting_v5	Albumin (g/dL) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_albumin_fasting_v6	Albumin (g/dL) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_albumin_out_v1	Albumin (g/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_albumin_out_v3	Albumin (g/dL) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_albumin_out_v4	Albumin (g/dL) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_albumin_out_v5	Albumin (g/dL) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_albumin_out_v6	Albumin (g/dL) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_albumin_res_v1	Albumin (g/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_albumin_res_v3	Albumin (g/dL) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_albumin_res_v4	Albumin (g/dL) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_albumin_res_v5	Albumin (g/dL) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_albumin_res_v6	Albumin (g/dL) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_albumin_spec_dt_v1	Albumin (g/dL) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_albumin_spec_dt_v3	Albumin (g/dL) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_albumin_spec_dt_v4	Albumin (g/dL) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_albumin_spec_dt_v5	Albumin (g/dL) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_albumin_spec_dt_v6	Albumin (g/dL) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alk_phos_clin_v1	Alkaline Phosphatase (IU/L) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_clin_v3	Alkaline Phosphatase (IU/L) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_clin_v4	Alkaline Phosphatase (IU/L) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_clin_v5	Alkaline Phosphatase (IU/L) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_clin_v6	Alkaline Phosphatase (IU/L) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_cmnt_v1	Alkaline Phosphatase (IU/L) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_alk_phos_cmnt_v3	Alkaline Phosphatase (IU/L) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_alk_phos_cmnt_v4	Alkaline Phosphatase (IU/L) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_alk_phos_cmnt_v5	Alkaline Phosphatase (IU/L) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alk_phos_cmnt_v6	Alkaline Phosphatase (IU/L) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_alk_phos_fasting_v1	Alkaline Phosphatase (IU/L) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_fasting_v3	Alkaline Phosphatase (IU/L) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_fasting_v4	Alkaline Phosphatase (IU/L) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_fasting_v5	Alkaline Phosphatase (IU/L) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_fasting_v6	Alkaline Phosphatase (IU/L) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_out_v1	Alkaline Phosphatase (IU/L) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_out_v3	Alkaline Phosphatase (IU/L) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_out_v4	Alkaline Phosphatase (IU/L) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_out_v5	Alkaline Phosphatase (IU/L) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_out_v6	Alkaline Phosphatase (IU/L) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_res_v1	Alkaline Phosphatase (IU/L) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alk_phos_res_v3	Alkaline Phosphatase (IU/L) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alk_phos_res_v4	Alkaline Phosphatase (IU/L) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alk_phos_res_v5	Alkaline Phosphatase (IU/L) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alk_phos_res_v6	Alkaline Phosphatase (IU/L) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alk_phos_spec_dt_v1	Alkaline Phosphatase (IU/L) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_alk_phos_spec_dt_v3	Alkaline Phosphatase (IU/L) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alk_phos_spec_dt_v4	Alkaline Phosphatase (IU/L) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alk_phos_spec_dt_v5	Alkaline Phosphatase (IU/L) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_alk_phos_spec_dt_v6	Alkaline Phosphatase (IU/L) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_anion_gap_clin_v1	Anion Gap - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_anion_gap_clin_v3	Anion Gap - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_anion_gap_clin_v4	Anion Gap - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_anion_gap_clin_v5	Anion Gap - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_anion_gap_clin_v6	Anion Gap - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_anion_gap_cmnt_v1	Anion Gap - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_anion_gap_cmnt_v3	Anion Gap - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_anion_gap_cmnt_v4	Anion Gap - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_anion_gap_cmnt_v5	Anion Gap - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_anion_gap_cmnt_v6	Anion Gap - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_anion_gap_fasting_v1	Anion Gap - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_anion_gap_fasting_v3	Anion Gap - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_anion_gap_fasting_v4	Anion Gap - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_anion_gap_fasting_v5	Anion Gap - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_anion_gap_fasting_v6	Anion Gap - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No"
01. Principal	bldchem_anion_gap_out_v1	Anion Gap - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_anion_gap_out_v3	Anion Gap - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_anion_gap_out_v4	Anion Gap - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_anion_gap_out_v5	Anion Gap - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_anion_gap_out_v6	Anion Gap - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_anion_gap_res_v1	Anion Gap - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_anion_gap_res_v3	Anion Gap - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_anion_gap_res_v4	Anion Gap - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_anion_gap_res_v5	Anion Gap - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_anion_gap_res_v6	Anion Gap - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_anion_gap_spec_dt_v1	Anion Gap - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_anion_gap_spec_dt_v3	Anion Gap - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_anion_gap_spec_dt_v4	Anion Gap - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_anion_gap_spec_dt_v5	Anion Gap - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_anion_gap_spec_dt_v6	Anion Gap - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bicarbonate_clin_v1	Bicarbonate (mmol/l) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_bicarbonate_clin_v3	Bicarbonate (mmol/l) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bicarbonate_clin_v4	Bicarbonate (mmol/l) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bicarbonate_clin_v5	Bicarbonate (mmol/l) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_bicarbonate_clin_v6	Bicarbonate (mmol/l) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bicarbonate_cmnt_v1	Bicarbonate (mmol/l) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_bicarbonate_cmnt_v3	Bicarbonate (mmol/l) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_bicarbonate_cmnt_v4	Bicarbonate (mmol/l) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_bicarbonate_cmnt_v5	Bicarbonate (mmol/l) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_bicarbonate_cmnt_v6	Bicarbonate (mmol/l) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_bicarbonate_fasting_v1	Bicarbonate (mmol/l) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bicarbonate_fasting_v3	Bicarbonate (mmol/l) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bicarbonate_fasting_v4	Bicarbonate (mmol/l) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bicarbonate_fasting_v5	Bicarbonate (mmol/l) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bicarbonate_fasting_v6	Bicarbonate (mmol/l) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No"
01. Principal	bldchem_bicarbonate_out_v1	Bicarbonate (mmol/l) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_bicarbonate_out_v3	Bicarbonate (mmol/l) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bicarbonate_out_v4	Bicarbonate (mmol/l) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bicarbonate_out_v5	Bicarbonate (mmol/l) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_bicarbonate_out_v6	Bicarbonate (mmol/l) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bicarbonate_res_v1	Bicarbonate (mmol/l) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_bicarbonate_res_v3	Bicarbonate (mmol/l) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bicarbonate_res_v4	Bicarbonate (mmol/l) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bicarbonate_res_v5	Bicarbonate (mmol/l) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bicarbonate_res_v6	Bicarbonate (mmol/l) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bicarbonate_spec_dt_v1	Bicarbonate (mmol/l) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bicarbonate_spec_dt_v3	Bicarbonate (mmol/l) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bicarbonate_spec_dt_v4	Bicarbonate (mmol/l) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bicarbonate_spec_dt_v5	Bicarbonate (mmol/l) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bicarbonate_spec_dt_v6	Bicarbonate (mmol/l) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bili_dir_clin_v1	Bilirubin Direct (mg/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A"
01. Principal	bldchem_bili_dir_clin_v3	Bilirubin Direct (mg/dL) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 0="No"
01. Principal	bldchem_bili_dir_clin_v4	Bilirubin Direct (mg/dL) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No"
01. Principal	bldchem_bili_dir_clin_v5	Bilirubin Direct (mg/dL) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bili_dir_clin_v6	Bilirubin Direct (mg/dL) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 0="No"
01. Principal	bldchem_bili_dir_cmnt_v1	Bilirubin Direct (mg/dL) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_bili_dir_cmnt_v3	Bilirubin Direct (mg/dL) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_bili_dir_cmnt_v4	Bilirubin Direct (mg/dL) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bili_dir_cmnt_v5	Bilirubin Direct (mg/dL) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_bili_dir_cmnt_v6	Bilirubin Direct (mg/dL) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_bili_dir_fasting_v1	Bilirubin Direct (mg/dL) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A"
01. Principal	bldchem_bili_dir_fasting_v3	Bilirubin Direct (mg/dL) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bili_dir_fasting_v4	Bilirubin Direct (mg/dL) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bili_dir_fasting_v5	Bilirubin Direct (mg/dL) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bili_dir_fasting_v6	Bilirubin Direct (mg/dL) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bili_dir_out_v1	Bilirubin Direct (mg/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A"
01. Principal	bldchem_bili_dir_out_v3	Bilirubin Direct (mg/dL) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 0="No"
01. Principal	bldchem_bili_dir_out_v4	Bilirubin Direct (mg/dL) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_bili_dir_out_v5	Bilirubin Direct (mg/dL) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bili_dir_out_v6	Bilirubin Direct (mg/dL) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bili_dir_res_v1	Bilirubin Direct (mg/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .N="N/A"
01. Principal	bldchem_bili_dir_res_v3	Bilirubin Direct (mg/dL) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	bldchem_bili_dir_res_v4	Bilirubin Direct (mg/dL) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	bldchem_bili_dir_res_v5	Bilirubin Direct (mg/dL) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bili_dir_res_v6	Bilirubin Direct (mg/dL) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	bldchem_bili_dir_spec_dt_v1	Bilirubin Direct (mg/dL) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .N="N/A"
01. Principal	bldchem_bili_dir_spec_dt_v3	Bilirubin Direct (mg/dL) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bili_dir_spec_dt_v4	Bilirubin Direct (mg/dL) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bili_dir_spec_dt_v5	Bilirubin Direct (mg/dL) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bili_dir_spec_dt_v6	Bilirubin Direct (mg/dL) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bilirubin_clin_v1	Bilirubin (mg/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_bilirubin_clin_v3	Bilirubin (mg/dL) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bilirubin_clin_v4	Bilirubin (mg/dL) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	bldchem_bilirubin_clin_v5	Bilirubin (mg/dL) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_bilirubin_clin_v6	Bilirubin (mg/dL) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_bilirubin_cmnt_v1	Bilirubin (mg/dL) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_bilirubin_cmnt_v3	Bilirubin (mg/dL) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_bilirubin_cmnt_v4	Bilirubin (mg/dL) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_bilirubin_cmnt_v5	Bilirubin (mg/dL) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_bilirubin_cmnt_v6	Bilirubin (mg/dL) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_bilirubin_fasting_v1	Bilirubin (mg/dL) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bilirubin_fasting_v3	Bilirubin (mg/dL) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bilirubin_fasting_v4	Bilirubin (mg/dL) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bilirubin_fasting_v5	Bilirubin (mg/dL) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bilirubin_fasting_v6	Bilirubin (mg/dL) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bilirubin_out_v1	Bilirubin (mg/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_bilirubin_out_v3	Bilirubin (mg/dL) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_bilirubin_out_v4	Bilirubin (mg/dL) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_bilirubin_out_v5	Bilirubin (mg/dL) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	bldchem_bilirubin_out_v6	Bilirubin (mg/dL) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_bilirubin_res_v1	Bilirubin (mg/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_bilirubin_res_v3	Bilirubin (mg/dL) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bilirubin_res_v4	Bilirubin (mg/dL) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bilirubin_res_v5	Bilirubin (mg/dL) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bilirubin_res_v6	Bilirubin (mg/dL) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bilirubin_spec_dt_v1	Bilirubin (mg/dL) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bilirubin_spec_dt_v3	Bilirubin (mg/dL) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bilirubin_spec_dt_v4	Bilirubin (mg/dL) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bilirubin_spec_dt_v5	Bilirubin (mg/dL) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bilirubin_spec_dt_v6	Bilirubin (mg/dL) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bun_clin_v1	BUN (mg/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_bun_clin_v3	BUN (mg/dL) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bun_clin_v4	BUN (mg/dL) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_clin_v5	BUN (mg/dL) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_bun_clin_v6	BUN (mg/dL) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bun_comments_v1	BUN (mg/dL) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_comments_v3	BUN (mg/dL) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_comments_v4	BUN (mg/dL) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bun_cmnt_v5	BUN (mg/dL) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_cmnt_v6	BUN (mg/dL) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_creat_clin_v1	Bun/Creatinine (Ratio) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_bun_creat_clin_v3	Bun/Creatinine (Ratio) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bun_creat_clin_v4	Bun/Creatinine (Ratio) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_creat_clin_v5	Bun/Creatinine (Ratio) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_bun_creat_clin_v6	Bun/Creatinine (Ratio) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bun_creat_cmnt_v1	Bun/Creatinine (Ratio) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_creat_cmnt_v3	Bun/Creatinine (Ratio) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_creat_cmnt_v4	Bun/Creatinine (Ratio) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_creat_cmnt_v5	Bun/Creatinine (Ratio) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_creat_cmnt_v6	Bun/Creatinine (Ratio) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_creat_fasting_v1	Bun/Creatinine (Ratio) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bun_creat_fasting_v3	Bun/Creatinine (Ratio) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bun_creat_fasting_v4	Bun/Creatinine (Ratio) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_creat_fasting_v5	Bun/Creatinine (Ratio) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bun_creat_fasting_v6	Bun/Creatinine (Ratio) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No"
01. Principal	bldchem_bun_creat_out_v1	Bun/Creatinine (Ratio) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_bun_creat_out_v3	Bun/Creatinine (Ratio) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bun_creat_out_v4	Bun/Creatinine (Ratio) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_creat_out_v5	Bun/Creatinine (Ratio) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_bun_creat_out_v6	Bun/Creatinine (Ratio) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bun_creat_res_v1	Bun/Creatinine (Ratio) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_bun_creat_res_v3	Bun/Creatinine (Ratio) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_creat_res_v4	Bun/Creatinine (Ratio) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_creat_res_v5	Bun/Creatinine (Ratio) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bun_creat_res_v6	Bun/Creatinine (Ratio) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_creat_spec_dt_v1	Bun/Creatinine (Ratio) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_bun_creat_spec_dt_v3	Bun/Creatinine (Ratio) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_creat_spec_dt_v4	Bun/Creatinine (Ratio) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_creat_spec_dt_v5	Bun/Creatinine (Ratio) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bun_creat_spec_dt_v6	Bun/Creatinine (Ratio) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_fasting_v1	BUN (mg/dL) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bun_fasting_v3	BUN (mg/dL) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bun_fasting_v4	BUN (mg/dL) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_fasting_v5	BUN (mg/dL) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_bun_fasting_v6	BUN (mg/dL) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No"
01. Principal	bldchem_bun_out_v1	BUN (mg/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bun_out_v3	BUN (mg/dL) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bun_out_v4	BUN (mg/dL) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_out_v5	BUN (mg/dL) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_bun_out_v6	BUN (mg/dL) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_bun_results_v1	BUN (mg/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_bun_results_v3	BUN (mg/dL) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_results_v4	BUN (mg/dL) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_results_v5	BUN (mg/dL) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_bun_results_v6	BUN (mg/dL) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_spec_dt_v1	BUN (mg/dL) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_bun_spec_dt_v3	BUN (mg/dL) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_spec_dt_v4	BUN (mg/dL) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_bun_spec_dt_v5	BUN (mg/dL) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bun_spec_dt_v6	BUN (mg/dL) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_calcium_clin_v1	Calcium (mg/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_calcium_clin_v3	Calcium (mg/dL) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_calcium_clin_v4	Calcium (mg/dL) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_calcium_clin_v5	Calcium (mg/dL) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_calcium_clin_v6	Calcium (mg/dL) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_calcium_cmnt_v1	Calcium (mg/dL) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_calcium_cmnt_v3	Calcium (mg/dL) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_calcium_cmnt_v4	Calcium (mg/dL) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_calcium_cmnt_v5	Calcium (mg/dL) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_calcium_cmnt_v6	Calcium (mg/dL) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_calcium_fasting_v1	Calcium (mg/dL) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_calcium_fasting_v3	Calcium (mg/dL) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_calcium_fasting_v4	Calcium (mg/dL) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_calcium_fasting_v5	Calcium (mg/dL) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_calcium_fasting_v6	Calcium (mg/dL) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No"
01. Principal	bldchem_calcium_out_v1	Calcium (mg/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_calcium_out_v3	Calcium (mg/dL) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_calcium_out_v4	Calcium (mg/dL) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_calcium_out_v5	Calcium (mg/dL) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_calcium_out_v6	Calcium (mg/dL) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_calcium_res_v1	Calcium (mg/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_calcium_res_v3	Calcium (mg/dL) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_calcium_res_v4	Calcium (mg/dL) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_calcium_res_v5	Calcium (mg/dL) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_calcium_res_v6	Calcium (mg/dL) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_calcium_spec_dt_v1	Calcium (mg/dL) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_calcium_spec_dt_v3	Calcium (mg/dL) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_calcium_spec_dt_v4	Calcium (mg/dL) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_calcium_spec_dt_v5	Calcium (mg/dL) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_calcium_spec_dt_v6	Calcium (mg/dL) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_chloride_clin_v1	Chloride (mmol/l) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_chloride_clin_v3	Chloride (mmol/l) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_chloride_clin_v4	Chloride (mmol/l) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_chloride_clin_v5	Chloride (mmol/l) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_chloride_clin_v6	Chloride (mmol/l) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_chloride_cmnt_v1	Chloride (mmol/l) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_chloride_cmnt_v3	Chloride (mmol/l) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_chloride_cmnt_v4	Chloride (mmol/l) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_chloride_cmnt_v5	Chloride (mmol/l) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_chloride_cmnt_v6	Chloride (mmol/l) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_chloride_fasting_v1	Chloride (mmol/l) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_chloride_fasting_v3	Chloride (mmol/l) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_chloride_fasting_v4	Chloride (mmol/l) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_chloride_fasting_v5	Chloride (mmol/l) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_chloride_fasting_v6	Chloride (mmol/l) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No"
01. Principal	bldchem_chloride_out_v1	Chloride (mmol/l) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_chloride_out_v3	Chloride (mmol/l) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_chloride_out_v4	Chloride (mmol/l) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_chloride_out_v5	Chloride (mmol/l) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_chloride_out_v6	Chloride (mmol/l) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_chloride_res_v1	Chloride (mmol/l) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_chloride_res_v3	Chloride (mmol/l) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_chloride_res_v4	Chloride (mmol/l) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_chloride_res_v5	Chloride (mmol/l) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_chloride_res_v6	Chloride (mmol/l) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_chloride_spec_dt_v1	Chloride (mmol/l) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_chloride_spec_dt_v3	Chloride (mmol/l) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_chloride_spec_dt_v4	Chloride (mmol/l) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_chloride_spec_dt_v5	Chloride (mmol/l) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_chloride_spec_dt_v6	Chloride (mmol/l) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_creatinine_clin_v1	Creatinine (mg/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_creatinine_clin_v3	Creatinine (mg/dL) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 0="No"
01. Principal	bldchem_creatinine_clin_v4	Creatinine (mg/dL) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_creatinine_clin_v5	Creatinine (mg/dL) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_creatinine_clin_v6	Creatinine (mg/dL) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_creatinine_cmnt_v1	Creatinine (mg/dL) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_creatinine_cmnt_v3	Creatinine (mg/dL) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_creatinine_cmnt_v4	Creatinine (mg/dL) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_creatinine_cmnt_v5	Creatinine (mg/dL) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_creatinine_cmnt_v6	Creatinine (mg/dL) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_creatinine_fasting_v1	Creatinine (mg/dL) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_creatinine_fasting_v3	Creatinine (mg/dL) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_creatinine_fasting_v4	Creatinine (mg/dL) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_creatinine_fasting_v5	Creatinine (mg/dL) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_creatinine_fasting_v6	Creatinine (mg/dL) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No"
01. Principal	bldchem_creatinine_out_v1	Creatinine (mg/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_creatinine_out_v3	Creatinine (mg/dL) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 0="No"
01. Principal	bldchem_creatinine_out_v4	Creatinine (mg/dL) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_creatinine_out_v5	Creatinine (mg/dL) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_creatinine_out_v6	Creatinine (mg/dL) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_creatinine_res_v1	Creatinine (mg/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_creatinine_res_v3	Creatinine (mg/dL) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	bldchem_creatinine_res_v4	Creatinine (mg/dL) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_creatinine_res_v5	Creatinine (mg/dL) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_creatinine_res_v6	Creatinine (mg/dL) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_creatinine_spec_dt_v1	Creatinine (mg/dL) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_creatinine_spec_dt_v3	Creatinine (mg/dL) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_creatinine_spec_dt_v4	Creatinine (mg/dL) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_creatinine_spec_dt_v5	Creatinine (mg/dL) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_creatinine_spec_dt_v6	Creatinine (mg/dL) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_globulin_clin_v1	Globulin (g/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_globulin_clin_v3	Globulin (g/dL) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_globulin_clin_v4	Globulin (g/dL) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_globulin_clin_v5	Globulin (g/dL) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_globulin_clin_v6	Globulin (g/dL) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_globulin_cmnt_v1	Globulin (g/dL) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_globulin_cmnt_v3	Globulin (g/dL) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_globulin_cmnt_v4	Globulin (g/dL) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_globulin_cmnt_v5	Globulin (g/dL) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_globulin_cmnt_v6	Globulin (g/dL) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_globulin_fasting_v1	Globulin (g/dL) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_globulin_fasting_v3	Globulin (g/dL) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_globulin_fasting_v4	Globulin (g/dL) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_globulin_fasting_v5	Globulin (g/dL) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_globulin_fasting_v6	Globulin (g/dL) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_globulin_out_v1	Globulin (g/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_globulin_out_v3	Globulin (g/dL) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_globulin_out_v4	Globulin (g/dL) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_globulin_out_v5	Globulin (g/dL) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_globulin_out_v6	Globulin (g/dL) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_globulin_res_v1	Globulin (g/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_globulin_res_v3	Globulin (g/dL) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_globulin_res_v4	Globulin (g/dL) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_globulin_res_v5	Globulin (g/dL) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_globulin_res_v6	Globulin (g/dL) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_globulin_spec_dt_v1	Globulin (g/dL) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_globulin_spec_dt_v3	Globulin (g/dL) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_globulin_spec_dt_v4	Globulin (g/dL) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_globulin_spec_dt_v5	Globulin (g/dL) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_globulin_spec_dt_v6	Globulin (g/dL) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_glucose_clin_v1	Glucose Serum (mg/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_glucose_clin_v3	Glucose Serum (mg/dL) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_glucose_clin_v4	Glucose Serum (mg/dL) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_glucose_clin_v5	Glucose Serum (mg/dL) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_glucose_clin_v6	Glucose Serum (mg/dL) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_glucose_cmnt_v1	Glucose Serum (mg/dL) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_glucose_cmnt_v3	Glucose Serum (mg/dL) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_glucose_cmnt_v4	Glucose Serum (mg/dL) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_glucose_cmnt_v5	Glucose Serum (mg/dL) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_glucose_cmnt_v6	Glucose Serum (mg/dL) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_glucose_fasting_v1	Glucose Serum (mg/dL) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_glucose_fasting_v3	Glucose Serum (mg/dL) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_glucose_fasting_v4	Glucose Serum (mg/dL) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_glucose_fasting_v5	Glucose Serum (mg/dL) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_glucose_fasting_v6	Glucose Serum (mg/dL) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No"
01. Principal	bldchem_glucose_out_v1	Glucose Serum (mg/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_glucose_out_v3	Glucose Serum (mg/dL) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_glucose_out_v4	Glucose Serum (mg/dL) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_glucose_out_v5	Glucose Serum (mg/dL) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_glucose_out_v6	Glucose Serum (mg/dL) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_glucose_res_v1	Glucose Serum (mg/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_glucose_res_v3	Glucose Serum (mg/dL) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_glucose_res_v4	Glucose Serum (mg/dL) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_glucose_res_v5	Glucose Serum (mg/dL) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_glucose_res_v6	Glucose Serum (mg/dL) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_glucose_spec_dt_v1	Glucose Serum (mg/dL) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_glucose_spec_dt_v3	Glucose Serum (mg/dL) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_glucose_spec_dt_v4	Glucose Serum (mg/dL) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_glucose_spec_dt_v5	Glucose Serum (mg/dL) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_glucose_spec_dt_v6	Glucose Serum (mg/dL) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_potassium_clin_v1	Potassium (mmol/l) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_potassium_clin_v3	Potassium (mmol/l) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_potassium_clin_v4	Potassium (mmol/l) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_potassium_clin_v5	Potassium (mmol/l) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_potassium_clin_v6	Potassium (mmol/l) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_potassium_cmnt_v1	Potassium (mmol/l) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_potassium_cmnt_v3	Potassium (mmol/l) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_potassium_cmnt_v4	Potassium (mmol/l) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_potassium_cmnt_v5	Potassium (mmol/l) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_potassium_cmnt_v6	Potassium (mmol/l) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_potassium_fasting_v1	Potassium (mmol/l) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_potassium_fasting_v3	Potassium (mmol/l) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_potassium_fasting_v4	Potassium (mmol/l) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_potassium_fasting_v5	Potassium (mmol/l) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_potassium_fasting_v6	Potassium (mmol/l) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No"
01. Principal	bldchem_potassium_out_v1	Potassium (mmol/l) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_potassium_out_v3	Potassium (mmol/l) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_potassium_out_v4	Potassium (mmol/l) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_potassium_out_v5	Potassium (mmol/l) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_potassium_out_v6	Potassium (mmol/l) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_potassium_res_v1	Potassium (mmol/l) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_potassium_res_v3	Potassium (mmol/l) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_potassium_res_v4	Potassium (mmol/l) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_potassium_res_v5	Potassium (mmol/l) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_potassium_res_v6	Potassium (mmol/l) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_potassium_spec_dt_v1	Potassium (mmol/l) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_potassium_spec_dt_v3	Potassium (mmol/l) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_potassium_spec_dt_v4	Potassium (mmol/l) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_potassium_spec_dt_v5	Potassium (mmol/l) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_potassium_spec_dt_v6	Potassium (mmol/l) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_protein_clin_v1	Total Protein (g/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_protein_clin_v3	Total Protein (g/dL) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_protein_clin_v4	Total Protein (g/dL) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_protein_clin_v5	Total Protein (g/dL) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_protein_clin_v6	Total Protein (g/dL) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_protein_cmnt_v1	Total Protein (g/dL) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_protein_cmnt_v3	Total Protein (g/dL) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_protein_cmnt_v4	Total Protein (g/dL) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_protein_cmnt_v5	Total Protein (g/dL) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_protein_cmnt_v6	Total Protein (g/dL) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_protein_fasting_v1	Total Protein (g/dL) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_protein_fasting_v3	Total Protein (g/dL) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_protein_fasting_v4	Total Protein (g/dL) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_protein_fasting_v5	Total Protein (g/dL) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_protein_fasting_v6	Total Protein (g/dL) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_protein_out_v1	Total Protein (g/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	bldchem_protein_out_v3	Total Protein (g/dL) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_protein_out_v4	Total Protein (g/dL) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_protein_out_v5	Total Protein (g/dL) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_protein_out_v6	Total Protein (g/dL) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_protein_res_v1	Total Protein (g/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_protein_res_v3	Total Protein (g/dL) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_protein_res_v4	Total Protein (g/dL) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_protein_res_v5	Total Protein (g/dL) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_protein_res_v6	Total Protein (g/dL) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_protein_spec_dt_v1	Total Protein (g/dL) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_protein_spec_dt_v3	Total Protein (g/dL) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_protein_spec_dt_v4	Total Protein (g/dL) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_protein_spec_dt_v5	Total Protein (g/dL) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_protein_spec_dt_v6	Total Protein (g/dL) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgop_ast_clin_v1	SGOP/AST (IU/L) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_sgop_ast_clin_v3	SGOP/AST (IU/L) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_sgop_ast_clin_v4	SGOP/AST (IU/L) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_sgop_ast_clin_v5	SGOP/AST (IU/L) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_clin_v6	SGOP/AST (IU/L) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_sgop_ast_cmnt_v1	SGOP/AST (IU/L) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_sgop_ast_cmnt_v3	SGOP/AST (IU/L) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sgop_ast_cmnt_v4	SGOP/AST (IU/L) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_sgop_ast_cmnt_v5	SGOP/AST (IU/L) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_sgop_ast_cmnt_v6	SGOP/AST (IU/L) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_sgop_ast_fasting_v1	SGOP/AST (IU/L) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_fasting_v3	SGOP/AST (IU/L) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_fasting_v4	SGOP/AST (IU/L) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_fasting_v5	SGOP/AST (IU/L) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_fasting_v6	SGOP/AST (IU/L) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_out_v1	SGOP/AST (IU/L) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_sgop_ast_out_v3	SGOP/AST (IU/L) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_out_v4	SGOP/AST (IU/L) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_out_v5	SGOP/AST (IU/L) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sgop_ast_out_v6	SGOP/AST (IU/L) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_sgop_ast_res_v1	SGOP/AST (IU/L) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_sgop_ast_res_v3	SGOP/AST (IU/L) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgop_ast_res_v4	SGOP/AST (IU/L) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgop_ast_res_v5	SGOP/AST (IU/L) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgop_ast_res_v6	SGOP/AST (IU/L) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgop_ast_spec_dt_v1	SGOP/AST (IU/L) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_sgop_ast_spec_dt_v3	SGOP/AST (IU/L) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgop_ast_spec_dt_v4	SGOP/AST (IU/L) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgop_ast_spec_dt_v5	SGOP/AST (IU/L) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgop_ast_spec_dt_v6	SGOP/AST (IU/L) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgpt_alt_clin_v1	SGPT/ALT (IU/L) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sgpt_alt_clin_v3	SGPT/ALT (IU/L) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_sgpt_alt_clin_v4	SGPT/ALT (IU/L) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_sgpt_alt_clin_v5	SGPT/ALT (IU/L) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_alt_clin_v6	SGPT/ALT (IU/L) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_sgpt_alt_cmnt_v1	SGPT/ALT (IU/L) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_alt_cmnt_v3	SGPT/ALT (IU/L) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_alt_cmnt_v4	SGPT/ALT (IU/L) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_alt_cmnt_v5	SGPT/ALT (IU/L) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_alt_cmnt_v6	SGPT/ALT (IU/L) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_alt_fasting_v1	SGPT/ALT (IU/L) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_alt_fasting_v3	SGPT/ALT (IU/L) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_alt_fasting_v4	SGPT/ALT (IU/L) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sgpt_alt_fasting_v5	SGPT/ALT (IU/L) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_alt_fasting_v6	SGPT/ALT (IU/L) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_alt_out_v1	SGPT/ALT (IU/L) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_sgpt_alt_out_v3	SGPT/ALT (IU/L) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_sgpt_alt_out_v4	SGPT/ALT (IU/L) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_sgpt_alt_out_v5	SGPT/ALT (IU/L) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_alt_out_v6	SGPT/ALT (IU/L) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_sgpt_alt_res_v1	SGPT/ALT (IU/L) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	bldchem_sgpt_alt_res_v3	SGPT/ALT (IU/L) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgpt_alt_res_v4	SGPT/ALT (IU/L) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgpt_alt_res_v5	SGPT/ALT (IU/L) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgpt_alt_res_v6	SGPT/ALT (IU/L) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgpt_alt_spec_dt_v1	SGPT/ALT (IU/L) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sgpt_al t_spec_dt_v3	SGPT/ALT (IU/L) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgpt_al t_spec_dt_v4	SGPT/ALT (IU/L) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgpt_al t_spec_dt_v5	SGPT/ALT (IU/L) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sgpt_al t_spec_dt_v6	SGPT/ALT (IU/L) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sodium _clin_v1	Sodium (mmol/l) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_sodium _clin_v3	Sodium (mmol/l) - Clinically Significant - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_sodium _clin_v4	Sodium (mmol/l) - Clinically Significant - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_sodium _clin_v5	Sodium (mmol/l) - Clinically Significant - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bldchem_sodium _clin_v6	Sodium (mmol/l) - Clinically Significant - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_sodium _cmnt_v1	Sodium (mmol/l) - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_sodium _cmnt_v3	Sodium (mmol/l) - Comments - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Char
01. Principal	bldchem_sodium _cmnt_v4	Sodium (mmol/l) - Comments - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sodium_cmnt_v5	Sodium (mmol/l) - Comments - Visit 5 (End of Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_sodium_cmnt_v6	Sodium (mmol/l) - Comments - Visit 6 (Follow-up) - [Blood Chemistry]		Char
01. Principal	bldchem_sodium_fasting_v1	Sodium (mmol/l) - Fasting - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_sodium_fasting_v3	Sodium (mmol/l) - Fasting - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_sodium_fasting_v4	Sodium (mmol/l) - Fasting - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_sodium_fasting_v5	Sodium (mmol/l) - Fasting - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	bldchem_sodium_fasting_v6	Sodium (mmol/l) - Fasting - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown" 0="No"
01. Principal	bldchem_sodium_out_v1	Sodium (mmol/l) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No"
01. Principal	bldchem_sodium_out_v3	Sodium (mmol/l) - Out Of Range - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_sodium_out_v4	Sodium (mmol/l) - Out Of Range - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_sodium_out_v5	Sodium (mmol/l) - Out Of Range - Visit 5 (End of Intervention) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bldchem_sodium_out_v6	Sodium (mmol/l) - Out Of Range - Visit 6 (Follow-up) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bldchem_sodium_res_v1	Sodium (mmol/l) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sodium_res_v3	Sodium (mmol/l) - Results - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_sodium_res_v4	Sodium (mmol/l) - Results - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_sodium_res_v5	Sodium (mmol/l) - Results - Visit 5 (End of Intervention) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sodium_res_v6	Sodium (mmol/l) - Results - Visit 6 (Follow-up) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_sodium_spec_dt_v1	Sodium (mmol/l) - Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study"
01. Principal	bldchem_sodium_spec_dt_v3	Sodium (mmol/l) - Specimen Collection Date - Visit 3 (Week 4 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_sodium_spec_dt_v4	Sodium (mmol/l) - Specimen Collection Date - Visit 4 (Week 8 Interim Study) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bldchem_sodium_spec_dt_v5	Sodium (mmol/l) - Specimen Collection Date - Visit 5 (End of Intervention) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bldchem_sodium_spec_dt_v6	Sodium (mmol/l) - Specimen Collection Date - Visit 6 (Follow-up) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Section 17: Hematology

Class	Variable	Label	Description	Format Text
01. Principal	hema_anc_clin_v1	ANC (k/uL) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	hema_anc_clin_v5	ANC (k/uL) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_anc_cmnt_v1	ANC (k/uL) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_anc_cmnt_v5	ANC (k/uL) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_anc_out_v1	ANC (k/uL) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	hema_anc_out_v5	ANC (k/uL) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_anc_res_v1	ANC (k/uL) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_anc_res_v5	ANC (k/uL) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_anc_spec_dt_v1	ANC (k/uL) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_anc_spec_dt_v5	ANC (k/uL) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_bands_clin_v1	Bands (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing"
01. Principal	hema_bands_clin_v5	Bands (%) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	hema_bands_cmnt_v1	Bands (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_bands_cmnt_v5	Bands (%) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_bands_out_v1	Bands (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing"
01. Principal	hema_bands_out_v5	Bands (%) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	hema_bands_res_v1	Bands (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_bands_res_v5	Bands (%) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	hema_bands_spec_dt_v1	Bands (%) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_bands_spec_dt_v5	Bands (%) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_basophil_clin_v1	Basophils (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	hema_basophil_clin_v5	Basophils (%) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_basophil_cmnt_v1	Basophils (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_basophil_cmnt_v5	Basophils (%) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_basophil_out_v1	Basophils (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	hema_basophil_out_v5	Basophils (%) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hema_basophil_res_v1	Basophils (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_basophil_res_v5	Basophils (%) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_basophil_spec_dt_v1	Basophils (%) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_basophil_spec_dt_v5	Basophils (%) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_eosinophil_clin_v1	Eosinophils (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	hema_eosinophil_clin_v5	Eosinophils (%) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No"
01. Principal	hema_eosinophil_cmnt_v1	Eosinophils (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_eosinophil_cmnt_v5	Eosinophils (%) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_eosinophil_out_v1	Eosinophils (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	hema_eosinophil_out_v5	Eosinophils (%) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	hema_eosinophil_res_v1	Eosinophils (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_eosinophil_res_v5	Eosinophils (%) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	hema_eosinophil_spec_dt_v1	Eosinophils (%) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_eosinophil_spec_dt_v5	Eosinophils (%) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_hematocrit_clin_v1	Hematocrit (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	hema_hematocrit_clin_v5	Hematocrit (%) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_hematocrit_cmnt_v1	Hematocrit (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_hematocrit_cmnt_v5	Hematocrit (%) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_hematocrit_out_v1	Hematocrit (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	hema_hematocrit_out_v5	Hematocrit (%) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_hematocrit_res_v1	Hematocrit (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_hematocrit_res_v5	Hematocrit (%) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_hematocrit_spec_dt_v1	Hematocrit (%) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_hematocrit_spec_dt_v5	Hematocrit (%) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	hema_hemoglobin_clin_v1	Hemoglobin (g/dL) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	hema_hemoglobin_clin_v5	Hemoglobin (g/dL) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_hemoglobin_cmnt_v1	Hemoglobin (g/dL) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_hemoglobin_cmnt_v5	Hemoglobin (g/dL) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_hemoglobin_out_v1	Hemoglobin (g/dL) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	hema_hemoglobin_out_v5	Hemoglobin (g/dL) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_hemoglobin_res_v1	Hemoglobin (g/dL) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_hemoglobin_res_v5	Hemoglobin (g/dL) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_hemoglobin_spec_dt_v1	Hemoglobin (g/dL) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_hemoglobin_spec_dt_v5	Hemoglobin (g/dL) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_lymphocyte_clin_v1	Lymphocytes (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	hema_lymphocyte_clin_v5	Lymphocytes (%) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hema_lymphocyte_cmnt_v1	Lymphocytes (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_lymphocyte_cmnt_v5	Lymphocytes (%) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_lymphocyte_out_v1	Lymphocytes (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	hema_lymphocyte_out_v5	Lymphocytes (%) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_lymphocyte_res_v1	Lymphocytes (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_lymphocyte_res_v5	Lymphocytes (%) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_lymphocyte_spec_dt_v1	Lymphocytes (%) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_lymphocyte_spec_dt_v5	Lymphocytes (%) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_monocyte_clin_v1	Monocytes (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	hema_monocyte_clin_v5	Monocytes (%) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_monocyte_cmnt_v1	Monocytes (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_monocyte_cmnt_v5	Monocytes (%) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_monocyte_out_v1	Monocytes (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hema_monocyte_out_v5	Monocytes (%) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_monocyte_res_v1	Monocytes (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_monocyte_res_v5	Monocytes (%) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_monocyte_spec_dt_v1	Monocytes (%) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_monocyte_spec_dt_v5	Monocytes (%) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_neutrophil_clin_v1	Neutrophils (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" 0="No"
01. Principal	hema_neutrophil_clin_v5	Neutrophils (%) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_neutrophil_cmnt_v1	Neutrophils (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_neutrophil_cmnt_v5	Neutrophils (%) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_neutrophil_out_v1	Neutrophils (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	hema_neutrophil_out_v5	Neutrophils (%) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_neutrophil_res_v1	Neutrophils (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study"
01. Principal	hema_neutrophil_res_v5	Neutrophils (%) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	hema_neutrophil_spec_dt_v1	Neutrophils (%) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_neutrophil_spec_dt_v5	Neutrophils (%) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_platelets_clin_v1	Platelets (k/mm3) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	hema_platelets_clin_v5	Platelets (k/mm3) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_platelets_cmnt_v1	Platelets (k/mm3) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_platelets_cmnt_v5	Platelets (k/mm3) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_platelets_out_v1	Platelets (k/mm3) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	hema_platelets_out_v5	Platelets (k/mm3) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_platelets_results_v1	Platelets (k/mm3) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_platelets_results_v5	Platelets (k/mm3) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_platelets_spec_dt_v1	Platelets (k/mm3) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_platelets_spec_dt_v5	Platelets (k/mm3) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	hema_pt_clin_v1	PT (sec) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	hema_pt_clin_v5	PT (sec) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	hema_pt_cmnt_v1	PT (sec) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_pt_cmnt_v5	PT (sec) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_pt_out_v1	PT (sec) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	hema_pt_out_v5	PT (sec) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	hema_pt_res_v1	PT (sec) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_pt_res_v5	PT (sec) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	hema_pt_spec_d t_v1	PT (sec) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_pt_spec_d t_v5	PT (sec) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_ptt_clin_v1	PTT (sec) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	hema_ptt_clin_v5	PTT (sec) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	hema_ptt_cmnt_v1	PTT (sec) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_ptt_cmnt_v5	PTT (sec) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char

Class	Variable	Label	Description	Format Text
01. Principal	hema_ptt_out_v1	PTT (sec) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	hema_ptt_out_v5	PTT (sec) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	hema_ptt_res_v1	PTT (sec) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_ptt_res_v5	PTT (sec) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	hema_ptt_spec_dt_v1	PTT (sec) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_ptt_spec_dt_v5	PTT (sec) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_rbc_clin_v1	RBC (m/mm3) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" 0="No"
01. Principal	hema_rbc_clin_v5	RBC (m/mm3) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_rbc_cmnt_v1	RBC (m/mm3) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_rbc_cmnt_v5	RBC (m/mm3) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_rbc_out_v1	RBC (m/mm3) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	hema_rbc_out_v5	RBC (m/mm3) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_rbc_res_v1	RBC (m/mm3) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study"

Class	Variable	Label	Description	Format Text
01. Principal	hema_rbc_res_v5	RBC (m/mm3) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_rbc_spec_dt_v1	RBC (m/mm3) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"
01. Principal	hema_rbc_spec_dt_v5	RBC (m/mm3) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_wbc_clin_v1	WBC (k/mm3) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No"
01. Principal	hema_wbc_clin_v5	WBC (k/mm3) - Clinically Significant - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_wbc_cmnt_v1	WBC (k/mm3) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_wbc_cmnt_v5	WBC (k/mm3) - Comments - Visit 5 (End of Intervention) - [Hematology]		Char
01. Principal	hema_wbc_out_v1	WBC (k/mm3) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	hema_wbc_out_v5	WBC (k/mm3) - Out Of Range - Visit 5 (End of Intervention) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_wbc_res_v1	WBC (k/mm3) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	hema_wbc_res_v5	WBC (k/mm3) - Results - Visit 5 (End of Intervention) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_wbc_spec_dt_v1	WBC (k/mm3) - Specimen Collection Date - Visit 1 (Screening) - [Hematology]		SAS Date .E="Not Eligible For Study"

Class	Variable	Label	Description	Format Text
01. Principal	hema_wbc_spec _dt_v5	WBC (k/mm3) - Specimen Collection Date - Visit 5 (End of Intervention) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Section 18: Other Lab Tests

Class	Variable	Label	Description	Format Text
01. Principal	othlab_clin_v1_1-2	Clinically Significant? - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No"
01. Principal	othlab_clin_v5_1-2	Clinically Significant? - Visit 5 (End of Intervention) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	othlab_clin_v6_1-3	Clinically Significant? - Visit 6 (Follow-up) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	othlab_cmnt_v1_1-2	Comments - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		Char
01. Principal	othlab_cmnt_v5_1-2	Comments - Visit 5 (End of Intervention) - Lab Test # - [Other Lab Tests]		Char
01. Principal	othlab_cmnt_v6_1-3	Comments - Visit 6 (Follow-up) - Lab Test # - [Other Lab Tests]		Char
01. Principal	othlab_fasting_v1_1-2	Fasting? - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No"
01. Principal	othlab_fasting_v5_1-2	Fasting? - Visit 5 (End of Intervention) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	othlab_fasting_v6_1-3	Fasting? - Visit 6 (Follow-up) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	othlab_num_v1	Number of Other Lab Tests - Visit 1 (Baseline) - [Other Lab Tests]		Numeric .E="Not Eligible For Study"
01. Principal	othlab_num_v5	Number of Other Lab Tests - Visit 5 (End of Intervention) - [Other Lab Tests]		Numeric .E="Not Eligible For Study"

Class	Variable	Label	Description	Format Text
01. Principal	othlab_num_v6	Number of Other Lab Tests - Visit 6 (Follow-up) - [Other Lab Tests]		Numeric .E="Not Eligible For Study"
01. Principal	othlab_out_v1_1-2	Out of Range? - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No"
01. Principal	othlab_out_v5_1-2	Out of Range? - Visit 5 (End of Intervention) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	othlab_out_v6_1-3	Out of Range? - Visit 6 (Follow-up) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	othlab_result_v1_1-2	Result - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	othlab_result_v5_1-2	Result - Visit 5 (End of Intervention) - Lab Test # - [Other Lab Tests]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	othlab_result_v6_1-3	Result - Visit 6 (Follow-up) - Lab Test # - [Other Lab Tests]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	othlab_spec_col_dt_v1_1-2	Specimen Collection Date - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		SAS Date .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	othlab_spec_col_dt_v5_1-2	Specimen Collection Date - Visit 5 (End of Intervention) - Lab Test # - [Other Lab Tests]		SAS Date .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	othlab_spec_col_dt_v6_1-3	Specimen Collection Date - Visit 6 (Follow-up) - Lab Test # - [Other Lab Tests]		SAS Date .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	othlab_test_v1_1-2	Test Name - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		Char
01. Principal	othlab_test_v5_1-2	Test Name - Visit 5 (End of Intervention) - Lab Test # - [Other Lab Tests]		Char
01. Principal	othlab_test_v6_1-3	Test Name - Visit 6 (Follow-up) - Lab Test # - [Other Lab Tests]		Char
01. Principal	othlab_units_v1_1-2	Units - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		Char

Class	Variable	Label	Description	Format Text
01. Principal	othlab_units_v5_1-2	Units - Visit 5 (End of Intervention) - Lab Test # - [Other Lab Tests]		Char
01. Principal	othlab_units_v6_1-3	Units - Visit 6 (Follow-up) - Lab Test # - [Other Lab Tests]		Char

Section 19: Biomarkers

Class	Variable	Label	Description	Format Text
01. Principal	bio_lte4_v2	LTE4 - Visit 2 (Baseline) - [Biomarkers]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bio_lte4_v5	LTE4 - Visit 5 (End of Intervention) - [Biomarkers]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bio_lte4_v6	LTE4 - Visit 6 (Follow-up) - [Biomarkers]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bio_pgem_v2	PGEM - Visit 2 (Baseline) - [Biomarkers]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bio_pgem_v5	PGEM - Visit 5 (End of Intervention) - [Biomarkers]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bio_pgem_v6	PGEM - Visit 6 (Follow-up) - [Biomarkers]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Section 20: Scores

Class	Variable	Label	Description	Format Text
01. Principal	scores_batch_v2	Batch - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_batch_v5	Batch - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_batch_v6	Batch - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_ccr_v2	CCR Scores - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_ccr_v5	CCR Scores - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_ccr_v6	CCR Scores - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_dv200_v2	DV200 - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_dv200_v5	DV200 - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_dv200_v6	DV200 - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_gb_v2	GB Scores - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_gb_v5	GB Scores - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_gb_v6	GB Scores - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_gustafson_v2	Gustafson Scores - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	scores_gustafson_v5	Gustafson Scores - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_gustafson_v6	Gustafson Scores - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_isolation_dt_v2	Isolation Date - Visit 2 (Baseline) - [Scores]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_isolation_dt_v5	Isolation Date - Visit 5 (End of Intervention) - [Scores]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_isolation_dt_v6	Isolation Date - Visit 6 (Follow-up) - [Scores]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_jpr_small_v2	JPR Small Scores - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_jpr_small_v5	JPR Small Scores - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_jpr_small_v6	JPR Small Scores - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_jpr_v2	JPR Scores - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_jpr_v5	JPR Scores - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_jpr_v6	JPR Scores - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_mean_rin_v2	Mean RIN - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_mean_rin_v5	Mean RIN - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_mean_rin_v6	Mean RIN - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_nature_v2	Nature Scores - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	scores_nature_v5	Nature Scores - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_nature_v6	Nature Scores - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_percepta_v2	Percepta Scores - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_percepta_v5	Percepta Scores - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_percepta_v6	Percepta Scores - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_rin_v2	RIN - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_rin_v5	RIN - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_rin_v6	RIN - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_rna_conc_v2	RNA Concentration (ng/ul) - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_rna_conc_v5	RNA Concentration (ng/ul) - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_rna_conc_v6	RNA Concentration (ng/ul) - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_rna_id_v2	RNA ID - Visit 2 (Baseline) - [Scores]		Char
01. Principal	scores_rna_id_v5	RNA ID - Visit 5 (End of Intervention) - [Scores]		Char
01. Principal	scores_rna_id_v6	RNA ID - Visit 6 (Follow-up) - [Scores]		Char
01. Principal	scores_sample_id_v2	Sample ID - Visit 2 (Baseline) - [Scores]		Char
01. Principal	scores_sample_id_v5	Sample ID - Visit 5 (End of Intervention) - [Scores]		Char
01. Principal	scores_sample_id_v6	Sample ID - Visit 6 (Follow-up) - [Scores]		Char

Class	Variable	Label	Description	Format Text
01. Principal	scores_steiling_v2	Steiling Scores - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_steiling_v5	Steiling Scores - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_steiling_v6	Steiling Scores - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_x260_230_v2	X260:230 Ratio - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_x260_230_v5	X260:230 Ratio - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_x260_230_v6	X260:230 Ratio - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_x260_280_v2	X260:280 Ratio - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_x260_280_v5	X260:280 Ratio - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_x260_280_v6	X260:280 Ratio - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_yield_v2	Yield (ug) - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_yield_v5	Yield (ug) - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_yield_v6	Yield (ug) - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_zhang_v2	Zhang Scores - Visit 2 (Baseline) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	scores_zhang_v5	Zhang Scores - Visit 5 (End of Intervention) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	scores_zhang_v6	Zhang Scores - Visit 6 (Follow-up) - [Scores]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"

Section 21: Verification

Class	Variable	Label	Description	Format Text
01. Principal	verif_sig_dt	Date of Signature - [Verification]		SAS Date .E="Not Eligible For Study"
01. Principal	verif_sig_present	Investigator Signature Present - [Verification]		.E="Not Eligible For Study" 1="Yes"