

UAZ2014-03-01 - Enhanced Person Data Dictionary

TABLE OF CONTENTS

Document Summary.....	3
UAZ2014-03-01 - Enhanced Person: Data Dictionary	4
Section 1: Identifiers	4
Section 2: Study-wide	5
Section 3: Registration	6
Section 4: Active Surveillance Status	8
Section 5: Medical/Surgery History	9
Section 6: Concomitant Medications	18
Section 7: Baseline Symptoms	19
Section 8: Physical Exam	20
Section 9: Digital Rectal Exam	26
Section 10: International Prostate Symptom Score	27
Section 11: PSA	33
Section 12: Pre-enrollment Biopsy/Pathology	35
Section 13: Blood Chemistry	38
Section 14: Hematology	60
Section 15: Other Lab Tests	92
Section 16: Randomization	93
Section 17: Intervention Administration	94
Section 18: Agent Interruption	96
Section 19: Compliance	97
Section 20: Post-Intervention Biopsy/Pathology	98
Section 21: Off Study	100
Section 22: Verification Form	101
Section 23: Comments	102

Document Summary

Property	Value
Document Title	UAZ2014-03-01 - Enhanced Person: Data Dictionary
Date Created	01/09/2023
Sections	23
Entries	1098
Document Filename	dictionary_enhanced_prsn.rtf

UAZ2014-03-01 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	ParticipantID	Participant ID		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	ae_num	Number Of Adverse Events		Numeric .R="Not Randomized"
01. Principal	treatment_arm	Treatment Arm		.R="Not Randomized" 1="Placebo" 2="Prostvac"
01. Principal	visit_dt_v01	Visit Date - Visit 1 (Screening)		SAS Date
01. Principal	visit_dt_v02	Visit Date - Visit 2 (Randomization)		SAS Date .R="Not Randomized"
01. Principal	visit_dt_v03	Visit Date - Visit 3 (Baseline Visit)		SAS Date .R="Not Randomized"
01. Principal	visit_dt_v04	Visit Date - Visit 4 (Day 14)		SAS Date .R="Not Randomized"
01. Principal	visit_dt_v05	Visit Date - Visit 5 (Day 28)		SAS Date .R="Not Randomized"
01. Principal	visit_dt_v06	Visit Date - Visit 6 (Day 56)		SAS Date .R="Not Randomized"
01. Principal	visit_dt_v07	Visit Date - Visit 7 (Day 84)		SAS Date .R="Not Randomized"
01. Principal	visit_dt_v08	Visit Date - Visit 8 (Day 112)		SAS Date .R="Not Randomized"
01. Principal	visit_dt_v09	Visit Date - Visit 9 (Day 140)		SAS Date .R="Not Randomized"
01. Principal	visit_dt_v10	Visit Date - Visit 10 (Post-Intervention)		SAS Date .R="Not Randomized"
01. Principal	visit_dt_v12	Visit Date - Visit 12 (6-Month Follow-Up)		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 3: Registration

Class	Variable	Label	Description	Format Text
01. Principal	reg_age	Age At Registration - [Registration]		Numeric .R="Not Randomized"
01. Principal	reg_consent_dt	Date Informed Consent Signed - [Registration]		SAS Date
01. Principal	reg_consortium	Registering Consortium - [Registration]		1="AZ017 - UAZ"
01. Principal	reg_contact	Participant Gives Permission for Future Contact - [Registration]		.M="Missing" 0="No" 1="Yes"
01. Principal	reg_country	Country Code - [Registration]		1="USA"
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" 3="Not Reported" 9="Unknown"
01. Principal	reg_gender	Gender - [Registration]		1="Male"
01. Principal	reg_institution_code	Institution Code - [Registration]		1="CA011 - USC" 2="CA016 - Cedars" 3="CA067 - UCSD" 5="CA088 - UCI" 6="MD043 - Johns Hopkins" 7="NCICCR - NCI-CCR"
01. Principal	reg_payment_method	Participant Method Of Payment - [Registration]		0="Self-Pay (No Insurance)" 1="Managed Care/Medicare" 2="Medicaid" 3="Medicaid and Medicare" 4="Medicare" 5="Medicare and Private Insurance" 6="Private Insurance" 7="State Supplemental Health Insurance" 8="Other" 9="Unknown"
01. Principal	reg_race1-3	Race - # - [Registration]		.N="N/A" 1="White" 2="Black or African American" 3="Native Hawaiian or Other Pacific Islander" 4="Asian" 5="American Indian or Alaska Native" 6="Unknown" 7="Not Reported"

Class	Variable	Label	Description	Format Text
01. Principal	reg_race_eth	Combination Race And Ethnicity - [Registration]		1="White, Non-Hispanic" 2="Black, Non-Hispanic" 3="Hispanic" 4="Native Hawaiian or Other Pacific Islander, Non-Hispanic" 5="Asian, Non-Hispanic" 6="American Indian or Alaska Native, Non-Hispanic" 7="Unknown" 8="Not Reported"
01. Principal	reg_repeat_biop	Repeat Biopsies - [Registration]		1="<=2" 2=">2"
01. Principal	reg_retention_blood	Permission For Retention - Blood Cells - [Registration]		.M="Missing" 0="No" 1="Yes"
01. Principal	reg_retention_serum	Permission For Retention - Serum - [Registration]		.M="Missing" 0="No" 1="Yes"
01. Principal	reg_retention_tissue	Permission For Retention - Tissue - [Registration]		.M="Missing" 0="No" 1="Yes"
01. Principal	reg_screen_dt	Screen Date - [Registration]		SAS Date
01. Principal	reg_specify_other_payment	Specify Other Payment Method - [Registration]		Char
01. Principal	reg_tac	Treatment Assignment Code (TAC) - [Registration]		1="TAC-0"

Section 4: Active Surveillance Status

Class	Variable	Label	Description	Format Text
01. Principal	surv_active_surv	On Active Surveillance - [Active Surveillance Status]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	surv_specify_other_treat	Specify Other Treatment - [Active Surveillance Status]		Char
01. Principal	surv_treat_initiated_dt	Date Treatment Initiated - [Active Surveillance Status]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	surv_treatment_type	Type of Treatment - [Active Surveillance Status]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Radiation" 2="Surgery" 3="Other"

Section 5: Medical/Surgery History

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_all_normal_v01	All Body Systems Normal - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 0="No" 1="Yes - All Normal" 2="Yes - Not All Assessed"
01. Principal	medsurg_all_normal_v12	All Body Systems Normal - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes - All Normal" 2="Yes - Not All Assessed"
01. Principal	medsurg_allergies_v01	Participant Has Allergies - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	medsurg_allergies_v12	Participant Has Allergies - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	medsurg_auto_comments_v01	Autoimmune Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_auto_comments_v12	Autoimmune Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_auto_finding_v01	Autoimmune Finding - Visit 1 (Screening) - [Medical/Surgery History]		.M="Missing" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_auto_finding_v12	Autoimmune Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_breasts_comments_v01	Breasts Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_breasts_comments_v12	Breasts Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_breasts_finding_v01	Breasts Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_breasts_finding_v12	Breasts Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_cardio_comments_v01	Cardiovascular Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_cardio_comments_v12	Cardiovascular Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_cardio_finding_v01	Cardiovascular Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_cardio_finding_v12	Cardiovascular Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_derm_comments_v01	Dermatologic Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_derm_comments_v12	Dermatologic Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_derm_finding_v01	Dermatologic Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_derm_finding_v12	Dermatologic Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_endo_comments_v01	Endocrine/Metabolic Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_endo_comments_v12	Endocrine/Metabolic Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_endo_finding_v01	Endocrine/Metabolic Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_endo_finding_v12	Endocrine/Metabolic Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_gastro_comments_v01	Gastrointestinal Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_gastro_comments_v12	Gastrointestinal Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_gastro_finding_v01	Gastrointestinal Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_gastro_finding_v12	Gastrointestinal Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_genit_comments_v01	Genitourinary Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_genit_comments_v12	Genitourinary Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_genit_finding_v01	Genitourinary Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_genit_finding_v12	Genitourinary Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_heent_comments_v01	H/E/E/N/T Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_heent_comments_v12	H/E/E/N/T Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_heent_finding_v01	H/E/E/N/T Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_heent_finding_v12	H/E/E/N/T Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_hema_comments_v01	Hematopoietic/Lymph Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_hema_comments_v12	Hematopoietic/Lymph Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_hema_finding_v01	Hematopoietic/Lymph Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_hema_finding_v12	Hematopoietic/Lymph Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_musc_comments_v01	Musculoskeletal Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_musc_comments_v12	Musculoskeletal Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_musc_finding_v01	Musculoskeletal Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_musc_finding_v12	Musculoskeletal Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_neck_comments_v01	Neck Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_neck_comments_v12	Neck Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_neck_finding_v01	Neck Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_neck_finding_v12	Neck Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_neuro_comments_v01	Neurologic Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_neuro_comments_v12	Neurologic Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_neuro_finding_v01	Neurologic Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_neuro_finding_v12	Neurologic Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_other1_cmt1_v01	Other Body System 1 Comment 1 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other1_cmt2_v01	Other Body System 1 Comment 2 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other1_cmt3_v01	Other Body System 1 Comment 3 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other1_cmt4_v01	Other Body System 1 Comment 4 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other1_finding_v01	Other Body System 1 Finding - Visit 1 (Screening) - [Medical/Surgery History]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	medsurg_other1_v01	Other Body System 1 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other2_cmt1_v01	Other Body System 2 Comment 1 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other2_cmt2_v01	Other Body System 2 Comment 2 - Visit 1 (Screening) - [Medical/Surgery History]		Char

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_other2_cmt3_v01	Other Body System 2 Comment 3 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other2_cmt4_v01	Other Body System 2 Comment 4 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other2_finding_v01	Other Body System 2 Finding - Visit 1 (Screening) - [Medical/Surgery History]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	medsurg_other2_v01	Other Body System 2 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other3_cmt1_v01	Other Body System 3 Comment 1 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other3_cmt2_v01	Other Body System 3 Comment 2 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other3_cmt3_v01	Other Body System 3 Comment 3 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other3_cmt4_v01	Other Body System 3 Comment 4 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other3_finding_v01	Other Body System 3 Finding - Visit 1 (Screening) - [Medical/Surgery History]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	medsurg_other3_v01	Other Body System 3 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other4_cmt1_v01	Other Body System 4 Comment 1 - Visit 1 (Screening) - [Medical/Surgery History]		Char

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_other4_cmt2_v01	Other Body System 4 Comment 2 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other4_cmt3_v01	Other Body System 4 Comment 3 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other4_cmt4_v01	Other Body System 4 Comment 4 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other4_finding_v01	Other Body System 4 Finding - Visit 1 (Screening) - [Medical/Surgery History]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	medsurg_other4_v01	Other Body System 4 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other5_cmt1_v01	Other Body System 5 Comment 1 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other5_cmt2_v01	Other Body System 5 Comment 2 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other5_cmt3_v01	Other Body System 5 Comment 3 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other5_cmt4_v01	Other Body System 5 Comment 4 - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_other5_finding_v01	Other Body System 5 Finding - Visit 1 (Screening) - [Medical/Surgery History]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	medsurg_other5_v01	Other Body System 5 - Visit 1 (Screening) - [Medical/Surgery History]		Char

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_resp_comments_v01	Respiratory Comments - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_resp_comments_v12	Respiratory Comments - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char
01. Principal	medsurg_resp_finding_v01	Respiratory Finding - Visit 1 (Screening) - [Medical/Surgery History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_resp_finding_v12	Respiratory Finding - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medsurg_specify_allergies_v01	Specify Allergies - Visit 1 (Screening) - [Medical/Surgery History]		Char
01. Principal	medsurg_specify_allergies_v12	Specify Allergies - Visit 12 (6-Month Follow-Up) - [Medical/Surgery History]		Char

Section 6: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	conmed_dose1-29	Dose - # - [Concomitant Medications]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	conmed_frequency1-29	Frequency - # - [Concomitant Medications]		.N="N/A" .R="Not Randomized" 1="BID (Twice/Day)" 2="BIW (2 Times/Week)" 3="HS (At Bedtime)" 4="OT (Other)" 5="Once" 6="PRN (As Needed)" 7="Q4H (Every 4 Hours)" 8="Q6H (Every 6 Hours)" 9="QD (Once/Day)" 10="QID (4 Times/Day)" 11="QOD (Every Other Day)" 12="QWK (Every Week)" 13="TID (3 Times/Day)"
01. Principal	conmed_medication1-29	Medication - # - [Concomitant Medications]		Char
01. Principal	conmed_num	Number of Medications - [Concomitant Medications]		Numeric .R="Not Randomized"
01. Principal	conmed_reason1-29	Reason - # - [Concomitant Medications]		Char
01. Principal	conmed_report_dt1-29	Medication Report Date - # - [Concomitant Medications]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	conmed_resolved_dt1-29	Resolved Date - # - [Concomitant Medications]		SAS Date .C="Continuing" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	conmed_start_dt1-29	Start Date - # - [Concomitant Medications]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	conmed_units1-29	Units - # - [Concomitant Medications]		Char

Section 7: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	bsymp_comments1-7	Comments - # - [Baseline Symptoms]		Char
01. Principal	bsymp_description1-7	Symptom Description - # - [Baseline Symptoms]		Char
01. Principal	bsymp_grade1-7	Grade - # - [Baseline Symptoms]		.N="N/A" .R="Not Randomized" 1="Mild" 2="Moderate" 3="Severe"
01. Principal	bsymp_num	Number Of Baseline Symptoms Reported - [Baseline Symptoms]		Numeric .R="Not Randomized"
01. Principal	bsymp_onset_dt1-7	Onset Date - # - [Baseline Symptoms]		SAS Date .N="N/A" .R="Not Randomized"

Section 8: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	phys_bp_diastolic_v01	Blood Pressure Diastolic - Visit 1 (Screening) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_bp_diastolic_v03	Blood Pressure Diastolic - Visit 3 (Baseline Visit) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_bp_diastolic_v04	Blood Pressure Diastolic - Visit 4 (Day 14) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_bp_diastolic_v05	Blood Pressure Diastolic - Visit 5 (Day 28) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_bp_diastolic_v06	Blood Pressure Diastolic - Visit 6 (Day 56) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_bp_diastolic_v07	Blood Pressure Diastolic - Visit 7 (Day 84) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_bp_diastolic_v08	Blood Pressure Diastolic - Visit 8 (Day 112) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_bp_diastolic_v09	Blood Pressure Diastolic - Visit 9 (Day 140) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_bp_diastolic_v10	Blood Pressure Diastolic - Visit 10 (Post-Intervention) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_bp_systolic_v01	Blood Pressure Systolic - Visit 1 (Screening) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_bp_systolic_v03	Blood Pressure Systolic - Visit 3 (Baseline Visit) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_bp_systolic_v04	Blood Pressure Systolic - Visit 4 (Day 14) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_bp_systolic_v05	Blood Pressure Systolic - Visit 5 (Day 28) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_bp_systolic_v06	Blood Pressure Systolic - Visit 6 (Day 56) - [Physical Exam]		Numeric .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	phys_bp_systolic_v07	Blood Pressure Systolic - Visit 7 (Day 84) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_bp_systolic_v08	Blood Pressure Systolic - Visit 8 (Day 112) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_bp_systolic_v09	Blood Pressure Systolic - Visit 9 (Day 140) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_bp_systolic_v10	Blood Pressure Systolic - Visit 10 (Post-Intervention) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_exam_done_v01	Exam Done - Visit 1 (Screening) - [Physical Exam]		.R="Not Randomized" 0="Exam Not Done" 1="Exam Done"
01. Principal	phys_exam_done_v03	Exam Done - Visit 3 (Baseline Visit) - [Physical Exam]		.R="Not Randomized" 0="Exam Not Done" 1="Exam Done"
01. Principal	phys_exam_done_v04	Exam Done - Visit 4 (Day 14) - [Physical Exam]		.R="Not Randomized" 0="Exam Not Done" 1="Exam Done"
01. Principal	phys_exam_done_v05	Exam Done - Visit 5 (Day 28) - [Physical Exam]		.R="Not Randomized" 0="Exam Not Done" 1="Exam Done"
01. Principal	phys_exam_done_v06	Exam Done - Visit 6 (Day 56) - [Physical Exam]		.R="Not Randomized" 0="Exam Not Done" 1="Exam Done"
01. Principal	phys_exam_done_v07	Exam Done - Visit 7 (Day 84) - [Physical Exam]		.R="Not Randomized" 0="Exam Not Done" 1="Exam Done"
01. Principal	phys_exam_done_v08	Exam Done - Visit 8 (Day 112) - [Physical Exam]		.R="Not Randomized" 0="Exam Not Done" 1="Exam Done"
01. Principal	phys_exam_done_v09	Exam Done - Visit 9 (Day 140) - [Physical Exam]		.R="Not Randomized" 0="Exam Not Done" 1="Exam Done"
01. Principal	phys_exam_done_v10	Exam Done - Visit 10 (Post-Intervention) - [Physical Exam]		.R="Not Randomized" 0="Exam Not Done" 1="Exam Done"
01. Principal	phys_exam_dt_v01	Examination Date - Visit 1 (Screening) - [Physical Exam]		SAS Date .R="Not Randomized"
01. Principal	phys_exam_dt_v03	Examination Date - Visit 3 (Baseline Visit) - [Physical Exam]		SAS Date .R="Not Randomized"
01. Principal	phys_exam_dt_v04	Examination Date - Visit 4 (Day 14) - [Physical Exam]		SAS Date .R="Not Randomized"
01. Principal	phys_exam_dt_v05	Examination Date - Visit 5 (Day 28) - [Physical Exam]		SAS Date .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	phys_exam_dt_v06	Examination Date - Visit 6 (Day 56) - [Physical Exam]		SAS Date .R="Not Randomized"
01. Principal	phys_exam_dt_v07	Examination Date - Visit 7 (Day 84) - [Physical Exam]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	phys_exam_dt_v08	Examination Date - Visit 8 (Day 112) - [Physical Exam]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	phys_exam_dt_v09	Examination Date - Visit 9 (Day 140) - [Physical Exam]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	phys_exam_dt_v10	Examination Date - Visit 10 (Post-Intervention) - [Physical Exam]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	phys_height_v01	Height (cm) - Visit 1 (Screening) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_height_v03	Height (cm) - Visit 3 (Baseline Visit) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_height_v04	Height (cm) - Visit 4 (Day 14) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_height_v05	Height (cm) - Visit 5 (Day 28) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_height_v06	Height (cm) - Visit 6 (Day 56) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_height_v07	Height (cm) - Visit 7 (Day 84) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_height_v08	Height (cm) - Visit 8 (Day 112) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_height_v09	Height (cm) - Visit 9 (Day 140) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_height_v10	Height (cm) - Visit 10 (Post-Intervention) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_karnofsky_v01	Karnofsky Performance Status - Visit 1 (Screening) - [Physical Exam]		.M="Missing" .R="Not Randomized" 80="80%" 90="90%" 100="100%"
01. Principal	phys_karnofsky_v03	Karnofsky Performance Status - Visit 3 (Baseline Visit) - [Physical Exam]		.M="Missing" .R="Not Randomized" 80="80%" 90="90%" 100="100%"

Class	Variable	Label	Description	Format Text
01. Principal	phys_karnofsky_v04	Karnofsky Performance Status - Visit 4 (Day 14) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 80="80%" 90="90%" 100="100%"
01. Principal	phys_karnofsky_v05	Karnofsky Performance Status - Visit 5 (Day 28) - [Physical Exam]		.M="Missing" .R="Not Randomized" 80="80%" 90="90%" 100="100%"
01. Principal	phys_karnofsky_v06	Karnofsky Performance Status - Visit 6 (Day 56) - [Physical Exam]		.M="Missing" .R="Not Randomized" 80="80%" 90="90%" 100="100%"
01. Principal	phys_karnofsky_v07	Karnofsky Performance Status - Visit 7 (Day 84) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 80="80%" 90="90%" 100="100%"
01. Principal	phys_karnofsky_v08	Karnofsky Performance Status - Visit 8 (Day 112) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 80="80%" 90="90%" 100="100%"
01. Principal	phys_karnofsky_v09	Karnofsky Performance Status - Visit 9 (Day 140) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 80="80%" 90="90%" 100="100%"
01. Principal	phys_karnofsky_v10	Karnofsky Performance Status - Visit 10 (Post-Intervention) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 80="80%" 90="90%" 100="100%"
01. Principal	phys_pulse_rate_v01	Pulse Rate - Visit 1 (Screening) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_pulse_rate_v03	Pulse Rate - Visit 3 (Baseline Visit) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_pulse_rate_v04	Pulse Rate - Visit 4 (Day 14) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_pulse_rate_v05	Pulse Rate - Visit 5 (Day 28) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_pulse_rate_v06	Pulse Rate - Visit 6 (Day 56) - [Physical Exam]		Numeric .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	phys_pulse_rate_v07	Pulse Rate - Visit 7 (Day 84) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_pulse_rate_v08	Pulse Rate - Visit 8 (Day 112) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_pulse_rate_v09	Pulse Rate - Visit 9 (Day 140) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_pulse_rate_v10	Pulse Rate - Visit 10 (Post-Intervention) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_temperature_v01	Temperature - Visit 1 (Screening) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_temperature_v03	Temperature - Visit 3 (Baseline Visit) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_temperature_v04	Temperature - Visit 4 (Day 14) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_temperature_v05	Temperature - Visit 5 (Day 28) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_temperature_v06	Temperature - Visit 6 (Day 56) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_temperature_v07	Temperature - Visit 7 (Day 84) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_temperature_v08	Temperature - Visit 8 (Day 112) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_temperature_v09	Temperature - Visit 9 (Day 140) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_temperature_v10	Temperature - Visit 10 (Post-Intervention) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_weight_v01	Weight (kg) - Visit 1 (Screening) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_weight_v03	Weight (kg) - Visit 3 (Baseline Visit) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_weight_v04	Weight (kg) - Visit 4 (Day 14) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_weight_v05	Weight (kg) - Visit 5 (Day 28) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	phys_weight_v06	Weight (kg) - Visit 6 (Day 56) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_weight_v07	Weight (kg) - Visit 7 (Day 84) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_weight_v08	Weight (kg) - Visit 8 (Day 112) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_weight_v09	Weight (kg) - Visit 9 (Day 140) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	phys_weight_v10	Weight (kg) - Visit 10 (Post-Intervention) - [Physical Exam]		Numeric .N="N/A" .R="Not Randomized"

Section 9: Digital Rectal Exam

Class	Variable	Label	Description	Format Text
01. Principal	rectal_comments_v01	Comments - Visit 1 (Screening) - [Digital Rectal Exam]		Char
01. Principal	rectal_comments_v10	Comments - Visit 10 (Post-Intervention) - [Digital Rectal Exam]		Char
01. Principal	rectal_comments_v12	Comments - Visit 12 (6-Month Follow-Up) - [Digital Rectal Exam]		Char
01. Principal	rectal_exam_dt_v01	Date Exam Performed - Visit 1 (Screening) - [Digital Rectal Exam]		SAS Date .R="Not Randomized"
01. Principal	rectal_exam_dt_v10	Date Exam Performed - Visit 10 (Post-Intervention) - [Digital Rectal Exam]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	rectal_exam_dt_v12	Date Exam Performed - Visit 12 (6-Month Follow-Up) - [Digital Rectal Exam]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	rectal_palpability_v01	Digital Rectal Exam - Visit 1 (Screening) - [Digital Rectal Exam]		Numeric .R="Not Randomized"
01. Principal	rectal_palpability_v10	Digital Rectal Exam - Visit 10 (Post-Intervention) - [Digital Rectal Exam]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	rectal_palpability_v12	Digital Rectal Exam - Visit 12 (6-Month Follow-Up) - [Digital Rectal Exam]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Section 10: International Prostate Symptom Score

Class	Variable	Label	Description	Format Text
01. Principal	ipss_frequency_v01	Frequency: How Often Have You Had To Urinate Less Than Every Two Hours? - Visit 1 (Screening) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_frequency_v07	Frequency: How Often Have You Had To Urinate Less Than Every Two Hours? - Visit 7 (Day 84) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_frequency_v10	Frequency: How Often Have You Had To Urinate Less Than Every Two Hours? - Visit 10 (Post-Intervention) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_frequency_v12	Frequency: How Often Have You Had To Urinate Less Than Every Two Hours? - Visit 12 (6-Month Follow-Up) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_incomplete_emptying_v01	Incomplete Emptying: How Often Have You Had The Sensation Of Not Emptying Your Bladder? - Visit 1 (Screening) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"

Class	Variable	Label	Description	Format Text
01. Principal	ipss_incomplete_emptying_v07	Incomplete Emptying: How Often Have You Had The Sensation Of Not Emptying Your Bladder? - Visit 7 (Day 84) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_incomplete_emptying_v10	Incomplete Emptying: How Often Have You Had The Sensation Of Not Emptying Your Bladder? - Visit 10 (Post-Intervention) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_incomplete_emptying_v12	Incomplete Emptying: How Often Have You Had The Sensation Of Not Emptying Your Bladder? - Visit 12 (6-Month Follow-Up) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_intermittency_v01	Intermittency: How Often Have You Found You Stopped And Started Again Several Times When You Urinated? - Visit 1 (Screening) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_intermittency_v07	Intermittency: How Often Have You Found You Stopped And Started Again Several Times When You Urinated? - Visit 7 (Day 84) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_intermittency_v10	Intermittency: How Often Have You Found You Stopped And Started Again Several Times When You Urinated? - Visit 10 (Post-Intervention) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"

Class	Variable	Label	Description	Format Text
01. Principal	ipss_intermittency_v12	Intermittency: How Often Have You Found You Stopped And Started Again Several Times When You Urinated? - Visit 12 (6-Month Follow-Up) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_nocturia_v01	Nocturia: How Many Times Did You Typically Get Up At Night To Urinate? - Visit 1 (Screening) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="None" 1="1 Time" 2="2 Times" 3="3 Times" 4="4 Times" 5="5 Or More Times"
01. Principal	ipss_nocturia_v07	Nocturia: How Many Times Did You Typically Get Up At Night To Urinate? - Visit 7 (Day 84) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="None" 1="1 Time" 2="2 Times" 3="3 Times" 4="4 Times" 5="5 Or More Times"
01. Principal	ipss_nocturia_v10	Nocturia: How Many Times Did You Typically Get Up At Night To Urinate? - Visit 10 (Post-Intervention) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="None" 1="1 Time" 2="2 Times" 3="3 Times" 4="4 Times" 5="5 Or More Times"
01. Principal	ipss_nocturia_v12	Nocturia: How Many Times Did You Typically Get Up At Night To Urinate? - Visit 12 (6-Month Follow-Up) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="None" 1="1 Time" 2="2 Times" 3="3 Times" 4="4 Times" 5="5 Or More Times"
01. Principal	ipss_qol_score_v01	Quality Of Life Score Due To Urinary Symptoms: If You Were To Spend The Rest Of Your Life With Your Urinary Condition Just The Way It Is Now - How Would You Feel About That? - Visit 1 (Screening) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Delighted" 1="Pleased" 2="Mostly Satisfied" 3="Mixed Satisfied And Dissatisfied" 4="Mostly Dissatisfied" 5="Unhappy" 6="Terrible"

Class	Variable	Label	Description	Format Text
01. Principal	ipss_qol_score_v07	Quality Of Life Score Due To Urinary Symptoms: If You Were To Spend The Rest Of Your Life With Your Urinary Condition Just The Way It Is Now - How Would You Feel About That? - Visit 7 (Day 84) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Delighted" 1="Pleased" 2="Mostly Satisfied" 3="Mixed Satisfied And Dissatisfied" 4="Mostly Dissatisfied" 5="Unhappy" 6="Terrible"
01. Principal	ipss_qol_score_v10	Quality Of Life Score Due To Urinary Symptoms: If You Were To Spend The Rest Of Your Life With Your Urinary Condition Just The Way It Is Now - How Would You Feel About That? - Visit 10 (Post-Intervention) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Delighted" 1="Pleased" 2="Mostly Satisfied" 3="Mixed Satisfied And Dissatisfied" 4="Mostly Dissatisfied" 5="Unhappy" 6="Terrible"
01. Principal	ipss_qol_score_v12	Quality Of Life Score Due To Urinary Symptoms: If You Were To Spend The Rest Of Your Life With Your Urinary Condition Just The Way It Is Now - How Would You Feel About That? - Visit 12 (6-Month Follow-Up) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Delighted" 1="Pleased" 2="Mostly Satisfied" 3="Mixed Satisfied And Dissatisfied" 4="Mostly Dissatisfied" 5="Unhappy" 6="Terrible"
01. Principal	ipss_straining_v01	Straining: How Often Have You Had To Strain To Start Urination? - Visit 1 (Screening) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_straining_v07	Straining: How Often Have You Had To Strain To Start Urination? - Visit 7 (Day 84) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"

Class	Variable	Label	Description	Format Text
01. Principal	ipss_straining_v10	Straining: How Often Have You Had To Strain To Start Urination? - Visit 10 (Post-Intervention) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_straining_v12	Straining: How Often Have You Had To Strain To Start Urination? - Visit 12 (6-Month Follow-Up) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_total_ipss_score_v01	Total IPSS Score - Visit 1 (Screening) - [International Prostate Symptom Score]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	ipss_total_ipss_score_v07	Total IPSS Score - Visit 7 (Day 84) - [International Prostate Symptom Score]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	ipss_total_ipss_score_v10	Total IPSS Score - Visit 10 (Post-Intervention) - [International Prostate Symptom Score]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	ipss_total_ipss_score_v12	Total IPSS Score - Visit 12 (6-Month Follow-Up) - [International Prostate Symptom Score]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	ipss_urgency_v01	Urgency: How Often Have You Found It Difficult To Postpone Urination? - Visit 1 (Screening) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_urgency_v07	Urgency: How Often Have You Found It Difficult To Postpone Urination? - Visit 7 (Day 84) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"

Class	Variable	Label	Description	Format Text
01. Principal	ipss_urgency_v10	Urgency: How Often Have You Found It Difficult To Postpone Urination? - Visit 10 (Post-Intervention) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_urgency_v12	Urgency: How Often Have You Found It Difficult To Postpone Urination? - Visit 12 (6-Month Follow-Up) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_weak_stream_v01	Weak Stream: How Often Have You Had A Weak Urinary Stream? - Visit 1 (Screening) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_weak_stream_v07	Weak Stream: How Often Have You Had A Weak Urinary Stream? - Visit 7 (Day 84) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_weak_stream_v10	Weak Stream: How Often Have You Had A Weak Urinary Stream? - Visit 10 (Post-Intervention) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"
01. Principal	ipss_weak_stream_v12	Weak Stream: How Often Have You Had A Weak Urinary Stream? - Visit 12 (6-Month Follow-Up) - [International Prostate Symptom Score]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not At All" 1="Less Than 1 Time In 5" 2="Less Than Half The Time" 3="About Half The Time" 4="More Than Half The Time" 5="Almost Always"

Section 11: PSA

Class	Variable	Label	Description	Format Text
01. Principal	psa_collected_dt_ex	Date Prostate-Specific Antigen Lab Test Specimen Collected - Extra Visit - [PSA]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	psa_collected_dt_v01	Date Prostate-Specific Antigen Lab Test Specimen Collected - Visit 1 (Screening) - [PSA]		SAS Date .R="Not Randomized"
01. Principal	psa_collected_dt_v03	Date Prostate-Specific Antigen Lab Test Specimen Collected - Visit 3 (Baseline Visit) - [PSA]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	psa_collected_dt_v07	Date Prostate-Specific Antigen Lab Test Specimen Collected - Visit 7 (Day 84) - [PSA]		SAS Date .R="Not Randomized"
01. Principal	psa_collected_dt_v07_2nd	Date Prostate-Specific Antigen Lab Test Specimen Collected - Second - Visit 7 (Day 84) - [PSA]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	psa_collected_dt_v10	Date Prostate-Specific Antigen Lab Test Specimen Collected - Visit 10 (Post-Intervention) - [PSA]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	psa_collected_dt_v12	Date Prostate-Specific Antigen Lab Test Specimen Collected - Visit 12 (6-Month Follow-Up) - [PSA]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	psa_comments_ex	Prostate-Specific Antigen Lab Test Comments - Extra Visit - [PSA]		Char
01. Principal	psa_comments_v01	Prostate-Specific Antigen Lab Test Comments - Visit 1 (Screening) - [PSA]		Char
01. Principal	psa_comments_v03	Prostate-Specific Antigen Lab Test Comments - Visit 3 (Baseline Visit) - [PSA]		Char
01. Principal	psa_comments_v07	Prostate-Specific Antigen Lab Test Comments - Visit 7 (Day 84) - [PSA]		Char

Class	Variable	Label	Description	Format Text
01. Principal	psa_comments_v07_2nd	Prostate-Specific Antigen Lab Test Comments - Second - Visit 7 (Day 84) - [PSA]		Char
01. Principal	psa_comments_v10	Prostate-Specific Antigen Lab Test Comments - Visit 10 (Post-Intervention) - [PSA]		Char
01. Principal	psa_comments_v12	Prostate-Specific Antigen Lab Test Comments - Visit 12 (6-Month Follow-Up) - [PSA]		Char
01. Principal	psa_results_ex	Prostate-Specific Antigen Lab Test Results (ng/ml) - Extra Visit - [PSA]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	psa_results_v01	Prostate-Specific Antigen Lab Test Results (ng/ml) - Visit 1 (Screening) - [PSA]		Numeric .R="Not Randomized"
01. Principal	psa_results_v03	Prostate-Specific Antigen Lab Test Results (ng/ml) - Visit 3 (Baseline Visit) - [PSA]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	psa_results_v07	Prostate-Specific Antigen Lab Test Results (ng/ml) - Visit 7 (Day 84) - [PSA]		Numeric .R="Not Randomized"
01. Principal	psa_results_v07_2nd	Prostate-Specific Antigen Lab Test Results (ng/ml) - Second - Visit 7 (Day 84) - [PSA]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	psa_results_v10	Prostate-Specific Antigen Lab Test Results (ng/ml) - Visit 10 (Post-Intervention) - [PSA]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	psa_results_v12	Prostate-Specific Antigen Lab Test Results (ng/ml) - Visit 12 (6-Month Follow-Up) - [PSA]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	psa_visit_dt_ex	Visit Date - Extra Visit - [PSA]		SAS Date .N="N/A" .R="Not Randomized"

Section 12: Pre-enrollment Biopsy/Pathology

Class	Variable	Label	Description	Format Text
01. Principal	prebx_collected_dt_rand	Date Specimen Collected - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		SAS Date .R="Not Randomized"
01. Principal	prebx_collected_dt_rand_ex	Date Specimen Collected - Extra - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	prebx_collected_dt_targ	Date Specimen Collected - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	prebx_collected_dt_targ_ex	Date Specimen Collected - Extra - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	prebx_num_gleason_rand	Gleason Score Primary Pattern Number - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	prebx_num_gleason_rand_ex	Gleason Score Primary Pattern Number - Extra - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	prebx_num_gleason_targ	Gleason Score Primary Pattern Number - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	prebx_num_gleason_targ_ex	Gleason Score Primary Pattern Number - Extra - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	prebx_num_pos_cores_rand	Number Of Positive Cores - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .R="Not Randomized"
01. Principal	prebx_num_pos_cores_rand_ex	Number Of Positive Cores - Extra - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	prebx_num_pos_cores_targ	Number Of Positive Cores - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	prebx_num_pos_cores_targ_ex	Number Of Positive Cores - Extra - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	prebx_total_cores_rand	Total Number Of Cores - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .R="Not Randomized"
01. Principal	prebx_total_cores_rand_ex	Total Number Of Cores - Extra - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	prebx_total_cores_targ	Total Number Of Cores - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	prebx_total_cores_targ_ex	Total Number Of Cores - Extra - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	prebx_txt_gleason_rand	Gleason Score Primary Pattern Text - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		Char
01. Principal	prebx_txt_gleason_rand_ex	Gleason Score Primary Pattern Text - Extra - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		Char
01. Principal	prebx_txt_gleason_targ	Gleason Score Primary Pattern Text - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		Char
01. Principal	prebx_txt_gleason_targ_ex	Gleason Score Primary Pattern Text - Extra - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		Char
01. Principal	prebx_type_bx_rand	Type Of Biopsy - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .R="Not Randomized"
01. Principal	prebx_type_bx_rand_ex	Type Of Biopsy - Extra - Random Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	prebx_type_bx_targ	Type Of Biopsy - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	prebx_type_bx_targ_ex	Type Of Biopsy - Extra - Targeted Biopsy - [Pre-enrollment Biopsy/Pathology]		Numeric .N="N/A" .R="Not Randomized"

Section 13: Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alb_glob_clin_sig_ex	Alb/Glob Ratio - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_alb_glob_clin_sig_v01	Alb/Glob Ratio - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_alb_glob_clin_sig_v07	Alb/Glob Ratio - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_alb_glob_clin_sig_v10	Alb/Glob Ratio - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_alb_glob_cmt_ex	Alb/Glob Ratio - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_alb_glob_cmt_v01	Alb/Glob Ratio - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_alb_glob_cmt_v07	Alb/Glob Ratio - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_alb_glob_cmt_v10	Alb/Glob Ratio - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_alb_glob_out_range_ex	Alb/Glob Ratio - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_alb_glob_out_range_v01	Alb/Glob Ratio - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_alb_glob_out_range_v07	Alb/Glob Ratio - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alb_glob_out_range_v10	Alb/Glob Ratio - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_alb_glob_result_ex	Alb/Glob Ratio - Result - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_alb_glob_result_v01	Alb/Glob Ratio - Result - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_alb_glob_result_v07	Alb/Glob Ratio - Result - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_alb_glob_result_v10	Alb/Glob Ratio - Result - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_albumin_clin_sig_ex	Albumin - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_albumin_clin_sig_v01	Albumin - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_albumin_clin_sig_v07	Albumin - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_albumin_clin_sig_v10	Albumin - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_albumin_cmt_ex	Albumin - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_albumin_cmt_v01	Albumin - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_albumin_cmt_v07	Albumin - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_albumin_cmt_v10	Albumin - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_albumin_out_range_ex	Albumin - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_albumin_out_range_v01	Albumin - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_albumin_out_range_v07	Albumin - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_albumin_out_range_v10	Albumin - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_albumin_result_ex	Albumin - Result (g/dL) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_albumin_result_v01	Albumin - Result (g/dL) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_albumin_result_v07	Albumin - Result (g/dL) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_albumin_result_v10	Albumin - Result (g/dL) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_alk_phos_clin_sig_ex	Alkaline Phosphatase - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_alk_phos_clin_sig_v01	Alkaline Phosphatase - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_alk_phos_clin_sig_v07	Alkaline Phosphatase - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_alk_phos_clin_sig_v10	Alkaline Phosphatase - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_alk_phos_cmt_ex	Alkaline Phosphatase - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_alk_phos_cmt_v01	Alkaline Phosphatase - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_alk_phos_cmt_v07	Alkaline Phosphatase - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alk_phos_cmt_v10	Alkaline Phosphatase - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_alk_phos_out_range_ex	Alkaline Phosphatase - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_out_range_v01	Alkaline Phosphatase - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_out_range_v07	Alkaline Phosphatase - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_out_range_v10	Alkaline Phosphatase - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_alk_phos_result_ex	Alkaline Phosphatase - Result (IU/L) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_alk_phos_result_v01	Alkaline Phosphatase - Result (IU/L) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_alk_phos_result_v07	Alkaline Phosphatase - Result (IU/L) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_alk_phos_result_v10	Alkaline Phosphatase - Result (IU/L) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_anion_gap_clin_sig_ex	Anion Gap - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_anion_gap_clin_sig_v01	Anion Gap - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_anion_gap_clin_sig_v07	Anion Gap - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_anion_gap_clin_sig_v10	Anion Gap - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_anion_gap_cmt_ex	Anion Gap - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_anion_gap_cmt_v01	Anion Gap - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_anion_gap_cmt_v07	Anion Gap - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_anion_gap_cmt_v10	Anion Gap - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_anion_gap_out_range_ex	Anion Gap - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_anion_gap_out_range_v01	Anion Gap - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_anion_gap_out_range_v07	Anion Gap - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_anion_gap_out_range_v10	Anion Gap - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_anion_gap_result_ex	Anion Gap - Result - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_anion_gap_result_v01	Anion Gap - Result - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_anion_gap_result_v07	Anion Gap - Result - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_anion_gap_result_v10	Anion Gap - Result - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_bicarb_clin_sig_ex	Bicarbonate - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bicarb_clin_sig_v01	Bicarbonate - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bicarb_clin_sig_v07	Bicarbonate - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bicarb_clin_sig_v10	Bicarbonate - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bicarb_cmt_ex	Bicarbonate - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_bicarb_cmt_v01	Bicarbonate - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_bicarb_cmt_v07	Bicarbonate - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_bicarb_cmt_v10	Bicarbonate - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_bicarb_out_range_ex	Bicarbonate - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bicarb_out_range_v01	Bicarbonate - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bicarb_out_range_v07	Bicarbonate - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bicarb_out_range_v10	Bicarbonate - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bicarb_result_ex	Bicarbonate - Result (mmol/l) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_bicarb_result_v01	Bicarbonate - Result (mmol/l) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_bicarb_result_v07	Bicarbonate - Result (mmol/l) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bicarb_result_v10	Bicarbonate - Result (mmol/l) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_bilirubin_clin_sig_ex	Bilirubin - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bilirubin_clin_sig_v01	Bilirubin - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bilirubin_clin_sig_v07	Bilirubin - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bilirubin_clin_sig_v10	Bilirubin - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bilirubin_cmt_ex	Bilirubin - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_bilirubin_cmt_v01	Bilirubin - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_bilirubin_cmt_v07	Bilirubin - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_bilirubin_cmt_v10	Bilirubin - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_bilirubin_out_range_ex	Bilirubin - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bilirubin_out_range_v01	Bilirubin - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bilirubin_out_range_v07	Bilirubin - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bilirubin_out_range_v10	Bilirubin - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bilirubin_result_ex	Bilirubin - Result (mg/dL) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bilirubin_result_v01	Bilirubin - Result (mg/dL) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_bilirubin_result_v07	Bilirubin - Result (mg/dL) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_bilirubin_result_v10	Bilirubin - Result (mg/dL) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_bun_clin_sig_ex	Bun - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bun_clin_sig_v01	Bun - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bun_clin_sig_v07	Bun - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bun_clin_sig_v10	Bun - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bun_comments_ex	Bun - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_bun_comments_v01	Bun - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_comments_v07	Bun - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_comments_v10	Bun - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_creatinine_ratio_clin_sig_ex	Bun/Creatinine Ratio - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bun_creatinine_ratio_clin_sig_v01	Bun/Creatinine Ratio - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bun_creat_clin_sig_v07	Bun/Creatinine Ratio - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bun_creat_clin_sig_v10	Bun/Creatinine Ratio - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_bun_creat_cmt_ex	Bun/Creatinine Ratio - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_bun_creat_cmt_v01	Bun/Creatinine Ratio - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_creat_cmt_v07	Bun/Creatinine Ratio - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_creat_cmt_v10	Bun/Creatinine Ratio - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_creat_out_range_ex	Bun/Creatinine Ratio - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bun_creat_out_range_v01	Bun/Creatinine Ratio - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bun_creat_out_range_v07	Bun/Creatinine Ratio - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bun_creat_out_range_v10	Bun/Creatinine Ratio - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bun_creat_result_ex	Bun/Creatinine Ratio - Result - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_bun_creat_result_v01	Bun/Creatinine Ratio - Result - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_bun_creat_result_v07	Bun/Creatinine Ratio - Result - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_bun_creat_result_v10	Bun/Creatinine Ratio - Result - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bun_out_range_ex	Bun - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bun_out_range_v01	Bun - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bun_out_range_v07	Bun - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bun_out_range_v10	Bun - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bun_result_ex	Bun - Result (mg/dL) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_bun_result_v01	Bun - Result (mg/dL) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_bun_result_v07	Bun - Result (mg/dL) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_bun_result_v10	Bun - Result (mg/dL) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_calcium_clin_sig_ex	Calcium - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_calcium_clin_sig_v01	Calcium - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_calcium_clin_sig_v07	Calcium - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_calcium_clin_sig_v10	Calcium - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_calcium_cmt_ex	Calcium - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_calcium_cmt_v01	Calcium - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_calcium_cmt_v07	Calcium - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_calcium_cmt_v10	Calcium - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_calcium_out_range_ex	Calcium - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_calcium_out_range_v01	Calcium - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_calcium_out_range_v07	Calcium - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_calcium_out_range_v10	Calcium - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_calcium_result_ex	Calcium - Result (mg/dL) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_calcium_result_v01	Calcium - Result (mg/dL) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_calcium_result_v07	Calcium - Result (mg/dL) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_calcium_result_v10	Calcium - Result (mg/dL) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_chloride_clin_sig_ex	Chloride - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_chloride_clin_sig_v01	Chloride - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_chloride_clin_sig_v07	Chloride - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_chloride_clin_sig_v10	Chloride - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_chloride_cmt_ex	Chloride - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_chloride_cmt_v01	Chloride - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_chloride_cmt_v07	Chloride - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_chloride_cmt_v10	Chloride - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_chloride_out_range_ex	Chloride - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_chloride_out_range_v01	Chloride - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_chloride_out_range_v07	Chloride - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_chloride_out_range_v10	Chloride - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_chloride_result_ex	Chloride - Result (mmol/l) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_chloride_result_v01	Chloride - Result (mmol/l) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_chloride_result_v07	Chloride - Result (mmol/l) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_chloride_result_v10	Chloride - Result (mmol/l) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_collecte d_dt_ex	Date Specimen Collected - Extra Visit - [Blood Chemistry]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	bldchem_collecte d_dt_v01	Date Specimen Collected - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .R="Not Randomized"
01. Principal	bldchem_collecte d_dt_v07	Date Specimen Collected - Visit 7 (Day 84) - [Blood Chemistry]		SAS Date .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_collected_dt_v10	Date Specimen Collected - Visit 10 (Post-Intervention) - [Blood Chemistry]		SAS Date .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_creatinine_clin_sig_ex	Creatinine - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_creatinine_clin_sig_v01	Creatinine - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_creatinine_clin_sig_v07	Creatinine - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_creatinine_clin_sig_v10	Creatinine - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_creatinine_cmt_ex	Creatinine - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_creatinine_cmt_v01	Creatinine - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_creatinine_cmt_v07	Creatinine - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_creatinine_cmt_v10	Creatinine - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_creatinine_out_range_ex	Creatinine - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_creatinine_out_range_v01	Creatinine - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_creatinine_out_range_v07	Creatinine - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_creatinine_out_range_v10	Creatinine - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.M="Missing" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_creatinine_result_ex	Creatinine - Result (mg/dL) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_creatinine_result_v01	Creatinine - Result (mg/dL) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_creatinine_result_v07	Creatinine - Result (mg/dL) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_creatinine_result_v10	Creatinine - Result (mg/dL) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_fasting_ex	Fasting - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_fasting_v01	Fasting - Visit 1 (Screening) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_fasting_v07	Fasting - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_fasting_v10	Fasting - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_globulin_clin_sig_ex	Globulin - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_globulin_clin_sig_v01	Globulin - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_globulin_clin_sig_v07	Globulin - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_globulin_clin_sig_v10	Globulin - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_globulin_cmt_ex	Globulin - Comments - Extra Visit - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_globulin_cmt_v01	Globulin - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_globulin_cmt_v07	Globulin - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_globulin_cmt_v10	Globulin - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_globulin_out_range_ex	Globulin - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_globulin_out_range_v01	Globulin - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_globulin_out_range_v07	Globulin - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_globulin_out_range_v10	Globulin - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_globulin_result_ex	Globulin - Result (g/dL) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_globulin_result_v01	Globulin - Result (g/dL) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_globulin_result_v07	Globulin - Result (g/dL) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_globulin_result_v10	Globulin - Result (g/dL) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_glu_serum_clin_sig_ex	Glucose Serum - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_glu_serum_clin_sig_v01	Glucose Serum - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_glu_serum_clin_sig_v07	Glucose Serum - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_glu_serum_clin_sig_v10	Glucose Serum - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_glu_serum_cmt_ex	Glucose Serum - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_glu_serum_cmt_v01	Glucose Serum - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_glu_serum_cmt_v07	Glucose Serum - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_glu_serum_cmt_v10	Glucose Serum - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_glu_serum_out_range_ex	Glucose Serum - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_glu_serum_out_range_v01	Glucose Serum - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_glu_serum_out_range_v07	Glucose Serum - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_glu_serum_out_range_v10	Glucose Serum - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_glu_serum_result_ex	Glucose Serum - Result (mg/dL) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_glu_serum_result_v01	Glucose Serum - Result (mg/dL) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_glu_serum_result_v07	Glucose Serum - Result (mg/dL) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_glu_serum_result_v10	Glucose Serum - Result (mg/dL) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_has_extra	Participant Has An Extra Visit - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_potassium_clin_sig_ex	Potassium - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_potassium_clin_sig_v01	Potassium - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_potassium_clin_sig_v07	Potassium - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_potassium_clin_sig_v10	Potassium - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_potassium_cmt_ex	Potassium - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_potassium_cmt_v01	Potassium - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_potassium_cmt_v07	Potassium - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_potassium_cmt_v10	Potassium - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_potassium_out_range_ex	Potassium - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_potassium_out_range_v01	Potassium - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_potassium_out_range_v07	Potassium - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_potassium_out_range_v10	Potassium - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_potassium_result_ex	Potassium - Result (mmol/l) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_potassium_result_v01	Potassium - Result (mmol/l) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_potassium_result_v07	Potassium - Result (mmol/l) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_potassium_result_v10	Potassium - Result (mmol/l) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_protein_clin_sig_ex	Total Protein - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_protein_clin_sig_v01	Total Protein - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_protein_clin_sig_v07	Total Protein - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_protein_clin_sig_v10	Total Protein - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_protein_cmt_ex	Total Protein - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_protein_cmt_v01	Total Protein - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_protein_cmt_v07	Total Protein - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_protein_cmt_v10	Total Protein - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_protein_out_range_ex	Total Protein - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_protein_out_range_v01	Total Protein - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_protein_out_range_v07	Total Protein - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_protein_out_range_v10	Total Protein - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_protein_result_ex	Total Protein - Result (g/dL) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_protein_result_v01	Total Protein - Result (g/dL) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_protein_result_v07	Total Protein - Result (g/dL) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_protein_result_v10	Total Protein - Result (g/dL) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_sgop_ast_clin_sig_ex	SGOP/AST - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_sgop_ast_clin_sig_v01	SGOP/AST - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_sgop_ast_clin_sig_v07	SGOP/AST - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_sgop_ast_clin_sig_v10	SGOP/AST - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_sgop_ast_cmt_ex	SGOP/AST - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_sgop_ast_cmt_v01	SGOP/AST - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_sgop_ast_cmt_v07	SGOP/AST - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_sgop_ast_cmt_v10	SGOP/AST - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sgop_ast_out_range_ex	SGOP/AST - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_out_range_v01	SGOP/AST - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_out_range_v07	SGOP/AST - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_out_range_v10	SGOP/AST - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgop_ast_result_ex	SGOP/AST - Result (IU/L) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_sgop_ast_result_v01	SGOP/AST - Result (IU/L) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_sgop_ast_result_v07	SGOP/AST - Result (IU/L) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_sgop_ast_result_v10	SGOP/AST - Result (IU/L) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_sgpt_alt_clin_sig_ex	SGPT/ALT - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_sgpt_alt_clin_sig_v01	SGPT/ALT - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_sgpt_alt_clin_sig_v07	SGPT/ALT - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_sgpt_alt_clin_sig_v10	SGPT/ALT - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_sgpt_alt_cmt_ex	SGPT/ALT - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_alt_cmt_v01	SGPT/ALT - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sgpt_al t_cmt_v07	SGPT/ALT - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_al t_cmt_v10	SGPT/ALT - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_al t_out_range_ex	SGPT/ALT - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_al t_out_range_v01	SGPT/ALT - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_al t_out_range_v07	SGPT/ALT - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_al t_out_range_v10	SGPT/ALT - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_al t_result_ex	SGPT/ALT - Result (IU/L) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_sgpt_al t_result_v01	SGPT/ALT - Result (IU/L) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_sgpt_al t_result_v07	SGPT/ALT - Result (IU/L) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldchem_sgpt_al t_result_v10	SGPT/ALT - Result (IU/L) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_sodium _clin_sig_ex	Sodium - Clinically Significant - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_sodium _clin_sig_v01	Sodium - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_sodium _clin_sig_v07	Sodium - Clinically Significant - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldchem_sodium _clin_sig_v10	Sodium - Clinically Significant - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sodium_cmt_ex	Sodium - Comments - Extra Visit - [Blood Chemistry]		Char
01. Principal	bldchem_sodium_cmt_v01	Sodium - Comments - Visit 1 (Screening) - [Blood Chemistry]		Char
01. Principal	bldchem_sodium_cmt_v07	Sodium - Comments - Visit 7 (Day 84) - [Blood Chemistry]		Char
01. Principal	bldchem_sodium_cmt_v10	Sodium - Comments - Visit 10 (Post-Intervention) - [Blood Chemistry]		Char
01. Principal	bldchem_sodium_out_range_ex	Sodium - Out Of Range - Extra Visit - [Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sodium_out_range_v01	Sodium - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sodium_out_range_v07	Sodium - Out Of Range - Visit 7 (Day 84) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sodium_out_range_v10	Sodium - Out Of Range - Visit 10 (Post-Intervention) - [Blood Chemistry]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sodium_result_ex	Sodium - Result (mmol/l) - Extra Visit - [Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_sodium_result_v01	Sodium - Result (mmol/l) - Visit 1 (Screening) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_sodium_result_v07	Sodium - Result (mmol/l) - Visit 7 (Day 84) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_sodium_result_v10	Sodium - Result (mmol/l) - Visit 10 (Post-Intervention) - [Blood Chemistry]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	bldchem_visit_dt_ex	Visit Date - Extra Visit - [Blood Chemistry]		SAS Date .N="N/A" .R="Not Randomized"

Section 14: Hematology

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_basop hils_cmt_v01	Absolute Basophils - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_abs_basop hils_cmt_v07	Absolute Basophils - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_abs_basop hils_cmt_v07_2nd	Absolute Basophils - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_abs_basop hils_cmt_v09	Absolute Basophils - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_basop hils_cmt_v10	Absolute Basophils - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_abs_basop hils_cmt_v12	Absolute Basophils - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_basop hils_out_v01	Absolute Basophils - Out Of Range - Visit 1 (Screening) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_basop hils_out_v07	Absolute Basophils - Out Of Range - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_basop hils_out_v07_2nd	Absolute Basophils - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_basop hils_out_v09	Absolute Basophils - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_basop hils_out_v10	Absolute Basophils - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_basop hils_out_v12	Absolute Basophils - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_basop hils_rslt_v01	Absolute Basophils - Result - Visit 1 (Screening) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_abs_basop hils_rslt_v07	Absolute Basophils - Result - Visit 7 (Day 84) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_abs_basop hils_rslt_v07_2nd	Absolute Basophils - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_abs_basop hils_rslt_v09	Absolute Basophils - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_basop hils_rslt_v10	Absolute Basophils - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_abs_basop hils_rslt_v12	Absolute Basophils - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_basop hils_sig_v01	Absolute Basophils - Clinically Significant - Visit 1 (Screening) - [Hematology]		.M="Missing" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_basop hils_sig_v07	Absolute Basophils - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_basop hils_sig_v07_2nd	Absolute Basophils - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_basop hils_sig_v09	Absolute Basophils - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_basop hils_sig_v10	Absolute Basophils - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_basophils_sig_v12	Absolute Basophils - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_eosinophi_cmt_v01	Absolute Eosinophils - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_abs_eosinophi_cmt_v07	Absolute Eosinophils - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_abs_eosinophi_cmt_v07_2nd	Absolute Eosinophils - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_abs_eosinophi_cmt_v09	Absolute Eosinophils - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_eosinophi_cmt_v10	Absolute Eosinophils - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_abs_eosinophi_cmt_v12	Absolute Eosinophils - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_eosinophi_out_v01	Absolute Eosinophils - Out Of Range - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_eosinophi_out_v07	Absolute Eosinophils - Out Of Range - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_eosinophi_out_v07_2nd	Absolute Eosinophils - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_eosinophi_out_v09	Absolute Eosinophils - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_eosinophi_out_v10	Absolute Eosinophils - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_eosinophi_out_v12	Absolute Eosinophils - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_eosinophi_rslt_v01	Absolute Eosinophils - Result - Visit 1 (Screening) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_abs_eosinophi_rslt_v07	Absolute Eosinophils - Result - Visit 7 (Day 84) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_abs_eosinophi_rslt_v07_2nd	Absolute Eosinophils - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_eosinophi_rslt_v09	Absolute Eosinophils - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_eosinophi_rslt_v10	Absolute Eosinophils - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_abs_eosinophi_rslt_v12	Absolute Eosinophils - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_eosinophi_sig_v01	Absolute Eosinophils - Clinically Significant - Visit 1 (Screening) - [Hematology]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_eosinophi_sig_v07	Absolute Eosinophils - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_eosinophi_sig_v07_2nd	Absolute Eosinophils - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_eosinophi_sig_v09	Absolute Eosinophils - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_eosinophi_sig_v10	Absolute Eosinophils - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_eosinophi_sig_v12	Absolute Eosinophils - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_cmt_v01	Absolute Granulocytes - Comments - Visit 1 (Screening) - [Hematology]		Char

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_granulocy_cmt_v07	Absolute Granulocytes - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_abs_granulocy_cmt_v07_2nd	Absolute Granulocytes - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_abs_granulocy_cmt_v09	Absolute Granulocytes - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_granulocy_cmt_v10	Absolute Granulocytes - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_abs_granulocy_cmt_v12	Absolute Granulocytes - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_granulocy_out_v01	Absolute Granulocytes - Out Of Range - Visit 1 (Screening) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_out_v07	Absolute Granulocytes - Out Of Range - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_out_v07_2nd	Absolute Granulocytes - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_out_v09	Absolute Granulocytes - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_out_v10	Absolute Granulocytes - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_out_v12	Absolute Granulocytes - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_rslt_v01	Absolute Granulocytes - Result - Visit 1 (Screening) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_granulocy_rslt_v07	Absolute Granulocytes - Result - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_granulocy_rslt_v07_2nd	Absolute Granulocytes - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_granulocy_rslt_v09	Absolute Granulocytes - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_granulocy_rslt_v10	Absolute Granulocytes - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_granulocy_rslt_v12	Absolute Granulocytes - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_granulocy_sig_v01	Absolute Granulocytes - Clinically Significant - Visit 1 (Screening) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_sig_v07	Absolute Granulocytes - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_sig_v07_2nd	Absolute Granulocytes - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_sig_v09	Absolute Granulocytes - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_sig_v10	Absolute Granulocytes - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_granulocy_sig_v12	Absolute Granulocytes - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_cmt_v01	Absolute Lymphocytes - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_abs_lymphocyt_cmt_v07	Absolute Lymphocytes - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_abs_lymphocyt_cmt_v07_2nd	Absolute Lymphocytes - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_lymphocyt_cmt_v09	Absolute Lymphocytes - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_lymphocyt_cmt_v10	Absolute Lymphocytes - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_abs_lymphocyt_cmt_v12	Absolute Lymphocytes - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_lymphocyt_out_v01	Absolute Lymphocytes - Out Of Range - Visit 1 (Screening) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_out_v07	Absolute Lymphocytes - Out Of Range - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_out_v07_2nd	Absolute Lymphocytes - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_out_v09	Absolute Lymphocytes - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_out_v10	Absolute Lymphocytes - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_out_v12	Absolute Lymphocytes - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_rslt_v01	Absolute Lymphocytes - Result - Visit 1 (Screening) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_lymphocyt_rslt_v07	Absolute Lymphocytes - Result - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_lymphocyt_rslt_v07_2nd	Absolute Lymphocytes - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_lymphocyt_rslt_v09	Absolute Lymphocytes - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_lymphocyt_rslt_v10	Absolute Lymphocytes - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_lymphocyt_rslt_v12	Absolute Lymphocytes - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_lymphocyt_sig_v01	Absolute Lymphocytes - Clinically Significant - Visit 1 (Screening) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_sig_v07	Absolute Lymphocytes - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_sig_v07_2nd	Absolute Lymphocytes - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_sig_v09	Absolute Lymphocytes - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_sig_v10	Absolute Lymphocytes - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_lymphocyt_sig_v12	Absolute Lymphocytes - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_monocytes_cmt_v01	Absolute Monocytes - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_abs_monocytes_cmt_v07	Absolute Monocytes - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_abs_monocytes_cmt_v07_2nd	Absolute Monocytes - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_abs_monocytes_cmt_v09	Absolute Monocytes - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_monocytes_cmt_v10	Absolute Monocytes - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_mono cytes_cmt_v12	Absolute Monocytes - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_mono cytes_out_v01	Absolute Monocytes - Out Of Range - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_mono cytes_out_v07	Absolute Monocytes - Out Of Range - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_mono cytes_out_v07_2 nd	Absolute Monocytes - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_mono cytes_out_v09	Absolute Monocytes - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_mono cytes_out_v10	Absolute Monocytes - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_mono cytes_out_v12	Absolute Monocytes - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_mono cytes_rslt_v01	Absolute Monocytes - Result - Visit 1 (Screening) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_abs_mono cytes_rslt_v07	Absolute Monocytes - Result - Visit 7 (Day 84) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_abs_mono cytes_rslt_v07_2 nd	Absolute Monocytes - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_mono cytes_rslt_v09	Absolute Monocytes - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_mono cytes_rslt_v10	Absolute Monocytes - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_abs_mono cytes_rslt_v12	Absolute Monocytes - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_monocytes_sig_v01	Absolute Monocytes - Clinically Significant - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_monocytes_sig_v07	Absolute Monocytes - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_monocytes_sig_v07_2nd	Absolute Monocytes - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_monocytes_sig_v09	Absolute Monocytes - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_monocytes_sig_v10	Absolute Monocytes - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_monocytes_sig_v12	Absolute Monocytes - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_neutrophil_cmt_v01	Absolute Neutrophils - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_abs_neutrophil_cmt_v07	Absolute Neutrophils - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_abs_neutrophil_cmt_v07_2nd	Absolute Neutrophils - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_abs_neutrophil_cmt_v09	Absolute Neutrophils - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_neutrophil_cmt_v10	Absolute Neutrophils - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_abs_neutrophil_cmt_v12	Absolute Neutrophils - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_abs_neutrophil_out_v01	Absolute Neutrophils - Out Of Range - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_neutr ophi_out_v07	Absolute Neutrophils - Out Of Range - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_neutr ophi_out_v07_2nd	Absolute Neutrophils - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_neutr ophi_out_v09	Absolute Neutrophils - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_neutr ophi_out_v10	Absolute Neutrophils - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_neutr ophi_out_v12	Absolute Neutrophils - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_neutr ophi_rslt_v01	Absolute Neutrophils - Result - Visit 1 (Screening) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_abs_neutr ophi_rslt_v07	Absolute Neutrophils - Result - Visit 7 (Day 84) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_abs_neutr ophi_rslt_v07_2nd	Absolute Neutrophils - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_neutr ophi_rslt_v09	Absolute Neutrophils - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_neutr ophi_rslt_v10	Absolute Neutrophils - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_abs_neutr ophi_rslt_v12	Absolute Neutrophils - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_abs_neutr ophi_sig_v01	Absolute Neutrophils - Clinically Significant - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_neutr ophi_sig_v07	Absolute Neutrophils - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_abs_neutroph_i_sig_v07_2nd	Absolute Neutrophils - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_neutroph_i_sig_v09	Absolute Neutrophils - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_neutroph_i_sig_v10	Absolute Neutrophils - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_abs_neutroph_i_sig_v12	Absolute Neutrophils - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_bands_cm_t_v01	Bands (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_bands_cm_t_v07	Bands (%) - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_bands_cm_t_v07_2nd	Bands (%) - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_bands_cm_t_v09	Bands (%) - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_bands_cm_t_v10	Bands (%) - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_bands_cm_t_v12	Bands (%) - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_bands_out_v01	Bands (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_bands_out_v07	Bands (%) - Out Of Range - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_bands_out_v07_2nd	Bands (%) - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_bands_out_v09	Bands (%) - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_bands_out_v10	Bands (%) - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_bands_out_v12	Bands (%) - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_bands_rslt_v01	Bands (%) - Result - Visit 1 (Screening) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_bands_rslt_v07	Bands (%) - Result - Visit 7 (Day 84) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_bands_rslt_v07_2nd	Bands (%) - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_bands_rslt_v09	Bands (%) - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_bands_rslt_v10	Bands (%) - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_bands_rslt_v12	Bands (%) - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_bands_sig_v01	Bands (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_bands_sig_v07	Bands (%) - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_bands_sig_v07_2nd	Bands (%) - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_bands_sig_v09	Bands (%) - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_bands_sig_v10	Bands (%) - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_bands_sig_v12	Bands (%) - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_basophils_cmt_v01	Basophils (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_basophils_cmt_v07	Basophils (%) - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_basophils_cmt_v07_2nd	Basophils (%) - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_basophils_cmt_v09	Basophils (%) - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_basophils_cmt_v10	Basophils (%) - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_basophils_cmt_v12	Basophils (%) - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_basophils_out_v01	Basophils (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_basophils_out_v07	Basophils (%) - Out Of Range - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_basophils_out_v07_2nd	Basophils (%) - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_basophils_out_v09	Basophils (%) - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_basophils_out_v10	Basophils (%) - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_basophils_out_v12	Basophils (%) - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_basophils_rslt_v01	Basophils (%) - Result - Visit 1 (Screening) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_basophils_rslt_v07	Basophils (%) - Result - Visit 7 (Day 84) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_basophils_rslt_v07_2nd	Basophils (%) - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_basophils_rslt_v09	Basophils (%) - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_basophils_rslt_v10	Basophils (%) - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_basophils_rslt_v12	Basophils (%) - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_basophils_sig_v01	Basophils (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_basophils_sig_v07	Basophils (%) - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_basophils_sig_v07_2nd	Basophils (%) - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_basophils_sig_v09	Basophils (%) - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_basophils_sig_v10	Basophils (%) - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_basophils_sig_v12	Basophils (%) - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_collection_dt_v01	Date Specimen Collected - Visit 1 (Screening) - [Hematology]		SAS Date .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_collection_dt_v07	Date Specimen Collected - Visit 7 (Day 84) - [Hematology]		SAS Date .R="Not Randomized"
01. Principal	hema_collection_dt_v07_2nd	Date Specimen Collected - Second - Visit 7 (Day 84) - [Hematology]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	hema_collection_dt_v09	Date Specimen Collected - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	SAS Date .N="N/A" .R="Not Randomized"
01. Principal	hema_collection_dt_v10	Date Specimen Collected - Visit 10 (Post-Intervention) - [Hematology]		SAS Date .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_collection_dt_v12	Date Specimen Collected - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	SAS Date .N="N/A" .R="Not Randomized"
01. Principal	hema_eosinophils_cmt_v01	Eosinophils (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_eosinophils_cmt_v07	Eosinophils (%) - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_eosinophils_cmt_v07_2nd	Eosinophils (%) - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_eosinophils_cmt_v09	Eosinophils (%) - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_eosinophils_cmt_v10	Eosinophils (%) - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_eosinophils_cmt_v12	Eosinophils (%) - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_eosinophils_out_v01	Eosinophils (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_eosinophils_out_v07	Eosinophils (%) - Out Of Range - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_eosinophils_out_v07_2nd	Eosinophils (%) - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_eosinophils_out_v09	Eosinophils (%) - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_eosinophils_out_v10	Eosinophils (%) - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_eosinophils_out_v12	Eosinophils (%) - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_eosinophils_rslt_v01	Eosinophils (%) - Result - Visit 1 (Screening) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_eosinophils_rslt_v07	Eosinophils (%) - Result - Visit 7 (Day 84) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_eosinophils_rslt_v07_2nd	Eosinophils (%) - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_eosinophils_rslt_v09	Eosinophils (%) - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_eosinophils_rslt_v10	Eosinophils (%) - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_eosinophils_rslt_v12	Eosinophils (%) - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_eosinophils_sig_v01	Eosinophils (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_eosinophils_sig_v07	Eosinophils (%) - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_eosinophils_sig_v07_2nd	Eosinophils (%) - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_eosinophils_sig_v09	Eosinophils (%) - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_eosinophils_sig_v10	Eosinophils (%) - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_eosinophils_sig_v12	Eosinophils (%) - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hematocrit_cmt_v01	Hematocrit - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_hematocrit_cmt_v07	Hematocrit - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_hematocrit_cmt_v07_2nd	Hematocrit - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_hematocrit_cmt_v09	Hematocrit - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_hematocrit_cmt_v10	Hematocrit - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_hematocrit_cmt_v12	Hematocrit - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_hematocrit_out_v01	Hematocrit - Out Of Range - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hematocrit_out_v07	Hematocrit - Out Of Range - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hematocrit_out_v07_2nd	Hematocrit - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hematocrit_out_v09	Hematocrit - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hematocrit_out_v10	Hematocrit - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hematocrit_out_v12	Hematocrit - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_hematocrit_rslt_v01	Hematocrit (%) - Result - Visit 1 (Screening) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_hematocrit_rslt_v07	Hematocrit (%) - Result - Visit 7 (Day 84) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_hematocrit_rslt_v07_2nd	Hematocrit (%) - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_hematocrit_rslt_v09	Hematocrit (%) - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_hematocrit_rslt_v10	Hematocrit (%) - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_hematocrit_rslt_v12	Hematocrit (%) - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_hematocrit_sig_v01	Hematocrit - Clinically Significant - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hematocrit_sig_v07	Hematocrit - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hematocrit_sig_v07_2nd	Hematocrit - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hematocrit_sig_v09	Hematocrit - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hematocrit_sig_v10	Hematocrit - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hematocrit_sig_v12	Hematocrit - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobin_cmt_v01	Hemoglobin - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_hemoglobin_cmt_v07	Hemoglobin - Comments - Visit 7 (Day 84) - [Hematology]		Char

Class	Variable	Label	Description	Format Text
01. Principal	hema_hemoglobi n_cmt_v07_2nd	Hemoglobin - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_hemoglobi n_cmt_v09	Hemoglobin - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_hemoglobi n_cmt_v10	Hemoglobin - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_hemoglobi n_cmt_v12	Hemoglobin - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_hemoglobi n_out_v01	Hemoglobin - Out Of Range - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobi n_out_v07	Hemoglobin - Out Of Range - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobi n_out_v07_2nd	Hemoglobin - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobi n_out_v09	Hemoglobin - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobi n_out_v10	Hemoglobin - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobi n_out_v12	Hemoglobin - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobi n_rslt_v01	Hemoglobin (g/dL) - Result - Visit 1 (Screening) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_hemoglobi n_rslt_v07	Hemoglobin (g/dL) - Result - Visit 7 (Day 84) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_hemoglobi n_rslt_v07_2nd	Hemoglobin (g/dL) - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_hemoglobi n_rslt_v09	Hemoglobin (g/dL) - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_hemoglobin_rslt_v10	Hemoglobin (g/dL) - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_hemoglobin_rslt_v12	Hemoglobin (g/dL) - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_hemoglobin_sig_v01	Hemoglobin - Clinically Significant - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobin_sig_v07	Hemoglobin - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobin_sig_v07_2nd	Hemoglobin - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobin_sig_v09	Hemoglobin - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobin_sig_v10	Hemoglobin - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_hemoglobin_sig_v12	Hemoglobin - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_lymphocytes_cmt_v01	Lymphocytes (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_lymphocytes_cmt_v07	Lymphocytes (%) - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_lymphocytes_cmt_v07_2nd	Lymphocytes (%) - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_lymphocytes_cmt_v09	Lymphocytes (%) - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_lymphocytes_cmt_v10	Lymphocytes (%) - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char

Class	Variable	Label	Description	Format Text
01. Principal	hema_lymphocytes_cmt_v12	Lymphocytes (%) - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_lymphocytes_out_v01	Lymphocytes (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_lymphocytes_out_v07	Lymphocytes (%) - Out Of Range - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_lymphocytes_out_v07_2nd	Lymphocytes (%) - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_lymphocytes_out_v09	Lymphocytes (%) - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_lymphocytes_out_v10	Lymphocytes (%) - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_lymphocytes_out_v12	Lymphocytes (%) - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_lymphocytes_rslt_v01	Lymphocytes (%) - Result - Visit 1 (Screening) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_lymphocytes_rslt_v07	Lymphocytes (%) - Result - Visit 7 (Day 84) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_lymphocytes_rslt_v07_2nd	Lymphocytes (%) - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_lymphocytes_rslt_v09	Lymphocytes (%) - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_lymphocytes_rslt_v10	Lymphocytes (%) - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_lymphocytes_rslt_v12	Lymphocytes (%) - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_lymphocytes_sig_v01	Lymphocytes (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_lymphocytes_sig_v07	Lymphocytes (%) - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_lymphocytes_sig_v07_2nd	Lymphocytes (%) - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_lymphocytes_sig_v09	Lymphocytes (%) - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_lymphocytes_sig_v10	Lymphocytes (%) - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_lymphocytes_sig_v12	Lymphocytes (%) - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_monocytes_comments_v01	Monocytes (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_monocytes_comments_v07	Monocytes (%) - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_monocytes_comments_v07_2nd	Monocytes (%) - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_monocytes_comments_v09	Monocytes (%) - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_monocytes_comments_v10	Monocytes (%) - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_monocytes_comments_v12	Monocytes (%) - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_monocytes_out_v01	Monocytes (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_monocytes_out_v07	Monocytes (%) - Out Of Range - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_monocytes_out_v07_2nd	Monocytes (%) - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_monocytes_out_v09	Monocytes (%) - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_monocytes_out_v10	Monocytes (%) - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.M="Missing" .O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_monocytes_out_v12	Monocytes (%) - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_monocytes_rslt_v01	Monocytes (%) - Result - Visit 1 (Screening) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_monocytes_rslt_v07	Monocytes (%) - Result - Visit 7 (Day 84) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_monocytes_rslt_v07_2nd	Monocytes (%) - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_monocytes_rslt_v09	Monocytes (%) - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_monocytes_rslt_v10	Monocytes (%) - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_monocytes_rslt_v12	Monocytes (%) - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_monocytes_sig_v01	Monocytes (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_monocytes_sig_v07	Monocytes (%) - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_monocytes_sig_v07_2nd	Monocytes (%) - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_monocytes_sig_v09	Monocytes (%) - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_monocytes_sig_v10	Monocytes (%) - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_monocytes_sig_v12	Monocytes (%) - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_neutrophils_cmt_v01	Neutrophils (%) - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_neutrophils_cmt_v07	Neutrophils (%) - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_neutrophils_cmt_v07_2nd	Neutrophils (%) - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_neutrophils_cmt_v09	Neutrophils (%) - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_neutrophils_cmt_v10	Neutrophils (%) - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_neutrophils_cmt_v12	Neutrophils (%) - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_neutrophils_out_v01	Neutrophils (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_neutrophils_out_v07	Neutrophils (%) - Out Of Range - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_neutrophils_out_v07_2nd	Neutrophils (%) - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_neutrophils_out_v09	Neutrophils (%) - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_neutrophils_out_v10	Neutrophils (%) - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_neutrophils_out_v12	Neutrophils (%) - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_neutrophils_rslt_v01	Neutrophils (%) - Result - Visit 1 (Screening) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_neutrophils_rslt_v07	Neutrophils (%) - Result - Visit 7 (Day 84) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_neutrophils_rslt_v07_2nd	Neutrophils (%) - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_neutrophils_rslt_v09	Neutrophils (%) - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_neutrophils_rslt_v10	Neutrophils (%) - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_neutrophils_rslt_v12	Neutrophils (%) - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_neutrophils_sig_v01	Neutrophils (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_neutrophils_sig_v07	Neutrophils (%) - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_neutrophils_sig_v07_2nd	Neutrophils (%) - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_neutrophils_sig_v09	Neutrophils (%) - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_neutrophils_sig_v10	Neutrophils (%) - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_neutrophils_sig_v12	Neutrophils (%) - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_platelets_cmt_v01	Platelets - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_platelets_cmt_v07	Platelets - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_platelets_cmt_v07_2nd	Platelets - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_platelets_cmt_v09	Platelets - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_platelets_cmt_v10	Platelets - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_platelets_cmt_v12	Platelets - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_platelets_out_v01	Platelets - Out Of Range - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_platelets_out_v07	Platelets - Out Of Range - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_platelets_out_v07_2nd	Platelets - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_platelets_out_v09	Platelets - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_platelets_out_v10	Platelets - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_platelets_out_v12	Platelets - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_platelets_result_v01	Platelets (k/mm3) - Result - Visit 1 (Screening) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_platelets_result_v07	Platelets (k/mm3) - Result - Visit 7 (Day 84) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_platelets_result_v07_2nd	Platelets (k/mm3) - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_platelets_rslt_v09	Platelets (k/mm3) - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_platelets_rslt_v10	Platelets (k/mm3) - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_platelets_rslt_v12	Platelets (k/mm3) - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_platelets_sig_v01	Platelets - Clinically Significant - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_platelets_sig_v07	Platelets - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_platelets_sig_v07_2nd	Platelets - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_platelets_sig_v09	Platelets - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_platelets_sig_v10	Platelets - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_platelets_sig_v12	Platelets - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_cmt_v01	Red Blood Cells - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_rbc_cmt_v07	Red Blood Cells - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_rbc_cmt_v07_2nd	Red Blood Cells - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_rbc_cmt_v09	Red Blood Cells - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char

Class	Variable	Label	Description	Format Text
01. Principal	hema_rbc_cmt_v 10	Red Blood Cells - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char
01. Principal	hema_rbc_cmt_v 12	Red Blood Cells - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_rbc_out_v 01	Red Blood Cells - Out Of Range - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_out_v 07	Red Blood Cells - Out Of Range - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_out_v 07_2nd	Red Blood Cells - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_out_v 09	Red Blood Cells - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_out_v 10	Red Blood Cells - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_out_v 12	Red Blood Cells - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_rslt_v 01	Red Blood Cells (m/mm3) - Result - Visit 1 (Screening) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_rbc_rslt_v 07	Red Blood Cells (m/mm3) - Result - Visit 7 (Day 84) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_rbc_rslt_v 07_2nd	Red Blood Cells (m/mm3) - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_rbc_rslt_v 09	Red Blood Cells (m/mm3) - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_rbc_rslt_v 10	Red Blood Cells (m/mm3) - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_rbc_rslt_v12	Red Blood Cells (m/mm3) - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_rbc_sig_v01	Red Blood Cells - Clinically Significant - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_sig_v07	Red Blood Cells - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_sig_v07_2nd	Red Blood Cells - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_sig_v09	Red Blood Cells - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_sig_v10	Red Blood Cells - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_rbc_sig_v12	Red Blood Cells - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_cmt_v01	White Blood Cells - Comments - Visit 1 (Screening) - [Hematology]		Char
01. Principal	hema_wbc_cmt_v07	White Blood Cells - Comments - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_wbc_cmt_v07_2nd	White Blood Cells - Comments - Second - Visit 7 (Day 84) - [Hematology]		Char
01. Principal	hema_wbc_cmt_v09	White Blood Cells - Comments - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_wbc_cmt_v10	White Blood Cells - Comments - Visit 10 (Post-Intervention) - [Hematology]		Char

Class	Variable	Label	Description	Format Text
01. Principal	hema_wbc_cmt_v12	White Blood Cells - Comments - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Char
01. Principal	hema_wbc_out_v01	White Blood Cells - Out Of Range - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_out_v07	White Blood Cells - Out Of Range - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_out_v07_2nd	White Blood Cells - Out Of Range - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_out_v09	White Blood Cells - Out Of Range - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_out_v10	White Blood Cells - Out Of Range - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_out_v12	White Blood Cells - Out Of Range - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_rslt_v01	White Blood Cells (k/mm3) - Result - Visit 1 (Screening) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_wbc_rslt_v07	White Blood Cells (k/mm3) - Result - Visit 7 (Day 84) - [Hematology]		Numeric .R="Not Randomized"
01. Principal	hema_wbc_rslt_v07_2nd	White Blood Cells (k/mm3) - Result - Second - Visit 7 (Day 84) - [Hematology]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_wbc_rslt_v09	White Blood Cells (k/mm3) - Result - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"
01. Principal	hema_wbc_rslt_v10	White Blood Cells (k/mm3) - Result - Visit 10 (Post-Intervention) - [Hematology]		Numeric .O="Not Obtained" .R="Not Randomized"
01. Principal	hema_wbc_rslt_v12	White Blood Cells (k/mm3) - Result - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_wbc_sig_v01	White Blood Cells - Clinically Significant - Visit 1 (Screening) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_sig_v07	White Blood Cells - Clinically Significant - Visit 7 (Day 84) - [Hematology]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_sig_v07_2nd	White Blood Cells - Clinically Significant - Second - Visit 7 (Day 84) - [Hematology]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_sig_v09	White Blood Cells - Clinically Significant - Other: Visit 9 (Day 140) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_sig_v10	White Blood Cells - Clinically Significant - Visit 10 (Post-Intervention) - [Hematology]		.O="Not Obtained" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_wbc_sig_v12	White Blood Cells - Clinically Significant - Other: Visit 12 (6-Month Follow-Up) - [Hematology]	Not a standard visit for this dataset	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Section 15: Other Lab Tests

Class	Variable	Label	Description	Format Text
01. Principal	othlab_clin_sig1-7	Clinically Significant - # - [Other Lab Tests]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No"
01. Principal	othlab_collected_dt1-7	Date Specimen Collected - # - [Other Lab Tests]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	othlab_comments1-7	Comments - # - [Other Lab Tests]		Char
01. Principal	othlab_fasting	Fasting - [Other Lab Tests]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 9="Unknown"
01. Principal	othlab_labtest1-7	Lab Test - # - [Other Lab Tests]		Char
01. Principal	othlab_num	Number Of Tests - [Other Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	othlab_out_range1-7	Out Of Range - # - [Other Lab Tests]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	othlab_result1-7	Result - # - [Other Lab Tests]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	othlab_units1-7	Units - # - [Other Lab Tests]		Char
01. Principal	othlab_visit_dt	Visit Date - [Other Lab Tests]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	othlab_visit_type	Visit Type - [Other Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 1="Visit 1 (Screening)" 7="Visit 7 (Day 84)" 9="Visit 9 (Day 140)" 10="Visit 10 (Post-Intervention)"

Section 16: Randomization

Class	Variable	Label	Description	Format Text
01. Principal	rand_dt	Date Participant Randomized - [Randomization]		SAS Date .R="Not Randomized"
01. Principal	rand_dt2	Date Participant Randomized - 2 - [Randomization]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	rand_has_second	Participant Has Second Randomization Number - [Randomization]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	rand_number	Randomization Number - [Randomization]		Numeric .R="Not Randomized"
01. Principal	rand_number2	Randomization Number - 2 - [Randomization]		Numeric .N="N/A" .R="Not Randomized"

Section 17: Intervention Administration

Class	Variable	Label	Description	Format Text
01. Principal	intadm_admin_st udy_vis_v03	Agent Administered At Study Visit - Visit 3 (Baseline Visit) - [Intervention Administration]		Numeric .R="Not Randomized"
01. Principal	intadm_admin_st udy_vis_v04	Agent Administered At Study Visit - Visit 4 (Day 14) - [Intervention Administration]		Numeric .R="Not Randomized"
01. Principal	intadm_admin_st udy_vis_v05	Agent Administered At Study Visit - Visit 5 (Day 28) - [Intervention Administration]		Numeric .R="Not Randomized"
01. Principal	intadm_admin_st udy_vis_v06	Agent Administered At Study Visit - Visit 6 (Day 56) - [Intervention Administration]		Numeric .R="Not Randomized"
01. Principal	intadm_admin_st udy_vis_v07	Agent Administered At Study Visit - Visit 7 (Day 84) - [Intervention Administration]		Numeric .R="Not Randomized"
01. Principal	intadm_admin_st udy_vis_v08	Agent Administered At Study Visit - Visit 8 (Day 112) - [Intervention Administration]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	intadm_admin_st udy_vis_v09	Agent Administered At Study Visit - Visit 9 (Day 140) - [Intervention Administration]		Numeric .R="Not Randomized"
01. Principal	intadm_reason_n ot_adm_v03	Explain Why Agent Not Administered - Visit 3 (Baseline Visit) - [Intervention Administration]		Char
01. Principal	intadm_reason_n ot_adm_v04	Explain Why Agent Not Administered - Visit 4 (Day 14) - [Intervention Administration]		Char
01. Principal	intadm_reason_n ot_adm_v05	Explain Why Agent Not Administered - Visit 5 (Day 28) - [Intervention Administration]		Char
01. Principal	intadm_reason_n ot_adm_v06	Explain Why Agent Not Administered - Visit 6 (Day 56) - [Intervention Administration]		Char

Class	Variable	Label	Description	Format Text
01. Principal	intadm_reason_not_adm_v07	Explain Why Agent Not Administered - Visit 7 (Day 84) - [Intervention Administration]		Char
01. Principal	intadm_reason_not_adm_v08	Explain Why Agent Not Administered - Visit 8 (Day 112) - [Intervention Administration]		Char
01. Principal	intadm_reason_not_adm_v09	Explain Why Agent Not Administered - Visit 9 (Day 140) - [Intervention Administration]		Char

Section 18: Agent Interruption

Class	Variable	Label	Description	Format Text
01. Principal	ag_int_agent_restarted	Agent Restarted - [Agent Interruption]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	ag_int_reason_restarted	Specify Reason Restarted - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Participant Decision" 2="Investigator Decision"
01. Principal	ag_int_reason_stopped1-2	Reason Stopped - # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Participant Decision" 2="Investigator Decision"
01. Principal	ag_int_restarted_dt	Specify Date Restarted - [Agent Interruption]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ag_int_specify_reason_stopped1-2	Specify Reason Stopped - # - [Agent Interruption]		Char
01. Principal	ag_int_stopped_dt1-2	Specify Date Stopped - # - [Agent Interruption]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ag_int_visit_type	Visit Type - [Agent Interruption]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 5="Visit 5 (Day 28)" 6="Visit 6 (Day 56)" 7="Visit 7 (Day 84)" 10="Visit 10 (Post-Intervention)"

Section 19: Compliance

Class	Variable	Label	Description	Format Text
01. Principal	comp_compliant	Participant Compliant - [Compliance]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	comp_firstdose_received_dt	Date First Dose Received By Subject - [Compliance]		SAS Date .R="Not Randomized"
01. Principal	comp_lastdose_received_dt	Date Last Dose Received By Subject - [Compliance]		SAS Date .R="Not Randomized"
01. Principal	comp_missed_any_doses	Were Any Doses Missed - [Compliance]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	comp_noncomp_reason	Specify Reason For Noncompliance - [Compliance]		Char
01. Principal	comp_num_interruptions	Number Of Interruptions - [Compliance]		Numeric .R="Not Randomized"

Section 20: Post-Intervention Biopsy/Pathology

Class	Variable	Label	Description	Format Text
01. Principal	postbx_collected_dt_rand	Date Specimen Collected - Random Biopsy - [Post-Intervention Biopsy/Pathology]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	postbx_collected_dt_targ	Date Specimen Collected - Targeted Biopsy - [Post-Intervention Biopsy/Pathology]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	postbx_num_gleason_rand	Gleason Score Primary Pattern Number - Random Biopsy - [Post-Intervention Biopsy/Pathology]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	postbx_num_gleason_targ	Gleason Score Primary Pattern Number - Targeted Biopsy - [Post-Intervention Biopsy/Pathology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	postbx_num_pos_cores_rand	Number Of Positive Cores - Random Biopsy - [Post-Intervention Biopsy/Pathology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	postbx_num_pos_cores_targ	Number Of Positive Cores - Targeted Biopsy - [Post-Intervention Biopsy/Pathology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	postbx_specify_rand	Specify Other Biopsy - Random Biopsy - [Post-Intervention Biopsy/Pathology]		Char
01. Principal	postbx_specify_targ	Specify Other Biopsy - Targeted Biopsy - [Post-Intervention Biopsy/Pathology]		Char
01. Principal	postbx_total_cores_rand	Total Number Of Cores - Random Biopsy - [Post-Intervention Biopsy/Pathology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	postbx_total_cores_targ	Total Number Of Cores - Targeted Biopsy - [Post-Intervention Biopsy/Pathology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	postbx_txt_gleason_rand	Gleason Score Primary Pattern Text - Random Biopsy - [Post-Intervention Biopsy/Pathology]		Char
01. Principal	postbx_txt_gleason_targ	Gleason Score Primary Pattern Text - Targeted Biopsy - [Post-Intervention Biopsy/Pathology]		Char
01. Principal	postbx_type_bx_rand	Type Of Biopsy - Random Biopsy - [Post-Intervention Biopsy/Pathology]		.F="No Record For This Visit" .R="Not Randomized" 1="MR-US fusion" 2="TRUS-guided"
01. Principal	postbx_type_bx_targ	Type Of Biopsy - Targeted Biopsy - [Post-Intervention Biopsy/Pathology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="MR-US fusion" 2="TRUS-guided"

Section 21: Off Study

Class	Variable	Label	Description	Format Text
01. Principal	offstdy_form_dt	Form Date - [Off Study]		SAS Date
01. Principal	offstdy_last_contact_dt	Date Of Last Contact - [Off Study]		SAS Date
01. Principal	offstdy_last_takenn_dt	Date Last Study Agent Taken - [Off Study]		SAS Date .N="N/A"
01. Principal	offstdy_off_followup_dt	Date Off Follow-up - [Off Study]		SAS Date .N="N/A"
01. Principal	offstdy_off_study_dt	Date Off Study - [Off Study]		SAS Date
01. Principal	offstdy_on_followup_dt	Date On Follow-up - [Off Study]		SAS Date .N="N/A"
01. Principal	offstdy_other_reason	Other Reason Explanation - [Off Study]		Char
01. Principal	offstdy_reason	Reason Off Study - [Off Study]		1="Study Complete" 2="Ineligible" 5="Participant Withdrawal" 6="Death" 8="Other, specify"

Section 22: Verification Form

Class	Variable	Label	Description	Format Text
01. Principal	verif_form_dt	Form Date - [Verification Form]		SAS Date .R="Not Randomized"
01. Principal	verif_signature_dt	Date Of Signature - [Verification Form]		SAS Date .R="Not Randomized"
01. Principal	verif_signature_present	Investigator Signature Present - [Verification Form]		.R="Not Randomized" 1="Yes"

Section 23: Comments

Class	Variable	Label	Description	Format Text
01. Principal	cmt_comments1-3	Comments - # - [Comments]		Char
01. Principal	cmt_field_name1-3	Field Name - # - [Comments]		Char
01. Principal	cmt_form_code1-3	Form Code - # - [Comments]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="COMM1 - Comments Page 1" 2="COMM2 - Comments Page 2" 3="CONMD - Concomitant Meds" 4="OFFST - Off Study" 5="RAND - Randomization"
01. Principal	cmt_form_dt1-3	Field Date - # - [Comments]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	cmt_num	Number Of Comments - [Comments]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	cmt_visit_type1-3	Visit Type - # - [Comments]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 2="Visit 2 (Randomization)" 5="Visit 5 (Day 28)" 10="Visit 10 (Post-Intervention)" 12="Visit 12 (6-Month Follow-Up)"