

MDA2016-08-02 - Enhanced Person Data Dictionary

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Document Summary

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MDA2016-08-02 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	mrno	Participant ID (MRNO)		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	build_dt	Build Date		SAS Date

Section 3: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_num	Number Of Adverse Events The Participant Experienced During The Study - [Adverse Events]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Section 4: Registration

Class	Variable	Label	Description	Format Text
01. Principal	reg_accession_num	Accession Number - [Registration]		Numeric
01. Principal	reg_age	Age At Registration - [Registration]	Age was calculated using Reg_Date and DOB that was in MM/YYYY format. DOB Day was set to 28.	Numeric
01. Principal	reg_biopsy_spec_col	Agree To Breast Core Biopsy Procedures And Specimen Collection For Described Research Studies - [Registration]		.M="Missing" 0="No" 1="Yes" 2="N/A"
01. Principal	reg_consent_dt	Date Informed Consent Signed - [Registration]		SAS Date
01. Principal	reg_consent_version_dt	Version Date Of Informed Consent - [Registration]		SAS Date
01. Principal	reg_consortia	Registering Consortium - [Registration]		1="TX035 (MD Anderson Cancer Center)"
01. Principal	reg_contact_future	Participant agreed To Be Contact About Future Research - [Registration]		.M="Missing" 0="No" 1="Yes"
01. Principal	reg_contact_results	Participant Agreed To Be Contacted To See If She Wishes To Learn About Results - [Registration]		.M="Missing" 0="No" 1="Yes"
01. Principal	reg_country	Participant Country Code - [Registration]		1="USA"
01. Principal	reg_ethnicity	Ethnicity - [Registration]		1="Hispanic or Latino" 2="Not Hispanic or Latino" 6="Unknown" 7="Not Reported"
01. Principal	reg_future_research	Left Over Biopsy Samples And Information May Be Used For Future Research - [Registration]		.M="Missing" 0="No" 1="Yes" 2="N/A"
01. Principal	reg_gender	Gender - [Registration]		0="Male" 1="Female" 3="Unspecified" 6="Unknown"
01. Principal	reg_informed_consent_version	Version Of Informed Consent - [Registration]		Char

Class	Variable	Label	Description	Format Text
01. Principal	reg_institution	Registering Institution - [Registration]		1="M. D. Anderson Cancer Center"
01. Principal	reg_interval_dt	Interval Date - [Registration]		SAS Date
01. Principal	reg_non_biopsy_kept	Non-Biopsy Samples May Be Kept In Biobank For Future Health Research - [Registration]		.M="Missing" 0="No" 1="Yes" 2="N/A"
01. Principal	reg_other_payment_method	Other Method Of Payment - [Registration]		Char
01. Principal	reg_payment_method1-2	Payment Method - # - [Registration]		.F="No Record For This Visit" 1="Private Insurance" 2="Medicaid" 3="Medicaid and Medicare" 4="Military Sponsored (including CHAMPUS & TriCare)" 5="Veterans Sponsored" 6="No Means of Payment (No Insurance)" 7="Medicare" 8="Medicare and Private Insurance" 9="Self-Pay (No Insurance)" 10="Managed Care/Medicare" 11="State Supplemental Health Insurance" 12="Military or Veterans Sponsored, NOS" 13="Other" 14="Unknown"
01. Principal	reg_payment_selected1-2	Payment Selected - # - [Registration]		.F="No Record For This Visit" 0="False" 1="True"
01. Principal	reg_race	Race - [Registration]		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"
01. Principal	reg_race_eth	Race Ethnicity Combination - [Registration]		1="White, Non-Hispanic" 2="Black, Non-Hispanic" 3="Hispanic" 4="Native Hawaiian or Other Pacific Islander" 5="Asian" 6="American Indian or Alaska Native" 7="Unknown" 8="Not Reported"
01. Principal	reg_race_selected	Race Selected - [Registration]		0="False" 1="True"
01. Principal	reg_registration_dt	Registering Date - [Registration]		SAS Date
01. Principal	reg_registration_time	Registering Time - [Registration]		SAS Time

Class	Variable	Label	Description	Format Text
01. Principal	reg_samples_info_kept	Samples And Information May Be Kept In Biobank For Future Research - [Registration]		.M="Missing" 0="No" 1="Yes" 2="N/A"
01. Principal	reg_screen1_dt	Screen 1 Date - [Registration]		SAS Date
01. Principal	reg_tac0	TAC-0 (Signed Informed Consent Document And Before Intervention) - [Registration]		0="No" 1="Yes"
01. Principal	reg_tob_alc_use	Tobacco And Alcohol Use Information May Be Used In Future Research - [Registration]		.M="Missing" 0="No" 1="Yes"
01. Principal	reg_visit_dt	Visit Date - [Registration]		SAS Date

Section 5: Dose Assignment/Intervention Admin

Class	Variable	Label	Description	Format Text
01. Principal	dose_assigned	Participant Assigned To Receive - [Dose Assignment/Intervention Admin]		.M="Missing" .N="N/A" 1="TAC1" 2="TAC2" 3="TAC3" 4="TAC4"
01. Principal	dose_enroll_dt	Enrollment Date - [Dose Assignment/Intervention Admin]		SAS Date .M="Missing" .N="N/A"
01. Principal	dose_interval_dt	Interval Date - [Dose Assignment/Intervention Admin]		SAS Date .M="Missing"
01. Principal	dose_participant_eligible	Is Participant Eligible For Inclusion On This Protocol - [Dose Assignment/Intervention Admin]		0="No" 1="Yes"
01. Principal	dose_provided_dt	Date Agent Provided To Participant - [Dose Assignment/Intervention Admin]		SAS Date .M="Missing" .N="N/A"
01. Principal	dose_screen2_dt	Screen 2 Date - [Dose Assignment/Intervention Admin]		SAS Date .M="Missing" .N="N/A"
01. Principal	dose_start_dt	Date Agent Started - [Dose Assignment/Intervention Admin]		SAS Date .M="Missing" .N="N/A"
01. Principal	dose_tac	Treatment Assignment Code (TAC) - [Dose Assignment/Intervention Admin]		.M="Missing" .N="N/A" 1="TAC1: Bexarotene 1% gel 10 mg applied topically to one unaffected breast QOD x 4 weeks" 2="TAC2: Bexarotene 1% gel 10 mg applied topically to one unaffected breast QOD x 7 days, then QD x 3 weeks" 3="TAC3: Bexarotene 1% gel 10 mg applied topically to one unaffected breast QOD x 7 days, then 10 mg QD x 1 week, then 20 mg QD x 2 weeks" 4="TAC4: Bexarotene 1% gel MTD applied topically to one unaffected breast x 4 weeks"

Section 6: Baseline Medical/Surgical History

Class	Variable	Label	Description	Format Text
01. Principal	medsurhist_all_sys_normal	Check Here If All Body Systems Are Normal - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="False" 1="True"
01. Principal	medsurhist_allergy_comments	Comments For Allergy/Drug Sensitivity - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_allergy_status	Allergy/Drug Sensitivity Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_breasts_comments	Comments For Breasts - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_breasts_status	Breasts Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_cardio_comments	Comments For Cardiovascular - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_cardio_status	Cardiovascular Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_derm_comments	Comments For Dermatologic - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_derm_status	Dermatologic Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"

Class	Variable	Label	Description	Format Text
01. Principal	medsurhist_endo_comments	Comments For Endocrine/Metabolic - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_endo_status	Endocrine/Metabolic Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_gastro_comments	Comments For Gastrointestinal - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_gastro_status	Gastrointestinal Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_genit_comments	Comments For Genitourinary - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_genit_status	Genitourinary Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_heart_comments	Comments For H/E/E/N/T - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_heart_status	H/E/E/N/T Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_hema_comments	Comments For Hematopoietic/Lymph - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_hema_status	Hematopoietic/Lymph Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"

Class	Variable	Label	Description	Format Text
01. Principal	medsurhist_interval_dt	Interval Date - [Baseline Medical/Surgical History]		SAS Date .R="Not Randomized"
01. Principal	medsurhist_musc_comments	Comments For Musculoskeletal - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_musc_status	Musculoskeletal Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_neck_comments	Comments For Neck - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_neck_status	Neck Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_neuro_comments	Comments For Neurologic - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_neuro_status	Neurologic Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_other_body_site	Specify Other Body System Site - [Baseline Medical/Surgical History]		.N="N/A" .R="Not Randomized" 1="General" 2="Psychiatric" 3="Other"
01. Principal	medsurhist_other_comments	Comments For Other Body System Site - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_other_status	Other Body System Site Status - [Baseline Medical/Surgical History]		.N="N/A" .R="Not Randomized" 1="Abnormal" 2="Normal"

Class	Variable	Label	Description	Format Text
01. Principal	medsurhist_resp_comments	Comments For Respiratory - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_resp_status	Respiratory Status - [Baseline Medical/Surgical History]		.R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_visit_dt	Visit Date - [Baseline Medical/Surgical History]		SAS Date .R="Not Randomized"

Section 7: Family History

Class	Variable	Label	Description	Format Text
01. Principal	famhist_age_at_dx1-9	Age At Diagnosis - # - [Family History]		Numeric .M="Missing" .N="N/A" .R="Not Randomized" 999="Unknown"
01. Principal	famhist_cancer_hist	Does Participant Have A Family History Of Breast Or Any Other Cancer - [Family History]	If this variable equals 1 (Yes) then the famhist_cancer_type, famhist_comments, famhist_relation, and famhist_age_at_dx variables are filled out. This is completed for 1 to 9 cancers.	.R="Not Randomized" 0="No" 1="Yes (Please Complete The Listing Below)"
01. Principal	famhist_cancer_type1-9	Cancer Type Of Family Member - # - [Family History]		Char
01. Principal	famhist_comments1-9	Comments - # - [Family History]		Char
01. Principal	famhist_interval_dt	Interval Date - [Family History]		SAS Date .R="Not Randomized"
01. Principal	famhist_relation1-9	Relation To Participant - # - [Family History]		Char
01. Principal	famhist_visit_dt	Visit Date - [Family History]		SAS Date .R="Not Randomized"

Section 8: Reproductive History

Class	Variable	Label	Description	Format Text
01. Principal	reprohist_1stbirth_age	Age At First Live Birth - [Reproductive History]		Numeric .R="Not Randomized" .U="Unknown"
01. Principal	reprohist_bra_cup_size	Bra Cup Size - [Reproductive History]		Char
01. Principal	reprohist_interval_dt	Interval Date - [Reproductive History]		SAS Date .R="Not Randomized"
01. Principal	reprohist_last_period_dt	Date Of Last Menstrual Period - [Reproductive History]		SAS Date .R="Not Randomized" .U="Unknown"
01. Principal	reprohist_last_period_flag	Date Of Last Menstrual Period Imputed Date Flag - [Reproductive History]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	reprohist_menarche_age	Age At Menarche - [Reproductive History]		Numeric .R="Not Randomized"
01. Principal	reprohist_meno_age	Age At Menopause - [Reproductive History]		Numeric .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	reprohist_meno_cause	How Was Menopause Induced - [Reproductive History]		.R="Not Randomized" 1="Naturally-induced" 2="Surgically-induced" 3="Chemically-induced" 7="N/A"
01. Principal	reprohist_num_children	Number Of Children - [Reproductive History]		Numeric .R="Not Randomized"
01. Principal	reprohist_visit_dt	Visit Date - [Reproductive History]		SAS Date .R="Not Randomized"

Section 9: Previous Intervention

Class	Variable	Label	Description	Format Text
01. Principal	prev_inter_hrt	Has the participant ever used Hormonal Replacement Therapy, SERMS, Aromatase Inhibitors (AIs) or oral Contraceptives? - [Previous Intervention]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	prev_inter_hrt_cmt	Hormonal Replacement Therapy, SERMS, Aromatase Inhibitors (AIs) or oral Contraceptives Comments/Results - [Previous Intervention]		Char
01. Principal	prev_inter_interval_dt	Interval Date - [Previous Intervention]		SAS Date .R="Not Randomized"
01. Principal	prev_inter_surg	Has the participant ever had Breast Surgery (including biopsies)? - [Previous Intervention]		.R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	prev_inter_surg_cmt	Breast Surgery (including biopsies) Comments/Results - [Previous Intervention]		Char
01. Principal	prev_inter_therapy_began_dt1-7	Previous Therapy Listing: Date Began - # - [Previous Intervention]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" .U="Unknown"
01. Principal	prev_inter_therapy_began_flag1-7	Previous Therapy Listing: Date Began Imputed Date Flag - # - [Previous Intervention]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	prev_inter_therapy_cmt1-7	Previous Therapy Listing: Comments - # - [Previous Intervention]		Char
01. Principal	prev_inter_therapy_comp_dt1-7	Previous Therapy Listing: Date Completed - # - [Previous Intervention]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	prev_inter_therapy_comp_flag1-7	Previous Therapy Listing: Date Completed Imputed Date Flag - # - [Previous Intervention]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	prev_inter_therapy_details1-7	Previous Therapy Listing: Therapy Details - # - [Previous Intervention]		Char
01. Principal	prev_inter_therapy_side1-7	Previous Therapy Listing: Breast Side (Right/Left) - # - [Previous Intervention]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Left" 2="Right"
01. Principal	prev_inter_therapy_type1-7	Previous Therapy Listing - # - [Previous Intervention]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Aromatase Inhibitors (AIs)" 2="Breast Surgery" 3="Hormonal Replacement Therapy (HRT)" 4="Oral Contraceptives" 5="Selective estrogen receptor modulators (SERMs)"
01. Principal	prev_inter_visit_dt	Visit Date - [Previous Intervention]		SAS Date .R="Not Randomized"

Section 10: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	base_symp_comments1-7	Comments - # - [Baseline Symptoms]		Char
01. Principal	base_symp_grade1-7	Grade - # - [Baseline Symptoms]		.N="N/A" .R="Not Randomized" 1="Mild (hardly noticeable)" 2="Moderate (noticeable/no bother)" 3="Severe (severe discomfort)" 4="Life Threatening (immediate risk of death)"
01. Principal	base_symp_interval_dt	Interval Date - [Baseline Symptoms]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	base_symp_no_symptoms	Check Here If None Reported (No Baseline Symptoms) - [Baseline Symptoms]		.R="Not Randomized" 0="False" 1="True"
01. Principal	base_symp_onset_dt1-7	Onset Date - # - [Baseline Symptoms]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	base_symp_onset_dt_imputed1-7	Onset Date Is A Partial Date (Imputed Date) - # - [Baseline Symptoms]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	base_symp_symptom_desc1-7	Symptom Description - # - [Baseline Symptoms]		Char
01. Principal	base_symp_visit_dt	Visit Date - [Baseline Symptoms]		SAS Date .M="Missing" .R="Not Randomized"

Section 11: Baseline Alcohol

Class	Variable	Label	Description	Format Text
01. Principal	alcohol_age_began	At What Age Did You Begin Drinking Regularly - [Baseline Alcohol]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	alcohol_age_began_b	At What Age Did You Begin Drinking Regularly Refused / Not Sure - [Baseline Alcohol]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Refused" 99="Do not know/Not sure"
01. Principal	alcohol_alcohol_type_checked	Alcohol Type Checked - [Baseline Alcohol]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	alcohol_at_least_12	In Your Entire Life Have You Had At Least 12 Drinks Of Any Alcohol - [Baseline Alcohol]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="Refused" 99="Do not know / Not sure"
01. Principal	alcohol_beer	Alcohol Type Selected - Beer - [Baseline Alcohol]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	alcohol_days_5plus	Past 12 Months How Many Days 5 Or More Drinks - [Baseline Alcohol]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	alcohol_days_timeframe	Timeframe - [Baseline Alcohol]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Week" 2="Month" 3="Year" 4="Refused" 99="Do not know / Not sure"
01. Principal	alcohol_drinks_per_day	Past 12 Months How Many Drinks Per Day - [Baseline Alcohol]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	alcohol_ever_5plus_daily	Ever Drink 5 Or More Drinks Almost Every Day - [Baseline Alcohol]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Refused" 99="Do not know / Not sure"

Class	Variable	Label	Description	Format Text
01. Principal	alcohol_heaviest_drinks	At Heaviest Point, How Many Drinks Per Day - [Baseline Alcohol]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	alcohol_heaviest_drinks_b	At Heaviest Point, How Many Drinks Per Day Refused / Not Sure - [Baseline Alcohol]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Refused" 99="Do not know/Not sure"
01. Principal	alcohol_interval_dt	Interval Date - [Baseline Alcohol]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	alcohol_liquor	Alcohol Type Selected - Liquor - [Baseline Alcohol]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	alcohol_number_of_days	Number Of Days You Drank Based On Timeframe Provided - [Baseline Alcohol]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	alcohol_since_last_drink	How Long Since You Drank Regularly - [Baseline Alcohol]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Never drank regularly" 1="Within the past month (0 to 1 month ago)" 2="Between 1 and 3 months (1 to 3 months ago)" 3="Between 3 and 6 months (3 to 6 months ago)" 4="Between 3 and 6 months (6 to 12 months ago)" 5="Between 1 and 5 years (1 to 5 years ago)" 6="Between 5 and 15 years (5 to 15 years ago)" 7="More than 15 years ago" 99="Do not know / Not sure"
01. Principal	alcohol_verified_dt	Verified Date - [Baseline Alcohol]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	alcohol_verified_time	Verified Time - [Baseline Alcohol]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	alcohol_visit_dt	Visit Date - [Baseline Alcohol]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	alcohol_wine	Alcohol Type Selected - Wine - [Baseline Alcohol]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	alcohol_wine_cooler	Alcohol Type Selected - Wine Cooler - [Baseline Alcohol]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	alcohol_years_drink	How Many Years Have You Been Drinking Or Did Drink - [Baseline Alcohol]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	alcohol_years_drink_b	How Many Years Have You Been Drinking Or Did Drink Refused / Not Sure - [Baseline Alcohol]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Refused" 99="Do not know/Not sure"

Section 12: Baseline Tobacco

Class	Variable	Label	Description	Format Text
01. Principal	tabacco_last_used_other	How Long Since Regular Use Of Other Forms Of Tobacco - [Baseline Tobacco]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Never used other forms of tobacco regularly" 1="Within the past month (0 to 1 month ago)" 2="Between 1 and 3 months (1 to 3 months ago)" 3="Between 3 and 6 months (3 to 6 months ago)" 4="Between 6 and 12 months (6 to 12 months ago)" 5="Between 1 and 5 years (1 to 5 years ago)" 6="Between 5 and 15 years (5 to 15 years ago)" 7="More than 15 years ago" 8="Do not know/Not sure"
01. Principal	tabacco_oth_timeframe	How Often Do/Did You Use Other Forms Of Tobacco (Per Day, Week, Month, Year) - [Baseline Tobacco]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Day" 2="Week" 3="Month" 4="Year" 5="Ever"
01. Principal	tabacco_after_waking	How Soon After You Wake Up Do You Smoke Your First Cigarette - [Baseline Tobacco]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Within 30 Minutes" 2="After 30 Minutes"
01. Principal	tabacco_cigarettes	Regularly Used 'Cigarettes' Was Checked - [Baseline Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tabacco_cigarettes_100	Have You Smoked At Least 100 Cigarettes (5 Packs) In Entire Life - [Baseline Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tabacco_cigarettes_daily	On Average, How Many Cigarettes Per Day - [Baseline Tobacco]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	tabacco_cigarettes_now	Do You Now Smoke Cigarettes - [Baseline Tobacco]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Never Smoked" 1="Not At All" 2="Some Days" 3="Everyday"

Class	Variable	Label	Description	Format Text
01. Principal	tobacco_cigars	Regularly Used 'Traditional Cigars, Cigarillos Or Filtered Cigars' Checked - [Baseline Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_ever_others	Have You Ever Used Other Forms Of Tobacco, Not Including Cigarettes - [Baseline Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_hookah	Regularly Used 'Hookah' Was Checked - [Baseline Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_interval_dt	Interval Date - [Baseline Tobacco]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tobacco_last_smoked	How Long Has It Been Since You Last Smoked A Cigarette - [Baseline Tobacco]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="I Smoked A Cigarette Today (At Least One Puff)" 2="1-7 Days" 3="Less Than 1 Month" 4="Less Than 1 Year" 5="More Than 1 Year" 99="Do Not Know / Do Not Remember"
01. Principal	tobacco_last_smoked_mo	Number Of Months Since Last Cigarette - [Baseline Tobacco]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	tobacco_last_smoked_yr	Number Of Years Since Last Cigarette - [Baseline Tobacco]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	tobacco_lived_30	Past 30 Days, Live Where People Smoke Indoors - [Baseline Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_lived_ever	Ever Live Where People Smoked Indoors - [Baseline Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_lived_years	In Total, For About How Many Years Live Where People Smoked Indoors - [Baseline Tobacco]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 99="Every Year"
01. Principal	tobacco_living_with	Are You Currently Living With A Smoker - [Baseline Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	tobacco_never_smoked_reg	Check Here If You Have Never Smoked Cigarettes Regularly - [Baseline Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="Unchecked" 1="Checked: Never Smoked Cigarettes Regularly"
01. Principal	tobacco_other_freq	How Often Do/Did You Use Other Forms Of Tobacco - [Baseline Tobacco]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Every Day" 2="Some Days"
01. Principal	tobacco_other_freq_num	How Often Do/Did You Use Other Forms Of Tobacco (Number) - [Baseline Tobacco]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	tobacco_smoking_age	How Old Were You When You First Began Smoking Cigarettes Regularly - [Baseline Tobacco]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	tobacco_smoking_age_1st	How Old Were You When You First Smoked A Cigarette - [Baseline Tobacco]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	tobacco_verified_dt	Verified Date - [Baseline Tobacco]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tobacco_verified_time	Verified Time - [Baseline Tobacco]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tobacco_visit_dt	Visit Date - [Baseline Tobacco]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tobacco_worked_30	Past 30 Days, Worked Where People Smoke Indoors - [Baseline Tobacco]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_worked_ever	Every Work Where People Smoked Indoors - [Baseline Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_worked_years	In Total For About How Many Years Work Where People Smoked Indoor - [Baseline Tobacco]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	tobacco_yrs_smoking	Total Years Of Smoking Cigarettes - [Baseline Tobacco]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 13: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	phys_appear_comments1-3	Comments Required If Abnormal: Appearance - # - [Physical Exam]		Char
01. Principal	phys_appear_status1-3	Status: Appearance - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_bmi1-3	Body Mass Index (BMI) - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	phys_breasts_comments1-3	Comments Required If Abnormal: Breasts - # - [Physical Exam]		Char
01. Principal	phys_breasts_status1-3	Status: Breasts - # - [Physical Exam]		.F="No Record For This Visit" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_diag_bp1-3	Diastolic Blood Pressure (mmHg) - # - [Physical Exam]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	phys_ecog1-3	Eastern Cooperative Oncology Group (ECOG) Performance Status - # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Normal activity. Fully active, able to carry on all pre-disease performance without restriction." 1="Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work." 2="Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours." 3="Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours." 4="Completely disabled; cannot carry on any selfcare; totally confined to bed or chair." 5="Dead"
01. Principal	phys_heart_comments1-3	Comments Required If Abnormal: Heart - # - [Physical Exam]		Char

Class	Variable	Label	Description	Format Text
01. Principal	phys_heart_status1-3	Status: Heart - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_height1-3	Height (cm) - # - [Physical Exam]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	phys_interval_dt1-3	Interval Date - # - [Physical Exam]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	phys_imp_dt1-3	Date Of The First Day Of The Last Menstrual Period (LMP) - # - [Physical Exam]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	phys_imp_dt_flag1-3	Date Of The First Day Of The Last Menstrual Period (LMP) - Imputed Date Flag - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	phys_lungs_comments1-3	Comments Required If Abnormal: Lungs - # - [Physical Exam]		Char
01. Principal	phys_lungs_status1-3	Status: Lungs - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_lymph_comments1-3	Comments Required If Abnormal: Lymph Nodes - # - [Physical Exam]		Char
01. Principal	phys_lymph_status1-3	Status: Lymph Nodes - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_other_body_system1-3	Specify Other Body System Site - # - [Physical Exam]		Char
01. Principal	phys_other_comments1-3	Comments Required If Abnormal: Other Body System - # - [Physical Exam]		Char
01. Principal	phys_other_status1-3	Status: Other Body System - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal"

Class	Variable	Label	Description	Format Text
01. Principal	phys_pulse_rate1-3	Pulse Rate - # - [Physical Exam]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	phys_resp_rate1-3	Respiration Rate - # - [Physical Exam]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	phys_skin_comments1-3	Comments Required If Abnormal: Skin - # - [Physical Exam]		Char
01. Principal	phys_skin_status1-3	Status: Skin - # - [Physical Exam]		.F="No Record For This Visit" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_syst_bp1-3	Systolic Blood Pressure (mmHg) - # - [Physical Exam]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	phys_temp1-3	Temperature (Celsius) - # - [Physical Exam]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	phys_visit_dt1-3	Visit Date - # - [Physical Exam]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	phys_weight1-3	Weight (kg) - # - [Physical Exam]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Section 14: Pregnancy Test

Class	Variable	Label	Description	Format Text
01. Principal	preg_collection_dt1-4	Date Specimen Collected - # - [Pregnancy Test]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	preg_interval_dt1-4	Interval Date - # - [Pregnancy Test]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	preg_lab_result1-4	Pregnancy Test Result - # - [Pregnancy Test]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Negative" 1="Positive" 2="Not Obtained"
01. Principal	preg_reason_not_collected1-4	Reason Pregnancy Data Was Not Collected - # - [Pregnancy Test]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Participant is female and not of childbearing potential"
01. Principal	preg_test_type1-4	Pregnancy Test Type - # - [Pregnancy Test]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Urine" 2="Serum"
01. Principal	preg_visit_dt1-4	Visit Date - # - [Pregnancy Test]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 16: Breast Imaging

Class	Variable	Label	Description	Format Text
01. Principal	imaging_comments	Comments - [Breast Imaging]		Char
01. Principal	imaging_composition	BI-RADS Breast Composition Category - [Breast Imaging]		.R="Not Randomized" 1="Almost Entirely Fat (BI-RADS 1/A)" 2="Scattered Fibroglandular Densities (BI-RADS 2/B)" 3="Heterogeneously Dense (BI-RADS 3/C)" 4="Extremely Dense (BI-RADS 4/D)"
01. Principal	imaging_interval_dt	Interval Date - [Breast Imaging]		SAS Date .R="Not Randomized"
01. Principal	imaging_previous	Previous Breast Imaging Within The Last 6 Months - [Breast Imaging]		.R="Not Randomized" 0="False" 1="True"
01. Principal	imaging_previous_dt	Date Of Previous Breast Imaging - [Breast Imaging]		SAS Date .R="Not Randomized"
01. Principal	imaging_results	Breast Imaging Results - [Breast Imaging]		.M="Missing" .R="Not Randomized" 1="BIRADS 1" 2="BIRADS 2"
01. Principal	imaging_visit_dt	Visit Date - [Breast Imaging]		SAS Date .R="Not Randomized"

Section 17: Clinical Lab - Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_albumin_clin_sig1-3	Lab Test Clinically Significant - Albumin - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_albumin_clin_sig_oth	Lab Test Clinically Significant - Albumin - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_albumin_cmt1-3	Lab Test Comments - Albumin - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_albumin_cmt_oth	Lab Test Comments - Albumin - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_albumin_not_obt1-3	Lab Test Not Obtained - Albumin - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_albumin_not_obt_oth	Lab Test Not Obtained - Albumin - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_albumin_out_range1-3	Lab Test Result - Out Of Range - Albumin - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_albumin_out_range_oth	Lab Test Result - Out Of Range - Albumin - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_albumin_result1-3	Lab Test Result - Albumin (g/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_albumin_result_oth	Lab Test Result - Albumin (g/dL) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alk_clin_sig1-3	Lab Test Clinically Significant - Alkaline Phosphatase - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_alk_clin_sig_oth	Lab Test Clinically Significant - Alkaline Phosphatase - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_alk_cmt1-3	Lab Test Comments - Alkaline Phosphatase - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_alk_cmt_oth	Lab Test Comments - Alkaline Phosphatase - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_alk_not_obt1-3	Lab Test Not Obtained - Alkaline Phosphatase - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_alk_not_obt_oth	Lab Test Not Obtained - Alkaline Phosphatase - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_alk_out_range1-3	Lab Test Result - Out Of Range - Alkaline Phosphatase - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_alk_out_range_oth	Lab Test Result - Out Of Range - Alkaline Phosphatase - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_alk_res ult1-3	Lab Test Result - Alkaline Phosphatase (IU/L) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_alk_res ult_oth	Lab Test Result - Alkaline Phosphatase (IU/L) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_bicarb_clin_sig1-3	Lab Test Clinically Significant - Bicarbonate - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bicarb_clin_sig_oth	Lab Test Clinically Significant - Bicarbonate - Other Visit Date - [Clinical Lab - Blood Chemistry]		.M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_bicarb_cmt1-3	Lab Test Comments - Bicarbonate - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_bicarb_cmt_oth	Lab Test Comments - Bicarbonate - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_bicarb_not_obt1-3	Lab Test Not Obtained - Bicarbonate - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bicarb_not_obt_oth	Lab Test Not Obtained - Bicarbonate - Other Visit Date - [Clinical Lab - Blood Chemistry]		.M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bicarb_out_range1-3	Lab Test Result - Out Of Range - Bicarbonate - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bicarb_out_range_oth	Lab Test Result - Out Of Range - Bicarbonate - Other Visit Date - [Clinical Lab - Blood Chemistry]		.M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bicarb_result1-3	Lab Test Result - Bicarbonate (mEq/L) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	bldchem_bicarb_result_oth	Lab Test Result - Bicarbonate (mEq/L) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_bilirubin_clin_sig1-3	Lab Test Clinically Significant - Total Bilirubin - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_bilirubin_clin_sig_oth	Lab Test Clinically Significant - Total Bilirubin - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bilirubin_cmt1-3	Lab Test Comments - Total Bilirubin - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_bilirubin_cmt_oth	Lab Test Comments - Total Bilirubin - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_bilirubin_not_obt1-3	Lab Test Not Obtained - Total Bilirubin - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bilirubin_not_obt_oth	Lab Test Not Obtained - Total Bilirubin - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bilirubin_out_range1-3	Lab Test Result - Out Of Range - Total Bilirubin - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bilirubin_out_range_oth	Lab Test Result - Out Of Range - Total Bilirubin - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bilirubin_result1-3	Lab Test Result - Total Bilirubin (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_bilirubin_result_oth	Lab Test Result - Total Bilirubin (mg/dL) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_bun_clin_sig1-3	Lab Test Clinically Significant - BUN - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_bun_clin_sig_oth	Lab Test Clinically Significant - BUN - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_bun_cmt1-3	Lab Test Comments - BUN - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_bun_cmt_oth	Lab Test Comments - BUN - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bun_no t_obt1-3	Lab Test Not Obtained - BUN - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bun_no t_obt_oth	Lab Test Not Obtained - BUN - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bun_ou t_range1-3	Lab Test Result - Out Of Range - BUN - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bun_ou t_range_oth	Lab Test Result - Out Of Range - BUN - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bun_re sult1-3	Lab Test Result - BUN (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_bun_re sult_oth	Lab Test Result - BUN (mg/dL) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_calcium _clin_sig1-3	Lab Test Clinically Significant - Calcium - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_calcium _clin_sig_oth	Lab Test Clinically Significant - Calcium - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_calcium _cmt1-3	Lab Test Comments - Calcium - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_calcium _cmt_oth	Lab Test Comments - Calcium - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_calcium _not_obt1-3	Lab Test Not Obtained - Calcium - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_calcium _not_obt_oth	Lab Test Not Obtained - Calcium - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_calcium_out_range1-3	Lab Test Result - Out Of Range - Calcium - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_calcium_out_range_oth	Lab Test Result - Out Of Range - Calcium - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_calcium_result1-3	Lab Test Result - Calcium (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_calcium_result_oth	Lab Test Result - Calcium (mg/dL) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_chloride_clin_sig1-3	Lab Test Clinically Significant - Chloride - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_chloride_clin_sig_oth	Lab Test Clinically Significant - Chloride - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_chloride_cmt1-3	Lab Test Comments - Chloride - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_chloride_cmt_oth	Lab Test Comments - Chloride - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_chloride_not_obt1-3	Lab Test Not Obtained - Chloride - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_chloride_not_obt_oth	Lab Test Not Obtained - Chloride - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_chloride_out_range1-3	Lab Test Result - Out Of Range - Chloride - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_chloride_out_range_oth	Lab Test Result - Out Of Range - Chloride - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_chloride_result1-3	Lab Test Result - Chloride (mEq/L) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_chloride_result_oth	Lab Test Result - Chloride (mEq/L) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_cholesterol_clin_sig1-3	Lab Test Clinically Significant - Total Cholesterol - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_cholesterol_clin_sig_oth	Lab Test Clinically Significant - Total Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		.M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_cholesterol_cmt1-3	Lab Test Comments - Total Cholesterol - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_cholesterol_cmt_oth	Lab Test Comments - Total Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_cholesterol_not_obt1-3	Lab Test Not Obtained - Total Cholesterol - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_cholesterol_not_obt_oth	Lab Test Not Obtained - Total Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		.M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_cholesterol_out_range1-3	Lab Test Result - Out Of Range - Total Cholesterol - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_cholesterol_out_range_oth	Lab Test Result - Out Of Range - Total Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		.M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_cholesterol_result1-3	Lab Test Result - Total Cholesterol (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_cholstrl_result_oth	Lab Test Result - Total Cholesterol (mg/dL) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_creatinine_clin_sig1-3	Lab Test Clinically Significant - Creatinine - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_creatinine_clin_sig_oth	Lab Test Clinically Significant - Creatinine - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_creatinine_cmt1-3	Lab Test Comments - Creatinine - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_creatinine_cmt_oth	Lab Test Comments - Creatinine - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_creatinine_not_obt1-3	Lab Test Not Obtained - Creatinine - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_creatinine_not_obt_oth	Lab Test Not Obtained - Creatinine - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_creatinine_out_range1-3	Lab Test Result - Out Of Range - Creatinine - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_creatinine_out_range_oth	Lab Test Result - Out Of Range - Creatinine - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_creatinine_result1-3	Lab Test Result - Creatinine (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_creatinine_result_oth	Lab Test Result - Creatinine (mg/dL) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_fasting1-3	Fasting - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown" 3="Unknown with Glucose, Triglycerides, Cholesterol, and HDL Cholesterol results marked with a ^{1*} "
01. Principal	bldchem_fasting_oth	Fasting - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown" 3="Unknown with Glucose, Triglycerides, Cholesterol, and HDL Cholesterol results marked with a ^{1*} "
01. Principal	bldchem_glucose_clin_sig1-3	Lab Test Clinically Significant - Glucose - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_glucose_clin_sig_oth	Lab Test Clinically Significant - Glucose - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_glucose_cmt1-3	Lab Test Comments - Glucose - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_glucose_cmt_oth	Lab Test Comments - Glucose - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_glucose_not_obt1-3	Lab Test Not Obtained - Glucose - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_glucose_not_obt_oth	Lab Test Not Obtained - Glucose - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_glucose_out_range1-3	Lab Test Result - Out Of Range - Glucose - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_glucose_out_range_oth	Lab Test Result - Out Of Range - Glucose - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_glucose_result1-3	Lab Test Result - Glucose (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_glucose_result_oth	Lab Test Result - Glucose (mg/dL) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_hdl_cholesterol_clin_sig1-3	Lab Test Clinically Significant - HDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_hdl_cholesterol_clin_sig_oth	Lab Test Clinically Significant - HDL Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_hdl_cholesterol_cmt1-3	Lab Test Comments - HDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_hdl_cholesterol_cmt_oth	Lab Test Comments - HDL Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_hdl_cholesterol_not_obt1-3	Lab Test Not Obtained - HDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_hdl_cholesterol_not_obt_oth	Lab Test Not Obtained - HDL Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_hdl_cholesterol_out_range1-3	Lab Test Result - Out Of Range - HDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_hdl_cholesterol_out_range_oth	Lab Test Result - Out Of Range - HDL Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_hdl_cholesterol_result1-3	Lab Test Result - HDL Cholesterol (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_hdl_cho_result_oth	Lab Test Result - HDL Cholesterol (mg/dL) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_interval_dt1-3	Interval Date - # - [Clinical Lab - Blood Chemistry]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	bldchem_interval_dt_oth	Interval Date - Other Visit Date - [Clinical Lab - Blood Chemistry]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	bldchem_ldl_cho_clin_sig1-3	Lab Test Clinically Significant - LDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_ldl_cho_clin_sig_oth	Lab Test Clinically Significant - LDL Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_ldl_cho_cmt1-3	Lab Test Comments - LDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_ldl_cho_cmt_oth	Lab Test Comments - LDL Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_ldl_cho_not_obt1-3	Lab Test Not Obtained - LDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_ldl_cho_not_obt_oth	Lab Test Not Obtained - LDL Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_ldl_cho_out_range1-3	Lab Test Result - Out Of Range - LDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_ldl_cho_out_range_oth	Lab Test Result - Out Of Range - LDL Cholesterol - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_ldl_cho_result1-3	Lab Test Result - LDL Cholesterol (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_ldl_cho l_result_oth	Lab Test Result - LDL Cholesterol (mg/dL) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_potassi um_clin_sig1-3	Lab Test Clinically Significant - Potassium - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_potassi um_clin_sig_oth	Lab Test Clinically Significant - Potassium - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_potassi um_cmt1-3	Lab Test Comments - Potassium - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_potassi um_cmt_oth	Lab Test Comments - Potassium - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_potassi um_not_obt1-3	Lab Test Not Obtained - Potassium - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_potassi um_not_obt_oth	Lab Test Not Obtained - Potassium - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_potassi um_out_range1-3	Lab Test Result - Out Of Range - Potassium - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_potassi um_out_range_ot h	Lab Test Result - Out Of Range - Potassium - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_potassi um_result1-3	Lab Test Result - Potassium (mEq/L) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_potassi um_result_oth	Lab Test Result - Potassium (mEq/L) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sgot_ast_clin_sig1-3	Lab Test Clinically Significant - AST (SGOT) - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_sgot_ast_clin_sig_oth	Lab Test Clinically Significant - AST (SGOT) - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_sgot_ast_cmt1-3	Lab Test Comments - AST (SGOT) - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_sgot_ast_cmt_oth	Lab Test Comments - AST (SGOT) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_sgot_ast_not_obt1-3	Lab Test Not Obtained - AST (SGOT) - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgot_ast_not_obt_oth	Lab Test Not Obtained - AST (SGOT) - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgot_ast_out_range1-3	Lab Test Result - Out Of Range - AST (SGOT) - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgot_ast_out_range_oth	Lab Test Result - Out Of Range - AST (SGOT) - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgot_ast_result1-3	Lab Test Result - AST (SGOT) (IU/L) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_sgot_ast_result_oth	Lab Test Result - AST (SGOT) (IU/L) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_sgpt_alt_clin_sig1-3	Lab Test Clinically Significant - ALT (SGPT) - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sgpt_alt_clin_sig_oth	Lab Test Clinically Significant - ALT (SGPT) - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_sgpt_alt_cmt1-3	Lab Test Comments - ALT (SGPT) - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_sgpt_alt_cmt_oth	Lab Test Comments - ALT (SGPT) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_sgpt_alt_not_obt1-3	Lab Test Not Obtained - ALT (SGPT) - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgpt_alt_not_obt_oth	Lab Test Not Obtained - ALT (SGPT) - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgpt_alt_out_range1-3	Lab Test Result - Out Of Range - ALT (SGPT) - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgpt_alt_out_range_oth	Lab Test Result - Out Of Range - ALT (SGPT) - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgpt_alt_result1-3	Lab Test Result - ALT (SGPT) (IU/L) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_sgpt_alt_result_oth	Lab Test Result - ALT (SGPT) (IU/L) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_sodium_clin_sig1-3	Lab Test Clinically Significant - Sodium - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_sodium_clin_sig_oth	Lab Test Clinically Significant - Sodium - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_sodium_cmt1-3	Lab Test Comments - Sodium - # - [Clinical Lab - Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sodium_cmt_oth	Lab Test Comments - Sodium - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_sodium_not_obt1-3	Lab Test Not Obtained - Sodium - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sodium_not_obt_oth	Lab Test Not Obtained - Sodium - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sodium_out_range1-3	Lab Test Result - Out Of Range - Sodium - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sodium_out_range_oth	Lab Test Result - Out Of Range - Sodium - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sodium_result1-3	Lab Test Result - Sodium (mEq/L) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_sodium_result_oth	Lab Test Result - Sodium (mEq/L) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_spec_collected_dt1-3	Date Specimen Collected - # - [Clinical Lab - Blood Chemistry]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	bldchem_spec_collected_dt_oth	Date Specimen Collected - Other Visit Date - [Clinical Lab - Blood Chemistry]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	bldchem_spec_collected_time1-3	Time Specimen Collected - # - [Clinical Lab - Blood Chemistry]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	bldchem_spec_collected_time_oth	Time Specimen Collected - Other Visit Date - [Clinical Lab - Blood Chemistry]		SAS Time .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_t3_clin_sig1-3	Lab Test Clinically Significant - T3 - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_t3_clin_sig_oth	Lab Test Clinically Significant - T3 - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_t3_cmt1-3	Lab Test Comments - T3 - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_t3_cmt_oth	Lab Test Comments - T3 - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_t3_not_obt1-3	Lab Test Not Obtained - T3 - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_t3_not_obt_oth	Lab Test Not Obtained - T3 - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_t3_out_range1-3	Lab Test Result - Out Of Range - T3 - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_t3_out_range_oth	Lab Test Result - Out Of Range - T3 - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_t3_result1-3	Lab Test Result - T3 - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_t3_result_oth	Lab Test Result - T3 - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_t3_units1-3	Lab Test Result Units - T3 - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_t3_units_oth	Lab Test Result Units - T3 - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_t4_clin_sig1-3	Lab Test Clinically Significant - T4 - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_t4_clin_sig_oth	Lab Test Clinically Significant - T4 - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_t4_cmt1-3	Lab Test Comments - T4 - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_t4_cmt_oth	Lab Test Comments - T4 - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_t4_not_obt1-3	Lab Test Not Obtained - T4 - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_t4_not_obt_oth	Lab Test Not Obtained - T4 - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_t4_out_range1-3	Lab Test Result - Out Of Range - T4 - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_t4_out_range_oth	Lab Test Result - Out Of Range - T4 - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_t4_result1-3	Lab Test Result - T4 - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_t4_result_oth	Lab Test Result - T4 - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_t4_units1-3	Lab Test Result Units - T4 - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_t4_units_oth	Lab Test Result Units - T4 - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_triglycerids_clin_sig1-3	Lab Test Clinically Significant - Triglycerides - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_triglycerids_clin_sig_oth	Lab Test Clinically Significant - Triglycerides - Other Visit Date - [Clinical Lab - Blood Chemistry]		.M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_triglycerids_cmt1-3	Lab Test Comments - Triglycerides - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_triglycerids_cmt_oth	Lab Test Comments - Triglycerides - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_triglycerids_not_obt1-3	Lab Test Not Obtained - Triglycerides - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_triglycerids_not_obt_oth	Lab Test Not Obtained - Triglycerides - Other Visit Date - [Clinical Lab - Blood Chemistry]		.M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_triglycerids_out_range1-3	Lab Test Result - Out Of Range - Triglycerides - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_triglycerids_out_range_oth	Lab Test Result - Out Of Range - Triglycerides - Other Visit Date - [Clinical Lab - Blood Chemistry]		.M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_triglycerids_result1-3	Lab Test Result - Triglycerides (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	bldchem_triglycerids_result_oth	Lab Test Result - Triglycerides (mg/dL) - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_tsh_clin_sig1-3	Lab Test Clinically Significant - TSH - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_tsh_clin_sig_oth	Lab Test Clinically Significant - TSH - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_tsh_cm t1-3	Lab Test Comments - TSH - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_tsh_cm t_oth	Lab Test Comments - TSH - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_tsh_not _obt1-3	Lab Test Not Obtained - TSH - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_tsh_not _obt_oth	Lab Test Not Obtained - TSH - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_tsh_out _range1-3	Lab Test Result - Out Of Range - TSH - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_tsh_out _range_oth	Lab Test Result - Out Of Range - TSH - Other Visit Date - [Clinical Lab - Blood Chemistry]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_tsh_res ult1-3	Lab Test Result - TSH - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	bldchem_tsh_res ult_oth	Lab Test Result - TSH - Other Visit Date - [Clinical Lab - Blood Chemistry]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	bldchem_tsh_uni ts1-3	Lab Test Result Units - TSH - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_tsh_uni ts_oth	Lab Test Result Units - TSH - Other Visit Date - [Clinical Lab - Blood Chemistry]		Char
01. Principal	bldchem_visit_dt 1-3	Visit Date - # - [Clinical Lab - Blood Chemistry]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	bldchem_visit_dt _oth	Visit Date - Other Visit Date - [Clinical Lab - Blood Chemistry]		SAS Date .N="N/A" .R="Not Randomized"

Section 18: Clinical Lab - Hematology

Class	Variable	Label	Description	Format Text
01. Principal	hema_anc_clin_sig1-3	Lab Test Clinically Significant - Absolute Neutrophil Count (ANC) - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_anc_cmt1-3	Lab Test Comments - Absolute Neutrophil Count (ANC) - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_anc_not_obt1-3	Lab Test Not Obtained - Absolute Neutrophil Count (ANC) - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_anc_out_range1-3	Lab Test Result - Out Of Range - Absolute Neutrophil Count (ANC) - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_anc_result1-3	Lab Test Result - Absolute Neutrophil Count (ANC) (K/uL) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	hema_bands_clin_sig1-3	Differential Lab Test Clinically Significant - Bands - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_bands_cmt1-3	Differential Lab Test Comments - Bands - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_bands_not_obt1-3	Differential Lab Test Not Obtained - Bands - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_bands_out_range1-3	Differential Lab Test Result - Out Of Range - Bands - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	hema_bands_result1-3	Differential Lab Test Result - Bands (%) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	hema_baso_clin_sig1-3	Differential Lab Test Clinically Significant - Basophils - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_baso_cmt1-3	Differential Lab Test Comments - Basophils - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_baso_not_obt1-3	Differential Lab Test Not Obtained - Basophils - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_baso_out_range1-3	Differential Lab Test Result - Out Of Range - Basophils - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_baso_result1-3	Differential Lab Test Result - Basophils (%) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	hema_eosino_clin_sig1-3	Differential Lab Test Clinically Significant - Eosinophils - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_eosino_cmt1-3	Differential Lab Test Comments - Eosinophils - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_eosino_not_obt1-3	Differential Lab Test Not Obtained - Eosinophils - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_eosino_out_range1-3	Differential Lab Test Result - Out Of Range - Eosinophils - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_eosino_result1-3	Differential Lab Test Result - Eosinophils (%) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_fasting1-3	Fasting - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_hematocrit_clin_sig1-3	Lab Test Clinically Significant - Hematocrit - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_hematocrit_cmt1-3	Lab Test Comments - Hematocrit - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_hematocrit_not_obt1-3	Lab Test Not Obtained - Hematocrit - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_hematocrit_out_range1-3	Lab Test Result - Out Of Range - Hematocrit - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_hematocrit_result1-3	Lab Test Result - Hematocrit (%) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	hema_hemoglobin_clin_sig1-3	Lab Test Clinically Significant - Hemoglobin - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_hemoglobin_cmt1-3	Lab Test Comments - Hemoglobin - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_hemoglobin_not_obt1-3	Lab Test Not Obtained - Hemoglobin - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_hemoglobin_out_range1-3	Lab Test Result - Out Of Range - Hemoglobin - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_hemoglobin_result1-3	Lab Test Result - Hemoglobin (g/dL) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	hema_interval_dt1-3	Interval Date - # - [Clinical Lab - Hematology]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_lympho_clin_sig1-3	Differential Lab Test Clinically Significant - Lymphocytes - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_lympho_cmt1-3	Differential Lab Test Comments - Lymphocytes - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_lympho_not_obt1-3	Differential Lab Test Not Obtained - Lymphocytes - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_lympho_out_range1-3	Differential Lab Test Result - Out Of Range - Lymphocytes - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_lympho_result1-3	Differential Lab Test Result - Lymphocytes (%) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	hema_mono_clin_sig1-3	Differential Lab Test Clinically Significant - Monocytes - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_mono_cmt1-3	Differential Lab Test Comments - Monocytes - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_mono_not_obt1-3	Differential Lab Test Not Obtained - Monocytes - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_mono_out_range1-3	Differential Lab Test Result - Out Of Range - Monocytes - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_mono_result1-3	Differential Lab Test Result - Monocytes (%) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	hema_neutro_clin_sig1-3	Differential Lab Test Clinically Significant - Neutrophils - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	hema_neutro_cm t1-3	Differential Lab Test Comments - Neutrophils - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_neutro_not _obt1-3	Differential Lab Test Not Obtained - Neutrophils - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_neutro_out _range1-3	Differential Lab Test Result - Out Of Range - Neutrophils - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_neutro_res ult1-3	Differential Lab Test Result - Neutrophils (%) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	hema_platelets_c lin_sig1-3	Lab Test Clinically Significant - Platelets - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_platelets_c mt1-3	Lab Test Comments - Platelets - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_platelets_n ot_obt1-3	Lab Test Not Obtained - Platelets - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_platelets_o ut_range1-3	Lab Test Result - Out Of Range - Platelets - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_platelets_r esult1-3	Lab Test Result - Platelets (K/uL) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	hema_rbc_clin_si g1-3	Lab Test Clinically Significant - RBC - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_rbc_cmt1- 3	Lab Test Comments - RBC - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_rbc_not_o bt1-3	Lab Test Not Obtained - RBC - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_rbc_out_ra nge1-3	Lab Test Result - Out Of Range - RBC - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	hema_rbc_result1-3	Lab Test Result - RBC (M/uL) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	hema_spec_col_dt1-3	Date Specimen Collected - # - [Clinical Lab - Hematology]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	hema_spec_col_time1-3	Time Specimen Collected - # - [Clinical Lab - Hematology]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	hema_visit_dt1-3	Visit Date - # - [Clinical Lab - Hematology]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	hema_visit_time1-3	Visit Time - # - [Clinical Lab - Hematology]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	hema_wbc_clin_sig1-3	Lab Test Clinically Significant - WBC - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_wbc_cmt1-3	Lab Test Comments - WBC - # - [Clinical Lab - Hematology]		Char
01. Principal	hema_wbc_not_obt1-3	Lab Test Not Obtained - WBC - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_wbc_out_range1-3	Lab Test Result - Out Of Range - WBC - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	hema_wbc_result1-3	Lab Test Result - WBC (K/uL) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Section 19: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	conmed_comments1-24	Comments - # - [Concomitant Medications]		Char
01. Principal	conmed_continuing1-24	Continuing Medication - # - [Concomitant Medications]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	conmed_dose1-24	Medication Dose - # - [Concomitant Medications]		Char
01. Principal	conmed_frequency1-24	Medication Frequency - # - [Concomitant Medications]		.N="N/A" .R="Not Randomized" 1="One Time (1X)" 2="Twice Daily (BID)" 3="Twice Per Week (BIW)" 4="At Bedtime (HS)" 5="As Needed (PRN)" 6="Every 3 Hours (Q3H)" 7="Every 6 Hours (Q6H)" 8="Every Morning (QAM)" 9="Every Day (QD)" 10="Four Times Daily (QID)" 11="Every Other Day (QOD)" 12="Every Evening (QPM)" 13="Every Week (QW)" 14="Three Times Daily (TID)" 15="Three Per Week (TIW)" 16="Other (OTH)" 17="Unknown (UNK)" "
01. Principal	conmed_interval_dt1-24	Interval Date - # - [Concomitant Medications]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	conmed_med_report_dt1-24	Medication Reported Date - # - [Concomitant Medications]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	conmed_medication1-24	Medication - # - [Concomitant Medications]		Char
01. Principal	conmed_oth_frequency1-24	Medication Other Frequency - # - [Concomitant Medications]		Char
01. Principal	conmed_oth_units1-24	Medication Other Units - # - [Concomitant Medications]		Char
01. Principal	conmed_reason1-24	Reason For Medication - # - [Concomitant Medications]		Char

Class	Variable	Label	Description	Format Text
01. Principal	conmed_start_dt 1-24	Medication Start Date - # - [Concomitant Medications]		SAS Date .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	conmed_start_dt _imp_flag1-24	Medication Start Date Is Imputed - # - [Concomitant Medications]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	conmed_stop_dt 1-24	Medication Stop Date - # - [Concomitant Medications]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	conmed_stop_dt _imp_flag1-24	Medication Stop Date Is Imputed - # - [Concomitant Medications]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	conmed_units1-2 4	Medication Units - # - [Concomitant Medications]		.N="N/A" .R="Not Randomized" 1="Percent (%)" 2="Capsule(Cap)" 3="Gram (g)" 4="Milliliter (ml)" 5="Puff Dosing Unit (Puff)" 6="Sachet Dosing Unit (Sachet)" 7="Tablet(Tab)" 8="Unit Dose (Units)" 9="Application (app)" 10="Drop (gtt)" 11="International Unit (iu)" 12="International Unit Per Kilogram (iu/kg)" 13="Kilogram (kg)" 14="Milliequivalent (mEq)" 15="Milligram(mg)" 16="Milligram Per Kilogram (mg/kg)" 17="Tablespoon Dosing Unit (tbs)" 18="Teaspoon Dosing Unit (tsp)" 19="Microgram (mcg)" 20="Microgram Per Kilogram (mcg/kg)" 21="Microgram Per Square Meter (mcg/m^2)" 22="Other (Oth)" 23="Unknown (Unk)"

Section 20: Eligibility

Class	Variable	Label	Description	Format Text
01. Principal	elig_comments	Comments - [Eligibility]		Char
01. Principal	elig_mdacc_patient_id	MDACC Patient Identifier - [Eligibility]		Char
01. Principal	elig_verification_status	Verification Status - [Eligibility]		1="Confirmed" 2="Ineligible" 3="Pending"
01. Principal	elig_verified_dt	Verified On Date - [Eligibility]		SAS Date

Section 21: Inclusion Criteria

Class	Variable	Label	Description	Format Text
01. Principal	incl_elig_ques_18plus	Is The Participant Female >=18 Years? - [Inclusion Criteria]		0="No" 1="Yes"
01. Principal	incl_elig_ques_bc_treatment	Is The Participant >= 6 Months From All Previous Breast Cancer Treatment (Including Endocrine Therapy)? - [Inclusion Criteria]		0="No" 1="Yes" 2="N/A"
01. Principal	incl_elig_ques_comply	Is The Participant Willing To Comply With All Study Intervention And Follow-Up Procedures Including The Ability To Apply The Study Drug To The Breast? - [Inclusion Criteria]		0="No" 1="Yes"
01. Principal	incl_elig_ques_consent	Does The Participant Have The Ability To Understand And The Willingness To Sign A Written Informed Consent Document? - [Inclusion Criteria]		0="No" 1="Yes"
01. Principal	incl_elig_ques_ecog	Is The ECOG Performance Status <=1 (Karnofsky >=70%)? - [Inclusion Criteria]		0="No" 1="Yes"
01. Principal	incl_elig_ques_high_risk	Is The Participant Defined As High Risk? - [Inclusion Criteria]		0="No" 1="Yes"
01. Principal	incl_elig_ques_imaging	Has The Participant Had Normal Breast Imaging/Mammogram Within 180 Days Of Day 0? - [Inclusion Criteria]		0="No" 1="Yes" 2="N/A"
01. Principal	incl_elig_ques_imaging_ques	Version Of The Breast Imaging/Mammogram Question That Participant Was Asked - [Inclusion Criteria]		Char
01. Principal	incl_elig_ques_liver_func	Does The Participant Have Normal Liver Function? - [Inclusion Criteria]		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	incl_elig_ques_liver_func_ques	Version Of The Liver Function Question That Participant Was Asked - [Inclusion Criteria]		Char
01. Principal	incl_elig_ques_neg_preg	Did The Participant Have Negative Pregnancy Results, Agree To Use Adequate Contraceptive, Or Is Defined As Post-Menopausal? - [Inclusion Criteria]		0="No" 1="Yes" 2="N/A"
01. Principal	incl_elig_ques_no_disease	No Evidence Of Disease (In Situ Or Invasive Cancer That Would Be Treated By Resection) At Trial Entry. Diagnosis Of Invasive Cancer Must Be At Least 5 Years Prior To Initiation On Trial. - [Inclusion Criteria]		0="No" 1="Yes" 2="N/A"
01. Principal	incl_elig_ques_tissue	Does The Participant Have Adequate Accessible Breast Tissue, Consisting Of One Breast Unaffected By Invasive Cancer, Which Has Not Been Radiated? A History Of Benign Core Biopsy Of This Breast Will Be Permitted - [Inclusion Criteria]		0="No" 1="Yes"
01. Principal	incl_elig_ques_uv_light	Ability To Avoid Exposure Of The Treated Breast Area To Sunlight And Artificial Ultraviolet Light During The Use Of Bexarotene Gel. - [Inclusion Criteria]		0="No" 1="Yes"
01. Principal	incl_interval_dt	Interval Date - [Inclusion Criteria]		SAS Date
01. Principal	incl_visit_dt	Visit Date - [Inclusion Criteria]		SAS Date

Section 22: Exclusion Criteria

Class	Variable	Label	Description	Format Text
01. Principal	excl_elig_ques_allergic	Does The Participant Have A History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Bexarotene Gel, Oral Or Topical Retinoids? - [Exclusion Criteria]		0="No" 1="Yes"
01. Principal	excl_elig_ques_cancer	Does The Participant Have A History Of Any Cancer Within The Last 3 Years, Except For Non-Melanoma Skin Cancer? See 4.1.1 As History Of Breast Cancer Must Be At Least >5 Years From Diagnosis - [Exclusion Criteria]		0="No" 1="Yes"
01. Principal	excl_elig_ques_hiv_hep_c	Does The Participant Have A History Of HIV Or Active Hepatitis C? - [Exclusion Criteria]		0="No" 1="Yes"
01. Principal	excl_elig_ques_illness	Does The Participant Have Any Uncontrolled Intercurrent Illness Including, Not Limited To, Infection, Congestive Heart Failure, Unstable Angina Pectoris, Cardiac Arrhythmia, Thromboembolic Disease, Or Certain Psychiatric Illnesses? - [Exclusion Criteria]		.M="Missing" 0="No" 1="Yes"
01. Principal	excl_elig_ques_invasive_bc	Does The Participant Have A Prior History Of Histologically Confirmed Bilateral Invasive Breast Cancer? - [Exclusion Criteria]		0="No" 1="Yes"
01. Principal	excl_elig_ques_meta_bc	Does The Participant Have A Prior History Or Evidence Of Metastatic Breast Cancer? - [Exclusion Criteria]		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	excl_elig_ques_preg	Is The Participant Pregnant, Or Has Given Birth, Or Nursed At Any Time During The Last 12 Months? - [Exclusion Criteria]		0="No" 1="Yes"
01. Principal	excl_elig_ques_retinol	Does The Participant Have A Current Use Of A Retinol Containing Agent Or Any Retinoid Analogue Drug Within The Last 30 Days? - [Exclusion Criteria]		0="No" 1="Yes"
01. Principal	excl_elig_ques_serms	Is The Participant Currently In Use Or <6 Months Since Use Of Selective Estrogen Receptor Modulators (SERMs) Or Aromatase Inhibitors Or Any Other Investigational Treatment For Breast Cancer Prevention Or Therapy? - [Exclusion Criteria]		0="No" 1="Yes"
01. Principal	excl_elig_ques_skin_lesions	Does The Participant Have Skin Lesions On The Breast? - [Exclusion Criteria]		0="No" 1="Yes"
01. Principal	excl_elig_ques_skin_lesions_ques	Version Of The Skin Lesion Question That Participant Was Asked - [Exclusion Criteria]		Char
01. Principal	excl_elig_ques_surgery	Has The Participant Had Bilateral Breast Surgery (Mastectomy, Segmental Mastectomy, Breast Augmentation Surgery, Including Breast Implants Or Breast Reductions) Or A Combination Of Breast Radiation And Surgery Involving Both Breasts? - [Exclusion Criteria]		0="No" 1="Yes"
01. Principal	excl_elig_ques_treatment	Has The Participant Had Treatment With Any Investigational Drug Or Investigational Biologic Within 30 Days Of Initiating Study Treatment Or During The Study? - [Exclusion Criteria]		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	excl_elig_ques_vit_a	Does The Participant Have A Dietary Vitamin A Intake \geq 5,000 IU/Day (As Determined By Dietary Supplementation)? - [Exclusion Criteria]		0="No" 1="Yes"
01. Principal	excl_interval_dt	Interval Date - [Exclusion Criteria]		SAS Date
01. Principal	excl_visit_dt	Visit Date - [Exclusion Criteria]		SAS Date

Section 23: Specimen Acquisition - Research Blood

Class	Variable	Label	Description	Format Text
01. Principal	spcbl_collection_dt1-2	Date Specimen Collected - # - [Specimen Acquisition - Research Blood]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	spcbl_collection_dt_oth1-2	Date Specimen Collected - Other For Visit Date # - [Specimen Acquisition - Research Blood]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	spcbl_collection_time1-2	Time Specimen Collected - # - [Specimen Acquisition - Research Blood]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcbl_collection_time_oth1-2	Time Specimen Collected - Other For Visit Date # - [Specimen Acquisition - Research Blood]		SAS Time .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	spcbl_interval_dt1-2	Interval Date - # - [Specimen Acquisition - Research Blood]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	spcbl_interval_dt_oth1-2	Interval Date - Other For Visit Date # - [Specimen Acquisition - Research Blood]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	spcbl_num_vials1-2	Number Of Vials - # - [Specimen Acquisition - Research Blood]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	spcbl_num_vials_oth1-2	Number Of Vials - Other For Visit Date # - [Specimen Acquisition - Research Blood]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	spcbl_received_dt1-2	Date Specimen Received - # - [Specimen Acquisition - Research Blood]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcbl_received_dt_oth1-2	Date Specimen Received - Other For Visit Date # - [Specimen Acquisition - Research Blood]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	spcbl_shipped_dt1-2	Date Specimen Shipped - # - [Specimen Acquisition - Research Blood]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	spcbl_shipped_dt_oth1-2	Date Specimen Shipped - Other For Visit Date # - [Specimen Acquisition - Research Blood]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	spcbl_specimen1-2	Specimen - # - [Specimen Acquisition - Research Blood]		.F="No Record For This Visit" .R="Not Randomized" 1="Serum"
01. Principal	spcbl_specimen_id1-2	Specimen ID - # - [Specimen Acquisition - Research Blood]		Char
01. Principal	spcbl_specimen_id_oth1-2	Specimen ID - Other For Visit Date # - [Specimen Acquisition - Research Blood]		Char
01. Principal	spcbl_specimen_oth1-2	Specimen - Other For Visit Date # - [Specimen Acquisition - Research Blood]		.N="N/A" .R="Not Randomized" 1="Serum"
01. Principal	spcbl_temperature1-2	Storage Temp (Celsius) - # - [Specimen Acquisition - Research Blood]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcbl_temperature_oth1-2	Storage Temp (Celsius) - Other For Visit Date # - [Specimen Acquisition - Research Blood]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	spcbl_visit_dt1-2	Visit Date - # - [Specimen Acquisition - Research Blood]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	spcbl_visit_dt_oth1-2	Visit Date - Other For Visit Date # - [Specimen Acquisition - Research Blood]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	spcbl_visit_time1-2	Visit Time - # - [Specimen Acquisition - Research Blood]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcbl_visit_time_oth1-2	Visit Time - Other For Visit Date # - [Specimen Acquisition - Research Blood]		SAS Time .N="N/A" .R="Not Randomized"
01. Principal	spcbl_volume1-2	Specimen Volume (0.5-1.0 ml/Tube) - # - [Specimen Acquisition - Research Blood]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	spcbl_volume_oth1-2	Specimen Volume (0.5-1.0 ml/Tube) - Other For Visit Date # - [Specimen Acquisition - Research Blood]		Numeric .N="N/A" .R="Not Randomized"

Section 24: Specimen Acquisition - Tissue Biopsy

Class	Variable	Label	Description	Format Text
01. Principal	spcts_collected_dt	Date Specimen Collected - [Specimen Acquisition - Tissue Biopsy]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	spcts_collected_time	Time Specimen Collected - [Specimen Acquisition - Tissue Biopsy]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcts_ff_cores	Number Of Cores From Fresh Frozen Specimen - [Specimen Acquisition - Tissue Biopsy]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	spcts_ff_location	Location For Fresh Frozen Specimen - [Specimen Acquisition - Tissue Biopsy]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Lower Left" 2="Medial Left" 3="Upper Left" 4="Lower Right" 5="Medial Right" 6="Upper Right"
01. Principal	spcts_ff_receive_dt	Date Fresh Frozen Specimen Received - [Specimen Acquisition - Tissue Biopsy]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	spcts_ff_receive_time	Time Fresh Frozen Specimen Received - [Specimen Acquisition - Tissue Biopsy]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	spcts_ff_shipped_dt	Date Fresh Frozen Specimen Shipped - [Specimen Acquisition - Tissue Biopsy]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	spcts_ff_specimen_id	Fresh Frozen Specimen ID - [Specimen Acquisition - Tissue Biopsy]		Char
01. Principal	spcts_formalin_cores	Number Of Cores From Formalin Fixed And Paraffin Embedded Specimen - [Specimen Acquisition - Tissue Biopsy]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	spcts_formalin_location	Location For Formalin Fixed And Paraffin Embedded Specimen - [Specimen Acquisition - Tissue Biopsy]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Lower Left" 2="Medial Left" 3="Upper Left" 4="Lower Right" 5="Medial Right" 6="Upper Right"
01. Principal	spcts_formalin_received_dt	Date Formalin Fixed And Paraffin Embedded Specimen Received - [Specimen Acquisition - Tissue Biopsy]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	spcts_formalin_received_time	Time Formalin Fixed And Paraffin Embedded Specimen Received - [Specimen Acquisition - Tissue Biopsy]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	spcts_formalin_shipped_dt	Date Formalin Fixed And Paraffin Embedded Specimen Shipped - [Specimen Acquisition - Tissue Biopsy]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	spcts_formalin_specimen_id	Formalin Fixed And Paraffin Embedded Specimen ID - [Specimen Acquisition - Tissue Biopsy]		Char
01. Principal	spcts_interval_dt	Interval Date - [Specimen Acquisition - Tissue Biopsy]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	spcts_rnalater_cores	Number Of Cores From RNAlater Specimen - [Specimen Acquisition - Tissue Biopsy]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	spcts_rnalater_location	Location For RNAlater Specimen - [Specimen Acquisition - Tissue Biopsy]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Lower Left" 2="Medial Left" 3="Upper Left" 4="Lower Right" 5="Medial Right" 6="Upper Right"
01. Principal	spcts_rnalater_received_dt	Date RNAlater Specimen Received - [Specimen Acquisition - Tissue Biopsy]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	spcts_rnalater_re ceived_time	Time RNAlater Specimen Received - [Specimen Acquisition - Tissue Biopsy]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	spcts_rnalater_s hipped_dt	Date RNAlater Specimen Shipped - [Specimen Acquisition - Tissue Biopsy]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	spcts_rnalater_s pecimen_id	RNAlater Specimen ID - [Specimen Acquisition - Tissue Biopsy]		Char

Section 25: Compliance

Class	Variable	Label	Description	Format Text
01. Principal	comp_drug_amt_missing	Amount Of Agent Missing/Not Accounted For This Period - [Compliance]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	comp_drug_amt_provided	Amount Of Agent Provided At Last Visit - [Compliance]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	comp_drug_amt_returned	Amount Of Agent Returned At This Visit - [Compliance]		Numeric .R="Not Randomized"
01. Principal	comp_drug_amt_taken	Amount Of Agent Taken During This Period - [Compliance]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	comp_drug_compliant	Is The Participant Compliant With Protocol Intervention - [Compliance]		.R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	comp_drug_first_dose_dt	First Dose Taken This Date - [Compliance]		SAS Date .R="Not Randomized"
01. Principal	comp_drug_group	Dose Study Group - [Compliance]		.R="Not Randomized" 1="Dose Escalation Group" 2="Dose Expansion Group"
01. Principal	comp_drug_interrupted	Was Agent Interrupted During This Period - [Compliance]		.R="Not Randomized" 0="No" 1="Yes" 2="N/A"
01. Principal	comp_drug_interval_dt	Interval Date - [Compliance]		SAS Date .R="Not Randomized"
01. Principal	comp_drug_last_dose_dt	Last Dose Taken This Date - [Compliance]		SAS Date .R="Not Randomized"
01. Principal	comp_drug_modified	Was Agent Regimen Modified During This Period - [Compliance]		.R="Not Randomized" 0="No" 1="Yes" 2="N/A"
01. Principal	comp_drug_num_interruptions	If Yes, Indicate Number Of Interruptions This Period - [Compliance]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	comp_drug_provided_now	Was Agent Provided At This Visit - [Compliance]		.R="Not Randomized" 0="No" 1="Yes" 2="N/A"
01. Principal	comp_drug_reason_non_comp	If No, Specify Reason For Noncompliance - [Compliance]		Char

Class	Variable	Label	Description	Format Text
01. Principal	comp_drug_tac	Current Intervention For Treatment Assignment Code (TAC) - [Compliance]		.R="Not Randomized" 1="TAC1: Bexarotene 1% gel 10 mg applied topically to one unaffected breast QOD x 4 weeks" 2="TAC2: Bexarotene 1% gel 10 mg applied topically to one unaffected breast QOD x 7 days, then QD x 3 weeks"
01. Principal	comp_drug_visit_dt	Visit Date - [Compliance]		SAS Date .R="Not Randomized"

Section 26: Telephone Contact

Class	Variable	Label	Description	Format Text
01. Principal	tele_changes_conmed1-3	Were Any Changes In Concomitant Medication Reported - # - [Telephone Contact]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes (Please enter information on Concomitant Medication CRF)" 2="N/A"
01. Principal	tele_compliance_reviewed1-3	Was Study Compliance Reviewed - # - [Telephone Contact]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="N/A"
01. Principal	tele_compliant_protocol1-3	Is The Participant Compliant With Protocol Intervention Per Telephone Conversation - # - [Telephone Contact]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="N/A" 9="Unknown"
01. Principal	tele_contact_dt1-3	Date Of Telephone Contact - # - [Telephone Contact]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tele_interval_dt1-3	Interval Date - # - [Telephone Contact]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tele_reported_symptoms_ae1-3	Did The Participant Report Any Symptoms Or Adverse Events - # - [Telephone Contact]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes (Please enter information on AE CRF)"

Section 27: Dermatology

Class	Variable	Label	Description	Format Text
01. Principal	derm_appearance_cmt	Body System/Site: Appearance - Comments Required If Abnormal; Provide Condition/Diagnosis - [Dermatology]		Char
01. Principal	derm_appearance_status	Body System/Site: Appearance - Status - [Dermatology]		.F="No Record For This Visit" .R="Not Randomized" 1="Abnormal" 2="Normal" 3="Not Examined"
01. Principal	derm_cardio_cmt	Body System/Site: Cardiovascular - Comments Required If Abnormal; Provide Condition/Diagnosis - [Dermatology]		Char
01. Principal	derm_cardio_status	Body System/Site: Cardiovascular - Status - [Dermatology]		.F="No Record For This Visit" .R="Not Randomized" 1="Abnormal" 2="Normal" 3="Not Examined"
01. Principal	derm_diastolic_bp	Diastolic Blood Pressure (mmHg) - [Dermatology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	derm_ecog	Eastern Cooperative Oncology Group (ECOG) Performance Status - [Dermatology]		.F="No Record For This Visit" .R="Not Randomized" 0="Normal activity. Fully active, able to carry on all pre-disease performance without restriction." 1="Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work." 2="Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours." 3="Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours." 4="Completely disabled; cannot carry on any selfcare; totally confined to bed or chair." 5="Dead"
01. Principal	derm_interval_dt	Interval Date - [Dermatology]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	derm_lymph_cmt	Body System/Site: Lymphatic And Hemic - Comments Required If Abnormal; Provide Condition/Diagnosis - [Dermatology]		Char
01. Principal	derm_lymph_status	Body System/Site: Lymphatic And Hemic - Status - [Dermatology]		.F="No Record For This Visit" .R="Not Randomized" 1="Abnormal" 2="Normal" 3="Not Examined"
01. Principal	derm_nervous_cmt	Body System/Site: Nervous - Comments Required If Abnormal; Provide Condition/Diagnosis - [Dermatology]		Char
01. Principal	derm_nervous_status	Body System/Site: Nervous - Status - [Dermatology]		.F="No Record For This Visit" .R="Not Randomized" 1="Abnormal" 2="Normal" 3="Not Examined"
01. Principal	derm_pulse_rate	Pulse Rate - [Dermatology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	derm_resp_cmt	Body System/Site: Respiratory - Comments Required If Abnormal; Provide Condition/Diagnosis - [Dermatology]		Char
01. Principal	derm_resp_status	Body System/Site: Respiratory - Status - [Dermatology]		.F="No Record For This Visit" .R="Not Randomized" 1="Abnormal" 2="Normal" 3="Not Examined"
01. Principal	derm_respiration_rate	Respiration Rate - [Dermatology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	derm_skin_cmt	Body System/Site: Skin And Appendages - Comments Required If Abnormal; Provide Condition/Diagnosis - [Dermatology]		Char
01. Principal	derm_skin_status	Body System/Site: Skin And Appendages - Status - [Dermatology]		.F="No Record For This Visit" .R="Not Randomized" 1="Abnormal" 2="Normal" 3="Not Examined"
01. Principal	derm_systolic_bp	Systolic Blood Pressure (mmHg) - [Dermatology]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	derm_temperature	Temperature (Celsius) - [Dermatology]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	derm_visit_dt	Visit Date - [Dermatology]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 28: Agent Modification

Class	Variable	Label	Description	Format Text
01. Principal	ag_int_interval_dt	Interval Date - [Agent Modification]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	ag_int_modified_dt	Specify Date Modified - [Agent Modification]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	ag_int_modified_frequency	Modified Frequency - [Agent Modification]		Char
01. Principal	ag_int_reason_mod	Reason Modified - [Agent Modification]		.F="No Record For This Visit" .R="Not Randomized" 1="AE/SAE, specify" 2="Other, specify"
01. Principal	ag_int_reason_not_full_restart	If No, Reason Full Dose Was Not Restarted - [Agent Modification]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="AE/SAE, specify" 2="Other, specify"
01. Principal	ag_int_reason_not_restarted	Specify Reason Full Dose Was Not Restarted - [Agent Modification]		Char
01. Principal	ag_int_restart_dt	If Yes, Specify Date Restarted At Full Dose - [Agent Modification]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ag_int_restart_full_dose	Was Agent Restarted At Full Dose - [Agent Modification]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	ag_int_specify_reason_mod	Specify Reason Modified - [Agent Modification]		Char
01. Principal	ag_int_tac	Treatment Assignment Code (TAC) - [Agent Modification]		.F="No Record For This Visit" .R="Not Randomized" 1="TAC-1" 2="TAC-2" 3="TAC-3"

Section 29: Followup Alcohol

Class	Variable	Label	Description	Format Text
01. Principal	alcohol_fu_days_5plus1-2	In The Past 30 Days On How Many Days Did You Have 5 Or More Drinks Per Day - # - [Followup Alcohol]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	alcohol_fu_days_timeframe1-2	Timeframe - # - [Followup Alcohol]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Week" 2="Month" 4="Refused" 99="Do not know / Not sure"
01. Principal	alcohol_fu_drink_30_1-2	During The Past 30 Days Did You Drink Any Alcoholic Beverages - # - [Followup Alcohol]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="Refused" 99="Do Not Know / Not Sure"
01. Principal	alcohol_fu_drinks_per_day1-2	On The Days When You Drank On Average About How Many Drinks Did You Have Per Day - # - [Followup Alcohol]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	alcohol_fu_interval_dt1-2	Interval Date - # - [Followup Alcohol]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	alcohol_fu_number_of_days1-2	Number Of Days Drinking Based On Timeframe Provided - # - [Followup Alcohol]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	alcohol_fu_verified_dt1-2	Verified Date - # - [Followup Alcohol]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	alcohol_fu_verified_time1-2	Verified Time - # - [Followup Alcohol]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	alcohol_fu_visit_dt1-2	Visit Date - # - [Followup Alcohol]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 30: Followup Tobacco

Class	Variable	Label	Description	Format Text
01. Principal	tobacco_fu_cigarettes_daily1-2	On Average, How Many Cigarettes Per Day - # - [Followup Tobacco]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	tobacco_fu_cigarettes_now1-2	Do You NOW Smoke Cigarettes - # - [Followup Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="Never Smoked" 1="Not At All" 2="Some Days" 3="Everyday"
01. Principal	tobacco_fu_interval_dt1-2	Interval Date - # - [Followup Tobacco]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tobacco_fu_last_smoked1-2	How Long Has It Been Since You Last Smoked A Cigarette - # - [Followup Tobacco]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="I Smoked A Cigarette Today (At Least One Puff)" 2="1-7 Days" 3="Less Than 1 Month" 4="Less Than 1 Year" 5="More Than 1 Year" 99="Do Not Know / Do Not Remember"
01. Principal	tobacco_fu_last_smoked_mo1-2	Number Of Months Since Last Cigarette - # - [Followup Tobacco]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	tobacco_fu_last_smoked_yr1-2	Number Of Years Since Last Cigarette - # - [Followup Tobacco]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized" 98="30+ years"
01. Principal	tobacco_fu_last_used_other1-2	How Long Since Regular Use Of Other Forms Of Tobacco - # - [Followup Tobacco]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Never used other forms of tobacco regularly" 1="Within the past month (0 to 1 month ago)" 2="Between 1 and 3 months (1 to 3 months ago)" 3="Between 3 and 6 months (3 to 6 months ago)" 4="Between 6 and 12 months (6 to 12 months ago)" 5="Between 1 and 5 years (1 to 5 years ago)" 6="Between 5 and 15 years (5 to 15 years ago)" 7="More than 15 years ago" 8="Do not know/Not sure"

Class	Variable	Label	Description	Format Text
01. Principal	tobacco_fu_other1-2	Since Your Last Visit Have You Used Other Forms Of Tobacco - # - [Followup Tobacco]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_fu_other_checked1-2	Since Last Visit, 'Other' Products was checked - # - [Followup Tobacco]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_fu_other_product1-2	Since Your Last Visit What Other Product Have You Used - # - [Followup Tobacco]		Char
01. Principal	tobacco_fu_smo_ked_after1-2	After The End Of Study Treatment - # - [Followup Tobacco]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Did Not Smoke At All" 1="Smoked Some Days" 2="Smoked Every Day" 98="Not Applicable (I Have Not Completed The Study Treatment)" 99="Do Not Know / Not Sure"
01. Principal	tobacco_fu_smo_ked_during1-2	During Study Treatment - # - [Followup Tobacco]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Did Not Smoke At All" 1="Smoked Some Days" 2="Smoked Every Day" 98="Not Applicable" 99="Do Not Know / Not Sure"
01. Principal	tobacco_fu_smo_ked_last_visit1-2	Since Your Last Visit To This Clinic - # - [Followup Tobacco]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Did Not Smoke At All" 1="Smoked Some Days" 2="Smoked Every Day" 98="Not Applicable (This Is My First Visit To This Clinic)" 99="Do Not Know / Not Sure"
01. Principal	tobacco_fu_verified_dt1-2	Verified Date - # - [Followup Tobacco]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tobacco_fu_verified_time1-2	Verified Time - # - [Followup Tobacco]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tobacco_fu_visit_dt1-2	Visit Date - # - [Followup Tobacco]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 31: Off Study

Class	Variable	Label	Description	Format Text
01. Principal	offst_agent_end_dt	Agent End Date - [Off Study]		SAS Date .N="N/A"
01. Principal	offst_did_not_have_adv_events	Participant Did Not Have Any Adverse Events - [Off Study]		0="False" 1="True"
01. Principal	offst_did_not_have_agent_mod	Participant Did Not Have Any Agent Modifications - [Off Study]		0="False" 1="True"
01. Principal	offst_did_not_take_con_meds	Participant Did Not Take Any Concomitant Medications - [Off Study]		0="False" 1="True"
01. Principal	offst_form_dt	Form Date - [Off Study]		SAS Date
01. Principal	offst_interval_dt	Interval Date - [Off Study]		SAS Date
01. Principal	offst_last_contact_dt	Date Of Last Contact - [Off Study]		SAS Date
01. Principal	offst_offstudy_dt	Off Study Date - [Off Study]		SAS Date
01. Principal	offst_reason	Reason Off Study: (Mark Only Primary Reason. Reasons Other Than Completed Study Require Explanation) - [Off Study]		1="Adverse Event/Serious Adverse Event (Complete AE CRF & SAE form, if applicable)" 2="Death (complete Death Report CRF & SAE form)" 3="Study Complete" 4="Disease Progression" 5="Lost to follow-up" 6="Ineligible" 7="Participant Refused Follow-up" 8="Participant Withdrawal" 9="Physician Decision" 10="Protocol Violation" 11="Protocol Defined Follow-up Completed" 12="Other, specify"
01. Principal	offst_reason_explanation	Reason Explanation - [Off Study]		Char

Section 32: Verification

Class	Variable	Label	Description	Format Text
01. Principal	verif_interval_dt	Interval Date - [Verification]		SAS Date
01. Principal	verif_signature_dt	Date Of Investigator S Signature - [Verification]		SAS Date
01. Principal	verif_signature_time	Time Of Investigator S Signature - [Verification]		SAS Time

Section 33: Comments

Class	Variable	Label	Description	Format Text
01. Principal	cmts_comments 1-4	Comments - # - [Comments]		Char
01. Principal	cmts_field_name 1-4	Field Name - # - [Comments]		Char
01. Principal	cmts_form_code 1-4	Field Code - # - [Comments]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Agent Modification" 2="Compliance" 3="Off Study" 4="Physical Exam" 5="Registration - Part 2" 6="Research Blood"
01. Principal	cmts_form_dt	Form Date - [Comments]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	cmts_interval_dt	Interval Date - [Comments]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 34: Study Specimen Shipping Form

Class	Variable	Label	Description	Format Text
01. Principal	ship_blocks1-6	Number of Blocks (Cryovials) - # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_blood_day1-6	Blood Day Selected - # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Day 0" 28="Day 28"
01. Principal	ship_blood_specimen_serum1-6	Blood Specimen Serum Selected - # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_interval_dt1-6	Interval Date - # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	ship_received_dt1-6	Received Date - # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	ship_received_time1-6	Received Time - # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	ship_shipped_dt1-6	Shipped Date - # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	ship_shipping_dt1-6	Shipping Date - # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	ship_shipping_time1-6	Shipping Time - # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	ship_specify_condition1-6	Specify How The Specimen Shipment Was Received - # - [Study Specimen Shipping Form]		Char
01. Principal	ship_specimen_condition1-6	How Was Specimen Shipment Received - # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .R="Not Randomized" 1="good condition" 2="poor condition, specify"
01. Principal	ship_tissue_day1-6	Tissue Day Selected - # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Day 0" 28="Day 28"

Class	Variable	Label	Description	Format Text
01. Principal	ship_tissue_specimen_ffpe1-6	Tissue Specimen FFPE Tissue Selected - # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_tissue_specimen_fresh1-6	Tissue Specimen Fresh Frozen Selected - # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_tissue_specimen_rna1-6	Tissue Specimen RNAlater Selected - # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_verified1_dt1-6	Date Verified 1 - # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	ship_verified1_time1-6	Time Verified 1 - # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	ship_verified2_dt1-6	Date Verified 2 - # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	ship_verified2_time1-6	Time Verified 2 - # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	ship_vials1-6	Number of Blood Vials - # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"