

MDA2014-04-01 - Enhanced Person Data Dictionary

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Document Summary

Property	Value
Document Title	MDA2014-04-01 - Enhanced Person: Data Dictionary
Date Created	03/01/2023
Sections	36
Entries	1003
Document Filename	dictionary_enhanced_prsn.rtf

MDA2014-04-01 - Enhanced Person: Data Dictionary

Section 1: Study-wide

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

Section 2: Unblinding

Class	Variable	Label	Description	Format Text
01. Principal	unblind_age	Age At Registration - [Unblinding]		Numeric
01. Principal	unblind_agent_dose	Agent Dose (mg) - [Unblinding]		.M="Missing" 1="25 mg"
01. Principal	unblind_agent_freq	Agent Frequency - [Unblinding]		.M="Missing" 1="QD - Once Daily" 2="TIW - Three Times A Week" 3="QW - Once A Week"
01. Principal	unblind_agent_name	Agent Name - [Unblinding]		.M="Missing" 1="Exemestane"
01. Principal	unblind_consortium_code	Registering Consortium Code - [Unblinding]		1="TX035"
01. Principal	unblind_institution	Registering Institution - [Unblinding]		1="Columbia University Medical Center" 2="European Institute Of Oncology" 3="Galliera Hospital" 4="M. D. Anderson Cancer Center" 5="Moffitt Cancer Center"
01. Principal	unblind_institution_code	Registering Institution Code - [Unblinding]		1="NY024" 2="41058" 3="41062" 4="TX035" 5="FL065"
01. Principal	unblind_protocol_number	DCP Protocol Number - [Unblinding]		1="MDA2014-04-01"
01. Principal	unblind_randomization_number	Randomization Number - [Unblinding]		Char
01. Principal	unblind_tac	Treatment Assignment Code: TAC1 - [Unblinding]		.M="Missing" 1="TAC1"

Section 3: Registration

Class	Variable	Label	Description	Format Text
01. Principal	reg_consent_version_date	Version Date Of Informed Consent - [Registration]		SAS Date .M="Missing" 7="N/A"
01. Principal	reg_consortium	Registering Consortium - [Registration]		1="TX035 (MD Anderson Cancer Center)"
01. Principal	reg_contact_consent	Participant Agreed To Be Contacted To See If She Wishes To Take Part In Other Research In The Future - [Registration]		.N="N/A" 0="False" 1="True"
01. Principal	reg_contact_consent_v11	Participant Agreed To Be Contacted To See If She Wishes To Take Part In Other Research In The Future v11 - [Registration]		.N="N/A" 0="False" 1="True"
01. Principal	reg_contact_dr_consent	OK To Contact Physician To See If Participant Wishes To Participate In Future Research - [Registration]		.N="N/A" 0="False" 1="True"
01. Principal	reg_country_code	Participant Country Code - [Registration]		3="ITA (Italy)" 5="USA (United States of America)"
01. Principal	reg_ethnicity	Ethnicity - [Registration]		1="Hispanic or Latino" 2="Not Hispanic or Latino" 3="Unknown" 4="Not Reported"
01. Principal	reg_gender	Gender - [Registration]		1="Female"
01. Principal	reg_informed_consent_date	Date Informed Consent Signed - [Registration]		SAS Date
01. Principal	reg_informed_consent_version	Version Of Informed Consent - [Registration]		Char
01. Principal	reg_interval	Interval - [Registration]		1="Event Interval Not Available" 2="Baseline" 4="Month 1"
01. Principal	reg_interval_date	Interval Date - [Registration]		SAS Date
01. Principal	reg_other_payment	Other Method Of Payment - [Registration]		.N="N/A" 1="+ AARP" 2="Italian National Health System" 7="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	reg_payment_method1-2	Payment Method - [Registration]		.N="N/A" 1="Private Insurance" 2="Medicaid" 3="Medicaid and Medicare" 7="Medicare" 8="Medicare and Private Insurance" 13="Unknown" 14="Other"
01. Principal	reg_payment_selected1-2	Payment Selected - [Registration]		.N="N/A" 0="False" 1="True"
01. Principal	reg_race1-2	Race - [Registration]		.N="N/A" 1="White" 2="Black Or African American" 3="American Indian or Alaska Native" 4="Asian" 5="Native Hawaiian or Other Pacific Islander" 6="Unknown" 9="Not Reported"
01. Principal	reg_race_selected1-2	Race Selected - [Registration]		.N="N/A" 0="False" 1="True"
01. Principal	reg_registration_date	Date of Registration - [Registration]		SAS Date .M="Missing"
01. Principal	reg_samples_consent	Participant Agreed Samples And Related information May Be Kept In Biobank For Use In Future Health Research - [Registration]		.N="N/A" 0="False" 1="True"
01. Principal	reg_samples_consent_v11	Participant Agreed Samples And Related information May Be Kept In Biobank For Use In Future Health Research v11 - [Registration]		.N="N/A" 0="False" 1="True"
01. Principal	reg_tac0	Treatment Assignment Code (TAC-0): Signed Informed Consent Document And Before Intervention - [Registration]		.N="N/A" 0="False" 1="True"
01. Principal	reg_visit_date	Visit Date - [Registration]		SAS Date

Section 4: Screening

Class	Variable	Label	Description	Format Text
01. Principal	screen_er_positive	Estrogen Receptor (ER) Positive (ER>= 10%) - [Screening]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	screen_interval	Interval - [Screening]		.R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 4="Month 1"
01. Principal	screen_interval_date	Interval Date - [Screening]		SAS Date .R="Not Randomized"
01. Principal	screen_meet_criteria	Does The Participant Meet All Screening Criteria - [Screening]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	screen_staining_date	Date Of Estrogen Receptor (ER) Staining - [Screening]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	screen_staining_date_na	Date Of Estrogen Receptor (ER) Staining - Not Applicable - [Screening]		.R="Not Randomized" 0="False" 1="True"
01. Principal	screen_tru_cut_date	Date Of Tru Cut With Staining Biopsy - [Screening]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	screen_tru_cut_date_na	Date Of Tru Cut With Staining Biopsy - Not Applicable - [Screening]		.R="Not Randomized" 0="False" 1="True"
01. Principal	screen_visit_date	Visit Date - [Screening]		SAS Date .R="Not Randomized"
01. Principal	screen_insitu_or_invasive	In Situ Or Invasive Carcinoma - [Screening]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Section 5: Screening Registration

Class	Variable	Label	Description	Format Text
01. Principal	scrreg_consent_date	Screening Informed Consent Date - [Screening Registration]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	scrreg_consent_date_na	Screening Informed Consent Date - Not Applicable - [Screening Registration]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	scrreg_interval	Interval - [Screening Registration]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline"
01. Principal	scrreg_interval_date	Interval Date - [Screening Registration]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	scrreg_screen_2_date	Screen 2 Date - [Screening Registration]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	scrreg_screen_2_date_na	Screen 2 Date - Not Applicable - [Screening Registration]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	scrreg_screening_date	Screening Registration Date - [Screening Registration]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	scrreg_tru_cut_biopsy_date	Tru Cut Biopsy Date - [Screening Registration]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	scrreg_tru_cut_biopsy_na	Tru Cut Biopsy Date - Not Applicable - [Screening Registration]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"

Section 6: Inclusion Criteria

Class	Variable	Label	Description	Format Text
01. Principal	incl_elig_age	Age <= 75 (prev10a2 Version Only) - [Inclusion Criteria]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Yes"
01. Principal	incl_elig_consent	Ability To Understand And The Willingness To Sign A Written Informed Consent Document - [Inclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 1="Yes"
01. Principal	incl_elig_ecog	ECOG Performance Status <=1 (Karnofsky >=70%; See Protocol Appendix A) - [Inclusion Criteria]	Karnofsky = 70% is defined as "Cares for self, unable to carry on normal activity or to do active work."	.F="No Record For This Visit" .R="Not Randomized" 1="Yes"
01. Principal	incl_elig_organ_marrow	Participants Must Have Normal Organ And Marrow Function - [Inclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	incl_elig_organ_marrow_ques	Organ Marrow Criteria Eligibility Question Version - [Inclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 1="Participants must have normal organ and marrow function as defined below: Leukocytes >=3,000/microliter, Absolute neutrophil count >=1,500/microliter, Platelets >=100,000/microliter, Total bilirubin <= 2 x institutional ULN, AST (SGOT)/ALT (SGPT) <=1.5 x institutional ULN, Creatinine within normal institutional limits (prev10a2 version only)" 2="Participants must have normal organ and marrow function as defined below: Leukocytes >=3,000/microliter, Absolute neutrophil count >=1,500/microliter, Platelets >=100,000/microliter, Total bilirubin <= 2 x institutional ULN, AST (SGOT)/ALT (SGPT) <=1.5 x institutional ULN, Creatinine <=1.5 x institutional ULN (10a2_8_9_2017 and 11a3_2_10_2018 versions)"
01. Principal	incl_elig_postmenopausal	Postmenopausal Women - [Inclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	incl_elig_postmenopausal_ques	Postmenopausal Criteria Eligibility Question Version - [Inclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 1="Postmenopausal women (* postmenopausal: age >= 60 years, or amenorrhea >= 12 months, or bilateral oophorectomy, or - in women with hysterectomy only- FSH > 30 IU/L if < 60 years old) with histologically-confirmed ER positive (>= 10%) primary breast cancer stage T0-2, N0-1, Mx. Women with larger tumors who refuse chemo and/or endocrine neoadjuvant therapy can be eligible (prev10a2 version only)" 2="Postmenopausal women (* postmenopausal: age >= 60 years, or amenorrhea >= 12 months, or bilateral oophorectomy, or - in women with hysterectomy only- FSH in the menopausal levels as per local institutional guidelines if < 60 years old) with histologically-confirmed ER positive (>= 10%) primary breast cancer stage T0-2, N0-1, Mx. Women with larger tumors who refuse chemo and/or endocrine neoadjuvant therapy can be eligible (10a2_8_9_2017 version only)" 3="Postmenopausal women (* postmenopausal: age >60 years, or amenorrhea = >12 months, or bilateral oophorectomy, or - in women with hysterectomy only- FSH in the menopausal levels as per local institutional guidelines if < 60 years old) with histologically-confirmed ER-positive (>= 10%) primary breast cancer stage cT0-2, cN0-1, Mx. Women with larger tumors who refuse chemo and/or endocrine neoadjuvant therapy can be eligible (11a3_2_10_2018 versions only)"
01. Principal	incl_interval	Interval - [Inclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 4="Month 1"
01. Principal	incl_interval_date	Interval Date - [Inclusion Criteria]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	incl_version_flag	Which Version Of Forms Were Used - [Inclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 1="prev10a2 Only" 2="10a2_8_9_2017 Only" 3="11a3_2_10_2018 Only" 4="prev10a2 and 10a2_8_9_2017" 6="10a2_8_9_2017 and 11a3_2_10_2018"
01. Principal	incl_visit_date	Visit Date - [Inclusion Criteria]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 7: Exclusion Criteria

Class	Variable	Label	Description	Format Text
01. Principal	excl_elig_allergic	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Exemestane - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
01. Principal	excl_elig_bmi	BMI<18.5 kg/m ² - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
01. Principal	excl_elig_cyp3a4	Concomitant Use Of CYP3A4 Inducer Medication (Rifampicin, Phenytonin, Carbamazepine, Phenobarbital, And St. John's Wort) - [Exclusion Criteria]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	excl_elig_hrt	Use Of HRT In The Last 30 Days - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	excl_elig_hrt_ques	Use Of HRT Question Version - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 1="Use of HRT in the last 30 days prior to the randomization (prev10a2 version)" 2="Use of systemic Hormone Replacement Therapy (HRT) in the last 30 days prior to the randomization. The use of non-systemic estrogen (such as vaginal estrogen use) is allowed. (10a2_8_9_2017 and 11a3_2_10_2018 versions)"
01. Principal	excl_elig_illness	Uncontrolled Intercurrent Illness - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
01. Principal	excl_elig_illness_ques	Uncontrolled Intercurrent Illness Question Version - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 1="Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with stu (prev10a2 version)" 2="Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements (10a2_8_9_2017 and 11a3_2_10_2018 versions)"

Class	Variable	Label	Description	Format Text
01. Principal	excl_elig_invest_agents	Receiving Investigational Agents - [Exclusion Criteria]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	excl_elig_malignancies	Other Co-Existing Malignancies - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
01. Principal	excl_elig_malignancies_ques	Co-Existing Malignancies Question Version - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 1="Other co-existing malignancies (with the exclusion of basal cell carcinoma or skin squamous cell carcinoma) diagnosed during the last 2 years before randomization (prev10a2 version)" 2="Other co-existing invasive malignancies (with the exclusion of basal cell carcinoma or skin squamous cell carcinoma) diagnosed during the last 2 years before randomization (10a2_8_9_2017 and 11a3_2_10_2018 versions)"
01. Principal	excl_elig_neo_therapy	Women Who Are Planning To Receive Neoadjuvant Therapy - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	excl_elig_osteo	History Of Severe Osteoporosis (T Score <= -4 Either Spine Or Hip), Or Presence Of Vertebral Fracture - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	excl_elig_pre_treat_bc	Previous Treatment For Breast Cancer - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
01. Principal	excl_elig_pre_treat_bc_ques	Previous Treatment For Breast Cancer Question Version - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 1="Previous treatment for breast cancer including chemotherapy and endocrine therapy (prev10a2 and 10a2_8_9_2017 version)" 2="Previous treatment for breast cancer including chemotherapy endocrine therapy, and radiotherapy. Women with prior DCIS who were treated with surgery only and whose treatment ended >2 years prior to enrollment are eligible for the trial. (11a3_2_10_2018 version only)"
01. Principal	excl_elig_serms	Use Of Any Chemopreventive Agents (SERM) In The Last 3 Months - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
01. Principal	excl_interval	Interval - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 4="Month 1"

Class	Variable	Label	Description	Format Text
01. Principal	excl_interval_date	Interval Date - [Exclusion Criteria]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	excl_version_flag	Which Version Of Forms Were Used - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 1="prev10a2 Only" 2="10a2_8_9_2017 Only" 3="11a3_2_10_2018 Only" 4="prev10a2 and 10a2_8_9_2017" 6="10a2_8_9_2017 and 11a3_2_10_2018"
01. Principal	excl_visit_date	Visit Date - [Exclusion Criteria]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 8: 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]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	medsurhist_allergy	Does The Participant Have Any Allergies - [Baseline Medical/Surgical History]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	medsurhist_allergy_spec	Does The Participant Have Any Allergies - Specify - [Baseline Medical/Surgical History]		Char
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]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 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]		.F="No Record For This Visit" .M="Missing" .N="N/A" .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

Class	Variable	Label	Description	Format Text
01. Principal	medsurhist_derm_status	Dermatologic Status - [Baseline Medical/Surgical History]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
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]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_gastr_o_comments	Comments For Gastrointestinal - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_gastr_o_status	Gastrointestinal Status - [Baseline Medical/Surgical History]		.F="No Record For This Visit" .N="N/A" .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]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_heen_t_comments	Comments For H/E/E/N/T - Required If Abnormal Provide Condition Diagnosis - [Baseline Medical/Surgical History]		Char
01. Principal	medsurhist_heen_t_status	H/E/E/N/T Status - [Baseline Medical/Surgical History]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"

Class	Variable	Label	Description	Format Text
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]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Not Assessed" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_interval	Interval - [Baseline Medical/Surgical History]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 4="Month 1"
01. Principal	medsurhist_interval_date	Interval Date - [Baseline Medical/Surgical History]		SAS Date .F="No Record For This Visit" .M="Missing" .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]		.F="No Record For This Visit" .N="N/A" .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]		.F="No Record For This Visit" .M="Missing" .N="N/A" .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

Class	Variable	Label	Description	Format Text
01. Principal	medsurhist_neuro_status	Neurologic Status - [Baseline Medical/Surgical History]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Abnormal" 2="Normal"
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]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_visit_date	Visit Date - [Baseline Medical/Surgical History]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 9: Baseline Medical/Surgical History - Other

Class	Variable	Label	Description	Format Text
01. Principal	medsurhist_otr_all_sys_normal	Check Here If All Body Systems Are Normal - [Baseline Medical/Surgical History - Other]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	medsurhist_otr_allergy	Does The Participant Have Any Allergies - [Baseline Medical/Surgical History - Other]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	medsurhist_otr_allergy_spec	If Yes, Participant Has Allergies, Specify - [Baseline Medical/Surgical History - Other]		Char
01. Principal	medsurhist_otr_comments1-3	Comments Required If Status Is Abnormal - # - [Baseline Medical/Surgical History - Other]		Char
01. Principal	medsurhist_otr_interval	Interval - [Baseline Medical/Surgical History - Other]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 4="Month 1"
01. Principal	medsurhist_otr_interval_date	Interval Date - [Baseline Medical/Surgical History - Other]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	medsurhist_otr_other_body_site1-3	Specify Other Body System Site - # - [Baseline Medical/Surgical History - Other]		Char
01. Principal	medsurhist_otr_status1-3	Status Of Other Body System Site - # - [Baseline Medical/Surgical History - Other]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Abnormal" 2="Normal"
01. Principal	medsurhist_otr_visit_date	Visit Date - [Baseline Medical/Surgical History - Other]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 10: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	base_symp_comments1-14	Comments - # - [Baseline Symptoms]		Char
01. Principal	base_symp_grade1-14	Grade - # - [Baseline Symptoms]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="1 (Mild)" 2="2 (Moderate)" 3="3 (Severe)"
01. Principal	base_symp_interval	Interval - [Baseline Symptoms]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 4="Month 1"
01. Principal	base_symp_interval_date	Interval Date - [Baseline Symptoms]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	base_symp_no_symptoms	No Reported Symptoms - No Baseline Symptoms - [Baseline Symptoms]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	base_symp_onset_date1-14	Onset Date - # - [Baseline Symptoms]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 8="Unknown"
01. Principal	base_symp_onset_date_imputed1-14	Onset date is a partial date (imputed_date) - # - [Baseline Symptoms]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	base_symp_symptom_desc1-14	Symptom Description - # - [Baseline Symptoms]		Char
01. Principal	base_symp_visit_date	Visit Date - [Baseline Symptoms]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 11: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	phys_abdomen_comments1-5	Comments Required If Abnormal: Abdomen - # - [Physical Exam]		Char
01. Principal	phys_abdomen_status1-5	Status: Abdomen - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_appear_comments1-5	Comments Required If Abnormal: Appearance - # - [Physical Exam]		Char
01. Principal	phys_appear_status1-5	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_bmi1-5	BMI (kg/m2) - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	phys_bp_not_obt1-5	Blood Pressure Not Obtained - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	physBreasts_comments1-5	Comments Required If Abnormal: Breasts - # - [Physical Exam]		Char
01. Principal	physBreasts_status1-5	Status: Breasts - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_chest_comments1-5	Comments Required If Abnormal: Chest - # - [Physical Exam]		Char
01. Principal	phys_chest_status1-5	Status: Chest - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"

Class	Variable	Label	Description	Format Text
01. Principal	phys_diastolic_bp1-5	Diastolic (BP mm Hg) - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	phys_ecog1-5	ECOG Performance Status - # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="" "Normal activity. Fully active, able to carry on all pre-disease performance without restriction." 1="" "Symptoms, but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work)."
01. Principal	phys_heart_comments1-5	Comments Required If Abnormal: Heart - # - [Physical Exam]		Char
01. Principal	phys_heart_statuses1-5	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_heent_comments1-5	Comments Required If Abnormal: H/E/E/N/T - # - [Physical Exam]		Char
01. Principal	phys_heent_statuses1-5	Status: H/E/E/N/T - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_height1-5	Height - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	phys_height_not_obt1-5	Height Not Obtained - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_height_unit1-5	Height Unit - # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="cm" 2="In"
01. Principal	phys_hip1-5	Hip - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	phys_hip_unit1-5	Hip Unit - # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="cm" 2="In"
01. Principal	phys_interval1-5	Interval - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 3="Month" 4="Month 1" 6="Follow-up 1" 7="Off Study"
01. Principal	phys_interval_date1-5	Interval Date - # - [Physical Exam]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	phys_lungs_comments1-5	Comments Required If Abnormal: Lungs - # - [Physical Exam]		Char
01. Principal	phys_lungs_status1-5	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_comments1-5	Comments Required If Abnormal: Lymph Nodes - # - [Physical Exam]		Char
01. Principal	phys_lymph_status1-5	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_muskel_comments1-5	Comments Required If Abnormal: Musculoskeletal - # - [Physical Exam]		Char
01. Principal	phys_muskel_status1-5	Status: Musculoskeletal - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_neuro_comments1-5	Comments Required If Abnormal: Neurological - # - [Physical Exam]		Char

Class	Variable	Label	Description	Format Text
01. Principal	phys_neuro_status1-5	Status: Neurological - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_no_body_sys1-5	No Body Systems Were Examined - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_not_done1-5	Not Done - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	phys_other_body_system1_1-5	Specify Other Body System Site 1 - # - [Physical Exam]		Char
01. Principal	phys_other_body_system2_1-5	Specify Other Body System Site 2 - # - [Physical Exam]		Char
01. Principal	phys_other_body_system3_1-5	Specify Other Body System Site 3 - # - [Physical Exam]		Char
01. Principal	phys_other_comments1_1-5	Other 1 Comments Required If Abnormal - # - [Physical Exam]		Char
01. Principal	phys_other_comments2_1-5	Other 2 Comments Required If Abnormal - # - [Physical Exam]		Char
01. Principal	phys_other_comments3_1-5	Other 3 Comments Required If Abnormal - # - [Physical Exam]		Char
01. Principal	phys_other_status1_1-5	Other 1 Status - # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal"
01. Principal	phys_other_status2_1-5	Other 2 Status - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal"
01. Principal	phys_other_status3_1-5	Other 3 Status - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal"
01. Principal	phys_pulse_rate1-5	Pulse Rate - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	phys_pulse_rate_not_obt1-5	Pulse Rate Not Obtained - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_ratio1-5	Ratio - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	phys_resp_rate1-5	Respiration Rate - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	phys_resp_rate_not_obt1-5	Respiration Rate Not Obtained - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_skin_comments1-5	Comments Required If Abnormal: Skin - # - [Physical Exam]		Char
01. Principal	phys_skin_status1-5	Status: Skin - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_systolic_bp1-5	Systolic (BP mm Hg) - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	phys_temp1-5	Temperature - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	phys_temp_not_obt1-5	Temperature Not Obtained - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_temp_unit1-5	Temperature Unit - # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="°Celsius" 2="°Fahrenheit"
01. Principal	phys_thyroid_comments1-5	Comments Required If Abnormal: Thyroid - # - [Physical Exam]		Char

Class	Variable	Label	Description	Format Text
01. Principal	phys_thyroid_status1-5	Status: Thyroid - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_vascular_comments1-5	Comments Required If Abnormal: Vascular - # - [Physical Exam]		Char
01. Principal	phys_vascular_status1-5	Status: Vascular - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phys_visit_date1-5	Visit Date - # - [Physical Exam]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	phys_waist1-5	Waist - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	phys_waist_unit1-5	Waist Unit - # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="cm" 2="In"
01. Principal	phys_weight1-5	Weight - # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	phys_weight_not_obt1-5	Weight Not Obtained - # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_weight_unit1-5	Weight Unit - # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="kg"

Section 12: Tobacco Assessment - Baseline

Class	Variable	Label	Description	Format Text
01. Principal	tobacco_after_waking	How Soon After You Wake Up Do You Smoke Your First Cigarette - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="After 30 minutes" 2="Within 30 minutes"
01. Principal	tobacco_cigarettes_100	Have You Smoked 100 Cigarettes Or More During Your Entire Lifetime? - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Do Not Know/Not Sure"
01. Principal	tobacco_cigarettes_daily	Average Number Of Cigarettes Smoked Daily - [Tobacco Assessment - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 777="N/A"
01. Principal	tobacco_cigarettes_now	Do You Now Smoke Cigarettes - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not at all" 1="Some days" 2="Everyday"
01. Principal	tobacco_ever_other	Have You Ever Used Other Forms Of Tobacco - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_interval	Interval - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 4="Month 1"
01. Principal	tobacco_interval_date	Interval Date - [Tobacco Assessment - Baseline]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tobacco_last_smoked	How Long Since You Last Smoked Regularly - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Never smoked regularly" 1="(0 to 1 month ago) Within the past month" 2="(1 to 3 months ago) Between 1 and 3 months" 6="(5 to 15 years ago) Between 5 and 15 years" 7="More than 15 years ago" 8="Do not know/Not sure"

Class	Variable	Label	Description	Format Text
01. Principal	tobacco_last_smoked_oth	How Long Since You Last Used Other Forms Of Tobacco Regularly (Daily) - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Never smoked regularly" 1="(0 to 1 month ago) Within the past month" 6="(5 to 15 years ago) Between 5 and 15 years"
01. Principal	tobacco_other_forms	What Other Forms Of Tobacco Do You Use? - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 5="Other, specify"
01. Principal	tobacco_other_forms_chk	What Other Forms Of Tobacco Do You Use - Other, Specify Check Box Value - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	tobacco_other_now	Do You Use Other Forms Of Tobacco Everyday, Some Days, Or Not At All - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not at all" 2="Everyday"
01. Principal	tobacco_other_specify	What Other Forms Of Tobacco Do You Use - Other, Specify - [Tobacco Assessment - Baseline]		Char
01. Principal	tobacco_smoking_age	At What Age Did You Begin Smoking Regularly - [Tobacco Assessment - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 777="N/A"
01. Principal	tobacco_smoking_age_unk	At What Age Did You Begin Smoking Regularly - Do Not Know - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	tobacco_think_quit_6mo	Are You Seriously Thinking About Quitting Smoking In The Next 6 Months - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_think_quit_mo	Are You Seriously Thinking About Quitting In The Next Month - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tobacco_tried_quit	Number Of Times In The Last 12 Months You Tried To Quit - [Tobacco Assessment - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	tobacco_verified_date	Verified Date - [Tobacco Assessment - Baseline]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tobacco_verified_time	Verified Time - [Tobacco Assessment - Baseline]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tobacco_visit_date	Visit Date - [Tobacco Assessment - Baseline]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tobacco_yrs_smoking	Years Smoking Regularly - [Tobacco Assessment - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 777="N/A"
01. Principal	tobacco_yrs_smoking_unk	Years Smoking Regularly - Do Not Know - [Tobacco Assessment - Baseline]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"

Section 13: Alcohol Assessment - Baseline

Class	Variable	Label	Description	Format Text
01. Principal	alcohol_age_began	At What Age Did You Begin Drinking Regularly - [Alcohol Assessment - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 777="N/A"
01. Principal	alcohol_age_began_not_known	Do Not Know At What Age Drinking Began - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	alcohol_at_least_12	During Your Entire Life, Have You Had At Least 12 Drinks Of Alcoholic Beverage - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 99="Don't know/Not sure"
01. Principal	alcohol_avg_days_checkbox	How Many Days Did You Drink On Average - Checkbox - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Some days" 99="Do not know/Not sure"
01. Principal	alcohol_avg_days_per	How Many Days Did You Drink On Average, Number Of Days Per Period - [Alcohol Assessment - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 99="Do not know/Not sure"
01. Principal	alcohol_avg_days_per_period	How Many Days Did You Drink On Average, Period - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Week" 2="Month" 3="Year"
01. Principal	alcohol_avg_drinks_checkbox	At The Heaviest Point, How Many Drinks Did You Drink On Average - Checkbox - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Number of drinks" 99="Do not know/Not sure"
01. Principal	alcohol_avg_num_drinks	At The Heaviest Point, How Many Drinks Did You Drink On Average - [Alcohol Assessment - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 99="Do not know/Not sure"
01. Principal	alcohol_beer	Did You Drink Beer - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	alcohol_consom_e_now	Do You Now Consume Alcohol - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not at all" 1="Some days" 2="Everyday"
01. Principal	alcohol_interval	Interval - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 4="Month 1"
01. Principal	alcohol_interval_date	Interval Date - [Alcohol Assessment - Baseline]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	alcohol_liquor	Did You Drink Liquor - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	alcohol_since_last_drink	How Long Has It Been Since You Last Drank Regularly - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Never drank regularly" 1="(0 to 1 month ago) Within the past month" 2="(1 to 3 months ago) Between 1 and 3 months" 3="(3 to 6 months ago) Between 3 and 6 months" 4="(6 to 12 months ago) Between 3 and 6 months" 5="(1 to 5 years ago) Between 1 and 5 years" 6="(5 to 15 years ago) Between 5 and 15 years" 7="More than 15 years ago" 99="Do not know / Not sure"
01. Principal	alcohol_verified_date	Verified Date - [Alcohol Assessment - Baseline]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	alcohol_verified_time	Verified Time - [Alcohol Assessment - Baseline]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	alcohol_visit_date	Visit Date - [Alcohol Assessment - Baseline]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	alcohol_wine	Did You Drink Wine - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	alcohol_wine_cooler	Did You Drink Wine Coolers - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	alcohol_yrs_drink_not_known	Do Not Know How Many Years Drinking - [Alcohol Assessment - Baseline]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	alcohol_yrs_drinking	How Many Years Have You Been Drinking Or Did You Drink Regularly - [Alcohol Assessment - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 777="N/A"

Section 14: ConMed Evaluation

Class	Variable	Label	Description	Format Text
01. Principal	ae_con_conmed_reported_v1	Were Any New Or Changes In Concomitant Medications Reported - v1 - Screening - [AE and ConMed Evaluation]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="N/A" 3="Not Evaluated"
01. Principal	ae_con_conmed_reported_v2	Were Any New Or Changes In Concomitant Medications Reported - v2 - Baseline - [AE and ConMed Evaluation]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="N/A" 3="Not Evaluated"
01. Principal	ae_con_conmed_reported_v3	Were Any New Or Changes In Concomitant Medications Reported - v3 - Telephone Contact (Day 1) - [AE and ConMed Evaluation]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="N/A" 3="Not Evaluated"
01. Principal	ae_con_conmed_reported_v4	Were Any New Or Changes In Concomitant Medications Reported - v4 - Telephone Contact (Day 20) - [AE and ConMed Evaluation]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="N/A" 3="Not Evaluated"
01. Principal	ae_con_conmed_reported_v5	Were Any New Or Changes In Concomitant Medications Reported - v5 - Final Visit - [AE and ConMed Evaluation]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="N/A" 3="Not Evaluated"

Section 15: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	conmed_continuing1-32	Continuing Medication - # - [Concomitant Medications]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	conmed_dose1-32	Medication Dose - # - [Concomitant Medications]		Char
01. Principal	conmed_frequency1-32	Medication Frequency - # - [Concomitant Medications]		.F="No Record For This Visit" .M="Missing" .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_interval1-32	Interval - # - [Concomitant Medications]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 3="Month" 4="Month 1" 6="Follow-up 1"
01. Principal	conmed_interval_date1-32	Interval Date - # - [Concomitant Medications]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	conmed_med_report_imp_flag1-32	Medication Reported Date Is Imputed - # - [Concomitant Medications]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	conmed_med_report_date1-32	Medication Reported Date - # - [Concomitant Medications]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	conmed_medication1-32	Medication - # - [Concomitant Medications]		Char
01. Principal	conmed_oth_frequency1-32	Medication Other Frequency - # - [Concomitant Medications]		Char
01. Principal	conmed_oth_units1-32	Medication Other Units - # - [Concomitant Medications]		Char
01. Principal	conmed_reason1-32	Reason For Medication - # - [Concomitant Medications]		Char
01. Principal	conmed_start_date1-32	Medication Start Date - # - [Concomitant Medications]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 8="Unknown"
01. Principal	conmed_start_dt_imp_flag1-32	Medication Start Date Is Imputed - # - [Concomitant Medications]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	conmed_stop_date1-32	Medication Stop Date - # - [Concomitant Medications]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	conmed_stop_dt_imp_flag1-32	Medication Stop Date Is Imputed - # - [Concomitant Medications]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	conmed_units1-3 2	Medication Units - # - [Concomitant Medications]		.F="No Record For This Visit" .M="Missing" .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 16: Menopause Quality Of Life Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	qol_accomplish_less_rating1-2	Rate How Much You Have Been Bothered By Accomplishing Less Than I Used To - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_aching_rating1-2	Rate How Much You Have Been Bothered By Aching In Muscles And Joints - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_anxious_rating1-2	Rate How Much You Have Been Bothered By Feeling Anxious Or Nervous - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_avoid_intimacy_rating1-2	Rate How Much You Have Been Bothered By Avoiding Intimacy - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_backache_rating1-2	Rate How Much You Have Been Bothered By Low Backache - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_bloated_rating1-2	Rate How Much You Have Been Bothered By Feeling Bloating - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_bthrd_by_accomplish_less1-2	Bothered By Accomplishing Less Than I Used To - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"

Class	Variable	Label	Description	Format Text
01. Principal	qol_bthrd_by_aching1-2	Bothered By Aching In Muscles And Joints - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_anxious1-2	Bothered By Feeling Anxious Or Nervous - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_avoid_intimacy1-2	Bothered By Avoiding Intimacy - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_backache1-2	Bothered By Low Backache - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_bloated1-2	Bothered By Feeling Bloating - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_depressed1-2	Bothered By Feeling Depressed Down Or Blue - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_diff_sleep1-2	Bothered By Difficulty Sleeping - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_dissatisfied1-2	Bothered By Being Dissatisfied With My Personal Life - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_dry_skin1-2	Bothered By Drying Skin - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_facial_hair1-2	Bothered By Increased Facial Hair - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_frequent_urine1-2	Bothered By Frequent Urination - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"

Class	Variable	Label	Description	Format Text
01. Principal	qol_bthrd_by_gas1-2	Bothered By Flatulence (Wind) Or Gas Pains - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_hot_flashes1-2	Bothered By Hot Flushes Or Flashes - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by impatient1-2	Bothered By Being Impatient With Other People - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_invol_urine1-2	Bothered By Involuntary Urination When Laughing Or Coughing - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_lack_energy1-2	Bothered By Feeling A Lack Of Energy - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_less_stamina1-2	Bothered By Decrease In Stamina - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_neck_head_pain1-2	Bothered By Aches In Neck Or Back Of Head - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_night_sweats1-2	Bothered By Night Sweats - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_poor_memory1-2	Bothered By Experiencing Poor Memory - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_sexual_changes1-2	Bothered By Changes In Your Sexual Desire - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_skin_change1-2	Bothered By Changes In Appearance Texture Or Tone Of Your Skin - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"

Class	Variable	Label	Description	Format Text
01. Principal	qol_bthrd_by_sweating1-2	Bothered By Sweating - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_tired1-2	Bothered By Feeling Tired Or Worn Out - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_vag_dryness1-2	Bothered By Vaginal Dryness During Intercourse - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_want_alone1-2	Bothered By Feelings Of Wanting To Be Alone - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_weak1-2	Bothered By Decrease In Physical Strength - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_bthrd_by_weight_gain1-2	Bothered By Weight Gain - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No, Not At All" 1="Yes, Bothered"
01. Principal	qol_depressed_rating1-2	Rate How Much You Have Been Bothered By Feeling Depressed Down Or Blue - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_diff_sleep_rating1-2	Rate How Much You Have Been Bothered By Difficulty Sleeping - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_dissatisfied_rating1-2	Rate How Much You Have Been Bothered By Being Dissatisfied With My Personal Life - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"

Class	Variable	Label	Description	Format Text
01. Principal	qol_dry_skin_rating1-2	Rate How Much You Have Been Bothered By Drying Skin - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_facial_hair_rating1-2	Rate How Much You Have Been Bothered By Increased Facial Hair - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_freq_urine_rating1-2	Rate How Much You Have Been Bothered By Frequent Urination - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_gas_rating1-2	Rate How Much You Have Been Bothered By Flatulence (Wind) Or Gas Pains - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_hot_flashes_rating1-2	Rate How Much You Have Been Bothered By Hot Flashes Or Flashes - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_impatient_rating1-2	Rate How Much You Have Been Bothered By Being Impatient With Other People - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_interval1-2	Interval - # - [Menopause Quality Of Life Questionnaire]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 3="Month" 4="Month 1" 6="Follow-up 1" 7="Off Study"
01. Principal	qol_interval_date1-2	Interval Date - # - [Menopause Quality Of Life Questionnaire]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	qol_invol_urine_rating1-2	Rate How Much You Have Been Bothered By Involuntary Urination When Laughing Or Coughing - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_lack_energy_rating1-2	Rate How Much You Have Been Bothered By Feeling A Lack Of Energy - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_less_stamina_rating1-2	Rate How Much You Have Been Bothered By Decrease In Stamina - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_neck_head_pain_rating1-2	Rate How Much You Have Been Bothered By Aches In Neck Or Back Of Head - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_night_sweats_rating1-2	Rate How Much You Have Been Bothered By Night Sweats - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_poor_memory_rating1-2	Rate How Much You Have Been Bothered By Experiencing Poor Memory - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_sexual_changes_rating1-2	Rate How Much You Have Been Bothered By Changes In Your Sexual Desire - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_skin_change_rating1-2	Rate How Much You Have Been Bothered By Changes In Appearance Texture Or Tone Of Your Skin - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"

Class	Variable	Label	Description	Format Text
01. Principal	qol_sweating_rating1-2	Rate How Much You Have Been Bothered By Sweating - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_tired_rating1-2	Rate How Much You Have Been Bothered By Feeling Tired Or Worn Out - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_vag_dryness_rating1-2	Rate How Much You Have Been Bothered By Vaginal Dryness During Intercourse - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_visit_date1-2	Visit Date - # - [Menopause Quality Of Life Questionnaire]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	qol_want_alone_rating1-2	Rate How Much You Have Been Bothered By Feelings Of Wanting To Be Alone - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_weak_rating1-2	Rate How Much You Have Been Bothered By Decrease In Physical Strength - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"
01. Principal	qol_weight_gain_rating1-2	Rate How Much You Have Been Bothered By Weight Gain - # - [Menopause Quality Of Life Questionnaire]	0=Not At All to 6=Extremely Bothered	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not At All" 6="Extremely Bothered"

Section 17: Eligibility Verification

Class	Variable	Label	Description	Format Text
01. Principal	elig_comments	Comments - [Eligibility Verification]		Char
01. Principal	elig_mdacc_patient_id	MDACC Patient Identifier - [Eligibility Verification]		Char
01. Principal	elig_rand_criteria	Meets Randomization Criteria? - [Eligibility Verification]		0="No" 1="Yes"
01. Principal	elig_rand_date	Randomization Date - [Eligibility Verification]		SAS Date .M="Missing"
01. Principal	elig_rand_indicator	Randomization Indicator - [Eligibility Verification]		.N="N/A" 1="Participant not eligible for randomization" 2="Randomization data inconsistent"
01. Principal	elig_verification_status	Verification Status - [Eligibility Verification]		.M="Missing" 1="Confirmed" 2="Ineligible" 3="Pending"
01. Principal	elig_verified_date	Verified Date - [Eligibility Verification]		SAS Date .M="Missing"

Section 18: Randomization

Class	Variable	Label	Description	Format Text
01. Principal	rand_accession	Accession - [Randomization]		Numeric
01. Principal	rand_agent_start_date_4wk	Potential Agent Start Date: 4 Weeks Of Treatment - [Randomization]		SAS Date .M="Missing"
01. Principal	rand_agent_start_date_5wk	Potential Agent Start Date: 5 Weeks Of Treatment - [Randomization]		SAS Date .M="Missing"
01. Principal	rand_agent_start_date_6wk	Potential Agent Start Date: 6 Weeks Of Treatment - [Randomization]		SAS Date .M="Missing"
01. Principal	rand_bmi	BMI (kg/m2) - [Randomization]		.M="Missing" 1=" < 25 kg/m2" 2=" >= 25kg/m2"
01. Principal	rand_eligibility_status	Eligibility Status: Is The Participant Eligible For Inclusion On This Protocol - [Randomization]		0="No" 1="Yes"
01. Principal	rand_enrollment_date	Participant Enrollment Date - [Randomization]		SAS Date .M="Missing" 7="N/A"
01. Principal	rand_institution	Institution - [Randomization]		1="Columbia University Medical Center" 2="European Institue Of Oncology" 3="Galliera Hospital" 4="M. D. Anderson Cancer Center" 5="Moffitt Cancer Center"
01. Principal	rand_interval	Interval - [Randomization]		1="Event Interval Not Available" 2="Baseline" 4="Month 1"
01. Principal	rand_interval_date	Interval Date - [Randomization]		SAS Date 9="Missing"
01. Principal	rand_not_applicable	Randomization: Not Applicable - [Randomization]		0="False" 1="True"
01. Principal	rand_randomization_date	Randomization Date - [Randomization]		SAS Date .M="Missing"
01. Principal	rand_randomization_no	Randomization Number - [Randomization]		Char
01. Principal	rand_reg_date	Registration Date - [Randomization]		SAS Date
01. Principal	rand_reg_time	Registration Time - [Randomization]		SAS Time

Class	Variable	Label	Description	Format Text
01. Principal	rand_sched_surg_date	Scheduled Surgery Date - [Randomization]		SAS Date .M="Missing" 7="N/A" 8="Unknown"
01. Principal	rand_site	Site - [Randomization]		1="CUMC" 2="EIO" 3="GALLIERA" 4="MDACC" 5="Moffitt"
01. Principal	rand_tac1	TAC1 (Exemestane 25 mg PO (Daily or Three Times A Week Or Once A Week) x 4 to 6 Weeks) - [Randomization]		.M="Missing" .R="Not Randomized" 1="Yes"
01. Principal	rand_trial	Trial - [Randomization]		Char

Section 19: Intervention Administration (Blinded Study)

Class	Variable	Label	Description	Format Text
01. Principal	intab_4wk_date	Date Agent Started For 4 Weeks Of Treatment - [Intervention Administration (Blinded Study)]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	intab_5wk_date	Date Agent Started For 5 Weeks Of Treatment - [Intervention Administration (Blinded Study)]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	intab_6wk_date	Date Agent Started For 6 Weeks Of Treatment - [Intervention Administration (Blinded Study)]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	intab_agent_number	Agent Number - [Intervention Administration (Blinded Study)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	intab_agent_placebo	Agent/Placebo - [Intervention Administration (Blinded Study)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Exemestane/Placebo 25 mg"
01. Principal	intab_comments	Comments - [Intervention Administration (Blinded Study)]		Char
01. Principal	intab_date_agent_provided	Date Agent Provided To Participant - [Intervention Administration (Blinded Study)]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	intab_date_agent_started	Date Agent Started - When Weeks Of Treatment Not Noted - [Intervention Administration (Blinded Study)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	intab_dose	Agent Dose - [Intervention Administration (Blinded Study)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="1 Tab"
01. Principal	intab_freq	Agent Frequency - [Intervention Administration (Blinded Study)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Daily (QD)"

Class	Variable	Label	Description	Format Text
01. Principal	intab_interval	Interval - [Intervention Administration (Blinded Study)]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 3="Month" 4="Month 1"
01. Principal	intab_interval_date	Interval Date - [Intervention Administration (Blinded Study)]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	intab_visit_date	Visit Date - [Intervention Administration (Blinded Study)]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	intab_wks_of_treatment	Date Agent Started Options - Weeks Of Treatment - [Intervention Administration (Blinded Study)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 4="4 weeks of treatment" 5="5 weeks of treatment" 6="6 weeks of treatment" 7="Other (Comment Required), Specify:"

Section 20: Compliance Drug Labels

Class	Variable	Label	Description	Format Text
01. Principal	comp_drug_interval	Interval - [Compliance Drug Labels]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 4="Month 1"
01. Principal	comp_drug_interval_date	Interval Date - [Compliance Drug Labels]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	comp_drug_labels_affixed	Were Labels Affixed - [Compliance Drug Labels]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	comp_drug_verified_date	Verified Date - [Compliance Drug Labels]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	comp_drug_verified_time	Verified Time - [Compliance Drug Labels]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	comp_drug_visit_date	Visit Date - [Compliance Drug Labels]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 21: Exemestane Pill Diary

Class	Variable	Label	Description	Format Text
01. Principal	expill_agent_returned	Agent Returned - [Exemestane Pill Diary]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	expill_date1-42	Date - Day # - [Exemestane Pill Diary]	Days 1 - 7 correspond to Wallet 1 Blister 1 Days 8 - 14 correspond to Wallet 1 Blister 2 Days 15 - 21 correspond to Wallet 1 Blister 3 Days 22 - 28 correspond to Wallet 2 Blister 1 Days 29 - 35 correspond to Wallet 2 Blister 2 Days 36 - 42 correspond to Wallet 2 Blister 3	SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	expill_interval	Interval - [Exemestane Pill Diary]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 3="Month" 4="Month 1" 5="Follow-up" 7="Off Study"
01. Principal	expill_interval_date	Interval Date - [Exemestane Pill Diary]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	expill_note1-42	Note - Day # - [Exemestane Pill Diary]	Days 1 - 7 correspond to Wallet 1 Blister 1 Days 8 - 14 correspond to Wallet 1 Blister 2 Days 15 - 21 correspond to Wallet 1 Blister 3 Days 22 - 28 correspond to Wallet 2 Blister 1 Days 29 - 35 correspond to Wallet 2 Blister 2 Days 36 - 42 correspond to Wallet 2 Blister 3	Char
01. Principal	expill_num_pills_given	Number Of Pills Given - [Exemestane Pill Diary]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	expill_num_pills_returned	Number Of Pills Returned - [Exemestane Pill Diary]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	expill_time1-42	Time - Day # - [Exemestane Pill Diary]	Days 1 - 7 correspond to Wallet 1 Blister 1 Days 8 - 14 correspond to Wallet 1 Blister 2 Days 15 - 21 correspond to Wallet 1 Blister 3 Days 22 - 28 correspond to Wallet 2 Blister 1 Days 29 - 35 correspond to Wallet 2 Blister 2 Days 36 - 42 correspond to Wallet 2 Blister 3	SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	expill_took_tablet1-42	Took 1 Tablet Yes/No - Day # - [Exemestane Pill Diary]	Days 1 - 7 correspond to Wallet 1 Blister 1 Days 8 - 14 correspond to Wallet 1 Blister 2 Days 15 - 21 correspond to Wallet 1 Blister 3 Days 22 - 28 correspond to Wallet 2 Blister 1 Days 29 - 35 correspond to Wallet 2 Blister 2 Days 36 - 42 correspond to Wallet 2 Blister 3	.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	expill_total_daily_dose	Total Daily Dose - [Exemestane Pill Diary]		.F="No Record For This Visit" .R="Not Randomized" 1="25 mg"
01. Principal	expill_verified_date	Verified Date - [Exemestane Pill Diary]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	expill_verified_time	Verified Time - [Exemestane Pill Diary]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	expill_visit	Visit Type When Visit Date Not Provided - [Exemestane Pill Diary]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="1" 2="2" 3="Baseline Visit" 4="Baseline/Final Visit" 5="Final Visit"
01. Principal	expill_visit_date	Visit Date When Visit Type Not Provided - [Exemestane Pill Diary]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Section 22: Drug Compliance

Class	Variable	Label	Description	Format Text
01. Principal	drug_comp_agent_name	Agent Name - [Drug Compliance]		.F="No Record For This Visit" .R="Not Randomized" 1="Exemestane/Placebo 25 mg"
01. Principal	drug_comp_amount_missing	Amount Of Agent Missing Not Accounted For This Period - [Drug Compliance]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	drug_comp_amount_returned	Amount Of Agent Returned At This Visit - [Drug Compliance]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	drug_comp_amount_taken	Amount Of Agent Taken During This Period - [Drug Compliance]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	drug_comp_amt_agent_last_vis	Amount Of Agent Provided At Last Visit - [Drug Compliance]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	drug_comp_amt_last_visit_na	Amount Of Agent Provided At Last Visit - Not Applicable Checkbox - [Drug Compliance]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_compliant	Is The Participant Compliant With Protocol Intervention - [Drug Compliance]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	drug_comp_dose	Agent Dose (Tab) - [Drug Compliance]		.F="No Record For This Visit" .R="Not Randomized" 1="1 Tab"
01. Principal	drug_comp_dose_freq	Frequency Of Agent Dose - [Drug Compliance]		.F="No Record For This Visit" .R="Not Randomized" 1="Daily (QD)"
01. Principal	drug_comp_first_dose_date	First Dose Taken This Date - [Drug Compliance]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	drug_comp_first_dose_time	First Dose Taken This Time - [Drug Compliance]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	drug_comp_first_unk	Unknown When First Dose Taken This Period - [Drug Compliance]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	drug_comp_interval	Interval - [Drug Compliance]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 3="Month" 4="Month 1" 6="Follow-up 1" 7="Off Study"
01. Principal	drug_comp_interval_date	Interval Date - [Drug Compliance]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	drug_comp_last_blister	Last Planned Date Corresponding to Blister - [Drug Compliance]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	drug_comp_last_day	Last Planned Date Corresponding to Day - [Drug Compliance]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	drug_comp_last_dose_date	Last Dose Taken This Date - [Drug Compliance]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	drug_comp_last_dose_time	Last Dose Taken This Time - [Drug Compliance]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	drug_comp_last_planned_dt	Last Planned Date - [Drug Compliance]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	drug_comp_last_planned_tm	Last Planned Time - [Drug Compliance]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	drug_comp_last_unk	Unknown When Last Dose Taken This Period - [Drug Compliance]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_last_wallet	Last Planned Date Corresponding to Wallet - [Drug Compliance]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	drug_comp_visit_date	Visit Date - [Drug Compliance]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	drug_comp_visit_time	Visit Time - [Drug Compliance]		SAS Time .F="No Record For This Visit" .R="Not Randomized"
01. Principal	drug_comp_w1b1d1_not_taken	Pill In Wallet 1, Blister 1, Day 1 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	drug_comp_w1b1d2_not_taken	Pill In Wallet 1, Blister 1, Day 2 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	drug_comp_w1b1d3_not_taken	Pill In Wallet 1, Blister 1, Day 3 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b1d4_not_taken	Pill In Wallet 1, Blister 1, Day 4 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b1d5_not_taken	Pill In Wallet 1, Blister 1, Day 5 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b1d6_not_taken	Pill In Wallet 1, Blister 1, Day 6 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b1d7_not_taken	Pill In Wallet 1, Blister 1, Day 7 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b2d1_not_taken	Pill In Wallet 1, Blister 2, Day 1 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b2d2_not_taken	Pill In Wallet 1, Blister 2, Day 2 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b2d3_not_taken	Pill In Wallet 1, Blister 2, Day 3 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b2d4_not_taken	Pill In Wallet 1, Blister 2, Day 4 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b2d5_not_taken	Pill In Wallet 1, Blister 2, Day 5 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b2d6_not_taken	Pill In Wallet 1, Blister 2, Day 6 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	drug_comp_w1b2d7_not_taken	Pill In Wallet 1, Blister 2, Day 7 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b3d1_not_taken	Pill In Wallet 1, Blister 3, Day 1 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b3d2_not_taken	Pill In Wallet 1, Blister 3, Day 2 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b3d3_not_taken	Pill In Wallet 1, Blister 3, Day 3 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b3d4_not_taken	Pill In Wallet 1, Blister 3, Day 4 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b3d5_not_taken	Pill In Wallet 1, Blister 3, Day 5 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b3d6_not_taken	Pill In Wallet 1, Blister 3, Day 6 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w1b3d7_not_taken	Pill In Wallet 1, Blister 3, Day 7 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b1d1_not_taken	Pill In Wallet 2, Blister 1, Day 1 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b1d2_not_taken	Pill In Wallet 2, Blister 1, Day 2 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b1d3_not_taken	Pill In Wallet 2, Blister 1, Day 3 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	drug_comp_w2b1d4_not_taken	Pill In Wallet 2, Blister 1, Day 4 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b1d5_not_taken	Pill In Wallet 2, Blister 1, Day 5 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b1d6_not_taken	Pill In Wallet 2, Blister 1, Day 6 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b1d7_not_taken	Pill In Wallet 2, Blister 1, Day 7 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b2d1_not_taken	Pill In Wallet 2, Blister 2, Day 1 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b2d2_not_taken	Pill In Wallet 2, Blister 2, Day 2 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b2d3_not_taken	Pill In Wallet 2, Blister 2, Day 3 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b2d4_not_taken	Pill In Wallet 2, Blister 2, Day 4 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b2d5_not_taken	Pill In Wallet 2, Blister 2, Day 5 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b2d6_not_taken	Pill In Wallet 2, Blister 2, Day 6 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b2d7_not_taken	Pill In Wallet 2, Blister 2, Day 7 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	drug_comp_w2b3d1_not_taken	Pill In Wallet 2, Blister 3, Day 1 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b3d2_not_taken	Pill In Wallet 2, Blister 3, Day 2 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b3d3_not_taken	Pill In Wallet 2, Blister 3, Day 3 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b3d4_not_taken	Pill In Wallet 2, Blister 3, Day 4 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b3d5_not_taken	Pill In Wallet 2, Blister 3, Day 5 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b3d6_not_taken	Pill In Wallet 2, Blister 3, Day 6 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	drug_comp_w2b3d7_not_taken	Pill In Wallet 2, Blister 3, Day 7 Not Taken - [Drug Compliance]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Section 23: Agent Interruption Form

Class	Variable	Label	Description	Format Text
01. Principal	ag_int_date_stopped1-2	Specify Date Stopped - # - [Agent Interruption Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ag_int_interval1-2	Interval - # - [Agent Interruption Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available" 3="Month"
01. Principal	ag_int_interval_date1-2	Interval Date - # - [Agent Interruption Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ag_int_reason_stopped1-2	Reason Stopped - # - [Agent Interruption Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 2="Participant decision, specify" 3="AE/SAE, specify" 4="Other, specify"
01. Principal	ag_int_specify_reason_stopped1-2	Specify Reason Stopped - # - [Agent Interruption Form]		Char

Section 24: AE Evaluation

Class	Variable	Label	Description	Format Text
01. Principal	ae_con_ae_reported_v1	Were Any New Or Changes In Adverse Events Reported - v1 - Screening - [AE and ConMed Evaluation]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="N/A"
01. Principal	ae_con_ae_reported_v2	Were Any New Or Changes In Adverse Events Reported - v2 - Baseline - [AE and ConMed Evaluation]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes" 2="N/A"
01. Principal	ae_con_ae_reported_v3	Were Any New Or Changes In Adverse Events Reported - v3 - Telephone Contact (Day 1) - [AE and ConMed Evaluation]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="N/A"
01. Principal	ae_con_ae_reported_v4	Were Any New Or Changes In Adverse Events Reported - v4 - Telephone Contact (Day 20) - [AE and ConMed Evaluation]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="N/A"
01. Principal	ae_con_ae_reported_v5	Were Any New Or Changes In Adverse Events Reported - v5 - Final Visit - [AE and ConMed Evaluation]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="N/A"

Section 25: Telephone Contact

Class	Variable	Label	Description	Format Text
01. Principal	tele_chg_concom_meds1-6	Were Any Changes In Concomitant Medications Reported - # - [Telephone Contact]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes (Complete Con Med CRF)" 7="N/A"
01. Principal	tele_contact_date1-6	Date of Contact - # - [Telephone Contact]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	tele_contact_result1-6	Contact Result - # - [Telephone Contact]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Spoke to Patient/Participant" 2="Spoke to family member" 4="Left voicemail message" 5="No contact made (End this form; do not complete remaining questions)"
01. Principal	tele_contact_time1-6	Time of Contact - # - [Telephone Contact]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	tele_contact_time_unk1-6	Contact Time Unknown - # - [Telephone Contact]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	tele_contact_type1-6	Contact Type - # - [Telephone Contact]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Home Phone" 2="Work Phone" 3="Home Cell" 4="Work Cell"
01. Principal	tele_interval1-6	Interval - # - [Telephone Contact]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available" 3="Month" 4="Month 1" 5="Follow-up" 6="Follow-up 1" 7="Off Study"
01. Principal	tele_interval_date1-6	Interval Date - # - [Telephone Contact]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	tele_reported_symptoms_ae1-6	Did The Participant Report Any Symptoms Or Adverse Events - # - [Telephone Contact]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes (Complete AE CRF)" 2="Too early to evaluate"

Section 26: Off Study

Class	Variable	Label	Description	Format Text
01. Principal	offst_agent_date_na	Agent End Date Not Applicable - [Off Study]		0="False" 1="True"
01. Principal	offst_agent_end_date	Agent End Date - [Off Study]		SAS Date .M="Missing" .N="N/A" 7="N/A"
01. Principal	offst_agent_end_time	Agent End Time - [Off Study]		SAS Time .M="Missing" .N="N/A" 7="N/A"
01. Principal	offst_comments	Off Study Reason Comments - [Off Study]		Char
01. Principal	offst_date_last_contact	Date Of Last Contact - [Off Study]		SAS Date .M="Missing" 7="N/A"
01. Principal	offst_date_off_followup	Date Off Follow-Up - [Off Study]		SAS Date .M="Missing" .N="N/A"
01. Principal	offst_date_on_followup	Date On Follow-Up - [Off Study]		SAS Date .M="Missing" .N="N/A"
01. Principal	offst_did_not_have_adv_events	Participant Did Not Have Any Adverse Events - [Off Study]		.N="N/A" 0="False" 1="True"
01. Principal	offst_did_not_have_adv_int	Participant Did Not Have Any Agent Interrupts - [Off Study]		.N="N/A" 0="False" 1="True"
01. Principal	offst_did_not_take_con_meds	Participant Did Not Take Any Con Meds - [Off Study]		.N="N/A" 0="False" 1="True"
01. Principal	offst_followup_na	Follow-Up Not Applicable - [Off Study]		.N="N/A" 0="False" 1="True"
01. Principal	offst_form_date	Form Date - [Off Study]		SAS Date
01. Principal	offst_interval	Interval - [Off Study]		1="Event Interval Not Available" 3="Month" 4="Month 1" 5="Follow-up" 7="Off Study"
01. Principal	offst_interval_date	Interval Date - [Off Study]		SAS Date
01. Principal	offst_off_study_date	Off Study Date - [Off Study]		SAS Date

Class	Variable	Label	Description	Format Text
01. Principal	offst_reason	Off Study Reason - [Off Study]		1="Adverse Event" 5="Other, specify" 6="Participant Withdrawal" 8="Physician Decision" 11="Study Complete" 12="Ineligible"

Section 27: Clinical Lab - Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	lab_bl_bilirubin_clin_sig1-4	Lab Test Clinically Significant - Total Bilirubin - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_bilirubin_cmt1-4	Lab Test Comments - Total Bilirubin - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_bilirubin_not_obt1-4	Lab Test Not Obtained - Total Bilirubin - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_bilirubin_out_range1-4	Lab Test Result - Out Of Range - Total Bilirubin - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_bilirubin_result1-4	Lab Test Result - Total Bilirubin - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0.19="<0.2"
01. Principal	lab_bl_bilirubin_units1-4	Lab Test Result Units - Total Bilirubin - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_bun_clin_sig1-4	Lab Test Clinically Significant - Bun - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_bun_cmt1-4	Lab Test Comments - Bun - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_bun_not_obt1-4	Lab Test Not Obtained - Bun - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_bun_out_range1-4	Lab Test Result - Out Of Range - Bun - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_bun_result1-4	Lab Test Result - Bun (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lab_bl_calcium_c lin_sig1-4	Lab Test Clinically Significant - Calcium - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_calcium_c mt1-4	Lab Test Comments - Calcium - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_calcium_n ot_obt1-4	Lab Test Not Obtained - Calcium - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_calcium_o ut_range1-4	Lab Test Result - Out Of Range - Calcium - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_calcium_r esult1-4	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	lab_bl_chloride_ clin_sig1-4	Lab Test Clinically Significant - Chloride - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_chloride_ cmt1-4	Lab Test Comments - Chloride - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_chloride_ not_obt1-4	Lab Test Not Obtained - Chloride - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_chloride_ out_range1-4	Lab Test Result - Out Of Range - Chloride - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_chloride_r esult1-4	Lab Test Result - Chloride - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_chloride_ units1-4	Lab Test Result Units - Chloride - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_cholester ol_clin_sig1-4	Lab Test Clinically Significant - Cholesterol - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_cholester ol_cmt1-4	Lab Test Comments - Cholesterol - # - [Clinical Lab - Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	lab_bl_cholesterol_not_obt1-4	Lab Test Not Obtained - Cholesterol - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_cholesterol_out_range1-4	Lab Test Result - Out Of Range - Cholesterol - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_cholesterol_result1-4	Lab Test Result - Cholesterol (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_creatinine_clin_sig1-4	Lab Test Clinically Significant - Creatinine - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_creatinine_cmt1-4	Lab Test Comments - Creatinine - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_creatinine_not_obt1-4	Lab Test Not Obtained - Creatinine - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_creatinine_out_range1-4	Lab Test Result - Out Of Range - Creatinine - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_creatinine_result1-4	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	lab_bl_date_last_dose1-4	Date Last Dose Taken - # - [Clinical Lab - Blood Chemistry]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	lab_bl_date_spec_collected1-4	Date Specimen Collected - # - [Clinical Lab - Blood Chemistry]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_fasting1-4	Fasting - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .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 '*'"

Class	Variable	Label	Description	Format Text
01. Principal	lab_bl_fsh_clin_sig1-4	Lab Test Clinically Significant - FSH - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_fsh_cmt1-4	Lab Test Comments - FSH - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_fsh_not_obt1-4	Lab Test Not Obtained - FSH - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_fsh_out_range1-4	Lab Test Result - Out Of Range - FSH - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_fsh_result1-4	Lab Test Result - FSH (mIU/mL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_glucose_clin_sig1-4	Lab Test Clinically Significant - Serum Glucose - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_glucose_cmt1-4	Lab Test Comments - Serum Glucose - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_glucose_not_obt1-4	Lab Test Not Obtained - Serum Glucose - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_glucose_out_range1-4	Lab Test Result - Out Of Range - Serum Glucose - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_glucose_result1-4	Lab Test Result - Serum Glucose (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_hdl_cholesterol_clin_sig1-4	Lab Test Clinically Significant - HDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_hdl_cholesterol_cmt1-4	Lab Test Comments - HDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	lab_bl_hdl_cholesterol_not_obt1-4	Lab Test Not Obtained - HDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_hdl_cholesterol_out_range1-4	Lab Test Result - Out Of Range - HDL Cholesterol - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_hdl_cholesterol_result1-4	Lab Test Result - HDL Cholesterol (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_interval1-4	Interval - # - [Clinical Lab - Blood Chemistry]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 3="Month" 4="Month 1" 6="Follow-up 1" 7="Off Study"
01. Principal	lab_bl_interval_date1-4	Interval Date - # - [Clinical Lab - Blood Chemistry]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_potassium_clin_sig1-4	Lab Test Clinically Significant - Potassium - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_potassium_comments1-4	Lab Test Comments - Potassium - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_potassium_not_obt1-4	Lab Test Not Obtained - Potassium - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_potassium_out_range1-4	Lab Test Result - Out Of Range - Potassium - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_potassium_result1-4	Lab Test Result - Potassium - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_potassium_units1-4	Lab Test Result Units - Potassium - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_sgot_ast_clin_sig1-4	Lab Test Clinically Significant - SGOT/AST - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lab_bl_sgot_ast_cmt1-4	Lab Test Comments - SGOT/AST - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_sgot_ast_not_obt1-4	Lab Test Not Obtained - SGOT/AST - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_sgot_ast_out_range1-4	Lab Test Result - Out Of Range - SGOT/AST - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_sgot_ast_result1-4	Lab Test Result - SGOT/AST - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_sgot_ast_units1-4	Lab Test Result Units - SGOT/AST - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_sgpt_alt_clin_sig1-4	Lab Test Clinically Significant - SGPT/ALT - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_sgpt_alt_cmt1-4	Lab Test Comments - SGPT/ALT - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_sgpt_alt_not_obt1-4	Lab Test Not Obtained - SGPT/ALT - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_sgpt_alt_out_range1-4	Lab Test Result - Out Of Range - SGPT/ALT - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_sgpt_alt_result1-4	Lab Test Result - SGPT/ALT - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_sgpt_alt_units1-4	Lab Test Result Units - SGPT/ALT - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_sodium_clin_sig1-4	Lab Test Clinically Significant - Sodium - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_sodium_cmt1-4	Lab Test Comments - Sodium - # - [Clinical Lab - Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	lab_bl_sodium_not_obt1-4	Lab Test Not Obtained - Sodium - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_sodium_out_range1-4	Lab Test Result - Out Of Range - Sodium - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_sodium_result1-4	Lab Test Result - Sodium - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_sodium_units1-4	Lab Test Result Units - Sodium - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_time_last_dose1-4	Time Last Dose Taken - # - [Clinical Lab - Blood Chemistry]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	lab_bl_time_spec_collected1-4	Time Specimen Collected - # - [Clinical Lab - Blood Chemistry]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_triglycerides_clin_sig1-4	Lab Test Clinically Significant - Triglycerides - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_triglycerides_cmt1-4	Lab Test Comments - Triglycerides - # - [Clinical Lab - Blood Chemistry]		Char
01. Principal	lab_bl_triglycerides_not_obt1-4	Lab Test Not Obtained - Triglycerides - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_triglycerides_out_range1-4	Lab Test Result - Out Of Range - Triglycerides - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_triglycerides_result1-4	Lab Test Result - Triglycerides (mg/dL) - # - [Clinical Lab - Blood Chemistry]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_unknown_time_dose_taken1-4	Unknown - Date And Time Last Dose Taken - # - [Clinical Lab - Blood Chemistry]		.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	lab_bl_visit_date 1-4	Visit Date - # - [Clinical Lab - Blood Chemistry]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_bl_visit_time 1-4	Visit Time - # - [Clinical Lab - Blood Chemistry]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Section 28: Clinical Lab - Hematology

Class	Variable	Label	Description	Format Text
01. Principal	lab_hema_anc_clin_sig1-3	Lab Test Clinically Significant - Absolute Neutrophil Count (ANC) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_anc_comments1-3	Lab Test Comments - Absolute Neutrophil Count (ANC) - # - [Clinical Lab - Hematology]		Char
01. Principal	lab_hema_anc_not_obt1-3	Lab Test Not Obtained - Absolute Neutrophil Count (ANC) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_anc_out_range1-3	Lab Test Result - Out Of Range - Absolute Neutrophil Count (ANC) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_anc_result1-3	Lab Test Result - Absolute Neutrophil Count (ANC) - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_anc_units1-3	Lab Test Result Units - Absolute Neutrophil Count (ANC) - # - [Clinical Lab - Hematology]		Char
01. Principal	lab_hema_date_spec_col1-3	Date Specimen Collected - # - [Clinical Lab - Hematology]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	lab_hema_fasting1-3	Fasting - # - [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	lab_hema_hematocrit_clin_sig1-3	Lab Test Clinically Significant - Hematocrit - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lab_hema_hematocrit_cmt1-3	Lab Test Comments - Hematocrit - # - [Clinical Lab - Hematology]		Char
01. Principal	lab_hema_hematocrit_not_obt1-3	Lab Test Not Obtained - Hematocrit - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_hematocrit_out_range1-3	Lab Test Result - Out Of Range - Hematocrit - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_hematocrit_result1-3	Lab Test Result - Hematocrit - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_hematocrit_units1-3	Lab Test Result Units - Hematocrit - # - [Clinical Lab - Hematology]		Char
01. Principal	lab_hema_hemoglobin_clin_sig1-3	Lab Test Clinically Significant - Hemoglobin - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_hemoglobin_cmt1-3	Lab Test Comments - Hemoglobin - # - [Clinical Lab - Hematology]		Char
01. Principal	lab_hema_hemoglobin_not_obt1-3	Lab Test Not Obtained - Hemoglobin - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_hemoglobin_out_range1-3	Lab Test Result - Out Of Range - Hemoglobin - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_hemoglobin_result1-3	Lab Test Result - Hemoglobin - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_hemoglobin_units1-3	Lab Test Result Units - Hemoglobin - # - [Clinical Lab - Hematology]		Char
01. Principal	lab_hema_interval1-3	Interval - # - [Clinical Lab - Hematology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 3="Month" 4="Month 1" 6="Follow-up 1" 7="Off Study"

Class	Variable	Label	Description	Format Text
01. Principal	lab_hema_interv al_date1-3	Interval Date - # - [Clinical Lab - Hematology]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_platele ts_clin_sig1-3	Lab Test Clinically Significant - Platelets - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_platele ts_cmt1-3	Lab Test Comments - Platelets - # - [Clinical Lab - Hematology]		Char
01. Principal	lab_hema_platele ts_not_obt1-3	Lab Test Not Obtained - Platelets - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_platele ts_out_range1-3	Lab Test Result - Out Of Range - Platelets - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_platele ts_result1-3	Lab Test Result - Platelets - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_platele ts_units1-3	Lab Test Result Units - Platelets - # - [Clinical Lab - Hematology]		Char
01. Principal	lab_hema_rbc_cli n_sig1-3	Lab Test Clinically Significant - RBC - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_rbc_c mt1-3	Lab Test Comments - RBC - # - [Clinical Lab - Hematology]		Char
01. Principal	lab_hema_rbc_n ot_obt1-3	Lab Test Not Obtained - RBC - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_rbc_o ut_range1-3	Lab Test Result - Out Of Range - RBC - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_rbc_re sult1-3	Lab Test Result - RBC - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_rbc_u nits1-3	Lab Test Result Units - RBC - # - [Clinical Lab - Hematology]		Char

Class	Variable	Label	Description	Format Text
01. Principal	lab_hema_time_spec_col1-3	Time Specimen Collected - # - [Clinical Lab - Hematology]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	lab_hema_visit_date1-3	Visit Date - # - [Clinical Lab - Hematology]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_visit_time1-3	Visit Time - # - [Clinical Lab - Hematology]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_wbc_clin_sig1-3	Lab Test Clinically Significant - WBC - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_wbc_comments1-3	Lab Test Comments - WBC - # - [Clinical Lab - Hematology]		Char
01. Principal	lab_hema_wbc_not_obt1-3	Lab Test Not Obtained - WBC - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_wbc_out_range1-3	Lab Test Result - Out Of Range - WBC - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_wbc_result1-3	Lab Test Result - WBC - # - [Clinical Lab - Hematology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_hema_wbc_units1-3	Lab Test Result Units - WBC - # - [Clinical Lab - Hematology]		Char

Section 29: Clinical Lab - Other

Class	Variable	Label	Description	Format Text
01. Principal	lab_oth_date_spec_col1-4	Date Specimen Collected - From Date # - [Clinical Lab - Other]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	lab_oth_fasting1-4	Fasting - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_interval1-4	Interval - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_interval_date1-4	Interval Date - From Date # - [Clinical Lab - Other]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_10_clin_sig1-4	Lab Test Clinically Significant - Lab Test 10 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_10_cmt1-4	Lab Test Comments - Lab Test 10 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test_10_name1-4	Lab Test Name - Lab Test 10 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_10_out_range1-4	Lab Test Result - Out of Range - Lab Test 10 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_10_result1-4	Lab Test Result - Lab Test 10 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_10_result_unit1-4	Lab Test Name Result Units - Lab Test 10 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_11_clin_sig1-4	Lab Test Clinically Significant - Lab Test 11 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lab_oth_lab_test 11_cmt1-4	Lab Test Comments - Lab Test 11 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test 11_name1-4	Lab Test Name - Lab Test 11 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 11_out_range1-4	Lab Test Result - Out of Range - Lab Test 11 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 11_result1-4	Lab Test Result - Lab Test 11 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 11_result_unit1-4	Lab Test Name Result Units - Lab Test 11 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 12_clin_sig1-4	Lab Test Clinically Significant - Lab Test 12 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 12_cmt1-4	Lab Test Comments - Lab Test 12 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test 12_name1-4	Lab Test Name - Lab Test 12 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 12_out_range1-4	Lab Test Result - Out of Range - Lab Test 12 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 12_result1-4	Lab Test Result - Lab Test 12 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 12_result_unit1-4	Lab Test Name Result Units - Lab Test 12 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 13_clin_sig1-4	Lab Test Clinically Significant - Lab Test 13 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 13_cmt1-4	Lab Test Comments - Lab Test 13 - From Date # - [Clinical Lab - Other]		Char

Class	Variable	Label	Description	Format Text
01. Principal	lab_oth_lab_test_13_name1-4	Lab Test Name - Lab Test 13 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_13_out_range1-4	Lab Test Result - Out of Range - Lab Test 13 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_13_result1-4	Lab Test Result - Lab Test 13 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_13_result_unit1-4	Lab Test Name Result Units - Lab Test 13 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_14_clin_sig1-4	Lab Test Clinically Significant - Lab Test 14 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_14_cmt1-4	Lab Test Comments - Lab Test 14 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test_14_name1-4	Lab Test Name - Lab Test 14 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_14_out_range1-4	Lab Test Result - Out of Range - Lab Test 14 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_14_result1-4	Lab Test Result - Lab Test 14 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_14_result_unit1-4	Lab Test Name Result Units - Lab Test 14 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_15_clin_sig1-4	Lab Test Clinically Significant - Lab Test 15 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_15_cmt1-4	Lab Test Comments - Lab Test 15 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test_15_name1-4	Lab Test Name - Lab Test 15 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lab_oth_lab_test_15_out_range1-4	Lab Test Result - Out of Range - Lab Test 15 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_15_result1-4	Lab Test Result - Lab Test 15 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_15_result_unit1-4	Lab Test Name Result Units - Lab Test 15 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_16_clin_sig1-4	Lab Test Clinically Significant - Lab Test 16 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_16_cmt1-4	Lab Test Comments - Lab Test 16 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test_16_name1-4	Lab Test Name - Lab Test 16 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_16_out_range1-4	Lab Test Result - Out of Range - Lab Test 16 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_16_result1-4	Lab Test Result - Lab Test 16 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_16_result_unit1-4	Lab Test Name Result Units - Lab Test 16 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_17_clin_sig1-4	Lab Test Clinically Significant - Lab Test 17 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_17_cmt1-4	Lab Test Comments - Lab Test 17 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test_17_name1-4	Lab Test Name - Lab Test 17 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_17_out_range1-4	Lab Test Result - Out of Range - Lab Test 17 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lab_oth_lab_test_17_result1-4	Lab Test Result - Lab Test 17 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_17_result_unit1-4	Lab Test Name Result Units - Lab Test 17 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_1_clin_sig1-4	Lab Test Clinically Significant - Lab Test 1 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_1_cmt1-4	Lab Test Comments - Lab Test 1 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test_1_name1-4	Lab Test Name - Lab Test 1 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_1_out_range1-4	Lab Test Result - Out of Range - Lab Test 1 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_1_result1-4	Lab Test Result - Lab Test 1 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_1_result_unit1-4	Lab Test Name Result Units - Lab Test 1 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_2_clin_sig1-4	Lab Test Clinically Significant - Lab Test 2 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_2_cmt1-4	Lab Test Comments - Lab Test 2 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test_2_name1-4	Lab Test Name - Lab Test 2 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_2_out_range1-4	Lab Test Result - Out of Range - Lab Test 2 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_2_result1-4	Lab Test Result - Lab Test 2 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lab_oth_lab_test_2_result_unit1-4	Lab Test Name Result Units - Lab Test 2 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_3_clin_sig1-4	Lab Test Clinically Significant - Lab Test 3 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_3_cmt1-4	Lab Test Comments - Lab Test 3 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test_3_name1-4	Lab Test Name - Lab Test 3 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_3_out_range1-4	Lab Test Result - Out of Range - Lab Test 3 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_3_result1-4	Lab Test Result - Lab Test 3 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_3_result_unit1-4	Lab Test Name Result Units - Lab Test 3 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_4_clin_sig1-4	Lab Test Clinically Significant - Lab Test 4 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_4_cmt1-4	Lab Test Comments - Lab Test 4 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test_4_name1-4	Lab Test Name - Lab Test 4 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_4_out_range1-4	Lab Test Result - Out of Range - Lab Test 4 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_4_result1-4	Lab Test Result - Lab Test 4 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test_4_result_unit1-4	Lab Test Name Result Units - Lab Test 4 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lab_oth_lab_test 5_clin_sig1-4	Lab Test Clinically Significant - Lab Test 5 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 5_cmt1-4	Lab Test Comments - Lab Test 5 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test 5_name1-4	Lab Test Name - Lab Test 5 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 5_out_range1-4	Lab Test Result - Out of Range - Lab Test 5 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 5_result1-4	Lab Test Result - Lab Test 5 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 5_result_unit1-4	Lab Test Name Result Units - Lab Test 5 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 6_clin_sig1-4	Lab Test Clinically Significant - Lab Test 6 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 6_cmt1-4	Lab Test Comments - Lab Test 6 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test 6_name1-4	Lab Test Name - Lab Test 6 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 6_out_range1-4	Lab Test Result - Out of Range - Lab Test 6 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 6_result1-4	Lab Test Result - Lab Test 6 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 6_result_unit1-4	Lab Test Name Result Units - Lab Test 6 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 7_clin_sig1-4	Lab Test Clinically Significant - Lab Test 7 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lab_oth_lab_test 7_cmt1-4	Lab Test Comments - Lab Test 7 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test 7_name1-4	Lab Test Name - Lab Test 7 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 7_out_range1-4	Lab Test Result - Out of Range - Lab Test 7 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 7_result1-4	Lab Test Result - Lab Test 7 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 7_result_unit1-4	Lab Test Name Result Units - Lab Test 7 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 8_clin_sig1-4	Lab Test Clinically Significant - Lab Test 8 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 8_cmt1-4	Lab Test Comments - Lab Test 8 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test 8_name1-4	Lab Test Name - Lab Test 8 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 8_out_range1-4	Lab Test Result - Out of Range - Lab Test 8 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 8_result1-4	Lab Test Result - Lab Test 8 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 8_result_unit1-4	Lab Test Name Result Units - Lab Test 8 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 9_clin_sig1-4	Lab Test Clinically Significant - Lab Test 9 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 9_cmt1-4	Lab Test Comments - Lab Test 9 - From Date # - [Clinical Lab - Other]		Char
01. Principal	lab_oth_lab_test 9_name1-4	Lab Test Name - Lab Test 9 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lab_oth_lab_test 9_out_range1-4	Lab Test Result - Out of Range - Lab Test 9 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 9_result1-4	Lab Test Result - Lab Test 9 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_lab_test 9_result_unit1-4	Lab Test Name Result Units - Lab Test 9 - From Date # - [Clinical Lab - Other]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lab_oth_time_sp ec_col1-4	Time Specimen Collected - From Date # - [Clinical Lab - Other]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	lab_oth_visit_dat e1-4	Visit Date - From Date # - [Clinical Lab - Other]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Section 30: Local Breast Tissue Histology

Class	Variable	Label	Description	Format Text
01. Principal	lbth_comments1-2	Comments - # - [Local Breast Tissue Histology]		Char
01. Principal	lbth_estr_method_oth_spec1_2nd	Second Estrogen Receptor Method Other Specify - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_estr_method_oth_spec2_2nd	Second Estrogen Receptor Method Other Specify - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_estrogen_date1-2	Estrogen Receptor Date - # - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lbth_estrogen_date1_2nd	Second Estrogen Receptor Date - 1 - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_estrogen_date2_2nd	Second Estrogen Receptor Date - 2 - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_estrogen_method1-2	Estrogen Receptor Method - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Immunohistochemistry (IHC)" 2="Nuclear Staining"
01. Principal	lbth_estrogen_method1_2nd	Second Estrogen Receptor Method - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Immunohistochemistry (IHC)"
01. Principal	lbth_estrogen_method2_2nd	Second Estrogen Receptor Method - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_estrogen_method_oth_spec1-2	Estrogen Receptor Method Other Specify - # - [Local Breast Tissue Histology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lbth_estrogen_percent_plus1-2	Estrogen Receptor % / + - # - [Local Breast Tissue Histology]		Char

Class	Variable	Label	Description	Format Text
01. Principal	lbth_estrogen_percent_plus1_2nd	Second Estrogen Receptor % / + - 1 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_estrogen_percent_plus2_2nd	Second Estrogen Receptor % / + - 2 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_estrogen_receptor_nd1-2	Estrogen Receptor Not Detected (ND) - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	lbth_estrogen_receptor_nd1_2nd	Second Estrogen Receptor Not Detected (ND) - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	lbth_estrogen_receptor_nd2_2nd	Second Estrogen Receptor Not Detected (ND) - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	lbth_estrogen_result1-2	Estrogen Receptor Result - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Positive"
01. Principal	lbth_estrogen_result1_2nd	Second Estrogen Receptor Result - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Positive"
01. Principal	lbth_estrogen_result2_2nd	Second Estrogen Receptor Result - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_grade1-2	Grade - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="0" 1="1" 2="2" 3="3" 5="DIN III" 6="High" 7="N/A" 8="Unknown" 1.5="1-2" 2.5="2-3"
01. Principal	lbth_grade1_2nd	Second Grade - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 2="2"

Class	Variable	Label	Description	Format Text
01. Principal	lbth_grade2_2nd	Second Grade - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="1" 2="2"
01. Principal	lbth_her2amp_date1-2	Her2 Amplification Date - # - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lbth_her2amp_method1-2	Her2 Amplification Method - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="FISH"
01. Principal	lbth_her2amp_percent_plus1-2	Her2 Amplification % / + - # - [Local Breast Tissue Histology]		Char
01. Principal	lbth_her2amp_receptor_nd1-2	Her2 Amplification Not Detected (ND) - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	lbth_her2amp_result1-2	Her2 Amplification Result - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Not amplified" 2="Amplified"
01. Principal	lbth_her2rec_date1-2	Her2 Receptor Date - # - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lbth_her2rec_method1-2	Her2 Receptor Method - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Immunohistochemistry (IHC)" 2="Hercept test"
01. Principal	lbth_her2rec_method_oth_spec1-2	Her2 Receptor Method Other Specify - # - [Local Breast Tissue Histology]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_her2rec_percent_plus1-2	Her2 Receptor % / + - # - [Local Breast Tissue Histology]		Char
01. Principal	lbth_her2rec_receptor_nd1-2	Her2 Receptor Not Detected (ND) - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	lbth_her2rec_result1-2	Her2 Receptor Result - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="0" 1="1+" 2="2+" 3="3+"
01. Principal	lbth_her2rec_result1_2nd	Second Her2 Receptor Result - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="1+"
01. Principal	lbth_her2rec_result2_2nd	Second Her2 Receptor Result - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_initial_biopsy_date1-2	Initial Biopsy Date - # - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	lbth_initial_biopsy_time1-2	Initial Biopsy Time - # - [Local Breast Tissue Histology]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	lbth_interval1-2	Interval - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 3="Month" 4="Month 1" 5="Follow-up" 7="Off Study"
01. Principal	lbth_interval_date1-2	Interval Date - # - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_inv_breast_cancer1-2	Invasive Breast Cancer - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Invasive Ductal Carcinoma" 2="Invasive Lobular Carcinoma" 3="Mixed Invasive Ductal and Lobular" 4="Other, specify"
01. Principal	lbth_inv_breast_cancer1_2nd	Second Invasive Breast Cancer - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Invasive Ductal Carcinoma" 3="Mixed Invasive Ductal and Lobular"

Class	Variable	Label	Description	Format Text
01. Principal	lbth_inv_breast_cancer2_2nd	Second Invasive Breast Cancer - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Invasive Ductal Carcinoma" 2="Invasive Lobular Carcinoma"
01. Principal	lbth_invasive_other_spec1-2	Invasive Breast Cancer Other; Specify - # - [Local Breast Tissue Histology]		Char
01. Principal	lbth_ki67_date1-2	Ki-67 Date - # - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lbth_ki67_method1-2	Ki-67 Method - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Immunohistochemistry (IHC)" 2="Nuclear Staining" 3="Other, specify"
01. Principal	lbth_ki67_method_oth_spec1-2	Ki-67 Method Other Specify - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 9="Unknown"
01. Principal	lbth_ki67_percent_plus1-2	Ki-67 % / + - # - [Local Breast Tissue Histology]		Char
01. Principal	lbth_ki67_percent_plus1_2nd	Second Ki-67 % / + - 1 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_ki67_percent_plus2_2nd	Second Ki-67 % / + - 2 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_ki67_receptor_nd1-2	Ki-67 Not Detected (ND) - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	lbth_ki67_result1-2	Ki-67 Result - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Negative" 1="Positive"
01. Principal	lbth_ki67_result1_2nd	Second Ki-67 Result - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Positive"
01. Principal	lbth_ki67_result2_2nd	Second Ki-67 Result - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lbth_last_dose_t aken_date1-2	Date Last Dose Taken - # - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A" 8="Unknown"
01. Principal	lbth_last_dose_t aken_time1-2	Time Last Dose Taken - # - [Local Breast Tissue Histology]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A" 8="Unknown"
01. Principal	lbth_location1-2	Location - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Right" 2="Left"
01. Principal	lbth_location1_2 nd	Second Location - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Right" 2="Left"
01. Principal	lbth_location2_2 nd	Second Location - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Right" 2="Left"
01. Principal	lbth_m_stage1-2	M Stage - # - [Local Breast Tissue Histology]		Char
01. Principal	lbth_n_stage1-2	N Stage - # - [Local Breast Tissue Histology]		Char
01. Principal	lbth_n_stage1_2 nd	Second N Stage - 1 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_n_stage2_2 nd	Second N Stage - 2 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_premalignan t_lesions1-2	Premalignant Lesions - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Ductal Carcinoma in Situ" 2="Lobular Carcinoma in Situ" 3="Mixed Ductal in Situ and Lobular in Situ" 5="Other, Specify:"
01. Principal	lbth_premalignan t_lesions1_2nd	Second Premalignant Lesions - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	lbth_premalignant_lesions2_2nd	Second Premalignant Lesions - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 2="Lobular Carcinoma in Situ"
01. Principal	lbth_premalignant_other_spec1-2	Premalignant Lesions Other; Specify - # - [Local Breast Tissue Histology]		Char
01. Principal	lbth_prog_date1-2	Progesterone Receptor Date - # - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	lbth_prog_method1-2	Progesterone Receptor Method - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Immunohistochemistry (IHC)" 2="Nuclear Staining"
01. Principal	lbth_prog_method_other_spec1-2	Progesterone Receptor Method Other Specify - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_prog_percent_plus1-2	Progesterone Receptor % / + - # - [Local Breast Tissue Histology]		Char
01. Principal	lbth_prog_percent_plus1_2nd	Second Progesterone Receptor % / + - 1 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_prog_percent_plus2_2nd	Second Progesterone Receptor % / + - 2 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_prog_receptor_nd1-2	Progesterone Receptor Not Detected (ND) - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	lbth_prog_receptor_nd1_2nd	Second Progesterone Receptor Not Detected (ND) - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	lbth_prog_receptor_nd2_2nd	Second Progesterone Receptor Not Detected (ND) - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	lbth_prog_result1-2	Progesterone Receptor Result - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Negative" 1="Positive"

Class	Variable	Label	Description	Format Text
01. Principal	lbth_prog_result 1_2nd	Second Progesterone Receptor Result - 1 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Positive"
01. Principal	lbth_prog_result 2_2nd	Second Progesterone Receptor Result - 2 - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_site1-2	Site - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="BREAST"
01. Principal	lbth_surgery_dat e1-2	Surgery Date - # - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A" 8="Unknown"
01. Principal	lbth_surgery_tim e1-2	Surgery Time - # - [Local Breast Tissue Histology]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A" 8="Unknown"
01. Principal	lbth_surgery_tim e1_2nd	Second Surgery Time - 1 - [Local Breast Tissue Histology]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	lbth_surgery_tim e2_2nd	Second Surgery Time - 2 - [Local Breast Tissue Histology]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_t_stage1-2	T Stage - # - [Local Breast Tissue Histology]		Char
01. Principal	lbth_t_stage1_2n d	Second T Stage - 1 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_t_stage2_2n d	Second T Stage - 2 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_time_last_d ose_unk_na1-2	Date And Time Last Dose Taken Unknown or Not Applicable - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 7="NA" 8="Unknown"
01. Principal	lbth_type_hist_c onfirmation1-2	Type Of Histologic Confirmation - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Invasive Breast Cancer" 2="Premalignant Lesions" 3="Benign" 4="NED (applicable only at surgery)"

Class	Variable	Label	Description	Format Text
01. Principal	lbth_visit_date1-2	Visit Date - # - [Local Breast Tissue Histology]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_visit_time1-2	Visit Time - # - [Local Breast Tissue Histology]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_visit_time1_2nd	Second Visit Time - 1 - [Local Breast Tissue Histology]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_visit_time2_2nd	Second Visit Time - 2 - [Local Breast Tissue Histology]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	lbth_width1-2	Width (cm) - # - [Local Breast Tissue Histology]		Char
01. Principal	lbth_width1_2nd	Second Width (cm) - 1 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_width2_2nd	Second Width (cm) - 2 - [Local Breast Tissue Histology]		Char
01. Principal	lbth_width_unkown1-2	Width Is Unknown - # - [Local Breast Tissue Histology]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Section 31: Specimen Acquisition Blood - Baseline

Class	Variable	Label	Description	Format Text
01. Principal	spcb1_interval	Interval - [Specimen Acquisition Blood - Baseline]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 4="Month 1"
01. Principal	spcb1_interval_date	Interval Date - [Specimen Acquisition Blood - Baseline]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcb1_serum_received_date	Date Serum Specimen Received - [Specimen Acquisition Blood - Baseline]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcb1_serum_ship_date	Date Serum Specimen Shipped - [Specimen Acquisition Blood - Baseline]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcb1_serum_spec_col_date	Date Serum Specimen Collected - [Specimen Acquisition Blood - Baseline]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcb1_serum_spec_col_time	Time Serum Specimen Collected - [Specimen Acquisition Blood - Baseline]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcb1_serum_temp	Storage Temperature Celsius For Serum - [Specimen Acquisition Blood - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcb1_serum_volume	Serum Specimen Volume (ml) - [Specimen Acquisition Blood - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcb1_visit_date	Visit Date - [Specimen Acquisition Blood - Baseline]		SAS Date .F="No Record For This Visit" .R="Not Randomized" 7="N/A"
01. Principal	spcb1_visit_time	Visit Time - [Specimen Acquisition Blood - Baseline]		SAS Time .F="No Record For This Visit" .R="Not Randomized" 7="N/A"
01. Principal	spcb1_wb_received_date	Date Whole Blood Specimen Received - [Specimen Acquisition Blood - Baseline]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	spcb11_wb_ship_date	Date Whole Blood Specimen Shipped - [Specimen Acquisition Blood - Baseline]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcb11_wb_spec_col_date	Date Whole Blood Specimen Collected - [Specimen Acquisition Blood - Baseline]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcb11_wb_spec_col_time	Time Whole Blood Specimen Collected - [Specimen Acquisition Blood - Baseline]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcb11_wb_temp	Storage Temperature Celsius For Whole Blood - [Specimen Acquisition Blood - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcb11_wb_volume	Whole Blood Specimen Volume (ml) - [Specimen Acquisition Blood - Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 32: Specimen Acquisition Blood - Final Visit

Class	Variable	Label	Description	Format Text
01. Principal	spcbl2_interval	Interval - [Specimen Acquisition Blood - Final Visit]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 3="Month" 4="Month 1" 6="Follow-up 1" 7="Off Study"
01. Principal	spcbl2_interval_date	Interval Date - [Specimen Acquisition Blood - Final Visit]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcbl2_serum_received_date	Date Serum Specimen Received - [Specimen Acquisition Blood - Final Visit]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcbl2_serum_received_time	Time Serum Specimen Received - [Specimen Acquisition Blood - Final Visit]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcbl2_serum_ship_date	Date Serum Specimen Shipped - [Specimen Acquisition Blood - Final Visit]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcbl2_serum_spec_col_date	Date Serum Specimen Collected - [Specimen Acquisition Blood - Final Visit]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcbl2_serum_spec_col_time	Time Serum Specimen Collected - [Specimen Acquisition Blood - Final Visit]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcbl2_serum_temp	Storage Temperature Celsius For Serum - [Specimen Acquisition Blood - Final Visit]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcbl2_serum_volume	Serum Specimen Volume (ml) - [Specimen Acquisition Blood - Final Visit]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcbl2_visit_date	Visit Date - [Specimen Acquisition Blood - Final Visit]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcbl2_visit_time	Visit Time - [Specimen Acquisition Blood - Final Visit]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	spcbl2_wb_recei ved_date	Date Whole Blood Specimen Received - [Specimen Acquisition Blood - Final Visit]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcbl2_wb_recei ved_time	Time Whole Blood Specimen Received - [Specimen Acquisition Blood - Final Visit]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcbl2_wb_ship_ date	Date Whole Blood Specimen Shipped - [Specimen Acquisition Blood - Final Visit]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcbl2_wb_spec _col_date	Date Whole Blood Specimen Collected - [Specimen Acquisition Blood - Final Visit]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcbl2_wb_spec _col_time	Time Whole Blood Specimen Collected - [Specimen Acquisition Blood - Final Visit]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 7="N/A"
01. Principal	spcbl2_wb_temp	Storage Temperature Celsius For Whole Blood - [Specimen Acquisition Blood - Final Visit]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	spcbl2_wb_volu me	Whole Blood Specimen Volume (ml) - [Specimen Acquisition Blood - Final Visit]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 33: Specimen Acquisition Tissue

Class	Variable	Label	Description	Format Text
01. Principal	spcts1_biop_collected_date1-2	Date Biopsy Specimen Collecte - # - [Specimen Acquisition Tissue]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	spcts1_biop_formalin1-2	Biopsy Specimen Is Formalin Fixed And Paraffin Embedded - # - [Specimen Acquisition Tissue]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	spcts1_biop_location1-2	Biopsy Specimen Location - # - [Specimen Acquisition Tissue]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Left" 2="Right"
01. Principal	spcts1_biop_received_date1-2	Date Biopsy Specimen Received - # - [Specimen Acquisition Tissue]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	spcts1_biop_ship_date1-2	Date Biopsy Specimen Shipped - # - [Specimen Acquisition Tissue]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	spcts1_biop_ship_time1-2	Time Biopsy Specimen Shipped - # - [Specimen Acquisition Tissue]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	spcts1_interval1-2	Interval - # - [Specimen Acquisition Tissue]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 3="Month"
01. Principal	spcts1_interval_date1-2	Interval Date - # - [Specimen Acquisition Tissue]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	spcts1_surg_collected_date1-2	Date Surgical Specimen Collecte - # - [Specimen Acquisition Tissue]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	spcts1_surg_for malin1-2	Surgical Specimen Is Formalin Fixed And Paraffin Embedded - # - [Specimen Acquisition Tissue]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	spcts1_surg_location1-2	Surgical Specimen Location - # - [Specimen Acquisition Tissue]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Left" 2="Right"
01. Principal	spcts1_surg_received_date1-2	Date Surgical Specimen Received - # - [Specimen Acquisition Tissue]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	spcts1_surg_ship_date1-2	Date Surgical Specimen Shipped - # - [Specimen Acquisition Tissue]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	spcts1_surg_ship_time1-2	Time Surgical Specimen Shipped - # - [Specimen Acquisition Tissue]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 7="N/A"
01. Principal	spcts1_visit_date1-2	Visit Date - # - [Specimen Acquisition Tissue]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	spcts1_visit_time1-2	Visit Time - # - [Specimen Acquisition Tissue]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Section 34: Verification Form

Class	Variable	Label	Description	Format Text
01. Principal	verif_interval	Interval - [Verification Form]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 3="Month" 5="Follow-up"
01. Principal	verif_interval_date	Interval Date - [Verification Form]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	verif_signature_date	Date Of Investigators Signature - [Verification Form]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	verif_signature_time	Time Of Investigators Signature - [Verification Form]		SAS Time .F="No Record For This Visit" .R="Not Randomized"

Section 35: Comments

Class	Variable	Label	Description	Format Text
01. Principal	cmts_comments 1-8	Comments - # - [Comments]		Char
01. Principal	cmts_field_name 1-8	Field Name - # - [Comments]		Char
01. Principal	cmts_form_code 1-8	Field Code - # - [Comments]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="AALCB (Alcohol Assessment-Baseline)" 2="AE (Adverse Events)" 4="AGINT (Agent Interruption)" 5="ATBCB (Tobacco Assessment-Baseline)" 6="BRSTH (Local Breast Tissue Histology)" 8="COMP (Compliance)" 12="DEMOG (Demography)" 15="INTAB (Intervention Administration – Blinded)" 16="LABBC (Blood Chemistry)" 17="LABHM (Hematology)" 18="LABOT (Other Lab Tests)" 19="MEDHX1 (Medical/Surgical History)" 20="OFFST (Off Study)" 21="PE (Physical Exam)" 22="RAND (Randomization)" 23="REG (Registration)" 25="SCRN (Screening)" 27="SPCBL2 (Specimen Acquisition – Blood, Final Visit)" 28="SPCTS1 (Specimen Acquisition – Tissue)" 30="TELCO (Telephone Contact)" 33="Exemestane Pill Diary" 34="QOL Questionnaire"
01. Principal	cmts_form_date	Form Date - [Comments]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	cmts_form_time	Form Time - [Comments]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	cmts_interval	Interval - [Comments]		.F="No Record For This Visit" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 5="Follow-up" 6="Follow-up 1" 7="Off Study"
01. Principal	cmts_interval_date	Interval Date - [Comments]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 36: Study Specimen Shipping Form

Class	Variable	Label	Description	Format Text
01. Principal	ship_1st_verified_date1_sd1-7	Date Verified 1 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_1st_verified_date2_sd1-7	Date Verified 2 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_1st_verified_date3_sd1-7	Date Verified 3 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_1st_verified_date4_sd1-7	Date Verified 4 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_1st_verified_time1_sd1-7	Time Verified 1 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_1st_verified_time2_sd1-7	Time Verified 2 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_1st_verified_time3_sd1-7	Time Verified 3 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_1st_verified_time4_sd1-7	Time Verified 4 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_2nd_verified_date1_sd1-7	Date Verified 1 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_2nd_verified_date2_sd1-7	Date Verified 2 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_2nd_verified_date3_sd1-7	Date Verified 3 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_2nd_verified_date4_sd1-7	Date Verified 4 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	ship_2nd_verified_time1_sd1-7	Time Verified 1 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_2nd_verified_time2_sd1-7	Time Verified 2 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_2nd_verified_time3_sd1-7	Time Verified 3 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_2nd_verified_time4_sd1-7	Time Verified 4 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_5slides_selected1_sd1-7	5 Unstained Slides Tissue Specimen Selected 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_5slides_selected2_sd1-7	5 Unstained Slides Tissue Specimen Selected 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	ship_5slides_selected3_sd1-7	5 Unstained Slides Tissue Specimen Selected 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_5slides_selected4_sd1-7	5 Unstained Slides Tissue Specimen Selected 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_5slides_specimen1_sd1-7	5 Unstained Slides Tissue Specimen 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_5slides_specimen2_sd1-7	5 Unstained Slides Tissue Specimen 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_5slides_specimen3_sd1-7	5 Unstained Slides Tissue Specimen 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"

Class	Variable	Label	Description	Format Text
01. Principal	ship_5slides_specimen4_sd1-7	5 Unstained Slides Tissue Specimen 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	ship_6slides_select1_sd1-7	6 Unstained Slides Tissue Specimen Selected 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	ship_6slides_select2_sd1-7	6 Unstained Slides Tissue Specimen Selected 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	ship_6slides_select3_sd1-7	6 Unstained Slides Tissue Specimen Selected 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_6slides_select4_sd1-7	6 Unstained Slides Tissue Specimen Selected 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_6slides_specimen1_sd1-7	6 Unstained Slides Tissue Specimen 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_6slides_specimen2_sd1-7	6 Unstained Slides Tissue Specimen 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_6slides_specimen3_sd1-7	6 Unstained Slides Tissue Specimen 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	ship_6slides_specimen4_sd1-7	6 Unstained Slides Tissue Specimen 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	ship_baseline_blood1_sd1-7	Blood From Baseline 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	ship_baseline_blood2_sd1-7	Blood From Baseline 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_baseline_blood3_sd1-7	Blood From Baseline 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_baseline_blood4_sd1-7	Blood From Baseline 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_baseline_tissue1_sd1-7	Tissue From Baseline 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_baseline_tissue2_sd1-7	Tissue From Baseline 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	ship_baseline_tissue3_sd1-7	Tissue From Baseline 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	ship_baseline_tissue4_sd1-7	Tissue From Baseline 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	ship_blocks_ffpe_tissue1_sd1-7	Blocks FFPE Tissue 1 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	ship_blocks_ffpe_tissue2_sd1-7	Blocks FFPE Tissue 2 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	ship_blocks_ffpe_tissue3_sd1-7	Blocks FFPE Tissue 3 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_blocks_ffpe_tissue4_sd1-7	Blocks FFPE Tissue 4 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_condition_received1_sd1-7	State Of Blood Samples/Tissue Received 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="good condition" 2="poor condition, specify"

Class	Variable	Label	Description	Format Text
01. Principal	ship_condition_received2_sd1-7	State Of Blood Samples/Tissue Received 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="good condition"
01. Principal	ship_condition_received3_sd1-7	State Of Blood Samples/Tissue Received 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="good condition"
01. Principal	ship_condition_received4_sd1-7	State Of Blood Samples/Tissue Received 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="good condition"
01. Principal	ship_final_blood1_sd1-7	Blood From Final Visit 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_final_blood2_sd1-7	Blood From Final Visit 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_final_blood3_sd1-7	Blood From Final Visit 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_final_blood4_sd1-7	Blood From Final Visit 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_frozen_tissue_select1_sd1-7	Frozen Tissue Specimen Selected 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	ship_frozen_tissue_select2_sd1-7	Frozen Tissue Specimen Selected 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	ship_frozen_tissue_select3_sd1-7	Frozen Tissue Specimen Selected 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	ship_frozen_tissue_select4_sd1-7	Frozen Tissue Specimen Selected 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_frozen_tissue_specimen1_sd1-7	Frozen Tissue Specimen 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	ship_frozen_tissue_specimen2_sd1-7	Frozen Tissue Specimen 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	ship_frozen_tissue_specimen3_sd1-7	Frozen Tissue Specimen 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No"
01. Principal	ship_frozen_tissue_specimen4_sd1-7	Frozen Tissue Specimen 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No"
01. Principal	ship_interval1_sd1-7	Interval 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available" 2="Baseline" 3="Month" 4="Month 1" 5="Follow-up" 6="Follow-up 1" 7="Off Study"
01. Principal	ship_interval2_sd1-7	Interval 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available"
01. Principal	ship_interval3_sd1-7	Interval 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available"
01. Principal	ship_interval4_sd1-7	Interval 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Event Interval Not Available"
01. Principal	ship_interval_date1_sd1-7	Interval Date 1 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_interval_date2_sd1-7	Interval Date 2 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	ship_interval_date3_sd1-7	Interval Date 3 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_interval_date4_sd1-7	Interval Date 4 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_poor_condition_specify1_sd1-7	If State Of Blood Samples/Tissue Is Poor Condition - Specify 1 - shipped date # - [Study Specimen Shipping Form]		Char
01. Principal	ship_poor_condition_specify2_sd1-7	If State Of Blood Samples/Tissue Is Poor Condition - Specify 2 - shipped date # - [Study Specimen Shipping Form]		Char
01. Principal	ship_poor_condition_specify3_sd1-7	If State Of Blood Samples/Tissue Is Poor Condition - Specify 3 - shipped date # - [Study Specimen Shipping Form]		Char
01. Principal	ship_poor_condition_specify4_sd1-7	If State Of Blood Samples/Tissue Is Poor Condition - Specify 4 - shipped date # - [Study Specimen Shipping Form]		Char
01. Principal	ship_received_date1_sd1-7	Received Date 1 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	ship_received_date2_sd1-7	Received Date 2 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_received_date3_sd1-7	Received Date 3 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_received_date4_sd1-7	Received Date 4 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_screening_tissue1_sd1-7	Tissue From Screening 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	ship_screening_tissue2_sd1-7	Tissue From Screening 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_screening_tissue3_sd1-7	Tissue From Screening 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	ship_screening_tissue4_sd1-7	Tissue From Screening 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	ship_serum_selected1_sd1-7	Serum Specimen Selected 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_serum_selected2_sd1-7	Serum Specimen Selected 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	ship_serum_selected3_sd1-7	Serum Specimen Selected 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	ship_serum_selected4_sd1-7	Serum Specimen Selected 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	ship_serum_specimen1_sd1-7	Serum Specimen 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	ship_serum_specimen2_sd1-7	Serum Specimen 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	ship_serum_specimen3_sd1-7	Serum Specimen 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	ship_serum_specimen4_sd1-7	Serum Specimen 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	ship_shipped_date_sd1-7	Shipped Date - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipped_time1_sd1-7	Shipped Time 1 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipped_time2_sd1-7	Shipped Time 2 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipped_time3_sd1-7	Shipped Time 3 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipped_time4_sd1-7	Shipped Time 4 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipping_date1_sd1-7	Shipping Date 1 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipping_date2_sd1-7	Shipping Date 2 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipping_date3_sd1-7	Shipping Date 3 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipping_date4_sd1-7	Shipping Date 4 - shipped date # - [Study Specimen Shipping Form]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipping_time1_sd1-7	Shipping Time 1 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipping_time2_sd1-7	Shipping Time 2 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipping_time3_sd1-7	Shipping Time 3 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_shipping_time4_sd1-7	Shipping Time 4 - shipped date # - [Study Specimen Shipping Form]		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	ship_surgery_tissue1_sd1-7	Tissue From Surgery 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_surgery_tissue2_sd1-7	Tissue From Surgery 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_surgery_tissue3_sd1-7	Tissue From Surgery 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	ship_surgery_tissue4_sd1-7	Tissue From Surgery 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	ship_to_institution1_sd1-7	Ship To Location 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Columbia University Medical Center" 2="European Institute of Oncology" 3="Haukeland University" 4="M. D. Anderson Cancer Center" 5="Syneos Health"
01. Principal	ship_to_institution2_sd1-7	Ship To Location 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 2="European Institute of Oncology"
01. Principal	ship_to_institution3_sd1-7	Ship To Location 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 2="European Institute of Oncology"
01. Principal	ship_to_institution4_sd1-7	Ship To Location 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 2="European Institute of Oncology"
01. Principal	ship_tracking_number1_sd1-7	Shipping Tracking Number 1 - shipped date # - [Study Specimen Shipping Form]		Char
01. Principal	ship_tracking_number2_sd1-7	Shipping Tracking Number 2 - shipped date # - [Study Specimen Shipping Form]		Char
01. Principal	ship_tracking_number3_sd1-7	Shipping Tracking Number 3 - shipped date # - [Study Specimen Shipping Form]		Char

Class	Variable	Label	Description	Format Text
01. Principal	ship_tracking_number4_sd1-7	Shipping Tracking Number 4 - shipped date # - [Study Specimen Shipping Form]		Char
01. Principal	ship_vials_blood1_sd1-7	Vials Blood 1 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	ship_vials_blood2_sd1-7	Vials Blood 2 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_vials_blood3_sd1-7	Vials Blood 3 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_vials_blood4_sd1-7	Vials Blood 4 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_vials_frozen_tissue1_sd1-7	Vials Frozen Tissue 1 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	ship_vials_frozen_tissue2_sd1-7	Vials Frozen Tissue 2 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_vials_frozen_tissue3_sd1-7	Vials Frozen Tissue 3 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_vials_frozen_tissue4_sd1-7	Vials Frozen Tissue 4 - shipped date # - [Study Specimen Shipping Form]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	ship_whole_blood_select1_sd1-7	Whole Blood Specimen Selected 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	ship_whole_blood_select2_sd1-7	Whole Blood Specimen Selected 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	ship_whole_blood_select3_sd1-7	Whole Blood Specimen Selected 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	ship_whole_blood_select4_sd1-7	Whole Blood Specimen Selected 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	ship_whole_blood_specimen1_sd1-7	Whole Blood Specimen 1 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	ship_whole_blood_specimen2_sd1-7	Whole Blood Specimen 2 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	ship_whole_blood_specimen3_sd1-7	Whole Blood Specimen 3 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	ship_whole_blood_specimen4_sd1-7	Whole Blood Specimen 4 - shipped date # - [Study Specimen Shipping Form]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"