

# NWU2017-09-01 - Enhanced Person Data Dictionary

## TABLE OF CONTENTS

Document Summary.....	3
NWU2017-09-01 - Enhanced Person: Data Dictionary .....	4
Section 1: Identifiers .....	4
Section 2: Study-wide .....	5
Section 3: Pre-Enrollment .....	6
Section 4: Eligibility .....	8
Section 5: Informed Consent Form .....	9
Section 6: Enrollment .....	11
Section 7: Alcohol Questionnaire (Baseline) .....	12
Section 8: Tobacco Questionnaire (Baseline) .....	15
Section 9: BESS Questionnaire .....	20
Section 10: Medical/Surgical History .....	27
Section 11: Baseline Symptoms .....	29
Section 12: Physical Exam .....	30
Section 13: Vitals .....	32
Section 14: Menopause .....	33
Section 15: Menstruation.....	34
Section 16: Breast Cup Size .....	35
Section 17: Skin.....	36
Section 18: TAC/TAD .....	37
Section 19: Skin Toxicity.....	38
Section 20: Concomitant Medications.....	40
Section 21: Adverse Events.....	43
Section 22: Pregnancy Test.....	44
Section 23: Alcohol Questionnaire (Follow-up) .....	45

Section 24: Tobacco Questionnaire (Follow-up) .....	46
Section 25: Participant Contact .....	51
Section 26: Agent Return And Compliance .....	52
Section 27: Agent Interruption .....	53
Section 28: Compliance .....	54
Section 29: Off Study .....	55
Section 30: Batch Shipment Specimen Inventory .....	56
Section 31: Specimen Collection (Tissue) .....	58
Section 32: Specimen Collection (Blood) .....	61
Section 33: Lab Tests .....	63
Section 34: Tissue/Plasma Concentrations .....	66
Section 35: Mastectomy Grossing .....	67
Section 36: Plasma .....	72
Section 37: Tumor Characteristics .....	73
Section 38: Ki-67 .....	76
Section 39: mRNA .....	77

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## Document Summary

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# NWU2017-09-01 - Enhanced Person: Data Dictionary

## Section 1: Identifiers

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Class	Variable	Label	Description	Format Text
01. Principal	<b>ptid</b>	Participant ID		Char

## Section 2: Study-wide

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Class	Variable	Label	Description	Format Text
01. Principal	<b>build_dt</b>	Build Date		SAS Date
01. Principal	<b>rand_num</b>	Randomization Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>tac</b>	Treatment Assignment Code (TAC)		.R="Not Randomized" 0="TAC0" 1="TAC1" 2="TAC2" 3="TAC3"
01. Principal	<b>treatment</b>	Treatment	TAC1: 10mg TAC2: 20mg TAC3: 10mg	.R="Not Randomized" 1="Endoxifen Gel" 2="Placebo Gel"
01. Principal	<b>visit_dt_v0-4</b>	Date Of Visit #		SAS Date .F="No Record For This Visit" .R="Not Randomized"

## Section 3: Pre-Enrollment

Class	Variable	Label	Description	Format Text
01. Principal	<b>preenr_age</b>	Age At Registration - [Pre-Enrollment]		Numeric
01. Principal	<b>preenrl_comments</b>	Comments - [Pre-Enrollment]		Char
01. Principal	<b>preenrl_country</b>	Participant Country Code - [Pre-Enrollment]		1="USA"
01. Principal	<b>preenrl_eligible</b>	Does This Participant Meet All Screening Criteria? - [Pre-Enrollment]		0="No" 1="Yes"
01. Principal	<b>preenrl_ethnicity</b>	Participant Ethnicity - [Pre-Enrollment]		1="Hispanic or Latino" 2="Not Hispanic or Latino" 3="Unknown" 9="Not Reported"
01. Principal	<b>preenrl_gender</b>	Participant Gender - [Pre-Enrollment]		1="Female" 2="Male"
01. Principal	<b>preenrl_institution</b>	Registering Institution - [Pre-Enrollment]		1="IL036 - Northwestern University" 2="NY016 - Memorial Sloan Kettering Cancer Center" 3="CA016 - Cedars-Sinai Medical Center"
01. Principal	<b>preenrl_pay_method</b>	Method Of Payment - [Pre-Enrollment]		1="Private Insurance" 2="Medicaid" 3="Medicaid and Medicare" 4="Military Sponsored (including CHAMPUS & TriCare)" 5="Veterans Sponsored" 6="No Means of Payment (No Insurance)" 7="Medicare" 8="Medicare and Private Insurance" 9="Self-Pay (No Insurance)" 10="Managed Care/Medicare" 11="State Supplemental Health Insurance" 12="Military or Veterans Sponsored, NOS" 13="Other" 99="Unknown"
01. Principal	<b>preenrl_race</b>	Participant Race - [Pre-Enrollment]		1="White" 2="Black or African American" 3="Native Hawaiian or Other Pacific Islander" 4="Asian" 5="American Indian or Alaska Native" 8="Unknown" 9="Not Reported"
01. Principal	<b>preenrl_sfail_rsn</b>	Primary Reason For Screen Failure (If Applicable) - [Pre-Enrollment]		.N="N/A" 1="Investigator Decision" 2="Participant Decision" 3="Did Not Meet Eligibility Criteria" 9="Other, Specify"

Class	Variable	Label	Description	Format Text
01. Principal	<b>prenr1_sid</b>	Screening Identification Number (SID) - [Pre-Enrollment]		Char

## Section 4: Eligibility

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Class	Variable	Label	Description	Format Text
01. Principal	<b>elig_comments</b>	Comments - [Eligibility]		Char
01. Principal	<b>elig_is_eligible</b>	Is The Participant Eligible For Inclusion On This Protocol? - [Eligibility]		.R="Not Randomized" 0="No" 1="Yes"



## Section 5: Informed Consent Form

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Class	Variable	Label	Description	Format Text
01. Principal	<b>icf_biobank</b>	Does The Participant Agree That Their Samples And Related Information May Be Kept In A Biobank For Use In Future Health Research? - [Informed Consent Form]		0="No" 1="Yes"
01. Principal	<b>icf_comments</b>	Comments - [Informed Consent Form]		Char
01. Principal	<b>icf_dna</b>	Does The Participant Agree That Their Samples For DNA May Be Kept In A Biobank For Use In Future Health Research? - [Informed Consent Form]		0="No" 1="Yes"
01. Principal	<b>icf_dt</b>	Date Of Consent - [Informed Consent Form]		SAS Date
01. Principal	<b>icf_form_dt</b>	Version Date - [Informed Consent Form]		SAS Date
01. Principal	<b>icf_form_number</b>	Version Number - [Informed Consent Form]		Numeric
01. Principal	<b>icf_future_contact</b>	Does The Participant Agree That The Study Doctor, Or Their Representative May Contact Them Or Their Physician To See In They Wish To Participate In Other Research In The Future? - [Informed Consent Form]		0="No" 1="Yes"
01. Principal	<b>icf_results</b>	Does The Participant Agree That Their Study Doctor, Or Their Representative, May Contact Them To See If They Wish To Learn The Results Of This Study? - [Informed Consent Form]		.M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>ics_tob_alc</b>	Does The Participant Agree That The Information From Their Tobacco And Alcohol Use Questionnaires May Be Used In Future Health Research? - [Informed Consent Form]		0="No" 1="Yes"

## Section 6: Enrollment

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Class	Variable	Label	Description	Format Text
01. Principal	<b>enroll_ag_start_dt</b>	Agent Start Date - [Enrollment]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	<b>enroll_comments</b>	Comments - [Enrollment]		Char
01. Principal	<b>enroll_rand_dt</b>	Randomization Date - [Enrollment]		SAS Date .R="Not Randomized"
01. Principal	<b>enroll_reg_dt</b>	Registration Date - [Enrollment]		SAS Date .R="Not Randomized"

## Section 7: Alcohol Questionnaire (Baseline)

Class	Variable	Label	Description	Format Text
01. Principal	<b>alc_bsl_age_drink</b>	At What Age Did You Begin Drinking Regularly? - [Alcohol Questionnaire (Baseline)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Refused" .U="Don't Know/Not Sure"
01. Principal	<b>alc_bsl_at_least_12</b>	In Your Entire Life, Have You Had At Least 12 Drinks Of Any Kind Of Alcoholic Beverage? - [Alcohol Questionnaire (Baseline)]		.F="No Record For This Visit" 0="No" 1="Yes" 2="Refused" 3="Don't know/Not sure"
01. Principal	<b>alc_bsl_beer_use</b>	Alcohol Use - Beer - [Alcohol Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>alc_bsl_binge_daily</b>	Was There Ever A Time Or Times In Your Life When You Drank 5 Or More Drinks Of Any Kind Of Alcoholic Beverage Almost Every Day? - [Alcohol Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 2="Refused" 3="Don't know/Not sure"
01. Principal	<b>alc_bsl_comments</b>	Comments - [Alcohol Questionnaire (Baseline)]		Char
01. Principal	<b>alc_bsl_inv_dt</b>	Date Signed By Investigator - [Alcohol Questionnaire (Baseline)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>alc_bsl_liquor_use</b>	Alcohol Use - Liquor - [Alcohol Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>alc_bsl_most_drank</b>	At The Heaviest Point, Either Now Or In The Past, On The Days When You Drank, About How Many Drinks Did You Drink A Day On The Average? - [Alcohol Questionnaire (Baseline)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Refused" .U="Don't Know/Not Sure"

Class	Variable	Label	Description	Format Text
01. Principal	<b>alc_bsl_p12m_5_or_more</b>	In The Past 12 Months, On How Many Days Did You Have 5 Or More Drinks Of Any Alcoholic Beverage? - [Alcohol Questionnaire (Baseline)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Refused" .U="Don't Know/Not Sure"
01. Principal	<b>alc_bsl_p12m_drink_freq</b>	In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcoholic Beverage? - Frequency - [Alcohol Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 1="Week" 2="Month" 3="Year" 8="Refused" 9="Don't Know/Not Sure"
01. Principal	<b>alc_bsl_p12m_drink_num</b>	In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcoholic Beverage? - Number - [Alcohol Questionnaire (Baseline)]		Numeric .F="No Record For This Visit"
01. Principal	<b>alc_bsl_p12m_drinks_day</b>	In The Past 12 Months, On Those Days That You Drank Alcoholic Beverages, On Average, How Many Drinks Did You Have Per Day? - [Alcohol Questionnaire (Baseline)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Refused" .U="Don't Know/Not Sure"
01. Principal	<b>alc_bsl_time_since_drank</b>	If You Do Not Currently Drink Alcoholic Beverages, But Did In The Past, How Long Has It Been Since You Last Drank Regularly? - [Alcohol Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="Within The Past Month (0 To 1 Month Ago)" 1="Between 1 And 3 Months (1 To 3 Months Ago)" 2="Between 3 And 6 Months (3 To 6 Months Ago)" 3="Between 6 And 12 Months (6 To 12 Months Ago)" 4="Between 1 And 5 Years (1 To 5 Years Ago)" 5="Between 5 And 15 Years (5 To 15 Years Ago)" 6="More Than 15 Years Ago" 7="Never Drank Regularly" 8="Refused" 9="Don't Know/Not Sure"
01. Principal	<b>alc_bsl_wine_cooler_use</b>	Alcohol Use - Wine Cooler - [Alcohol Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>alc_bsl_wine_use</b>	Alcohol Use - Wine - [Alcohol Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>alc_bsl_years_drink</b>	How Many Years Have You Been Drinking (Or Did You Drink) Regularly? - [Alcohol Questionnaire (Baseline)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Refused" .U="Don't Know/Not Sure"

## Section 8: Tobacco Questionnaire (Baseline)

Class	Variable	Label	Description	Format Text
01. Principal	<b>tob_bsl_age_reg</b>	How Old Were You When You First Began Smoking Cigarettes Regularly? - [Tobacco Questionnaire (Baseline)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tob_bsl_age_smoked</b>	How Old Were You When You First Smoked A Cigarette - [Tobacco Questionnaire (Baseline)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tob_bsl_bidis</b>	Other Tobacco Products Used Regularly: Bidis - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_child_live_smk_cat</b>	Thinking Of All Your Childhood And Adult Years, Have You Ever Lived In A Place Where Other People Smoked Cigarettes Indoors? - Category - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_child_live_smk_num</b>	Thinking Of All Your Childhood And Adult Years, Have You Ever Lived In A Place Where Other People Smoked Cigarettes Indoors? - Number - [Tobacco Questionnaire (Baseline)]		Numeric .C="Choose Not To Answer" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tob_bsl_cigarettes</b>	Other Tobacco Products Used Regularly: Cigarettes - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_cigars</b>	Other Tobacco Products Used Regularly: Traditional Cigars, Cigarillos, Or Filtered Cigars - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tob_bsl_cigs_day</b>	On Average, When You Smoked, About How Many Cigarettes Do You Smoke A Day? - [Tobacco Questionnaire (Baseline)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tob_bsl_clove_cig</b>	Other Tobacco Products Used Regularly: Clove Cigarettes Or Kreteks - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_comments</b>	Comments - [Tobacco Questionnaire (Baseline)]		Char
01. Principal	<b>tob_bsl_e_cig</b>	Other Tobacco Products Used Regularly: E-Cigarettes Or Other Electronic Nicotine Delivery System - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_hookah</b>	Other Tobacco Products Used Regularly: Hookah - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_inv_dt</b>	Date Signed By Investigator - [Tobacco Questionnaire (Baseline)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tob_bsl_live_30_smoker</b>	In The Past 30 Days, Have You Lived In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_live_with_smoker</b>	Are You Currently Living With A Smoker? - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" 0="No" 1="Yes"



Class	Variable	Label	Description	Format Text
01. Principal	<b>tob_bsl_oth_last_use</b>	If You Do Not Currently Use Other Forms Of Tobacco, But Did In The Past, How Long Has It Been Since You Last Used Other Forms Of Tobacco Regularly? - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="Within The Past Month (0 To 1 Month Ago)" 1="Between 1 And 3 Months (1 To 3 Months Ago)" 2="Between 3 And 6 Months (3 To 6 Months Ago)" 3="Between 6 And 12 Months (6 To 12 Months Ago)" 4="Between 1 And 5 Years (1 To 5 Years Ago)" 5="Between 5 And 15 Years (5 To 15 Years Ago)" 6="More Than 15 Years Ago" 7="Never Used Other Forms Of Tobacco Regularly" 9="Don't Know/Not Sure"
01. Principal	<b>tob_bsl_oth_tob_spec</b>	Other Tobacco Use (Specify) - [Tobacco Questionnaire (Baseline)]		Char
01. Principal	<b>tob_bsl_oth_tob_use</b>	Have You Ever Used Other Forms Of Tobacco, Not Including Cigarettes? - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_other</b>	Other Tobacco Products Used Regularly: Other - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_other_cat</b>	How Often Do You Use Other Forms Of Tobacco? - Category - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 1="Every Day" 2="Some Days"
01. Principal	<b>tob_bsl_other_freq</b>	How Often Do You Use Other Forms Of Tobacco? - Frequency - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 1="Times/Day" 2="Days/Week" 3="Days/Month" 4="Days/Year"
01. Principal	<b>tob_bsl_other_num</b>	How Often Do You Use Other Forms Of Tobacco? - Number - [Tobacco Questionnaire (Baseline)]		Numeric .C="Choose Not To Answer" .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tob_bsl_paan</b>	Other Tobacco Products Used Regularly: Paan With Tobacco, Gutka, Zarda, Khaini - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_pipe</b>	Other Tobacco Products Used Regularly: Pipes - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_smoke_100_cigs</b>	Have You Smoked At Least 100 Cigarettes In Your Entire Life? - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" 0="No" 1="Yes" 2="Don't Know/Not Sure"
01. Principal	<b>tob_bsl_smoke_now</b>	Do You Now Smoke Cigarettes? - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="Not At All" 1="Everyday" 2="Some Days"
01. Principal	<b>tob_bsl_smokeless</b>	Other Tobacco Products Used Regularly: Smokeless Tobacco (Like Dip, Chew, Or Snuff) - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_snus</b>	Other Tobacco Products Used Regularly: Snus - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_time_last_cig_cat</b>	How Long Has It Been Since You Last Smoked A Cigarette - Category - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="I Smoked A Cigarette Today" 2="Cigarette In The Last 1-7 Days" 3="Cigarette In Less Than 1 Month" 4="Cigarette In Less Than 1 Year" 5="Cigarette In More Than 1 Year" 6="Don't Know/Don't Remember"
01. Principal	<b>tob_bsl_time_last_cig_freq</b>	How Long Has It Been Since You Last Smoked A Cigarette - Frequency - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Days" 2="Weeks" 3="Months" 4="Years"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tob_bsl_time_last_cig_num</b>	How Long Has It Been Since You Last Smoked A Cigarette - Number - [Tobacco Questionnaire (Baseline)]		Numeric .C="Choose Not To Answer" .F="No Record For This Visit" .M="Missing" .N="N/A" .U="Don't Know/Not Sure"
01. Principal	<b>tob_bsl_wake_first_cig</b>	How Soon After You Wake Up Do You Smoke Your First Cigarette? - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Within 30 Minutes" 2="After 30 Minutes"
01. Principal	<b>tob_bsl_water_pipe</b>	Other Tobacco Products Used Regularly: Water Pipe - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_work_30_smoke</b>	In The Past 30 Days, Have You Worked In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_work_smoke_cat</b>	Thinking Of All The Years You Have Worked, Have You Ever Worked In A Place Where Other People Smoked Cigarettes Indoors? - Category - [Tobacco Questionnaire (Baseline)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>tob_bsl_work_smoke_num</b>	Thinking Of All The Years You Have Worked, Have You Ever Worked In A Place Where Other People Smoked Cigarettes Indoors? - Number - [Tobacco Questionnaire (Baseline)]		Numeric .C="Choose Not To Answer" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tob_bsl_years_smoked</b>	How Many Total Years Have You Smoked (Or Did You Smoke) Cigarettes? - [Tobacco Questionnaire (Baseline)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

## Section 9: BESS Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	<b>bess_abdom_pain_v0/bess_abdom_pain_v2</b>	Abdominal Pain - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_accident_v0/bess_accident_v2</b>	Tendency Toward Accidents - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_avoid_soc_affair_v0/bess_avoid_soc_affair_v2</b>	Avoidance Of Social Affairs - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_back_pain_v0/bess_back_pain_v2</b>	Back Pain Or Problems - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_blurred_vision_v0/bess_blurred_vision_v2</b>	Blurred Vision - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_breast_tender_v0/bess_breast_tender_v2</b>	Breast Sensitivity/Tenderness - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_chest_pain_v0/bess_chest_pain_v2</b>	Chest Pains - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bess_cold_sweats_v0/bess_cold_sweats_v2</b>	Cold Sweats - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_comments_v0/bess_comments_v2</b>	Comments - Visit # - [BESS Questionnaire]		Char
01. Principal	<b>bess_constip_v0/bess_constip_v2</b>	Constipation - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_cramps_v0/bess_cramps_v2</b>	Cramps - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_dec_appet_v0/bess_dec_appet_v2</b>	Decreased Appetite - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_diarr_v0/bess_diarr_v2</b>	Diarrhea - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_diff_blad_laugh_v0/bess_diff_blad_laugh_v2</b>	Difficulty With Bladder Control (When Laughing Or Crying) - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_diff_blad_oth_v0/bess_diff_blad_oth_v2</b>	Difficulty With Bladder Control (At Other Times) - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bess_diff_breath_v0/bess_diff_breath_v2</b>	Difficulty Breathing - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_diff_concentr_v0/bess_diff_concentr_v2</b>	Difficulty Concentrating - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_dizziness_v0/bess_dizziness_v2</b>	Dizziness, Faintness - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_dry_mouth_v0/bess_dry_mouth_v2</b>	Dry Mouth - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_easily_distr_v0/bess_easily_distr_v2</b>	Easily Distracted - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_excitability_v0/bess_excitability_v2</b>	Excitability - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_feel_suffocated_v0/bess_feel_suffocated_v2</b>	Feeling Of Suffocation - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" .M="Missing" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_forget_v0/bess_forget_v2</b>	Forgetfulness - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bess_fuzzy_vis_v0/bess_fuzzy_vis_v2</b>	Blind Spots, Fuzzy Vision - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_gen_ache_v0/bess_gen_ache_v2</b>	General Aches And Pains - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_genit_itch_v0/bess_genit_itch_v2</b>	Genital Itching/Irritation - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_head_ache_v0/bess_head_ache_v2</b>	Headaches - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_hot_flash_v0/bess_hot_flash_v2</b>	Hot Flashes - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_joint_pain_v0/bess_joint_pain_v2</b>	Joint Pain - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_low_energy_v0/bess_low_energy_v2</b>	Low Energy - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_musc_stiff_v0/bess_musc_stiff_v2</b>	Muscle Stiffness - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bess_naps_v0/bess_naps_v2</b>	Tendency To Take Naps, Stay In Bed - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_nausea_v0/bess_nausea_v2</b>	Nausea - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_night_sweats_v0/bess_night_sweats_v2</b>	Night Sweats - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_numb_v0/bess_numb_v2</b>	Numbness, Tingling - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_oth_prob_v0/bess_oth_prob_v2</b>	Any Other Problems? - Visit # - [BESS Questionnaire]		Char
01. Principal	<b>bess_pain_inter_v0/bess_pain_inter_v2</b>	Pain With Intercourse - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" .M="Missing" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_pain_leg_feet_v0/bess_pain_leg_feet_v2</b>	Pain Or Cramps In The Legs Or Feet - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_ring_ears_v0/bess_ring_ears_v2</b>	Ringing In Ears - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"



Class	Variable	Label	Description	Format Text
01. Principal	<b>bess_short_temp_v0/bess_short_temp_v2</b>	Short Temper - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_swelling_hands_feet_v0/bess_swelling_hands_feet_v2</b>	Swelling Of Hands Or Feet - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_unhappy_appearance_body_v0/bess_unhappy_appearance_body_v2</b>	Unhappy With The Appearance Of My Body - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_vaginal_bleeding_v0/bess_vaginal_bleeding_v2</b>	Vaginal Bleeding Or Spotting - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_vaginal_discharge_v0/bess_vaginal_discharge_v2</b>	Vaginal Discharge - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_vaginal_dryness_v0/bess_vaginal_dryness_v2</b>	Vaginal Dryness - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_vomiting_v0/bess_vomiting_v2</b>	Vomiting - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_wake_early_v0/bess_wake_early_v2</b>	Early Awakening - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bess_weight_gain_v0/bess_weight_gain_v2</b>	Weight Gain - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"
01. Principal	<b>bess_weight_loss_v0/bess_weight_loss_v2</b>	Weight Loss - Visit # - [BESS Questionnaire]		.F="No Record For This Visit" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely" 9="Missing/Blank/NA"

## Section 10: Medical/Surgical History

Class	Variable	Label	Description	Format Text
01. Principal	<b>medhx_any_abn_v0/medhx_any_abn_v2</b>	Were Any Systems/Sites Abnormal? - Visit # - [Medical/Surgical History]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>medhx_breast_status_v0/medhx_breast_status_v2</b>	Breasts Status - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_cardio_status_v0/medhx_cardio_status_v2</b>	Cardiovascular Status - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_comments_v0/medhx_comments_v2</b>	Comments - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_derma_status_v0/medhx_derma_status_v2</b>	Dermatologic Status - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_endometria_status_v0/medhx_endometria_status_v2</b>	Endocrine/Metabolic Status - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_gastro_status_v0/medhx_gastro_status_v2</b>	Gastrointestinal Status - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_genito_status_v0/medhx_genito_status_v2</b>	Genitourinary Status - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_heent_status_v0/medhx_heent_status_v2</b>	H/E/E/N/T Status - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_hema_status_v0/medhx_hema_status_v2</b>	Hematopoietic/Lymph Status - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_muscskel_status_v0/medhx_muscskel_status_v2</b>	Musculoskeletal Status - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_neck_status_v0/medhx_neck_status_v2</b>	Neck Status - Visit # - [Medical/Surgical History]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>medhx_neuro_status_v0/medhx_neuro_status_v2</b>	Neurologic Status - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_oth_name_v0/medhx_oth_name_v2</b>	Other Body System/Site Name - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_oth_statuses_v0/medhx_oth_status_v2</b>	Other Body System/Site Status - Visit # - [Medical/Surgical History]		Char
01. Principal	<b>medhx_resp_status_v0/medhx_resp_status_v2</b>	Respiratory Status - Visit # - [Medical/Surgical History]		Char

## Section 11: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	<b>bsymp_comments1-3</b>	Comments - Symptom # - [Baseline Symptoms]		Char
01. Principal	<b>bsymp_description1-3</b>	Description - Symptom # - [Baseline Symptoms]		Char
01. Principal	<b>bsymp_num</b>	Number Of Symptoms - [Baseline Symptoms]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>bsymp_onset_dt1-3</b>	Onset Date - Symptom # - [Baseline Symptoms]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	<b>bsymp_severity1-3</b>	Severity - Symptom # - [Baseline Symptoms]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Mild" 2="Moderate" 3="Severe" 4="Life Threatening"

## Section 12: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	<b>pe_abdomen_status_v0/pe_abdomen_status_v2</b>	Abdomen Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_abnormal_v0/pe_abnormal_v2</b>	Were Any Systems/Sites Abnormal? - Visit # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>pe_appearance_status_v0/pe_appearance_status_v2</b>	Appearance Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_breast_status_v0/pe_breast_status_v2</b>	Breasts Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_chest_status_v0/pe_chest_status_v2</b>	Chest Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_comments_v0/pe_comments_v2</b>	Comments - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_genit_status_v0/pe_genit_status_v2</b>	Genitalia Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_heart_status_v0/pe_heart_status_v2</b>	Heart Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_heent_status_v0/pe_heent_status_v2</b>	H/E/E/N/T Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_lungs_status_v0/pe_lungs_status_v2</b>	Lungs Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_lymph_status_v0/pe_lymph_status_v2</b>	Lymph Nodes Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_muscskel_status_v0/pe_muscskel_status_v2</b>	Musculoskeletal Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_neuro_status_v0/pe_neuro_status_v2</b>	Neurological Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_oth_name_v0/pe_oth_name_v2</b>	Other Body System/Site Name - Visit # - [Physical Exam]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>pe_oth_status_v0/pe_oth_status_v2</b>	Other Body System/Site Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_pelvis_status_v0/pe_pelvis_status_v2</b>	Pelvis Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_rectal_status_v0/pe_rectal_status_v2</b>	Rectal Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_skin_status_v0/pe_skin_status_v2</b>	Skin Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_thyroid_status_v0/pe_thyroid_status_v2</b>	Thyroid Status - Visit # - [Physical Exam]		Char
01. Principal	<b>pe_vascular_status_v0/pe_vascular_status_v2</b>	Vascular Status - Visit # - [Physical Exam]		Char

## Section 13: Vitals

Class	Variable	Label	Description	Format Text
01. Principal	<b>vitals_bmi_v0/vitals_bmi_v2-3</b>	Body Mass Index (BMI) - Visit # - [Vitals]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>vitals_bp_diastolic_v0/vitals_bp_diastolic_v2-3</b>	Diastolic Blood Pressure - Visit # - [Vitals]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>vitals_bp_systolic_v0/vitals_bp_systolic_v2-3</b>	Systolic Blood Pressure - Visit # - [Vitals]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>vitals_comments_v0/vitals_comments_v2-3</b>	Comments - Visit # - [Vitals]		Char
01. Principal	<b>vitals_ecog_v0/vitals_ecog_v2-3</b>	ECOG Performance Status - Visit # - [Vitals]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Fully Active, Able To Carry On All Pre-Disease Performance Without Restriction." 1="Restricted In Physically Strenuous Activity But Ambulatory And Able To Carry Out Work Of A Light Or Sedentary Nature, E.G., Light House Work, Office Work." 2="Ambulatory And Capable Of All Self Care But Unable To Carry Out Any Work Activities. Up And About More Than 50% Of Waking Hours." 3="Capable Of Only Limited Selfcare, Confined To Bed Or Chair More Than 50% Of Waking Hours." 4="Completely Disabled. Cannot Carry On Any Selfcare. Totally Confined To Bed Or Chair." 5="Dead"
01. Principal	<b>vitals_height_v0/vitals_height_v2-3</b>	Height (cm) - Visit # - [Vitals]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>vitals_pulse_v0/vitals_pulse_v2-3</b>	Pulse - Visit # - [Vitals]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>vitals_temp_v0/vitals_temp_v2-3</b>	Temperature (C) - Visit # - [Vitals]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>vitals_weight_v0/vitals_weight_v2-3</b>	Weight (kg) - Visit # - [Vitals]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"



## Section 14: Menopause

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Class	Variable	Label	Description	Format Text
01. Principal	<b>meno_comments</b>	Comments - [Menopause]		Char
01. Principal	<b>meno_hysterectomy</b>	Had A Hysterectomy? - [Menopause]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>meno_last6_dt</b>	Date Of Last Menstrual Period (If Participant Had Period In Last 6 Months) - [Menopause]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	<b>meno_one_ovary</b>	Have At Least One Ovary? - [Menopause]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>meno_over55</b>	Over The Age Of 55? - [Menopause]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>meno_period_last6</b>	Had A Period In The Last 6 Months? - [Menopause]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>meno_period_stopped</b>	Did The Period Stop Spontaneously? - [Menopause]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>meno_status</b>	Premenopausal Or Postmenopausal? - [Menopause]		.R="Not Randomized" 1="Premenopausal" 2="Postmenopausal"
01. Principal	<b>meno_stop_dt</b>	Date Of Last Menstrual Period (If The Period Stopped Spontaneously) - [Menopause]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	<b>meno_stop_rsn</b>	If No Hysterectomy, What Is The Reason For Stopping Periods? - [Menopause]		Char

## Section 15: Menstruation

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Class	Variable	Label	Description	Format Text
01. Principal	<b>menst_comments_v0-1/menst_comments_v3-4</b>	Comments - Visit # - [Menstruation]		Char
01. Principal	<b>menst_length_v0-1/menst_length_v3-4</b>	Typical Length Of Menstrual Cycle (Number Of Days) - Visit # - [Menstruation]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>menst_no_last_rsn_oth_v0-1/menst_no_last_rsn_oth_v3-4</b>	If No Last Menstrual Period Date, Specify Why - Other - Visit # - [Menstruation]		Char
01. Principal	<b>menst_no_last_rsn_v0-1/menst_no_last_rsn_v3-4</b>	If No Last Menstrual Period Date, Specify Why - Visit # - [Menstruation]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Participant Did Not Have Period" 2="Information Not Obtainable" 3="Other, Please Specify"
01. Principal	<b>menst_period_dt_v0-1/menst_period_dt_v3-4</b>	Last Menstrual Period Date - Visit # - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

## Section 16: Breast Cup Size

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Class	Variable	Label	Description	Format Text
01. Principal	<b>cupsz_comments</b>	Comments - [Breast Cup Size]		Char
01. Principal	<b>cupsz_size</b>	Breast Cup Size - [Breast Cup Size]		Char

## Section 17: Skin

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Class	Variable	Label	Description	Format Text
01. Principal	<b>skin_comments_v0-1</b>	Comments - Visit # - [Skin]		Char
01. Principal	<b>skin_photo_v0-1</b>	Photos Taken Of Breast Skin? - Visit # - [Skin]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>skin_redcap_v0-1</b>	Photos Uploaded Onto Redcap? - Visit # - [Skin]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>skin_upload_dt_v0-1</b>	Date Of Photo Upload - Visit # - [Skin]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

## Section 18: TAC/TAD

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Class	Variable	Label	Description	Format Text
01. Principal	<b>tactad_comments1-2</b>	Comments - Treatment # - [TAC/TAD]		Char
01. Principal	<b>tactad_start_dt1-2</b>	Start Date - Treatment # - [TAC/TAD]		SAS Date .F="No Record For This Visit"
01. Principal	<b>tactad_tac1-2</b>	Treatment Assignment Code (TAC) - Treatment # - [TAC/TAD]		.F="No Record For This Visit" 0="TAC0" 1="TAC1" 2="TAC2" 3="TAC3" 4="TAC4"

## Section 19: Skin Toxicity

Class	Variable	Label	Description	Format Text
01. Principal	<b>tox_comments1-7</b>	Comments - Contact # - [Skin Toxicity]		Char
01. Principal	<b>tox_dry1-7</b>	Breast Skin Dry From Gel Application? - Contact # - [Skin Toxicity]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tox_dry_red_itch1-7</b>	If Breast Skin Dry From Gel Application, Is It Red, Or Itchy? - Contact # - [Skin Toxicity]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tox_dt1-7</b>	Contact Date - Contact # - [Skin Toxicity]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>tox_hives1-7</b>	Hives On The Breast Skin Where Gel Was Applied? - Contact # - [Skin Toxicity]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tox_hives_meds1-7</b>	If Hives On The Breast Skin Where Gel Was Applied, Taking Any Medicine For This? - Contact # - [Skin Toxicity]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tox_hives_size1-7</b>	If Hives On The Breast Skin Where Gel Was Applied, How Big Is The Area? - Contact # - [Skin Toxicity]		Char
01. Principal	<b>tox_itch1-7</b>	Skin Itchy From Gel Application? - Contact # - [Skin Toxicity]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tox_itch_meds1-7</b>	If Skin Itchy From Gel Application, Taking Any Medicine For This? - Contact # - [Skin Toxicity]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tox_itch_sev1-7</b>	If Skin Itchy From Gel Application, How Severe? - Contact # - [Skin Toxicity]		Char
01. Principal	<b>tox_pain1-7</b>	Pain On Breast Skin? - Contact # - [Skin Toxicity]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tox_pain_sev1-7</b>	If Pain On Breast Skin, How Severe? - Contact # - [Skin Toxicity]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>tox_rash1-7</b>	Rash On Breast Skin? - Contact # - [Skin Toxicity]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tox_rash_meds1-7</b>	If Rash On Breast Skin, Taking Any Medicine For This? - Contact # - [Skin Toxicity]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tox_rash_pic1-7</b>	If Rash On Breast Skin, Uploaded A Picture Of Rash Onto Redcap? - Contact # - [Skin Toxicity]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tox_rash_size1-7</b>	If Rash On Breast Skin, How Big Is The Affected Area? - Contact # - [Skin Toxicity]		Char

## Section 20: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	<b>conmed_comments1-11</b>	Comments - Medication # - [Concomitant Medications]		Char
01. Principal	<b>conmed_dose1-11</b>	Dose - Medication # - [Concomitant Medications]		Char
01. Principal	<b>conmed_freq1-11</b>	Dose Frequency - Medication # - [Concomitant Medications]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="BID" 2="HS" 3="OTH" 4="PRN" 5="Q2h" 6="Q4h" 7="Q6h" 8="Q8h" 9="QAM" 10="QD" 11="QID" 12="QPM" 13="TID" 99="UNK"
01. Principal	<b>conmed_freq_oth1-11</b>	Dose Frequency: Other, Specify - Medication # - [Concomitant Medications]		Char
01. Principal	<b>conmed_indication1-11</b>	Indication - Medication # - [Concomitant Medications]		Char
01. Principal	<b>conmed_name1-11</b>	Name - Medication # - [Concomitant Medications]		Char
01. Principal	<b>conmed_num</b>	Number Of Concomitant Medications - [Concomitant Medications]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>conmed_rep_dt1-11</b>	Report Date - Medication # - [Concomitant Medications]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	<b>conmed_start_dt1-11</b>	Start Date - Medication # - [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	<b>conmed_stop_dt 1-11</b>	Stop Date - Medication # - [Concomitant Medications]		SAS Date .C="Continuous" .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>conmed_units1-1 1</b>	Units - Medication # - [Concomitant Medications]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="%" 2="app" 3="Bq" 4="Cap" 5="Ci" 6="Cplt" 7="DF" 8="G" 9="GBq" 10="gtt" 11="iu" 12="iu/kg" 13="J/cm2" 14="KBq" 15="kg" 16="kiu" 17="l" 18="MBq" 19="mCi" 20="mEq" 21="mg" 22="mg/kg" 23="mg/m2" 24="Miu" 25="ML" 26="mL" 27="mmol" 28="mol" 29="nCi" 30="ng" 31="Oth" 32="PG" 33="Puff" 34="Sachet" 35="Tab" 36="tbs" 37="tsp" 38="uCi" 39="ug" 40="ug/kg" 41="ug/m2"  [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	<b>[...continued]</b> <b>conmed_units1-11</b>			[...continued] 42="UL" 43="UMOL" 44="Units" 99="Unknown"
01. Principal	<b>conmed_units_oth1-11</b>	Units: Other, Specify - Medication # - [Concomitant Medications]		Char

## Section 21: Adverse Events

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

## Section 22: Pregnancy Test

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Class	Variable	Label	Description	Format Text
01. Principal	<b>preg_comments_ex</b>	Comments - Extra Visit - [Pregnancy Test]		Char
01. Principal	<b>preg_comments_v0/preg_comments_v2</b>	Comments - Visit # - [Pregnancy Test]		Char
01. Principal	<b>preg_results_ex</b>	Results - Extra Visit - [Pregnancy Test]		.N="Not Applicable, Not Female Of Child-Bearing Potential" .R="Not Randomized" 0="Negative" 1="Positive"
01. Principal	<b>preg_results_v0/preg_results_v2</b>	Results - Visit # - [Pregnancy Test]		.F="No Record For This Visit" .N="Not Applicable, Not Female Of Child-Bearing Potential" .R="Not Randomized" 0="Negative" 1="Positive"

## Section 23: Alcohol Questionnaire (Follow-up)

Class	Variable	Label	Description	Format Text
01. Principal	<b>alc_fup_avg_drinks</b>	On The Days When You Drank, On Average, About How Many Drinks Did You Have? - [Alcohol Questionnaire (Follow-up)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Choose Not To Answer" .U="Don't Know/Not Sure"
01. Principal	<b>alc_fup_comments</b>	Comments - [Alcohol Questionnaire (Follow-up)]		Char
01. Principal	<b>alc_fup_inv_dt</b>	Date Signed By Investigator - [Alcohol Questionnaire (Follow-up)]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>alc_fup_p30d_5_or_more</b>	In The Past 30 Days, On How Many Days Did You Have 5 Or More Drinks Per Day? - [Alcohol Questionnaire (Follow-up)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Choose Not To Answer" .U="Don't Know/Not Sure"
01. Principal	<b>alc_fup_p30d_any</b>	During The Past 30 Days, Did You Drink Any Alcoholic Beverages? - [Alcohol Questionnaire (Follow-up)]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>alc_fup_p30d_freq</b>	During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages? - Frequency - [Alcohol Questionnaire (Follow-up)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Week" 2="Month" 3="Year" 4="Refused" 5="Don't Know/Not Sure"
01. Principal	<b>alc_fup_p30d_num</b>	During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages? - Number - [Alcohol Questionnaire (Follow-up)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

## Section 24: Tobacco Questionnaire (Follow-up)

Class	Variable	Label	Description	Format Text
01. Principal	<b>tob_fup_bidis</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - Bidis - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tob_fup_cig_end_freq1-2</b>	After The End Of Study Treatment, Please Indicate Whether You Smoked Cigarettes Every Day, Some Days, Or Not At All. - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Did Not Smoke At All" 1="Smoked Every Day" 2="Smoked Some Days" 3="Don't Know/Not Sure" 4="Not Applicable (I Have Not Completed The Study Treatment)"
01. Principal	<b>tob_fup_cig_trt_freq</b>	During Study Treatment, Please Indicate Whether You Smoked Cigarettes Every Day, Some Days, Or Not At All. - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Did Not Smoke At All" 1="Smoked Every Day" 2="Smoked Some Days" 3="Don't Know/Not Sure" 4="Not Applicable"
01. Principal	<b>tob_fup_cigarettes</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - Cigarettes - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tob_fup_cigars</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - Traditional Cigars, Cigarillos Or Filtered Cigars - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tob_fup_cigs_da y</b>	On Average When You Have Smoked, About How Many Cigarettes Do You (Or Did You) Smoke A Day? (A Pack Usually Has 20 Cigarettes In It). (Number Of Cigarettes Per Day) - [Tobacco Questionnaire (Follow-up)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tob_fup_clove_ci g</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - Clove Cigarettes Or Kreteks - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tob_fup_commen ts</b>	Comments - [Tobacco Questionnaire (Follow-up)]		Char
01. Principal	<b>tob_fup_e_cig</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - E-Cigarettes Or Other Electronic Nicotine Delivery System - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tob_fup_hookah</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - Hookah - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tob_fup_inv_dt</b>	Date Signed By Investigator - [Tobacco Questionnaire (Follow-up)]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tob_fup_oth_last_use</b>	If You Do Not Currently Use Other Forms Of Tobacco, But Did In The Past, How Long Has It Been Since You Last Used Other Forms Of Tobacco Regularly? - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Within The Past Month (0 To 1 Month Ago)" 1="Between 1 And 3 Months (1 To 3 Months Ago)" 2="Between 3 And 6 Months (3 To 6 Months Ago)" 3="Between 6 And 12 Months (6 To 12 Months Ago)" 4="Between 1 And 5 Years (1 To 5 Years Ago)" 5="Between 5 And 15 Years (5 To 15 Years Ago)" 6="More Than 15 Years Ago" 7="Never Used Other Forms Of Tobacco Regularly" 8="Don't Know/Not Sure"
01. Principal	<b>tob_fup_oth_tob_spec</b>	Other Tobacco Use (Specify) - [Tobacco Questionnaire (Follow-up)]		Char
01. Principal	<b>tob_fup_oth_tob_use</b>	Since Your Last Visit, Have You Used Other Forms Of Tobacco, Not Including Cigarettes? - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tob_fup_other</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - Other - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tob_fup_other_cat</b>	How Often Do You/Did You Use Other Forms Of Tobacco? - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Every Day" 2="Some Days"
01. Principal	<b>tob_fup_other_freq</b>	How Often Do You/Did You Use Other Forms Of Tobacco? (Per Day, Week, Month, Year) - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Times/Day" 2="Days/Week" 3="Days/Month" 4="Days/Year"
01. Principal	<b>tob_fup_other_num</b>	How Often Do You/Did You Use Other Forms Of Tobacco? (Number) - [Tobacco Questionnaire (Follow-up)]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"



Class	Variable	Label	Description	Format Text
01. Principal	<b>tob_fup_paan</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - Paan With Tobacco, Gutka, Zarda, Khaini - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tob_fup_pipe</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - Pipes - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tob_fup_smoke_now</b>	Do You Now Smoke Cigarettes? - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Every Day" 2="Some Days" 3="Not At All"
01. Principal	<b>tob_fup_smokeless</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - Smokeless Tobacco, Like Dip, Chew, Or Snuff - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tob_fup_snus</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - Snus - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>tob_fup_time_last_cig_cat</b>	How Long Has It Been Since You Last Smoked A Cigarette (Even One Or Two Puffs)? - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="I Smoked A Cigarette Today" 2="Cigarette In The Last 1-7 Days" 3="Cigarette In Less Than 1 Month" 4="Cigarette In Less Than 1 Year" 5="Cigarette In More Than 1 Year" 6="Don't Know/Don't Remember"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tob_fup_time_last_cig_freq</b>	If Applicable, Write A Number For How Many Days, Weeks, Months, Or Years It Has Been Since Your Last Cigarette. (Days, Weeks, Months, Years) - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Days" 2="Weeks" 3="Months" 4="Years"
01. Principal	<b>tob_fup_time_last_cig_num</b>	If Applicable, Write A Number For How Many Days, Weeks, Months, Or Years It Has Been Since Your Last Cigarette. (Number) - [Tobacco Questionnaire (Follow-up)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tob_fup_water_pipe</b>	Since Your Last Visit, Which Of The Following Products Have You Used? (Check All That Apply) - Waterpipe - [Tobacco Questionnaire (Follow-up)]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"

## Section 25: Participant Contact

Class	Variable	Label	Description	Format Text
01. Principal	<b>pcon_comments 1-8</b>	Comments - Contact # - [Participant Contact]		Char
01. Principal	<b>pcon_compliant1 -8</b>	Is The Participant Compliant With Protocol Intervention - Contact # - [Participant Contact]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	<b>pcon_conmed1-8</b>	Were Any Changes In Concomitant Medications Reported? (Either New Medications Started Or Previous Medications Stopped?) - Contact # - [Participant Contact]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="N/A"
01. Principal	<b>pcon_dt1-8</b>	Date Of Contact - Contact # - [Participant Contact]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	<b>pcon_symp_ae1- 8</b>	Did The Participant Report Any Symptoms Or Adverse Events? - Contact # - [Participant Contact]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 9="Too Early To Evaluate"

## Section 26: Agent Return And Compliance

Class	Variable	Label	Description	Format Text
01. Principal	<b>agrc_both_breasts</b>	Did Participant Apply Gel To Both Breasts? - [Agent Return And Compliance]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>agrc_comments</b>	Comments - [Agent Return And Compliance]		Char
01. Principal	<b>agrc_compliant</b>	Is Participant Compliant (80 PCT Or More Of Agent Used) With Protocol Intervention? - [Agent Return And Compliance]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>agrc_dispense_date</b>	Agent Dispensing Date - [Agent Return And Compliance]		SAS Date .R="Not Randomized"
01. Principal	<b>agrc_dispense_weight</b>	Weight Of Gel Canister At Dispensing (Grams) - [Agent Return And Compliance]		Numeric .R="Not Randomized"
01. Principal	<b>agrc_rand_num</b>	Randomization Number - [Agent Return And Compliance]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	<b>agrc_return_cap</b>	Returned Gel Canister Weighed With The Cap On? - [Agent Return And Compliance]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>agrc_return_dt</b>	Agent Return Date - [Agent Return And Compliance]		SAS Date .R="Not Randomized"
01. Principal	<b>agrc_return_weight</b>	Weight Of Returned Gel Canister (Grams) - [Agent Return And Compliance]		Numeric .R="Not Randomized"
01. Principal	<b>agrc_rsn_noncomp</b>	Reason For Noncompliance - [Agent Return And Compliance]		Char

## Section 27: Agent Interruption

Class	Variable	Label	Description	Format Text
01. Principal	<b>agent_amount_missed</b>	Amount Of Agent Missed (# Of Gel Doses, Where 1 Dose = Application To Both Breasts) - [Agent Interruption]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>agent_comments</b>	Comments - [Agent Interruption]		Char
01. Principal	<b>agent_interrupt_dt</b>	Interruption Date - [Agent Interruption]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>agent_restart_dt</b>	If Restarted, Specify Date - [Agent Interruption]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>agent_restarted</b>	Was Agent Restarted? - [Agent Interruption]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>agent_rsn_stop</b>	Reason Stopped - [Agent Interruption]		.F="No Record For This Visit" .R="Not Randomized" 1="Investigator Decision, Specify" 2="Participant Decision, Specify" 3="Participant Forgot" 4="AE/SAE, Specify" 5="Other, Specify"
01. Principal	<b>agent_rsn_stop_spec</b>	Reason Stopped (Specify) - [Agent Interruption]		Char

## Section 28: Compliance

Class	Variable	Label	Description	Format Text
01. Principal	<b>comp_both_breasts</b>	Did Participant Apply Gel To Both Breasts? - [Compliance]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>comp_cap_on</b>	Returned Gel Canister Weighed With The Cap On? - [Compliance]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>comp_comments</b>	Comments - [Compliance]		Char
01. Principal	<b>comp_compliant_diary</b>	Is Participant Compliant Based On Diary? - [Compliance]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>comp_compliant_weight</b>	Is Participant Compliant Based On Gel Weight? - [Compliance]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>comp_days_intervention</b>	Days On Intervention - [Compliance]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>comp_gel_at_dispense</b>	Weight Of Gel Canister At Dispensing (Grams) - [Compliance]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>comp_gel_at_return</b>	Weight Of Returned Gel Canister (Grams) - [Compliance]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>comp_gel_used</b>	Weight Of Gel Used (Grams) - [Compliance]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>comp_min_gel_required</b>	Minimum Weight Of Gel Required (Grams) - [Compliance]		Numeric .M="Missing" .R="Not Randomized"

## Section 29: Off Study

Class	Variable	Label	Description	Format Text
01. Principal	<b>off_agent_end_dt</b>	Agent End Date - [Off Study]		SAS Date .M="Missing"
01. Principal	<b>off_agent_end_reason</b>	Reason Off Agent - [Off Study]		.M="Missing" 1="AE/SAE" 2="Completed Protocol-Prescribed Intervention" 3="Completed Treatment" 4="Concomitant Medication" 5="Death" 6="Inadequate Agent Supply" 7="Lost To Follow-Up" 8="Medical Contraindication" 9="Non-Compliant Participant" 10="Pregnancy" 11="Withdraw Consent" 99="Other, Specify"
01. Principal	<b>off_agent_end_reason_spec</b>	Reason Off Agent - Other (Specify) - [Off Study]		Char
01. Principal	<b>off_comments</b>	Comments - [Off Study]		Char
01. Principal	<b>off_dt</b>	Off Study Date - [Off Study]		SAS Date
01. Principal	<b>off_last_contact_dt</b>	Date Of Last Contact - [Off Study]		SAS Date
01. Principal	<b>off_rsn</b>	Reason Off Study - [Off Study]		1="Adverse Event" 2="Death" 3="Disease Progression" 4="Lost To Follow-Up" 6="Participant Withdrawal" 7="Participant Refused Follow-Up" 8="Physician Decision" 9="Protocol Defined Follow-Up Completed" 10="Protocol Violation" 11="Study Complete" 12="Ineligible" 99="Other, Specify"
01. Principal	<b>off_rsn_spec</b>	Reason Off Study - Other (Specify) - [Off Study]		Char

## Section 30: Batch Shipment Specimen Inventory

Class	Variable	Label	Description	Format Text
01. Principal	<b>ship_comments1-2</b>	Comments - Shipment # - [Batch Shipment Specimen Inventory]		Char
01. Principal	<b>ship_dt1-2</b>	Date Of Shipment - Shipment # - [Batch Shipment Specimen Inventory]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>ship_edta_bf_num1-2</b>	Number Of Aliquots - EDTA/Purple Top Buffy Coat - Shipment # - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>ship_edta_pl_num1-2</b>	Number Of Aliquots - EDTA/Purple Top Plasma - Shipment # - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>ship_nacit_pl_num1-2</b>	Number Of Aliquots - NaCit/Blue Top Plasma - Shipment # - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>ship_num</b>	Number Of Shipments - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>ship_post_drug_num1-2</b>	Number Of Cryovials - Post-Therapy Drug Concentration Assays Frozen Tissue - Shipment # - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>ship_pre_blk_num1-2</b>	Number Of FFPE Blocks - Pre-Therapy DCNB Clinical Specimen - Shipment # - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>ship_pre_sl_num1-2</b>	Number Of Slides - Pre-Therapy DCNB Clinical Specimen - Shipment # - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"



Class	Variable	Label	Description	Format Text
01. Principal	<b>ship_ptfr_blk_num1-2</b>	Number Of FFPE Blocks - Post-Therapy Benign Fresh Tissue Specimen - Shipment # - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>ship_ptsg_blk_num1-2</b>	Number Of FFPE Blocks - Post-Therapy Surgical Clinical Specimen - Shipment # - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>ship_ptsg_sl_num1-2</b>	Number Of Slides - Post-Therapy Surgical Clinical Specimen - Shipment # - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

## Section 31: Specimen Collection (Tissue)

Class	Variable	Label	Description	Format Text
01. Principal	<b>tis_comments</b>	Comments - [Specimen Collection (Tissue)]		Char
01. Principal	<b>tis_post_benign</b>	Post-Therapy Benign Fresh Tissue - Number Of FFPE Blocks - [Specimen Collection (Tissue)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_post_benign_dt</b>	Post-Therapy Benign Fresh Tissue - Specimen Collection Date And Time Specimen Collected - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_post_benign_storage</b>	Post-Therapy Benign Fresh Tissue - Storage Location And Temperature (Centigrade) - [Specimen Collection (Tissue)]		Char
01. Principal	<b>tis_post_benign_time</b>	Post-Therapy Benign Fresh Tissue - Specimen Collection Date And Time Specimen Collected (Time) - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_post_conc_comments</b>	Post-Therapy Drug Concentration Assays Frozen Tissue - Comments - [Specimen Collection (Tissue)]		Char
01. Principal	<b>tis_post_conc_dt</b>	Post-Therapy Drug Concentration Assays Frozen Tissue - Specimen Collection Date And Time Specimen Collected - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_post_conc_storage</b>	Post-Therapy Drug Concentration Assays Frozen Tissue - Storage Location And Temperature (Centigrade) - [Specimen Collection (Tissue)]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>tis_post_conc_time</b>	Post-Therapy Drug Concentration Assays Frozen Tissue - Specimen Collection Date And Time Specimen Collected (Time) - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_post_cryovial</b>	Post-Therapy Drug Concentration Assays Frozen Tissue - Number Of Cryovials - [Specimen Collection (Tissue)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_post_surg_block</b>	Post-Therapy Surgical Specimen - Number Of FFPE Blocks - [Specimen Collection (Tissue)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_post_surg_block_dt</b>	Post-Therapy Surgical Specimen - Specimen Collection Date And Time Specimen Collected - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_post_surg_block_time</b>	Post-Therapy Surgical Specimen - Specimen Collection Date And Time Specimen Collected (Time) - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_post_surg_comments</b>	Post-Therapy Surgical Specimen - Comments - [Specimen Collection (Tissue)]		Char
01. Principal	<b>tis_post_surg_slides</b>	Post-Therapy Surgical Specimen - Number Of Slides - [Specimen Collection (Tissue)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_post_surg_slides_dt</b>	Post-Therapy Surgical Specimen - Collection Date And Time Specimen Collected - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_post_surg_storage</b>	Post-Therapy Surgical Specimen - Storage Location/Temperature - [Specimen Collection (Tissue)]		Char
01. Principal	<b>tis_pre_block</b>	Pre-Surgical DCNB Clinical Specimen - Number Of FFPE Blocks - [Specimen Collection (Tissue)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tis_pre_block_dt</b>	Pre-Surgical DCNB Clinical Specimen FFPE Block - Specimen Collection Date And Time Specimen Collected - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_pre_comments</b>	Pre-Surgical DCNB Clinical Specimen - Comments - [Specimen Collection (Tissue)]		Char
01. Principal	<b>tis_pre_slide</b>	Pre-Surgical DCNB Clinical Specimen - Number Of Slides - [Specimen Collection (Tissue)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_pre_slide_dt</b>	Pre-Surgical DCNB Clinical Specimen Slides - Specimen Collection Date And Time Specimen Collected - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>tis_pre_storage</b>	Pre-Surgical DCNB Clinical Specimen - Storage Location And Temperature (Centigrade) - [Specimen Collection (Tissue)]		Char

## Section 32: Specimen Collection (Blood)

Class	Variable	Label	Description	Format Text
01. Principal	<b>bspec_comments_v0/bspec_comments_v2</b>	Comments - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	<b>bspec_dt_v0/bspec_dt_v2</b>	Specimen Collection Date - Visit # - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>bspec_part1_comments_v0/bspec_part1_comments_v2</b>	RB Part 1 - Comments - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	<b>bspec_part1_daughter_v0/bspec_part1_daughter_v2</b>	RB Part 1 - Number Of Daughter Specimens Associated With Parent Specimen - Visit # - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>bspec_part1_storage_v0/bspec_part1_storage_v2</b>	RB Part 1 - Storage Location/Time - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	<b>bspec_part1_storage_v0/bspec_part1_storage_v2</b>	RB Part 1 - Storage Location/Time - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	<b>bspec_part1_storage_v0/bspec_part1_storage_v2</b>	RB Part 1 - Storage Location/Time - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	<b>bspec_part1_type_v0/bspec_part1_type_v2</b>	RB Part 1 - Parent Specimen Type - Visit # - [Specimen Collection (Blood)]		.F="No Record For This Visit" .R="Not Randomized" 1="NaCit/Blue Top Tube" 2="EDTA Purple Top Tube"
01. Principal	<b>bspec_part2_comments_v0/bspec_part2_comments_v2</b>	RB Part 2 - Comments - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	<b>bspec_part2_daughter_v0/bspec_part2_daughter_v2</b>	RB Part 2 - Number Of Daughter Specimens Associated With Parent Specimen - Visit # - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>bspec_part2_storage_v0/bspec_part2_storage_v2</b>	RB Part 2 - Storage Location/Time - Visit # - [Specimen Collection (Blood)]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>bspec_part2_type_v0/bspec_part2_type_v2</b>	RB Part 2 - Parent Specimen Type - Visit # - [Specimen Collection (Blood)]		.F="No Record For This Visit" .R="Not Randomized" 1="NaCit/Blue Top Tube" 2="EDTA Purple Top Tube"
01. Principal	<b>bspec_part3_comments_v0/bspec_part3_comments_v2</b>	RB Part 3 - Comments - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	<b>bspec_part3_daughter_v0/bspec_part3_daughter_v2</b>	RB Part 3 - Number Of Daughter Specimens Associated With Parent Specimen - Visit # - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>bspec_part3_storage_v0/bspec_part3_storage_v2</b>	RB Part 3 - Storage Location/Time - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	<b>bspec_part3_type_v0/bspec_part3_type_v2</b>	RB Part 3 - Parent Specimen Type - Visit # - [Specimen Collection (Blood)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="NaCit/Blue Top Tube" 2="EDTA Purple Top Tube"
01. Principal	<b>bspec_part4_comments_v0/bspec_part4_comments_v2</b>	RB Part 4 - Comments - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	<b>bspec_part4_daughter_v0/bspec_part4_daughter_v2</b>	RB Part 4 - Number Of Daughter Specimens Associated With Parent Specimen - Visit # - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>bspec_part4_storage_v0/bspec_part4_storage_v2</b>	RB Part 4 - Storage Location/Time - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	<b>bspec_part4_type_v0/bspec_part4_type_v2</b>	RB Part 4 - Parent Specimen Type - Visit # - [Specimen Collection (Blood)]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="NaCit/Blue Top Tube" 2="EDTA Purple Top Tube"
01. Principal	<b>bspec_time_v0/bspec_time_v2</b>	Time Specimen Collected - Visit # - [Specimen Collection (Blood)]		SAS Time .F="No Record For This Visit" .R="Not Randomized"

## Section 33: Lab Tests

Class	Variable	Label	Description	Format Text
01. Principal	<b>labs_alk_phos_clin_v0/labs_alk_phos_clin_v2</b>	Alkaline Phosphatase - Clinically Significant? - Visit # - [Lab Tests]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_alk_phos_oor_v0/labs_alk_phos_oor_v2</b>	Alkaline Phosphatase - Out Of Range? - Visit # - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_alk_phos_rslt_v0/labs_alk_phos_rslt_v2</b>	Alkaline Phosphatase - Result (U/L) - Visit # - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>labs_alt_clin_v0/labs_alt_clin_v2</b>	ALT - Clinically Significant? - Visit # - [Lab Tests]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_alt_oor_v0/labs_alt_oor_v2</b>	ALT - Out Of Range? - Visit # - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_alt_rslt_v0/labs_alt_rslt_v2</b>	ALT - Result (U/L) - Visit # - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>labs_ast_clin_v0/labs_ast_clin_v2</b>	AST - Clinically Significant? - Visit # - [Lab Tests]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_ast_oor_v0/labs_ast_oor_v2</b>	AST - Out Of Range? - Visit # - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_ast_rslt_v0/labs_ast_rslt_v2</b>	AST - Result (U/L) - Visit # - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>labs_bili_clin_v0/labs_bili_clin_v2</b>	Total Bilirubin - Clinically Significant? - Visit # - [Lab Tests]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_bili_oor_v0/labs_bili_oor_v2</b>	Total Bilirubin - Out Of Range? - Visit # - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_bili_rslt_v0/labs_bili_rslt_v2</b>	Total Bilirubin - Result (mg/dL) - Visit # - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>labs_bun_clin_v0</b> <b>/labs_bun_clin_v2</b>	BUN - Clinically Significant? - Visit # - [Lab Tests]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_bun_oor_v0</b> <b>/labs_bun_oor_v2</b>	BUN - Out Of Range? - Visit # - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_bun_rslt_v0</b> <b>/labs_bun_rslt_v2</b>	BUN - Result (mg/L) - Visit # - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>labs_comments_v0</b> <b>/labs_comments_v2</b>	Comments - Visit # - [Lab Tests]		Char
01. Principal	<b>labs_creat_clin_v0</b> <b>/labs_creat_clin_v2</b>	Creatinine - Clinically Significant? - Visit # - [Lab Tests]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_creat_oor_v0</b> <b>/labs_creat_oor_v2</b>	Creatinine - Out Of Range? - Visit # - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_creat_rslt_v0</b> <b>/labs_creat_rslt_v2</b>	Creatinine - Result (mg/dL) - Visit # - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>labs_oth1_clin_v0</b> <b>/labs_oth1_clin_v2</b>	Other Test 1 - Clinically Significant? - Visit # - [Lab Tests]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_oth1_name_v0</b> <b>/labs_oth1_name_v2</b>	Other Test 1 - Test Name - Visit # - [Lab Tests]		Char
01. Principal	<b>labs_oth1_rslt_v0</b> <b>/labs_oth1_rslt_v2</b>	Other Test 1 - Result - Visit # - [Lab Tests]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>labs_oth1_units_v0</b> <b>/labs_oth1_units_v2</b>	Other Test 1 - Units - Visit # - [Lab Tests]		Char
01. Principal	<b>labs_oth2_clin_v0</b> <b>/labs_oth2_clin_v2</b>	Other Test 2 - Clinically Significant? - Visit # - [Lab Tests]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_oth2_name_v0</b> <b>/labs_oth2_name_v2</b>	Other Test 2 - Test Name - Visit # - [Lab Tests]		Char
01. Principal	<b>labs_oth2_rslt_v0</b> <b>/labs_oth2_rslt_v2</b>	Other Test 2 - Result - Visit # - [Lab Tests]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"



Class	Variable	Label	Description	Format Text
01. Principal	<b>labs_oth2_units_v0/labs_oth2_units_v2</b>	Other Test 2 - Units - Visit # - [Lab Tests]		Char
01. Principal	<b>labs_oth3_clin_v0/labs_oth3_clin_v2</b>	Other Test 3 - Clinically Significant? - Visit # - [Lab Tests]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	<b>labs_oth3_name_v0/labs_oth3_name_v2</b>	Other Test 3 - Test Name - Visit # - [Lab Tests]		Char
01. Principal	<b>labs_oth3_rslt_v0/labs_oth3_rslt_v2</b>	Other Test 3 - Result - Visit # - [Lab Tests]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>labs_oth3_units_v0/labs_oth3_units_v2</b>	Other Test 3 - Units - Visit # - [Lab Tests]		Char
01. Principal	<b>labs_oth_oor_v0/labs_oth_oor_v2</b>	Were Any Other Blood Chemistry Tests Out Of Range? - Visit # - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"

## Section 34: Tissue/Plasma Concentrations

Class	Variable	Label	Description	Format Text
01. Principal	<b>conc_b1_e_enx1-6</b>	E ENX (ng/g) - Primary # - [Drug Concentrations]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>conc_b1_id1-6</b>	Tissue ID - Primary # - [Drug Concentrations]		Char
01. Principal	<b>conc_b1_z_enx1-6</b>	Z ENX (ng/g) - Primary # - [Drug Concentrations]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>conc_b2_e_enx1-6</b>	E ENX (ng/g) - Secondary # - [Drug Concentrations]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>conc_b2_id1-6</b>	Tissue ID - Secondary # - [Drug Concentrations]		Char
01. Principal	<b>conc_b2_z_enx1-6</b>	Z ENX (ng/g) - Secondary # - [Drug Concentrations]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>conc_pl_e_enx</b>	E ENX (ng/mL) - Plasma - [Drug Concentrations]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>conc_pl_masking_id</b>	Plasma Masking Code - [Drug Concentrations]		Char
01. Principal	<b>conc_pl_z_enx</b>	Z ENX (ng/mL) - Plasma - [Drug Concentrations]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>conc_primary_breast</b>	Primary Breast - [Drug Concentrations]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Left" 2="Right"
01. Principal	<b>conc_surg_type</b>	Surgery Type - [Drug Concentrations]		.M="Missing" .R="Not Randomized" 1="Unilateral" 2="Bilateral"

## Section 35: Mastectomy Grossing

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgross_breast_side1-2</b>	Right Or Left Breast? - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_comments1-2</b>	Comments - Mastectomy # - [Mastectomy Grossing]		Char
01. Principal	<b>mgross_deep_dist_a1_1-2</b>	Distance From Deep Surface (cm) - Sample 1 (Slice A) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_deep_dist_a2_1-2</b>	Distance From Deep Surface (cm) - Sample 2 (Slice A) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_deep_dist_b3_1-2</b>	Distance From Deep Surface (cm) - Sample 3 (Slice B) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_deep_dist_b4_1-2</b>	Distance From Deep Surface (cm) - Sample 4 (Slice B) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_deep_dist_c5_1-2</b>	Distance From Deep Surface (cm) - Sample 5 (Slice C) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_deep_dist_ln7_1-2</b>	Distance From Deep Surface (cm) - Sample 7 (Lymph Node) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_deep_dist_tm6_1-2</b>	Distance From Deep Surface (cm) - Sample 6 (Tumor) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_drug_weight_a1_1-2</b>	Weight Of Drug Sample (mg) - Sample 1 (Slice A) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgross_drug_weight_a2_1-2</b>	Weight Of Drug Sample (mg) - Sample 2 (Slice A) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_drug_weight_b3_1-2</b>	Weight Of Drug Sample (mg) - Sample 3 (Slice B) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_drug_weight_b4_1-2</b>	Weight Of Drug Sample (mg) - Sample 4 (Slice B) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_drug_weight_c5_1-2</b>	Weight Of Drug Sample (mg) - Sample 5 (Slice C) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_drug_weight_ln7_1-2</b>	Weight Of Drug Sample (mg) - Sample 7 (Lymph Node) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_drug_weight_tm6_1-2</b>	Weight Of Drug Sample (mg) - Sample 6 (Tumor) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_hist_weight_a1_1-2</b>	Weight Of Histology Sample (mg) - Sample 1 (Slice A) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_hist_weight_a2_1-2</b>	Weight Of Histology Sample (mg) - Sample 2 (Slice A) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_hist_weight_b3_1-2</b>	Weight Of Histology Sample (mg) - Sample 3 (Slice B) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_hist_weight_b4_1-2</b>	Weight Of Histology Sample (mg) - Sample 4 (Slice B) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_hist_weight_c5_1-2</b>	Weight Of Histology Sample (mg) - Sample 5 (Slice C) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgross_hist_weight_in7_1-2</b>	Weight Of Histology Sample (mg) - Sample 7 (Lymph Node) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_hist_weight_tm6_1-2</b>	Weight Of Histology Sample (mg) - Sample 6 (Tumor) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_nip_dist_a1_1-2</b>	Distance From Nipple (cm) - Sample 1 (Slice A) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_nip_dist_a2_1-2</b>	Distance From Nipple (cm) - Sample 2 (Slice A) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_nip_dist_b3_1-2</b>	Distance From Nipple (cm) - Sample 3 (Slice B) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_nip_dist_b4_1-2</b>	Distance From Nipple (cm) - Sample 4 (Slice B) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_nip_dist_c5_1-2</b>	Distance From Nipple (cm) - Sample 5 (Slice C) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_nip_dist_in7_1-2</b>	Distance From Nipple (cm) - Sample 7 (Lymph Node) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_nip_dist_tm6_1-2</b>	Distance From Nipple (cm) - Sample 6 (Tumor) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_num</b>	Number Of Mastectomies - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mgross_slice_a_num1-2</b>	Central Slice (Slice A) Number - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgross_slice_b_num1-2</b>	Lateral Slice (Slice B) Number - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_slice_c_num1-2</b>	Medial Slice (Slice C) Number - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_slice_num1-2</b>	Number Of Slices - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_spec_height1-2</b>	Entire Mastectomy Specimen Dimensions - Height (cm) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_spec_length1-2</b>	Entire Mastectomy Specimen Dimensions - Length (cm) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_spec_weight1-2</b>	Entire Mastectomy Specimen Weight (In Grams) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_spec_width1-2</b>	Entire Mastectomy Specimen Dimensions - Width (cm) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_ss_dist_a1_1-2</b>	Distance From Superficial Surface (cm) - Sample 1 (Slice A) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_ss_dist_a2_1-2</b>	Distance From Superficial Surface (cm) - Sample 2 (Slice A) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_ss_dist_b3_1-2</b>	Distance From Superficial Surface (cm) - Sample 3 (Slice B) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_ss_dist_b4_1-2</b>	Distance From Superficial Surface (cm) - Sample 4 (Slice B) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgross_ss_dist_c5_1-2</b>	Distance From Superficial Surface (cm) - Sample 5 (Slice C) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_ss_dist_ln7_1-2</b>	Distance From Superficial Surface (cm) - Sample 7 (Lymph Node) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_ss_dist_tm6_1-2</b>	Distance From Superficial Surface (cm) - Sample 6 (Tumor) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_thickness1-2</b>	Average Slice Thickness (mm) - Mastectomy # - [Mastectomy Grossing]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>mgross_tumescence1-2</b>	Tumescence Used? - Mastectomy # - [Mastectomy Grossing]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"

## Section 36: Plasma

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Class	Variable	Label	Description	Format Text
01. Principal	<b>plasma_igf1_v0/p lasma_igf1_v2</b>	Insulin-Like Growth Factor 1 (ng/mL) - Visit # - [Plasma]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>plasma_igfbp3_v 0/plasma_igfbp3_ v2</b>	Insulin-Like Growth Factor-Binding Protein 3 (ng/mL) - Visit # - [Plasma]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	<b>plasma_shbg_v0/ plasma_shbg_v2</b>	Sex Hormone Binding Globulin (nmol/L) - Visit # - [Plasma]		Numeric .M="Missing" .R="Not Randomized"



## Section 37: Tumor Characteristics

Class	Variable	Label	Description	Format Text
01. Principal	<b>tumor_breast_v0_1-2</b>	Right Or Left Breast? - Tumor # - Visit 0 (Screening) - [Tumor Characteristics]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Right" 2="Left"
01. Principal	<b>tumor_breast_v2_1-2</b>	Right Or Left Breast? - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Right" 2="Left"
01. Principal	<b>tumor_comments_v0_1-2</b>	Comments - Tumor # - Visit 0 (Screening) - [Tumor Characteristics]		Char
01. Principal	<b>tumor_comments_v2_1-2</b>	Comments - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		Char
01. Principal	<b>tumor_er_status_v0_1-2</b>	Estrogen Receptor Status (% Positive Cells) - Tumor # - Visit 0 (Screening) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>tumor_er_status_v2_1-2</b>	Estrogen Receptor Status (% Positive Cells) - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>tumor_fish_v0_1-2</b>	FISH - Tumor # - Visit 0 (Screening) - [Tumor Characteristics]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Amplified" 2="Non-amplified" 3="Not Done"
01. Principal	<b>tumor_fish_v2_1-2</b>	FISH - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Amplified" 2="Non-amplified" 3="Not Done"
01. Principal	<b>tumor_her2_status_v0_1-2</b>	HER2 Status - Tumor # - Visit 0 (Screening) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tumor_her2_status_v2_1-2</b>	HER2 Status - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>tumor_hist_oth_v0_1-2</b>	Tumor Histology - Other Specify - Tumor # - Visit 0 (Screening) - [Tumor Characteristics]		Char
01. Principal	<b>tumor_hist_oth_v2_1-2</b>	Tumor Histology - Other Specify - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		Char
01. Principal	<b>tumor_hist_v0_1-2</b>	Tumor Histology - Tumor # - Visit 0 (Screening) - [Tumor Characteristics]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Invasive Ductal" 2="Invasive Lobular" 3="DCIS" 4="Other"
01. Principal	<b>tumor_hist_v2_1-2</b>	Tumor Histology - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Invasive Ductal" 2="Invasive Lobular" 3="DCIS" 4="Other"
01. Principal	<b>tumor_ki67_v0_1-2</b>	Ki-67 (% Positive Cells) - Tumor # - Visit 0 (Screening) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>tumor_ki67_v2_1-2</b>	Ki-67 (% Positive Cells) - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>tumor_nodes_pos_v2_1-2</b>	Number Of Positive Nodes - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>tumor_nodes_total_v2_1-2</b>	Number Of Nodes Taken - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>tumor_num_v0/tumor_num_v2</b>	Number Of Tumors Examined - Visit # - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tumor_pr_status_v0_1-2</b>	Progesterone Receptor Status (% Positive Cells) - Tumor # - Visit 0 (Screening) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>tumor_pr_status_v2_1-2</b>	Progesterone Receptor Status (% Positive Cells) - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>tumor_size_v0_1-2</b>	Size Of Tumor At Initial Presentation (Based On Imaging Measurements - Long Axis) (cm) - Tumor # - Visit 0 (Screening) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>tumor_size_v2_1-2</b>	Size Of Tumor At Initial Presentation (Based On Imaging Measurements - Long Axis) (cm) - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	<b>tumor_stage_v0_1-2</b>	Clinical Nodal Staging Based On Physical Exam Or Imaging - Tumor # - Visit 2 (Day Of Surgery) - [Tumor Characteristics]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Axillary, Mobile" 2="Axillary, Matted" 3="Infraclavicular" 4="Supraclavicular" 5="No Abnormal Nodes" 9="Not Recorded/Unknown"

## Section 38: Ki-67

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Class	Variable	Label	Description	Format Text
01. Principal	<b>ki67_comments</b>	Comments - [Ki-67]		Char
01. Principal	<b>ki67_dcis_pct_v0 /ki67_dcis_pct_v 2</b>	DCIS % - Visit # - [Ki-67]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>ki67_ic_pct_v0/ki 67_ic_pct_v2</b>	IC % - Visit # - [Ki-67]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	<b>ki67_lesion_matc hed</b>	Baseline And Post-Treatment Matched Lesions - [Ki-67]		Char

## Section 39: mRNA

Class	Variable	Label	Description	Format Text
01. Principal	<b>mrna_areg_v0/mrna_areg_v2</b>	AREG - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_aspm_v0/mrna_aspm_v2</b>	ASPM - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_aurka_v0/mrna_aurka_v2</b>	AURKA - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_bag1_v0/mrna_bag1_v2</b>	BAG1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_bcl2_v0/mrna_bcl2_v2</b>	BCL2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_bgn_v0/mrna_bgn_v2</b>	BGN - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_birc5_v0/mrna_birc5_v2</b>	BIRC5 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_ccnb1_v0/mrna_ccnb1_v2</b>	CCNB1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_cd68_v0/mrna_cd68_v2</b>	CD68 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_cd8a_v0/mrna_cd8a_v2</b>	CD8A - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_cdk1_v0/mrna_cdk1_v2</b>	CDK1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_cep55_v0/mrna_cep55_v2</b>	CEP55 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_col11a1_v0/mrna_col11a1_v2</b>	COL11A1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_col17a1_v0/mrna_col17a1_v2</b>	COL17A1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_col4a5_v0/mrna_col4a5_v2</b>	COL4A5 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mrna_col9a2_v0/ mrna_col9a2_v2</b>	COL9A2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_comp_v0/ mrna_comp_v2</b>	COMP - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_ctla4_v0/m rna_ctla4_v2</b>	CTLA4 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_ctsv_v0/mr na_ctsv_v2</b>	CTSV - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_ect2_v0/mr na_ect2_v2</b>	ECT2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_erbb2_v0/ mrna_erbb2_v2</b>	ERBB2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_esr1_v0/mr na_esr1_v2</b>	ESR1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_fn1_v0/mrn a_fn1_v2</b>	FN1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_foxp3_v0/ mrna_foxp3_v2</b>	FOXP3 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_frem1_v0/ mrna_frem1_v2</b>	FREM1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_grb7_v0/mr na_grb7_v2</b>	GRB7 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_gstm1_v0/ mrna_gstm1_v2</b>	GSTM1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_id4_v0/mrn a_id4_v2</b>	ID4 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_igfbp2_v0/ mrna_igfbp2_v2</b>	IGFBP2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_il17b_v0/m rna_il17b_v2</b>	IL17B - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_il24_v0/mr na_il24_v2</b>	IL24 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_itgav_v0/m rna_itgav_v2</b>	ITGAV - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	mrna_lag3_v0/mrna_lag3_v2	LAG3 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_areg_v0/mrna_log2_areg_v2	Log2 Of AREG - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_aspm_v0/mrna_log2_aspm_v2	Log2 Of ASPM - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_aurka_v0/mrna_log2_aurka_v2	Log2 Of AURKA - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_bag1_v0/mrna_log2_bag1_v2	Log2 Of BAG1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_bcl2_v0/mrna_log2_bcl2_v2	Log2 Of BCL2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_bgn_v0/mrna_log2_bgn_v2	Log2 Of BGN - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_birc5_v0/mrna_log2_birc5_v2	Log2 Of BIRC5 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_ccnb1_v0/mrna_log2_ccnb1_v2	Log2 Of CCNB1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_cd68_v0/mrna_log2_cd68_v2	Log2 Of CD68 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_cd8a_v0/mrna_log2_cd8a_v2	Log2 Of CD8A - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_cdk1_v0/mrna_log2_cdk1_v2	Log2 Of CDK1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_cep55_v0/mrna_log2_cep55_v2	Log2 Of CEP55 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_col11a1_v0/mrna_log2_col11a1_v2	Log2 Of COL11A1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_col17a1_v0/mrna_log2_col17a1_v2	Log2 Of COL17A1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_col4a5_v0/mrna_log2_col4a5_v2	Log2 Of COL4A5 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_col9a2_v0/mrna_log2_col9a2_v2	Log2 Of COL9A2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mrna_log2_comp_v0/mrna_log2_comp_v2</b>	Log2 Of COMP - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_ctla4_v0/mrna_log2_ctla4_v2</b>	Log2 Of CTLA4 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_ctsv_v0/mrna_log2_ctsv_v2</b>	Log2 Of CTSV - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_ect2_v0/mrna_log2_ect2_v2</b>	Log2 Of ECT2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_erbb2_v0/mrna_log2_erbb2_v2</b>	Log2 Of ERBB2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_esr1_v0/mrna_log2_esr1_v2</b>	Log2 Of ESR1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_fn1_v0/mrna_log2_fn1_v2</b>	Log2 Of FN1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_foxp3_v0/mrna_log2_foxp3_v2</b>	Log2 Of FOXP3 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_frem1_v0/mrna_log2_frem1_v2</b>	Log2 Of FREM1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_grb7_v0/mrna_log2_grb7_v2</b>	Log2 Of GRB7 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_gstm1_v0/mrna_log2_gstm1_v2</b>	Log2 Of GSTM1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_id4_v0/mrna_log2_id4_v2</b>	Log2 Of ID4 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_igfbp2_v0/mrna_log2_igfbp2_v2</b>	Log2 Of IGFBP2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_il17b_v0/mrna_log2_il17b_v2</b>	Log2 Of IL17B - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_il24_v0/mrna_log2_il24_v2</b>	Log2 Of IL24 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_itgav_v0/mrna_log2_itgav_v2</b>	Log2 Of ITGAV - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_lag3_v0/mrna_log2_lag3_v2</b>	Log2 Of LAG3 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"



Class	Variable	Label	Description	Format Text
01. Principal	mrna_log2_mki67_v0/mrna_log2_mki67_v2	Log2 Of MKI67 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_mmp11_v0/mrna_log2_mmp11_v2	Log2 Of MMP11 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_mmp3_v0/mrna_log2_mmp3_v2	Log2 Of MMP3 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_mmp9_v0/mrna_log2_mmp9_v2	Log2 Of MMP9 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_mybl2_v0/mrna_log2_mybl2_v2	Log2 Of MYBL2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_nkg7_v0/mrna_log2_nkg7_v2	Log2 Of NKG7 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_pdc1_v0/mrna_log2_pdc1_v2	Log2 Of PDCD1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_pdgfa_v0/mrna_log2_pdgfa_v2	Log2 Of PDGFA - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_pgr_v0/mrna_log2_pgr_v2	Log2 Of PGR - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_plk1_v0/mrna_log2_plk1_v2	Log2 Of PLK1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_plod2_v0/mrna_log2_plod2_v2	Log2 Of PLOD2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_pttg1_v0/mrna_log2_pttg1_v2	Log2 Of PTTG1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_rad54l_v0/mrna_log2_rad54l_v2	Log2 Of RAD54L - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_rrm2_v0/mrna_log2_rrm2_v2	Log2 Of RRM2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_scube2_v0/mrna_log2_scube2_v2	Log2 Of SCUBE2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_serpina5_v0/mrna_log2_serpina5_v2	Log2 Of SERPINA5 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	mrna_log2_serpinh1_v0/mrna_log2_serpinh1_v2	Log2 Of SERPINH1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mrna_log2_spp1_v0/mrna_log2_spp1_v2</b>	Log2 Of SPP1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_tnfrsf11a_v0/mrna_log2_tnfrsf11a_v2</b>	Log2 Of TNFRSF11A - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_top2a_v0/mrna_log2_top2a_v2</b>	Log2 Of TOP2A - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_ube2c_v0/mrna_log2_ube2c_v2</b>	Log2 Of UBE2C - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_log2_wnt4_v0/mrna_log2_wnt4_v2</b>	Log2 Of WNT4 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_mki67_v0/mrna_mki67_v2</b>	MKI67 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_mmp11_v0/mrna_mmp11_v2</b>	MMP11 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_mmp3_v0/mrna_mmp3_v2</b>	MMP3 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_mmp9_v0/mrna_mmp9_v2</b>	MMP9 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_mybl2_v0/mrna_mybl2_v2</b>	MYBL2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_nkg7_v0/mrna_nkg7_v2</b>	NKG7 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_pcd1_v0/mrna_pcd1_v2</b>	PDCD1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_pdgfa_v0/mrna_pdgfa_v2</b>	PDGFA - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_pgr_v0/mrna_pgr_v2</b>	PGR - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_plk1_v0/mrna_plk1_v2</b>	PLK1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_plod2_v0/mrna_plod2_v2</b>	PLOD2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_pttg1_v0/mrna_pttg1_v2</b>	PTTG1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mrna_rad54l_v0/ mrna_rad54l_v2</b>	RAD54L - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_rrm2_v0/ mrna_rrm2_v2</b>	RRM2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_scube2_v0/ mrna_scube2_v2</b>	SCUBE2 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_serpina5_v 0/mrna_serpina5 _v2</b>	SERPINA5 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_serpinh1_v 0/mrna_serpinh1 _v2</b>	SERPINH1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_spp1_v0/ mrna_spp1_v2</b>	SPP1 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_tnfrsf11a_v 0/mrna_tnfrsf11a _v2</b>	TNFRSF11A - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_top2a_v0/ mrna_top2a_v2</b>	TOP2A - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_ube2c_v0/ mrna_ube2c_v2</b>	UBE2C - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	<b>mrna_wnt4_v0/ mrna_wnt4_v2</b>	WNT4 - Visit # - [mRNA]		Numeric .F="No Record For This Visit" .R="Not Randomized"