

# NWU2015-06-04 - Enhanced Person Data Dictionary

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## Document Summary

Property	Value
Document Title	NWU2015-06-04 - Enhanced Person: Data Dictionary
Date Created	09/20/2023
Sections	40
Entries	891
Document Filename	dictionary_enhanced_prsn.rtf

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# NWU2015-06-04 - 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>unblind_arm</b>	Arm - [Unblinding]		.F="No Record For This Visit" 1="Tamoxifen" 2="4-hydroxytamoxifen Gel"
01. Principal	<b>visit_dt_ex</b>	Visit Date (Extra)		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>visit_dt_v1</b>	Visit Date 1 (Baseline)		SAS Date .E="Not Eligible For Study"
01. Principal	<b>visit_dt_v2</b>	Visit Date 2 (Day Of Surgery)		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	<b>visit_dt_v3</b>	Visit Date 3 (Post-Surgery)		SAS Date .F="No Record For This Visit" .N="N/A"

## Section 3: Pre-Enrollment

Class	Variable	Label	Description	Format Text
01. Principal	<b>preenrl_age_at_s creen</b>	Age At Screen - [Pre-Enrollment]		Numeric
01. Principal	<b>preenrl_biop_dat e</b>	Date Of Diagnostic Core Needle Biopsy - [Pre-Enrollment]		SAS Date .M="Missing"
01. Principal	<b>preenrl_biop_site</b>	Was The Core Biopsy Performed At The Participant's Accrual Site? - [Pre-Enrollment]		0="No" 1="Yes"
01. Principal	<b>preenrl_brca</b>	Breast Cancer Gene (BRCA) Status - [Pre-Enrollment]		.M="Missing" 0="None" 1="BRCA1+" 2="BRCA2+" 3="BRCA1+ and BRCA2+" 9="Unknown/Not Tested"
01. Principal	<b>preenrl_comment s</b>	Comments - [Pre-Enrollment]		Char
01. Principal	<b>preenrl_country</b>	Participant Country Code - [Pre-Enrollment]		1="USA" 2="Canada" 3="China" 4="Italy" 5="Mexico"
01. Principal	<b>preenrl_eligible</b>	Does This Participant Meet All Screening Criteria? - [Pre-Enrollment]		0="No" 1="Yes"
01. Principal	<b>preenrl_ethn</b>	Participant Ethnicity - [Pre-Enrollment]		1="Hispanic or Latino" 2="Not Hispanic or Latino" 3="Not Reported" 9="Unknown"
01. Principal	<b>preenrl_gender</b>	Participant Gender - [Pre-Enrollment]		0="Male" 1="Female" 3="Unspecified" 9="Unknown"
01. Principal	<b>preenrl_inst</b>	Registering Institution - [Pre-Enrollment]		1="IL036 Northwestern University" 2="KY015 Saint Elizabeth Medical Center South" 3="MN026 Mayo Clinic" 4="NC010 Duke University" 5="NY016 Memorial Sloan Kettering Cancer Center" 7="OH027 Cleveland Clinic Foundation" 8="KS004 University of Kansas Cancer Center"
01. Principal	<b>preenrl_meno</b>	Menopausal Status - [Pre-Enrollment]		1="Premenopausal" 2="Postmenopausal"

Class	Variable	Label	Description	Format Text
01. Principal	<b>preenrl_paym</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_race1-3</b>	Participant Race # - [Pre-Enrollment]		.M="Missing" 1="American Indian or Alaska Native" 2="Asian" 3="Black or African American" 4="Native Hawaiian or Other Pacific Islander" 5="Not Reported" 6="White" 9="Unknown"
01. Principal	<b>preenrl_screen_date</b>	Screen Date - [Pre-Enrollment]		SAS Date
01. Principal	<b>preenrl_sfai_rsn</b>	If No, Specify Primary Reason For Screen Failure - [Pre-Enrollment]		.N="N/A" 1="Investigator decision" 2="Participant decision" 3="Did not meet eligibility criteria" 4="Other, specify"
01. Principal	<b>preenrl_sfai_rsn_oth</b>	Screen Failure: Other, Specify - [Pre-Enrollment]		Char
01. Principal	<b>preenrl_sid</b>	Screening Identification Number (SID) - [Pre-Enrollment]		Char
01. Principal	<b>preenrl_specify</b>	If No, Specify Where The Core Biopsy Was Performed - [Pre-Enrollment]		Char

## Section 4: Eligibility

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Class	Variable	Label	Description	Format Text
01. Principal	<b>elig_is_eligible</b>	Is The Participant Eligible For Inclusion On This Protocol? - [Eligibility]		.E="Not Eligible For Study" 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_biobank_ex</b>	Does The Participant Agree That Their Samples And Related Information May Be Kept In A Biobank For Use In Future Health Research?: Extra Visit - [Informed Consent Form]		.N="N/A" 0="No" 1="Yes"
01. Principal	<b>icf_comments</b>	Comments - [Informed Consent Form]		Char
01. Principal	<b>icf_comments_ex</b>	Comments: Extra Visit - [Informed Consent Form]		Char
01. Principal	<b>icf_date</b>	Consent Date - [Informed Consent Form]		SAS Date
01. Principal	<b>icf_date_ex</b>	Extra Visit - [Informed Consent Form]		SAS Date .N="N/A"
01. Principal	<b>icf_form_date</b>	Consent Form Version Date - [Informed Consent Form]		SAS Date
01. Principal	<b>icf_form_date_ex</b>	Consent Form Version Date: Extra Visit - [Informed Consent Form]		SAS Date .N="N/A"
01. Principal	<b>icf_form_number</b>	Consent Form Version Number - [Informed Consent Form]		Numeric
01. Principal	<b>icf_form_number_ex</b>	Consent Form Version Number: Extra Visit - [Informed Consent Form]		Numeric .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>icf_future</b>	Does The Participant Agree That The Study Doctor, Or Their Representative May Contact Them Or Their Physician To See If They Wish To Participate In Other Research In The Future? - [Informed Consent Form]		0="No" 1="Yes"
01. Principal	<b>icf_future_ex</b>	Does The Participant Agree That The Study Doctor, Or Their Representative May Contact Them Or Their Physician To See If They Wish To Participate In Other Research In The Future?: Extra Visit - [Informed Consent Form]		.N="N/A" 0="No" 1="Yes"
01. Principal	<b>icf_has_extra</b>	Participant Has Extra Data - [Informed Consent Form]		0="No" 1="Yes"
01. Principal	<b>icf_rsfts</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"
01. Principal	<b>icf_rsfts_ex</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?: Extra Visit - [Informed Consent Form]		.M="Missing" .N="N/A" 0="No" 1="Yes"

## Section 6: Enrollment

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Class	Variable	Label	Description	Format Text
01. Principal	<b>enroll_agent_start_date</b>	Date Agent Started - [Enrollment]		SAS Date .E="Not Eligible For Study" .M="Missing"
01. Principal	<b>enroll_comments</b>	Comments - [Enrollment]		Char
01. Principal	<b>enroll_rand_date</b>	Participant Randomization Date - [Enrollment]		SAS Date .E="Not Eligible For Study"
01. Principal	<b>enroll_reg_date</b>	Participant Registration Date - [Enrollment]		SAS Date .F="No Record For This Visit"

## Section 7: Medical History

Class	Variable	Label	Description	Format Text
01. Principal	<b>medhx_breast_comments_ex</b>	Breast: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_breast_comments_v1</b>	Breast: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_breast_comments_v2</b>	Breast: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_breast_ex</b>	Breasts: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_breast_v1</b>	Breasts: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_breast_v2</b>	Breasts: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_cardio_comments_ex</b>	Cardiovascular: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_cardio_comments_v1</b>	Cardiovascular: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_cardio_comments_v2</b>	Cardiovascular: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_cardio_ex</b>	Cardiovascular: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_cardio_v1</b>	Cardiovascular: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_cardio_v2</b>	Cardiovascular: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"

Class	Variable	Label	Description	Format Text
01. Principal	<b>medhx_comments_ex</b>	Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_comments_v1</b>	Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_comments_v2</b>	Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_date_ex</b>	Visit Date - Visit (Extra) - [Medical History]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>medhx_derm_comments_ex</b>	Dermatologic: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_derm_comments_v1</b>	Dermatologic: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_derm_comments_v2</b>	Dermatologic: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_derm_ex</b>	Dermatologic: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_derm_v1</b>	Dermatologic: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_derm_v2</b>	Dermatologic: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_endo_comments_ex</b>	Endocrine/Metabolic: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_endo_comments_v1</b>	Endocrine/Metabolic: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_endo_comments_v2</b>	Endocrine/Metabolic: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_endo_ex</b>	Endocrine/Metabolic: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"

Class	Variable	Label	Description	Format Text
01. Principal	<b>medhx_endo_v1</b>	Endocrine/Metabolic: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_endo_v2</b>	Endocrine/Metabolic: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_gast_comments_ex</b>	Gastrointestinal: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_gast_comments_v1</b>	Gastrointestinal: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_gast_comments_v2</b>	Gastrointestinal: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_gast_ex</b>	Gastrointestinal: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_gast_v1</b>	Gastrointestinal: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_gast_v2</b>	Gastrointestinal: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_gen_comments_ex</b>	Genitourinary: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_gen_comments_v1</b>	Genitourinary: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_gen_comments_v2</b>	Genitourinary: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_gen_ex</b>	Genitourinary: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_gen_v1</b>	Genitourinary: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"

Class	Variable	Label	Description	Format Text
01. Principal	<b>medhx_gen_v2</b>	Genitourinary: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_has_extra</b>	Participant Has Extra Data - [Medical History]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>medhx_heent_comments_ex</b>	H/E/E/N/T: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_heent_comments_v1</b>	H/E/E/N/T: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_heent_comments_v2</b>	H/E/E/N/T: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_heent_ex</b>	H/E/E/N/T: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_heent_v1</b>	H/E/E/N/T: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_heent_v2</b>	H/E/E/N/T: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_hema_comments_ex</b>	Hematopoietic/Lymph: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_hema_comments_v1</b>	Hematopoietic/Lymph: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_hema_comments_v2</b>	Hematopoietic/Lymph: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_hema_ex</b>	Hematopoietic/Lymph: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_hema_v1</b>	Hematopoietic/Lymph: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_hema_v2</b>	Hematopoietic/Lymph: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"

Class	Variable	Label	Description	Format Text
01. Principal	<b>medhx_musc_comments_ex</b>	Musculoskeletal: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_musc_comments_v1</b>	Musculoskeletal: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_musc_comments_v2</b>	Musculoskeletal: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_musc_ex</b>	Musculoskeletal: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_musc_v1</b>	Musculoskeletal: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_musc_v2</b>	Musculoskeletal: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_neck_comments_ex</b>	Neck: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_neck_comments_v1</b>	Neck: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_neck_comments_v2</b>	Neck: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_neck_ex</b>	Neck: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_neck_v1</b>	Neck: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_neck_v2</b>	Neck: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_neur_comments_ex</b>	Neurologic: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_neur_comments_v1</b>	Neurologic: Comments - Visit 1 (Baseline) - [Medical History]		Char



Class	Variable	Label	Description	Format Text
01. Principal	<b>medhx_neur_comments_v2</b>	Neurologic: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_neur_ex</b>	Neurologic: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_neur_v1</b>	Neurologic: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_neur_v2</b>	Neurologic: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_oth_abnormal_ex</b>	Were Any Other Systems/Sites Abnormal? - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>medhx_oth_abnormal_v1</b>	Were Any Other Systems/Sites Abnormal? - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>medhx_oth_abnormal_v2</b>	Were Any Other Systems/Sites Abnormal? - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>medhx_oth_comments_ex</b>	Other Body System/Site: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_oth_comments_v1</b>	Other Body System/Site: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_oth_comments_v2</b>	Other Body System/Site: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_oth_ex</b>	Specify Other Body System/Site: Status - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_oth_v1</b>	Specify Other Body System/Site: Status - Visit 1 (Baseline) - [Medical History]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>medhx_oth_v2</b>	Specify Other Body System/Site: Status - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_resp_comments_ex</b>	Respiratory: Comments - Visit (Extra) - [Medical History]		Char
01. Principal	<b>medhx_resp_comments_v1</b>	Respiratory: Comments - Visit 1 (Baseline) - [Medical History]		Char
01. Principal	<b>medhx_resp_comments_v2</b>	Respiratory: Comments - Visit 2 (Day Of Surgery) - [Medical History]		Char
01. Principal	<b>medhx_resp_ex</b>	Respiratory: Status - Visit (Extra) - [Medical History]		.F="No Record For This Visit" .N="N/A" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_resp_v1</b>	Respiratory: Status - Visit 1 (Baseline) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>medhx_resp_v2</b>	Respiratory: Status - Visit 2 (Day Of Surgery) - [Medical History]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"

## Section 8: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	<b>pe_abd_comments_v1</b>	Abdomen: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_abd_comments_v2</b>	Abdomen: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_abd_comments_v3</b>	Abdomen: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_abd_comments_v1</b>	Abdomen: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_abd_comments_v2</b>	Abdomen: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_abd_comments_v3</b>	Abdomen: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_abd_status_v1</b>	Abdomen Status - Visit 1 (Baseline) - [Physical Exam]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>pe_abd_status_v2</b>	Abdomen Status - Visit 2 (Day Of Surgery) - [Physical Exam]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>pe_abd_status_v3</b>	Abdomen Status - Visit 3 (Post-Surgery) - [Physical Exam]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>pe_app_comments_v1</b>	Appearance: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_app_comments_v2</b>	Appearance: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>pe_app_comments_v3</b>	Appearance: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>peBreastsComments2_v1</b>	Breasts: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>peBreastsComments2_v2</b>	Breasts: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>peBreastsComments2_v3</b>	Breasts: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>peBreastsComments_v1</b>	Breasts: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>peBreastsComments_v2</b>	Breasts: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>peBreastsComments_v3</b>	Breasts: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>peBreastsStatus_v1</b>	Breasts Status - Visit 1 (Baseline) - [Physical Exam]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>peBreastsStatus_v2</b>	Breasts Status - Visit 2 (Day Of Surgery) - [Physical Exam]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>peBreastsStatus_v3</b>	Breasts Status - Visit 3 (Post-Surgery) - [Physical Exam]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>peChestComments_v1</b>	Chest: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>peChestComments_v2</b>	Chest: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>pe_chest_comments_v3</b>	Chest: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_comments_v1</b>	Comments - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_comments_v2</b>	Comments - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_comments_v3</b>	Comments - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_genita_comments_v1</b>	Genitalia: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_genita_comments_v2</b>	Genitalia: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_genita_comments_v3</b>	Genitalia: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_heart_comments_v1</b>	Heart: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_heart_comments_v2</b>	Heart: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_heart_comments_v3</b>	Heart: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_heent_comments_v1</b>	H/E/E/N/T: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_heent_comments_v2</b>	H/E/E/N/T: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_heent_comments_v3</b>	H/E/E/N/T: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>pe_lungs_comments_v1</b>	Lungs: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_lungs_comments_v2</b>	Lungs: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_lungs_comments_v3</b>	Lungs: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_lymno_comments_v1</b>	Lymph Nodes: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_lymno_comments_v2</b>	Lymph Nodes: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_lymno_comments_v3</b>	Lymph Nodes: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_muscul_comments_v1</b>	Musculoskeletal: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_muscul_comments_v2</b>	Musculoskeletal: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_muscul_comments_v3</b>	Musculoskeletal: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_neurol_comments_v1</b>	Neurological: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_neurol_comments_v2</b>	Neurological: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>pe_neurol_comments_v3</b>	Neurological: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_nodes_comments_v1</b>	Axillary Nodes: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_nodes_comments_v2</b>	Axillary Nodes: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_nodes_comments_v3</b>	Axillary Nodes: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_nodes_status_v1</b>	Axillary Nodes: Status - Visit 1 (Baseline) - [Physical Exam]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>pe_nodes_status_v2</b>	Axillary Nodes: Status - Visit 2 (Day Of Surgery) - [Physical Exam]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>pe_nodes_status_v3</b>	Axillary Nodes: Status - Visit 3 (Post-Surgery) - [Physical Exam]		.F="No Record For This Visit" 0="Normal" 1="Abnormal" 9="Not assessed"
01. Principal	<b>pe_oth_abnormal_v1</b>	Were Any Other Systems/Sites Abnormal? - Visit 1 (Baseline) - [Physical Exam]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>pe_oth_abnormal_v2</b>	Were Any Other Systems/Sites Abnormal? - Visit 2 (Day Of Surgery) - [Physical Exam]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>pe_oth_abnormal_v3</b>	Were Any Other Systems/Sites Abnormal? - Visit 3 (Post-Surgery) - [Physical Exam]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>pe_oth_comments_v1</b>	Other Body System/Site: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>pe_oth_comments_v2</b>	Other Body System/Site: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_oth_comments_v3</b>	Other Body System/Site: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_oth_v1</b>	Specify Other Body System/Site (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_oth_v2</b>	Specify Other Body System/Site (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_oth_v3</b>	Specify Other Body System/Site (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_pelvis_comments_v1</b>	Pelvis: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_pelvis_comments_v2</b>	Pelvis: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_pelvis_comments_v3</b>	Pelvis: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_rectal_comments_v1</b>	Rectal: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_rectal_comments_v2</b>	Rectal: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_rectal_comments_v3</b>	Rectal: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char



Class	Variable	Label	Description	Format Text
01. Principal	<b>pe_skin_comments_v1</b>	Skin: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_skin_comments_v2</b>	Skin: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_skin_comments_v3</b>	Skin: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_thy_comments_v1</b>	Thyroid: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_thy_comments_v2</b>	Thyroid: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_thy_comments_v3</b>	Thyroid: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_vascul_comments_v1</b>	Vascular: Comments (Required If Abnormal) - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	<b>pe_vascul_comments_v2</b>	Vascular: Comments (Required If Abnormal) - Visit 2 (Day Of Surgery) - [Physical Exam]		Char
01. Principal	<b>pe_vascul_comments_v3</b>	Vascular: Comments (Required If Abnormal) - Visit 3 (Post-Surgery) - [Physical Exam]		Char

## Section 9: Pregnancy Test

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Class	Variable	Label	Description	Format Text
01. Principal	<b>pregt_comments_v1</b>	Comments - Visit 1 (Baseline) - [Pregnancy Test])		Char
01. Principal	<b>pregt_comments_v2</b>	Comments - Visit 2 (Day Of Surgery) - [Pregnancy Test])		Char
01. Principal	<b>pregt_results_v1</b>	Results - Visit 1 (Baseline) - [Pregnancy Test])		.F="No Record For This Visit" .N="Not Applicable" 0="Negative" 1="Positive" 9="Not Applicable, Not Female Of Child-Bearing Potential"
01. Principal	<b>pregt_results_v2</b>	Results - Visit 2 (Day Of Surgery) - [Pregnancy Test])		.F="No Record For This Visit" .N="Not Applicable" 0="Negative" 1="Positive" 9="Not Applicable, Not Female Of Child-Bearing Potential"

## Section 10: Vital Signs

Class	Variable	Label	Description	Format Text
01. Principal	<b>vitals_bp_diastolic_v1</b>	Diastolic Blood Pressure - Visit 1 (Baseline) - [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>vitals_bp_diastolic_v2</b>	Diastolic Blood Pressure - Visit 2 (Day Of Surgery) - [Vital Signs]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>vitals_bp_diastolic_v3</b>	Diastolic Blood Pressure - Visit 3 (Post-Surgery) - [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>vitals_bp_systolic_v1</b>	Systolic Blood Pressure - Visit 1 (Baseline) - [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>vitals_bp_systolic_v2</b>	Systolic Blood Pressure - Visit 2 (Day Of Surgery) - [Vital Signs]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>vitals_bp_systolic_v3</b>	Systolic Blood Pressure - Visit 3 (Post-Surgery) - [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>vitals_comments_v1</b>	Comments - Visit 1 (Baseline) - [Vital Signs]		Char
01. Principal	<b>vitals_comments_v2</b>	Comments - Visit 2 (Day Of Surgery) - [Vital Signs]		Char
01. Principal	<b>vitals_comments_v3</b>	Comments - Visit 3 (Post-Surgery) - [Vital Signs]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>vitals_ecog_v1</b>	ECOG Performance Status - Visit 1 (Baseline) - [Vital Signs]		.F="No Record For This Visit" .M="Missing" 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_ecog_v2</b>	ECOG Performance Status - Visit 2 (Day Of Surgery) - [Vital Signs]		.F="No Record For This Visit" .M="Missing" .N="N/A" 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"

Class	Variable	Label	Description	Format Text
01. Principal	<b>vitals_ecog_v3</b>	ECOG Performance Status - Visit 3 (Post-Surgery) [Vital Signs]		.F="No Record For This Visit" .M="Missing" .N="N/A" 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_v1</b>	Height (cm) - Visit 1 (Baseline) - [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>vitals_height_v2</b>	Height (cm) - Visit 2 (Day Of Surgery) - [Vital Signs]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>vitals_height_v3</b>	Height (cm) - Visit 3 (Post-Surgery) [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>vitals_pulse_v1</b>	Pulse - Visit 1 (Baseline) - [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>vitals_pulse_v2</b>	Pulse - Visit 2 (Day Of Surgery) - [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>vitals_pulse_v3</b>	Pulse - Visit 3 (Post-Surgery) [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>vitals_temp_v1</b>	Temperature (C) - Visit 1 (Baseline) - [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>vitals_temp_v2</b>	Temperature (C) - Visit 2 (Day Of Surgery) - [Vital Signs]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>vitals_temp_v3</b>	Temperature (C) - Visit 3 (Post-Surgery) [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>vitals_weight_v1</b>	Weight (kg) - Visit 1 (Baseline) - [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>vitals_weight_v2</b>	Weight (kg) - Visit 2 (Day Of Surgery) - [Vital Signs]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>vitals_weight_v3</b>	Weight (kg) - Visit 3 (Post-Surgery) [Vital Signs]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

## Section 11: 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>	Size - [Breast Cup Size]		Char

## Section 12: Blood Specimen Collection

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Class	Variable	Label	Description	Format Text
01. Principal	<b>bldspec_daughter_v1_1-4</b>	Number Of Daughter Specimens - Specimen 4 - Visit 1 (Baseline) - [Blood Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>bldspec_daughter_v2_1-4</b>	Number Of Daughter Specimens - Specimen 4 - Visit 2 (Day Of Surgery) - [Blood Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>bldspec_time_v1</b>	Time - Visit 1 (Baseline) - [Blood Specimen Collection]		SAS Time .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>bldspec_time_v2</b>	Time - Visit 2 (Day Of Surgery) - [Blood Specimen Collection]		SAS Time .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>bldspec_type_v1_1-4</b>	Parent Specimen Type - Specimen 4 - Visit 1 (Baseline) - [Blood Specimen Collection]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 1="NaCit/Blue Top Tube" 2="EDTA Purple Top Tube"
01. Principal	<b>bldspec_type_v2_1-4</b>	Parent Specimen Type - Specimen 4 - Visit 2 (Day Of Surgery) - [Blood Specimen Collection]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 1="NaCit/Blue Top Tube" 2="EDTA Purple Top Tube"



## Section 13: Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	<b>bldchem_alt_cs_ex</b>	ALT: If Out Of Range, Is It Clinically Significant? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>bldchem_alt_cs_v1</b>	ALT: If Out Of Range, Is It Clinically Significant?- Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>bldchem_alt_cs_v2</b>	ALT: If Out Of Range, Is It Clinically Significant? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>bldchem_alt_oor_ex</b>	ALT: Out Of Range? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_alt_oor_v1</b>	ALT: Out Of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	<b>bldchem_alt_oor_v2</b>	ALT: Out Of Range? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>bldchem_alt_rslt_ex</b>	ALT: Result (U/L) - Visit (Extra) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .N="N/A"
01. Principal	<b>bldchem_alt_rslt_v1</b>	ALT: Result (U/L) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	<b>bldchem_alt_rslt_v2</b>	ALT: Result (U/L) - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>bldchem_ast_cs_ex</b>	AST: If Out Of Range, Is It Clinically Significant? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_ast_cs_v1</b>	AST: If Out Of Range, Is It Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes" 96="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bldchem_ast_cs_v2</b>	AST: If Out Of Range, Is It Clinically Significant? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>bldchem_ast_oor_ex</b>	AST: Out Of Range? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_ast_oor_v1</b>	AST: Out Of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	<b>bldchem_ast_oor_v2</b>	AST: Out Of Range? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>bldchem_ast_rslt_ex</b>	AST: Result (U/L) - Visit (Extra) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .N="N/A"
01. Principal	<b>bldchem_ast_rslt_v1</b>	AST: Result (U/L) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	<b>bldchem_ast_rslt_v2</b>	AST: Result (U/L) - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>bldchem_bili_cs_ex</b>	Bilirubin: If Out Of Range, Is It Clinically Significant? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_bili_cs_v1</b>	Bilirubin: If Out Of Range, Is It Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>bldchem_bili_cs_v2</b>	Bilirubin: If Out Of Range, Is It Clinically Significant? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>bldchem_bili_oor_ex</b>	Bilirubin: Out Of Range? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_bili_oor_v1</b>	Bilirubin: Out Of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bldchem_bili_oor_v2</b>	Bilirubin: Out Of Range? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>bldchem_bili_rslt_ex</b>	Bilirubin: Result (mg/dl) - Visit (Extra) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .N="N/A"
01. Principal	<b>bldchem_bili_rslt_v1</b>	Bilirubin: Result (mg/dl) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	<b>bldchem_bili_rslt_v2</b>	Bilirubin: Result (mg/dl) - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>bldchem_comments_ex</b>	Comments - Visit (Extra) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_comments_v1</b>	Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_comments_v2</b>	Comments - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_creat_cs_ex</b>	Creatinine: Out Of Range, Is It Clinically Significant? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_creat_cs_v1</b>	Creatinine: Out Of Range, Is It Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_creat_cs_v2</b>	Creatinine: Out Of Range, Is It Clinically Significant? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_creat_or_ex</b>	Creatinine: Out Of Range? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_creat_or_v1</b>	Creatinine: Out Of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	<b>bldchem_creat_or_v2</b>	Creatinine: Out Of Range? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bldchem_creat_rslt_ex</b>	Creatinine: Result (mg/dl) - Visit (Extra) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .N="N/A"
01. Principal	<b>bldchem_creat_rslt_v1</b>	Creatinine: Result (mg/dl) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study"
01. Principal	<b>bldchem_creat_rslt_v2</b>	Creatinine: Result (mg/dl) - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>bldchem_date_ex</b>	Visit Date (Extra) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .N="N/A"
01. Principal	<b>bldchem_fasting_ex</b>	Fasting? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes" 99="Unknown"
01. Principal	<b>bldchem_fasting_v1</b>	Fasting? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes" 99="Unknown"
01. Principal	<b>bldchem_fasting_v2</b>	Fasting? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 99="Unknown"
01. Principal	<b>bldchem_has_extra</b>	Participant Has Extra Data - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	<b>bldchem_oth1_cs_ex</b>	Other Test 1: If Out Of Range, Is It Clinically Significant? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes" 99="Unknown"
01. Principal	<b>bldchem_oth1_cs_v1</b>	Other Test 1: If Out Of Range, Is It Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>bldchem_oth1_cs_v2</b>	Other Test 1: If Out Of Range, Is It Clinically Significant? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>bldchem_oth1_ex</b>	Other Test 1: Specify - Visit (Extra) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>bldchem_oth1_or_ex</b>	Other Test 1: Out Of Range? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_oth1_or_v1</b>	Other Test 1: Out Of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>bldchem_oth1_or_v2</b>	Other Test 1: Out Of Range? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_oth1_result_ex</b>	Other Test 1: Result - Visit (Extra) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	<b>bldchem_oth1_result_v1</b>	Other Test 1: Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	<b>bldchem_oth1_result_v2</b>	Other Test 1: Result - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	<b>bldchem_oth1_unit_ex</b>	Other Test 1: Units - Visit (Extra) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth1_unit_v1</b>	Other Test 1: Units - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth1_unit_v2</b>	Other Test 1: Units - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth1_v1</b>	Other Test 1: Specify - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth1_v2</b>	Other Test 1: Specify - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth2_cs_ex</b>	Other Test 2: If Out Of Range, Is It Clinically Significant? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes" 99="Unknown"
01. Principal	<b>bldchem_oth2_cs_v1</b>	Other Test 2: If Out Of Range, Is It Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes" 96="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bldchem_oth2_cs_v2</b>	Other Test 2: If Out Of Range, Is It Clinically Significant? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>bldchem_oth2_ex</b>	Other Test 2: Specify - Visit (Extra) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth2_or_ex</b>	Other Test 2: Out Of Range? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_oth2_or_v1</b>	Other Test 2: Out Of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>bldchem_oth2_or_v2</b>	Other Test 2: Out Of Range? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_oth2_rslt_ex</b>	Other Test 2: Result - Visit (Extra) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	<b>bldchem_oth2_rslt_v1</b>	Other Test 2: Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	<b>bldchem_oth2_rslt_v2</b>	Other Test 2: Result - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	<b>bldchem_oth2_unit_ex</b>	Other Test 2: Units - Visit (Extra) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth2_unit_v1</b>	Other Test 2: Units - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth2_unit_v2</b>	Other Test 2: Units - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth2_v1</b>	Other Test 2: Specify - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth2_v2</b>	Other Test 2: Specify - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth3_cs_ex</b>	Other Test 3: If Out Of Range, Is It Clinically Significant? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes" 99="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bldchem_oth3_cs_v1</b>	Other Test 3: If Out Of Range, Is It Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>bldchem_oth3_cs_v2</b>	Other Test 3: If Out Of Range, Is It Clinically Significant? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>bldchem_oth3_ex</b>	Other Test 3: Specify - Visit (Extra) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth3_or_ex</b>	Other Test 3: Out Of Range? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_oth3_or_v1</b>	Other Test 3: Out Of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>bldchem_oth3_or_v2</b>	Other Test 3: Out Of Range? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_oth3_rslt_ex</b>	Other Test 3: Result - Visit (Extra) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	<b>bldchem_oth3_rslt_v1</b>	Other Test 3: Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	<b>bldchem_oth3_rslt_v2</b>	Other Test 3: Result - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	<b>bldchem_oth3_unit_ex</b>	Other Test 3: Units - Visit (Extra) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth3_unit_v1</b>	Other Test 3: Units - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth3_unit_v2</b>	Other Test 3: Units - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth3_v1</b>	Other Test 3: Specify - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	<b>bldchem_oth3_v2</b>	Other Test 3: Specify - Visit 2 (Day Of Surgery) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>bldchem_others_oor_ex</b>	Were Any Other Blood Chemistry Tests Out Of Range? - Visit (Extra) - [Blood Chemistry]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_others_oor_v1</b>	Were Any Other Blood Chemistry Tests Out Of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	<b>bldchem_others_oor_v2</b>	Were Any Other Blood Chemistry Tests Out Of Range? - Visit 2 (Day Of Surgery) - [Blood Chemistry]		.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>bldchem_time_ex</b>	Time Of Visit (Extra) - [Blood Chemistry]		SAS Time .E="Not Eligible For Study" .M="Missing" .N="N/A"
01. Principal	<b>bldchem_time_v1</b>	Time Of Visit 1 (Baseline) - [Blood Chemistry]		SAS Time .E="Not Eligible For Study" .M="Missing"
01. Principal	<b>bldchem_time_v2</b>	Time Of Visit 2 (Day Of Surgery) - [Blood Chemistry]		SAS Time .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"



## Section 14: Hematology

Class	Variable	Label	Description	Format Text
01. Principal	<b>hema_anc_cs_v1</b>	Absolute Neutrophil Count: If Out Of Range, Is It Clinically Significant?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_anc_cs_v2</b>	Absolute Neutrophil Count: If Out Of Range, Is It Clinically Significant?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_anc_oor_v1</b>	Absolute Neutrophil Count: Out Of Range?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>hema_anc_oor_v2</b>	Absolute Neutrophil Count: Out Of Range?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>hema_anc_rslt_v1</b>	Absolute Neutrophil Count (K/uL): Visit 1 (Baseline) - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>hema_anc_rslt_v2</b>	Absolute Neutrophil Count (K/uL): Visit 2 (Day Of Surgery) - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>hema_comments_v1</b>	Comments: Visit 1 (Baseline) - [Hematology]		Char
01. Principal	<b>hema_comments_v2</b>	Comments: Visit 2 (Day Of Surgery) - [Hematology]		Char
01. Principal	<b>hema_oth1_cs_v1</b>	Other Test 1: If Out Of Range, Is It Clinically Significant?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_oth1_cs_v2</b>	Other Test 1: If Out Of Range, Is It Clinically Significant?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_oth1_oor_v1</b>	Other Test 1: Out Of Range?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>hema_oth1_oor_v2</b>	Other Test 1: Out Of Range?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>hema_oth1_rslt_v1</b>	Other Test 1: Result: Visit 1 (Baseline) - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>hema_oth1_rslt_v2</b>	Other Test 1: Result: Visit 2 (Day Of Surgery) - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>hema_oth1_unit_v1</b>	Other Test 1: Units: Visit 1 (Baseline) - [Hematology]		Char
01. Principal	<b>hema_oth1_unit_v2</b>	Other Test 1: Units: Visit 2 (Day Of Surgery) - [Hematology]		Char
01. Principal	<b>hema_oth1_v1</b>	Other Test 1: Specify Other Test: Visit 1 (Baseline) - [Hematology]		Char
01. Principal	<b>hema_oth1_v2</b>	Other Test 1: Specify Other Test: Visit 2 (Day Of Surgery) - [Hematology]		Char
01. Principal	<b>hema_oth2_cs_v1</b>	Other Test 2: If Out Of Range, Is It Clinically Significant?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_oth2_cs_v2</b>	Other Test 2: If Out Of Range, Is It Clinically Significant?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_oth2_oor_v1</b>	Other Test 2: Out Of Range?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>hema_oth2_oor_v2</b>	Other Test 2: Out Of Range?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>hema_oth2_rslt_v1</b>	Other Test 2: Result: Visit 1 (Baseline) - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>hema_oth2_rslt_v2</b>	Other Test 2: Result: Visit 2 (Day Of Surgery) - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>hema_oth2_unit_v1</b>	Other Test 2: Units: Visit 1 (Baseline) - [Hematology]		Char
01. Principal	<b>hema_oth2_unit_v2</b>	Other Test 2: Units: Visit 2 (Day Of Surgery) - [Hematology]		Char
01. Principal	<b>hema_oth2_v1</b>	Other Test 2: Specify Other Test: Visit 1 (Baseline) - [Hematology]		Char
01. Principal	<b>hema_oth2_v2</b>	Other Test 2: Specify Other Test: Visit 2 (Day Of Surgery) - [Hematology]		Char
01. Principal	<b>hema_oth3_cs_v1</b>	Other Test 3: If Out Of Range, Is It Clinically Significant?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_oth3_cs_v2</b>	Other Test 3: If Out Of Range, Is It Clinically Significant?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_oth3_oor_v1</b>	Other Test 3: Out Of Range?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>hema_oth3_oor_v2</b>	Other Test 3: Out Of Range?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>hema_oth3_rslt_v1</b>	Other Test 3: Result: Visit 1 (Baseline) - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>hema_oth3_rslt_v2</b>	Other Test 3: Result: Visit 2 (Day Of Surgery) - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>hema_oth3_unit_v1</b>	Other Test 3: Units: Visit 1 (Baseline) - [Hematology]		Char
01. Principal	<b>hema_oth3_unit_v2</b>	Other Test 3: Units: Visit 2 (Day Of Surgery) - [Hematology]		Char
01. Principal	<b>hema_oth3_v1</b>	Other Test 3: Specify Other Test: Visit 1 (Baseline) - [Hematology]		Char
01. Principal	<b>hema_oth3_v2</b>	Other Test 3: Specify Other Test: Visit 2 (Day Of Surgery) - [Hematology]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>hema_others_oor_v1</b>	Were Any Other Hematology Tests Out Of Range?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>hema_others_oor_v2</b>	Were Any Other Hematology Tests Out Of Range?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>hema_plate_cs_v1</b>	Platelet If Out Of Range, Is It Clinically Significant?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_plate_cs_v2</b>	Platelet If Out Of Range, Is It Clinically Significant?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_plate_oor_v1</b>	Platelet Out Of Range?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>hema_plate_oor_v2</b>	Platelet Out Of Range?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>hema_plate_rslt_v1</b>	Platelet (K/uL): Visit 1 (Baseline) - [Hematology]		Numeric .F="No Record For This Visit"
01. Principal	<b>hema_plate_rslt_v2</b>	Platelet (K/uL): Visit 2 (Day Of Surgery) - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>hema_time_v1</b>	Time Of Visit 1 (Baseline) - [Hematology]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>hema_time_v2</b>	Time Of Visit 2 (Day Of Surgery) - [Hematology]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>hema_wbc_cs_v1</b>	White Blood Cells: If Out Of Range, Is It Clinically Significant?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_wbc_cs_v2</b>	White Blood Cells: If Out Of Range, Is It Clinically Significant?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 96="N/A"
01. Principal	<b>hema_wbc_oor_v1</b>	White Blood Cells: Out Of Range?: Visit 1 (Baseline) - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>hema_wbc_oor_v 2</b>	White Blood Cells: Out Of Range?: Visit 2 (Day Of Surgery) - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>hema_wbc_rslt_v 1</b>	White Blood Cells: (#/uL): Visit 1 (Baseline) - [Hematology]		Numeric .F="No Record For This Visit"
01. Principal	<b>hema_wbc_rslt_v 2</b>	White Blood Cells: (#/uL): Visit 2 (Day Of Surgery) - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"

## Section 15: Plasma - Coagulation Proteins

Class	Variable	Label	Description	Format Text
01. Principal	<b>pl_coag_factor_ix_v1</b>	Factor IX - Visit 1 (Baseline) - [Plasma - Coagulation Proteins]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_coag_factor_ix_v2</b>	Factor IX - Visit 2 (Day Of Surgery) - [Plasma - Coagulation Proteins]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_coag_fviii_act_v1</b>	Factor VIII Activity - Visit 1 (Baseline) - [Plasma - Coagulation Proteins]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_coag_fviii_act_v2</b>	Factor VIII Activity - Visit 2 (Day Of Surgery) - [Plasma - Coagulation Proteins]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_coag_protein_s_ag_v1</b>	Protein S Antigen Total Visit 1 (Baseline) - [Plasma - Coagulation Proteins]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_coag_protein_s_ag_v2</b>	Protein S Antigen Total - Visit 2 (Day Of Surgery) - [Plasma - Coagulation Proteins]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_coag_vwf_ag_v1</b>	Von Willebrand Factor Antigen - Visit 1 (Baseline) - [Plasma - Coagulation Proteins]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_coag_vwf_ag_v2</b>	Von Willebrand Factor Antigen - Visit 2 (Day Of Surgery) - [Plasma - Coagulation Proteins]		Numeric .F="No Record For This Visit" .M="Missing"

## Section 16: Plasma - Hormones

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Class	Variable	Label	Description	Format Text
01. Principal	<b>pl_hormone_e2_v1</b>	E2 (pg/mL) - Visit 1 (Baseline) - [Plasma - Hormones]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_hormone_e2_v2</b>	E2 (pg/mL) - Visit 2 (Day Of Surgery) - [Plasma - Hormones]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_hormone_p4_v1</b>	P4 (ng/mL) - Visit 1 (Baseline) - [Plasma - Hormones]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_hormone_p4_v2</b>	P4 (ng/mL) - Visit 2 (Day Of Surgery) - [Plasma - Hormones]		Numeric .F="No Record For This Visit" .M="Missing"

## Section 17: Plasma - Markers

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Class	Variable	Label	Description	Format Text
01. Principal	<b>pl_igf1_v1</b>	Insulin-Like Growth Factor 1 (ng/ml) - Visit 1 (Baseline) - [Plasma - Markers]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_igf1_v2</b>	Insulin-Like Growth Factor 1 (ng/ml) - Visit 2 (Day Of Surgery) - [Plasma - Markers]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_igfbp3_v1</b>	Insulin-Like Growth Factor-Binding Protein 3 (ng/ml) - Visit 1 (Baseline) - [Plasma - Markers]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_igfbp3_v2</b>	Insulin-Like Growth Factor-Binding Protein 3 (ng/ml) - Visit 2 (Day Of Surgery) - [Plasma - Markers]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_shbg_v1</b>	Sex Hormone Binding Globulin (nmol/l) - Visit 1 (Baseline) - [Plasma - Markers]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pl_shbg_v2</b>	Sex Hormone Binding Globulin (nmol/l) - Visit 2 (Day Of Surgery) - [Plasma - Markers]		Numeric .F="No Record For This Visit" .M="Missing"



## Section 18: IHC Markers

Class	Variable	Label	Description	Format Text
01. Principal	<b>ihc_cd68_macro_dens_v1</b>	Macrophage Density - Visit 1 (Baseline) - [IHC Markers]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ihc_cd68_macro_dens_v2</b>	Macrophage Density - Visit 2 (Day Of Surgery) - [IHC Markers]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ihc_cox2_allred_v1</b>	COX2 Allred - Visit 1 (Baseline) - [IHC Markers]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ihc_cox2_allred_v2</b>	COX2 Allred - Visit 2 (Day Of Surgery) - [IHC Markers]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ihc_p16_pct_pos_v1</b>	P16 Percent Positive - Visit 1 (Baseline) - [IHC Markers]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ihc_p16_pct_pos_v2</b>	P16 Percent Positive - Visit 2 (Day Of Surgery) - [IHC Markers]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ihc_p16_prop_score_v1</b>	P16 Prop Score - Visit 1 (Baseline) - [IHC Markers]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ihc_p16_prop_score_v2</b>	P16 Prop Score - Visit 2 (Day Of Surgery) - [IHC Markers]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

## Section 19: Menstruation

Class	Variable	Label	Description	Format Text
01. Principal	<b>menst_comments_ex1-2</b>	Comments - Extra Visit # - [Menstruation]		Char
01. Principal	<b>menst_comments_v1</b>	Comments - Visit 1 (Baseline) - [Menstruation]		Char
01. Principal	<b>menst_comments_v2</b>	Comments - Visit 2 (Day Of Surgery) - [Menstruation]		Char
01. Principal	<b>menst_comments_v3</b>	Comments - Visit 3 (Post-Surgery) - [Menstruation]		Char
01. Principal	<b>menst_conf_date_ex1-2</b>	Confirmed Next Menstrual Period Date - Extra Visit # - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>menst_conf_date_v1</b>	Confirmed Next Menstrual Period Date - Visit 1 (Baseline) - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>menst_conf_date_v2</b>	Confirmed Next Menstrual Period Date - Visit 2 (Day Of Surgery) - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>menst_conf_date_v3</b>	Confirmed Next Menstrual Period Date - Visit 3 (Post-Surgery) - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>menst_conf_other_ex1-2</b>	Confirmed Other, Please Specify: - Extra Visit # - [Menstruation]		Char
01. Principal	<b>menst_conf_other_v1</b>	Confirmed Other, Please Specify: - Visit 1 (Baseline) - [Menstruation]		Char
01. Principal	<b>menst_conf_other_v2</b>	Confirmed Other, Please Specify: - Visit 2 (Day Of Surgery) - [Menstruation]		Char
01. Principal	<b>menst_conf_other_v3</b>	Confirmed Other, Please Specify: - Visit 3 (Post-Surgery) - [Menstruation]		Char
01. Principal	<b>menst_conf_why_ex1-2</b>	If No Confirmed Next Menstrual Period Date, Specify Why - Extra Visit # - [Menstruation]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Participant did not have period" 2="Other, please specify" 9="Information not obtainable"

Class	Variable	Label	Description	Format Text
01. Principal	<b>menst_conf_why_v1</b>	If No Confirmed Next Menstrual Period Date, Specify Why - Visit 1 (Baseline) - [Menstruation]		.F="No Record For This Visit" .M="Missing" 1="Participant did not have period" 2="Other, please specify" 9="Information not obtainable"
01. Principal	<b>menst_conf_why_v2</b>	If No Confirmed Next Menstrual Period Date, Specify Why - Visit 2 (Day Of Surgery) - [Menstruation]		.F="No Record For This Visit" .M="Missing" 1="Participant did not have period" 2="Other, please specify" 9="Information not obtainable"
01. Principal	<b>menst_conf_why_v3</b>	If No Confirmed Next Menstrual Period Date, Specify Why - Visit 3 (Post-Surgery) - [Menstruation]		.F="No Record For This Visit" .M="Missing" 1="Participant did not have period" 2="Other, please specify" 9="Information not obtainable"
01. Principal	<b>menst_date_ex1-2</b>	Visit Date - Extra Visit # - [Menstruation]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>menst_has_extra</b>	Participant Has Extra Data - [Menstruation]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>menst_length_ex1-2</b>	Typical Length Of Menstrual Cycle (Number Of Days) - Extra Visit # - [Menstruation]		Char
01. Principal	<b>menst_length_v1</b>	Typical Length Of Menstrual Cycle (Number Of Days) - Visit 1 (Baseline) - [Menstruation]		Char
01. Principal	<b>menst_length_v2</b>	Typical Length Of Menstrual Cycle (Number Of Days) - Visit 2 (Day Of Surgery) - [Menstruation]		Char
01. Principal	<b>menst_length_v3</b>	Typical Length Of Menstrual Cycle (Number Of Days) - Visit 3 (Post-Surgery) - [Menstruation]		Char
01. Principal	<b>menst_next_date_ex1-2</b>	Estimated Next Menstrual Period Date - Extra Visit # - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>menst_next_date_v1</b>	Estimated Next Menstrual Period Date - Visit 1 (Baseline) - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>menst_next_date_v2</b>	Estimated Next Menstrual Period Date - Visit 2 (Day Of Surgery) - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>menst_next_date_v3</b>	Estimated Next Menstrual Period Date - Visit 3 (Post-Surgery) - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>menst_next_why_ex1-2</b>	If No Estimated Next Menstrual Period Date, Specify Why - Extra Visit # - [Menstruation]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Participant did not have period" 2="Other, please specify" 9="Information not obtainable"
01. Principal	<b>menst_next_why_v1</b>	If No Estimated Next Menstrual Period Date, Specify Why - Visit 1 (Baseline) - [Menstruation]		.F="No Record For This Visit" .M="Missing" 1="Participant does not have period" 2="Other, please specify" 9="Information not obtainable"
01. Principal	<b>menst_next_why_v2</b>	If No Estimated Next Menstrual Period Date, Specify Why - Visit 2 (Day Of Surgery) - [Menstruation]		.F="No Record For This Visit" .M="Missing" 1="Participant does not have period" 2="Other, please specify" 9="Information not obtainable"
01. Principal	<b>menst_next_why_v3</b>	If No Estimated Next Menstrual Period Date, Specify Why - Visit 3 (Post-Surgery) - [Menstruation]		.F="No Record For This Visit" .M="Missing" 1="Participant does not have period" 2="Other, please specify" 9="Information not obtainable"
01. Principal	<b>menst_other_ex1-2</b>	Other, Please Specify - Extra Visit # - [Menstruation]		Char
01. Principal	<b>menst_other_v1</b>	Other, Please Specify - Visit 1 (Baseline) - [Menstruation]		Char
01. Principal	<b>menst_other_v2</b>	Other, Please Specify - Visit 2 (Day Of Surgery) - [Menstruation]		Char
01. Principal	<b>menst_other_v3</b>	Other, Please Specify - Visit 3 (Post-Surgery) - [Menstruation]		Char
01. Principal	<b>menst_period_date_ex1-2</b>	Last Menstrual Period Date - Extra Visit # - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>menst_period_date_v1</b>	Last Menstrual Period Date - Visit 1 (Baseline) - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>menst_period_date_v2</b>	Last Menstrual Period Date - Visit 2 (Day Of Surgery) - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>menst_period_date_v3</b>	Last Menstrual Period Date - Visit 3 (Post-Surgery) - [Menstruation]		SAS Date .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>menst_why_ex1-2</b>	If No Last Menstrual Period Date, Specify Why - Extra Visit # - [Menstruation]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Participant did not have period" 2="Other, please specify" 9="Information not obtainable"
01. Principal	<b>menst_why_v1</b>	If No Last Menstrual Period Date, Specify Why - Visit 1 (Baseline) - [Menstruation]		.F="No Record For This Visit" .M="Missing" 1="Participant did not have period" 2="Other, please specify" 9="Information not obtainable"
01. Principal	<b>menst_why_v2</b>	If No Last Menstrual Period Date, Specify Why - Visit 2 (Day Of Surgery) - [Menstruation]		.F="No Record For This Visit" .M="Missing" 1="Participant did not have period" 2="Other, please specify" 9="Information not obtainable"
01. Principal	<b>menst_why_v3</b>	If No Last Menstrual Period Date, Specify Why - Visit 3 (Post-Surgery) - [Menstruation]		.F="No Record For This Visit" .M="Missing" 1="Participant did not have period" 2="Other, please specify" 9="Information not obtainable"

## Section 20: BESS Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	<b>bess_abdom_pain_v1</b>	Abdominal Pain - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_abdom_pain_v2</b>	Abdominal Pain - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Tendency Toward Accidents - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_accident_v2</b>	Tendency Toward Accidents - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Avoidance Of Social Affairs - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_avoid_soc_affair_v2</b>	Avoidance Of Social Affairs - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_back_pain_v1</b>	Back Pain Or Problems - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_back_pain_v2</b>	Back Pain Or Problems - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Blurred Vision - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_blurred_vision_v2</b>	Blurred Vision - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Breast Sensitivity/Tenderness - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_breast_tender_v2</b>	Breast Sensitivity/Tenderness - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_chest_pain_v1</b>	Chest Pains - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_chest_pain_v2</b>	Chest Pains - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_cold_sweats_v1</b>	Cold Sweats - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_cold_sweats_v2</b>	Cold Sweats - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Comments - Visit 1 (Baseline) - [BESS Questionnaire]		Char
01. Principal	<b>bess_comments_v2</b>	Comments - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		Char
01. Principal	<b>bess_constip_v1</b>	Constipation - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_constip_v2</b>	Constipation - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_cramps_v1</b>	Cramps - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_cramps_v2</b>	Cramps - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Decreased Appetite - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_dec_appet_v2</b>	Decreased Appetite - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Diarrhea - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_diarr_v2</b>	Diarrhea - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_blad_laugh_v1</b>	Difficulty With Bladder Control (When Laughing Or Crying) - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_diff_blad_laugh_v2</b>	Difficulty With Bladder Control (When Laughing Or Crying) - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Difficulty With Bladder Control (At Other Times) - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_diff_blad_oth_v2</b>	Difficulty With Bladder Control (At Other Times) - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_breath_v1</b>	Difficulty Breathing - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_diff_breath_v2</b>	Difficulty Breathing - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_conce ntr_v1</b>	Difficulty Concentrating - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_diff_conce ntr_v2</b>	Difficulty Concentrating - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v 1</b>	Dizziness, Faintness - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_dizziness_v 2</b>	Dizziness, Faintness - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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 _v1</b>	Dry Mouth - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_dry_mouth _v2</b>	Dry Mouth - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_easily_distr_v1</b>	Easily Distracted - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_easily_distr_v2</b>	Easily Distracted - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Excitability - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_excitability_v2</b>	Excitability - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Feeling Of Suffocation - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_feel_suffocated_v2</b>	Feeling Of Suffocation - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_forget_v1</b>	Forgetfulness - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v2</b>	Forgetfulness - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_fuzzy_vis_v1</b>	Blind Spots, Fuzzy Vision - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_fuzzy_vis_v2</b>	Blind Spots, Fuzzy Vision - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	General Aches And Pains - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_gen_ache_v2</b>	General Aches And Pains - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_genit_itch_v1</b>	Genital Itching/Irritation - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_genit_itch_v2</b>	Genital Itching/Irritation - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Headaches - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_head_ache_v2</b>	Headaches - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Hot Flashes - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_hot_flash_v2</b>	Hot Flashes - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_joint_pain_v1</b>	Joint Pain - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_joint_pain_v2</b>	Joint Pain - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Low Energy - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_low_energy_v2</b>	Low Energy - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Muscle Stiffness - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_musc_stiff_v2</b>	Muscle Stiffness - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Tendency To Take Naps, Stay In Bed - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_naps_v2</b>	Tendency To Take Naps, Stay In Bed - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Nausea - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_nausea_v2</b>	Nausea - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Night Sweats - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_night_sweats_v2</b>	Night Sweats - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_numv_v1</b>	Numbness, Tingling - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_numv_v2</b>	Numbness, Tingling - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Any Other Problems? - Visit 1 (Baseline) - [BESS Questionnaire]		Char
01. Principal	<b>bess_oth_prob_v2</b>	Any Other Problems? - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		Char
01. Principal	<b>bess_pain_inter_v1</b>	Pain With Intercourse - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_inter_v2</b>	Pain With Intercourse - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_pain_leg_feet_v1</b>	Pain Or Cramps In The Legs Or Feet - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v2</b>	Pain Or Cramps In The Legs Or Feet - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_ring_ears_v1</b>	Ringing In Ears - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_ring_ears_v2</b>	Ringing In Ears - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_short_temp_v1</b>	Short Temper - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_short_temp_v2</b>	Short Temper - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_swell_hands_feet_v1</b>	Swelling Of Hands Or Feet - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_swell_hands_feet_v2</b>	Swelling Of Hands Or Feet - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_unhap_app_body_v1</b>	Unhappy With The Appearance Of My Body - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_unhap_app_body_v2</b>	Unhappy With The Appearance Of My Body - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_vag_bleed_v1</b>	Vaginal Bleeding Or Spotting - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_vag_bleed_v2</b>	Vaginal Bleeding Or Spotting - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_vag_dis_v1</b>	Vaginal Discharge - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_vag_dis_v2</b>	Vaginal Discharge - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_vag_dry_v1</b>	Vaginal Dryness - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_vag_dry_v2</b>	Vaginal Dryness - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_vomit_v1</b>	Vomiting - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_vomit_v2</b>	Vomiting - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Early Awakening - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_wake_early_v2</b>	Early Awakening - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Weight Gain - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_weight_gain_v2</b>	Weight Gain - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_v1</b>	Weight Loss - Visit 1 (Baseline) - [BESS Questionnaire]		.E="Not Eligible For Study" .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_weight_loss_v2</b>	Weight Loss - Visit 2 (Day Of Surgery) - [BESS Questionnaire]		.E="Not Eligible For Study" .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 21: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	<b>basesym_comments1-8</b>	Comments - [Baseline Symptoms]		Char
01. Principal	<b>basesym_desc1-8</b>	Description - [Baseline Symptoms]		Char
01. Principal	<b>basesym_onset_date1-8</b>	Onset Date - [Baseline Symptoms]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>basesym_severity1-8</b>	Severity - [Baseline Symptoms]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 1="Mild" 2="Moderate" 3="Severe" 4="Life Threatening"

## Section 22: Tissue Specimen Collection

Class	Variable	Label	Description	Format Text
01. Principal	<b>tissue_date_ex</b>	Visit Date (Extra) - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>tissue_postdcis_block</b>	Post-Therapy DCIS Surgical Specimen: Number Of Formalin-Fixed, Paraffin-Embedded (FFPE) Blocks - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_postdcis_block_date</b>	Post-Therapy DCIS Surgical Specimen: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_postdcis_block_date_ex</b>	Post-Therapy DCIS Surgical Specimen: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>tissue_postdcis_block_ex</b>	Post-Therapy DCIS Surgical Specimen: Number Of Formalin-Fixed, Paraffin-Embedded (FFPE) Blocks - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>tissue_postdcis_block_time</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_postdcis_block_time_ex</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_postdcis_comments</b>	Post-Therapy Surgical Specimen: Comments - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postdcis_comments_ex</b>	Post-Therapy Surgical Specimen: Comments - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postdcis_slide</b>	Post-Therapy DCIS Surgical Specimen: Number Of Slides - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tissue_postdcis_slide_date</b>	Post-Therapy DCIS Surgical Specimen: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_postdcis_slide_date_ex</b>	Post-Therapy DCIS Surgical Specimen: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_postdcis_slide_ex</b>	Post-Therapy DCIS Surgical Specimen: Number Of Slides - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>tissue_postdcis_slide_time</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_postdcis_slide_time_ex</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_postdcis_store</b>	Post-Therapy DCIS Surgical Specimen: Storage Location/Temperature - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postdcis_store_ex</b>	Post-Therapy DCIS Surgical Specimen: Storage Location/Temperature - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postdrug_comments</b>	Post-Therapy Drug Concentration Assays Frozen Tissue: Comments - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postdrug_comments_ex</b>	Post-Therapy Drug Concentration Assays Frozen Tissue: Comments - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postdrug_cryo</b>	Post-Therapy Drug Concentration Assays Frozen Tissue: Number Of Cryovials - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_postdrug_cryo_ex</b>	Post-Therapy Drug Concentration Assays Frozen Tissue: Number Of Cryovials - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"



Class	Variable	Label	Description	Format Text
01. Principal	<b>tissue_postdrug_date</b>	Post-Therapy Drug Concentration Assays Frozen Tissue: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_postdrug_date_ex</b>	Post-Therapy Drug Concentration Assays Frozen Tissue: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_postdrug_store</b>	Post-Therapy Drug Concentration Assays Frozen Tissue: Storage Location And Temperature (C) - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postdrug_store_ex</b>	Post-Therapy Drug Concentration Assays Frozen Tissue: Storage Location And Temperature (C) - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postdrug_time</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_postdrug_time_ex</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_postfresh_block</b>	Post-Therapy Benign Fresh Tissue: Number Of FFPE Blocks - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_postfresh_block_ex</b>	Post-Therapy Benign Fresh Tissue: Number Of FFPE Blocks - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_postfresh_comments</b>	Post-Therapy Benign Fresh Tissue: Comments - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postfresh_comments_ex</b>	Post-Therapy Benign Fresh Tissue: Comments - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postfresh_date</b>	Post-Therapy Benign Fresh Tissue: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tissue_postfresh_date_ex</b>	Post-Therapy Benign Fresh Tissue: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_postfresh_store</b>	Post-Therapy Benign Fresh Tissue: Storage Location And Temperature (C) - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postfresh_store_ex</b>	Post-Therapy Benign Fresh Tissue: Storage Location And Temperature (C) - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_postfresh_time</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_postfresh_time_ex</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_predcnb_block</b>	Pre-Surgical DCNB DCIS Clinical Specimen: Number Of FFPE Blocks - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_predcnb_block_date</b>	Pre-Surgical DCNB DCIS Clinical Specimen FFPE Block: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_predcnb_block_date_ex</b>	Pre-Surgical DCNB DCIS Clinical Specimen FFPE Block: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_predcnb_block_ex</b>	Pre-Surgical DCNB DCIS Clinical Specimen: Number Of FFPE Blocks - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_predcnb_block_time</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_predcnb_block_time_ex</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tissue_predcnb_comments</b>	Pre-Surgical DCNB Ductal Carcinoma In Situ (DCIS) Clinical Specimen: Comments - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_predcnb_comments_ex</b>	Pre-Surgical DCNB Ductal Carcinoma In Situ (DCIS) Clinical Specimen: Comments - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_predcnb_slide</b>	Pre-Surgical DCNB DCIS Clinical Specimen: Number Of Slides - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_predcnb_slide_date</b>	Pre-Surgical DCNB DCIS Clinical Specimen Slides: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_predcnb_slide_date_ex</b>	Pre-Surgical DCNB DCIS Clinical Specimen Slides: Date Specimen Collected - [Tissue Specimen Collection]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_predcnb_slide_ex</b>	Pre-Surgical DCNB DCIS Clinical Specimen: Number Of Slides - [Tissue Specimen Collection]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_predcnb_slide_time</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_predcnb_slide_time_ex</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tissue_predcnb_store</b>	Pre-Surgical DCNB DCIS Clinical Specimen: Storage Location And Temperature (C) - [Tissue Specimen Collection]		Char
01. Principal	<b>tissue_predcnb_store_ex</b>	Pre-Surgical DCNB DCIS Clinical Specimen: Storage Location And Temperature (C) - [Tissue Specimen Collection]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>tissue_time</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tissue_time_ex</b>	Visit Time - [Tissue Specimen Collection]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"

## Section 23: Tumor Characteristics: Baseline

Class	Variable	Label	Description	Format Text
01. Principal	<b>tumbase_atypia</b>	Presence Of Atypia - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .M="Missing" 0="Not present" 1="ADH" 2="ALH" 3="LCIS"
01. Principal	<b>tumbase_atypia_ex</b>	Presence Of Atypia - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .N="N/A" 0="Not present" 1="ADH" 2="ALH" 3="LCIS"
01. Principal	<b>tumbase_blockreq</b>	Has Diagnostic FFPE Block Or Sections And Core Been Requested? - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>tumbase_blockreq_ex</b>	Has Diagnostic FFPE Block Or Sections And Core Been Requested? - [Tumor Characteristics: Baseline]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>tumbase_breast</b>	Right Or Left Breast? - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .M="Missing" 1="Right" 2="Left"
01. Principal	<b>tumbase_breast_ex</b>	Right Or Left Breast? - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .N="N/A" 1="Right" 2="Left"
01. Principal	<b>tumbase_comments</b>	Comments - [Tumor Characteristics: Baseline]		Char
01. Principal	<b>tumbase_comments_ex</b>	Comments - [Tumor Characteristics: Baseline]		Char
01. Principal	<b>tumbase_er</b>	Estrogen Receptor Status (% pos cells) - [Tumor Characteristics: Baseline]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tumbase_er_ex</b>	Estrogen Receptor Status (% pos cells) - [Tumor Characteristics: Baseline]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>tumbase_fish</b>	FISH - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" 0="Non-amplified" 1="Amplified" 9="Not done"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tumbase_fish_ex</b>	FISH - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .N="N/A" 0="Non-amplified" 1="Amplified" 9="Not done"
01. Principal	<b>tumbase_ifno</b>	If No, Please Add A Comment - [Tumor Characteristics: Baseline]		Char
01. Principal	<b>tumbase_ifno_ex</b>	If No, Please Add A Comment - [Tumor Characteristics: Baseline]		Char
01. Principal	<b>tumbase_micro</b>	Presence Of Microinvasion? - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 9="Unknown"
01. Principal	<b>tumbase_micro_ex</b>	Presence Of Microinvasion? - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes" 9="Unknown"
01. Principal	<b>tumbase_microsusp</b>	Is There A Focus Suspicious For Microinvasion? - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>tumbase_microsusp_ex</b>	Is There A Focus Suspicious For Microinvasion? - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>tumbase_necrosis</b>	Presence Of Necrosis - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" 0="No" 1="Yes" 9="Unknown"
01. Principal	<b>tumbase_necrosis_ex</b>	Presence Of Necrosis - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes" 9="Unknown"
01. Principal	<b>tumbase_nucgrade</b>	Pathology: Nuclear Grade - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" 1="High" 2="Intermediate" 3="Low" 9="Unknown"
01. Principal	<b>tumbase_nucgrade_ex</b>	Pathology: Nuclear Grade - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .N="N/A" 1="High" 2="Intermediate" 3="Low" 9="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tumbase_pr</b>	Progesterone Receptor Status (% pos cells) - [Tumor Characteristics: Baseline]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tumbase_pr_ex</b>	Progesterone Receptor Status (% pos cells) - [Tumor Characteristics: Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumbase_size_largest</b>	Size Of DCIS Focus In The Core With The Largest Focus (mm) - [Tumor Characteristics: Baseline]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tumbase_size_largest_ex</b>	Size Of DCIS Focus In The Core With The Largest Focus (mm) - [Tumor Characteristics: Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumbase_size_sum</b>	If DCIS Is Present In Multiple Cores: The Sum Of Sizes Across Multiple Cores (mm) - [Tumor Characteristics: Baseline]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tumbase_size_sum_ex</b>	If DCIS Is Present In Multiple Cores: The Sum Of Sizes Across Multiple Cores (mm) - [Tumor Characteristics: Baseline]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumbase_tdlus</b>	Presence Of Normal Terminal Ductal-Lobular Units (TDLU) - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 9="Unknown"
01. Principal	<b>tumbase_tdlus_ex</b>	Presence Of Normal Terminal Ductal-Lobular Units (TDLU) - [Tumor Characteristics: Baseline]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes" 9="Unknown"

## Section 24: Tumor Characteristics: Surgery

Class	Variable	Label	Description	Format Text
01. Principal	<b>tumsurg_atypia1-2</b>	Presence Of Atypia - [Tumor Characteristics: Surgery]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="Not present" 1="ADH" 2="ALH" 3="LCIS"
01. Principal	<b>tumsurg_breast1-2</b>	Right Or Left Breast? - [Tumor Characteristics: Surgery]		.F="No Record For This Visit" .N="N/A" 1="Right" 2="Left"
01. Principal	<b>tumsurg_cavity1-2</b>	Are Cavity Shave Margins Taken? - [Tumor Characteristics: Surgery]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>tumsurg_comments1-2</b>	Comments - [Tumor Characteristics: Surgery]		Char
01. Principal	<b>tumsurg_dcis1-2</b>	Is DCIS Present At Time Of Surgery? - [Tumor Characteristics: Surgery]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>tumsurg_er1-2</b>	Estrogen Receptor Status Of DCIS (% pos cells) - [Tumor Characteristics: Surgery]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumsurg_fish1-2</b>	FISH - [Tumor Characteristics: Surgery]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="Non-amplified" 1="Amplified" 9="Not done"
01. Principal	<b>tumsurg_her21-22</b>	Human Epidermal Growth Factor Receptor 2 (HER2) Status - [Tumor Characteristics: Surgery]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="0" 1="1+" 2="2+" 3="3+" 9="Not done"
01. Principal	<b>tumsurg_invasive1-2</b>	Are Invasive Components Present? - [Tumor Characteristics: Surgery]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"



Class	Variable	Label	Description	Format Text
01. Principal	<b>tumsurg_ki671-672</b>	Ki-67 (% Pos Cells) - [Tumor Characteristics: Surgery]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumsurg_margin1-2</b>	Margin Status - [Tumor Characteristics: Surgery]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Positive (ink on tumor)" 2="Close (< 2 mm but not touching ink)" 3="Free (> = 2 mm)"
01. Principal	<b>tumsurg_necrosis1-2</b>	Presence Of Necrosis - [Tumor Characteristics: Surgery]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes" 9="Unknown"
01. Principal	<b>tumsurg_nodes1-2</b>	Number Of Nodes Taken - [Tumor Characteristics: Surgery]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumsurg_nodes_pos1-2</b>	Number Of Nodes Positive - [Tumor Characteristics: Surgery]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumsurg_nucgrade1-2</b>	Pathology: Nuclear Grade - [Tumor Characteristics: Surgery]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="High" 2="Intermediate" 3="Low" 9="Unknown"
01. Principal	<b>tumsurg_pr1-2</b>	Progesterone Receptor Status Of DCIS (% pos cells) - [Tumor Characteristics: Surgery]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumsurg_size_dcis1-2</b>	Size Of Tumor: Span Of DCIS (mm) - [Tumor Characteristics: Surgery]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumsurg_size_dcis_num1-2</b>	Number Of Sections With DCIS - [Tumor Characteristics: Surgery]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumsurg_size_longest1-2</b>	Size Of Tumor: Longest Dimension In A Single Focus (mm) - [Tumor Characteristics: Surgery]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumsurg_size_second1-2</b>	Size Of Tumor: Second Longest Dimension (mm) - [Tumor Characteristics: Surgery]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tumsurg_surgtime1-2</b>	Time Of Surgery - [Tumor Characteristics: Surgery]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumsurg_tdlus1-2</b>	Presence Of Normal Terminal Ductal-Lobular Units (TDLU) - [Tumor Characteristics: Surgery]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes" 9="Unknown"
01. Principal	<b>tumsurg_time1-2</b>	Visit Time - [Tumor Characteristics: Surgery]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>tumsurg_weight1-2</b>	Weight Of Main Specimen (g) - [Tumor Characteristics: Surgery]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

## Section 25: Terminal Duct Lobular Units

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Class	Variable	Label	Description	Format Text
01. Principal	<b>tdlu_ki67_li_v1</b>	Ki-67 LI - Visit 1 (Baseline) - [Terminal Duct Lobular Units]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tdlu_ki67_li_v2</b>	Ki-67 LI - Visit 2 (Day of Surgery) - [Terminal Duct Lobular Units]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tdlu_ki67_neg_cells_v1</b>	Ki-67 Negative Cells - Visit 1 (Baseline) - [Terminal Duct Lobular Units]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tdlu_ki67_neg_cells_v2</b>	Ki-67 Negative Cells - Visit 2 (Day of Surgery) - [Terminal Duct Lobular Units]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tdlu_ki67_pos_cells_v1</b>	Ki-67 Positive Cells - Visit 1 (Baseline) - [Terminal Duct Lobular Units]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tdlu_ki67_pos_cells_v2</b>	Ki-67 Positive Cells - Visit 2 (Day of Surgery) - [Terminal Duct Lobular Units]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tdlu_total_cells_v1</b>	Total Cells - Visit 1 (Baseline) - [Terminal Duct Lobular Units]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tdlu_total_count_v2</b>	Total Cells - Visit 2 (Day of Surgery) - [Terminal Duct Lobular Units]		Numeric .F="No Record For This Visit" .M="Missing"

## Section 26: TAC TAD

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Class	Variable	Label	Description	Format Text
01. Principal	<b>tactad_comments1-3</b>	Comments - [TAC TAD]		Char
01. Principal	<b>tactad_num</b>	Number of Observations - [TAC TAD]		Numeric
01. Principal	<b>tactad_start_date1-3</b>	Start Date - [TAC TAD]		SAS Date .N="N/A"
01. Principal	<b>tactad_tac1-3</b>	Treatment Assignment Code (TAC) - [TAC TAD]		.N="N/A" 0="TAC-0" 1="TAC1" 2="TAC2" 3="TAC3"

## Section 27: Drug Concentrations

Class	Variable	Label	Description	Format Text
01. Principal	<b>conc_b1_adipo1-5</b>	Percent Adipocytes Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b1_e_4oht1-5</b>	4-OHT (ng/g) Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b1_e_enx1-5</b>	4-ENX (ng/g) Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b1_epith1-5</b>	Percent Epithelium Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b1_id1-5</b>	Primary Tissue ID # - [Drug Concentrations]		Char
01. Principal	<b>conc_b1_ndt1-5</b>	NDT (ng/g) Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b1_nnddt1-5</b>	NNDDT (ng/g) Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b1_strom1-5</b>	Percent Stroma Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b1_tam1-5</b>	Tamoxifen (ng/g) Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b1_z_4_enx1-5</b>	4-ENX (ng/g) Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b1_z_4_oht1-5</b>	4-OHT (ng/g) Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b1_z_4oht1-5</b>	4-OHT (ng/g) Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>conc_b1_z_enx1-5</b>	4-ENX (ng/g) Primary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_adipo1-5</b>	Percent Adipocytes Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_e_4oht1-5</b>	4-OHT (ng/g) Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_e_enx1-5</b>	4-ENX (ng/g) Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_epith1-5</b>	Percent Epithelium Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_id1-5</b>	Secondary Tissue ID # - [Drug Concentrations]		Char
01. Principal	<b>conc_b2_ndt1-5</b>	NDT (ng/g) Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_nnddt1-5</b>	NNDDT (ng/g) Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_strom1-5</b>	Percent Stroma Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_tam1-5</b>	Tamoxifen (ng/g) Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_z_4_enx1-5</b>	4-ENX (ng/g) Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_z_4_oht1-5</b>	4-OHT (ng/g) Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_z_4oht1-5</b>	4-OHT (ng/g) Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_b2_z_enx1-5</b>	4-ENX (ng/g) Secondary # - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>conc_pl_e_4oht</b>	4-OHT (ng/mL) Plasma - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_pl_e_enx</b>	4-ENX (ng/mL) Plasma - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_pl_hus_id</b>	HUS ID Plasma - [Drug Concentrations]		Char
01. Principal	<b>conc_pl_ndt</b>	NDT (ng/mL) Plasma - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_pl_nnddt</b>	NNDT (ng/mL) Plasma - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_pl_tam</b>	Tamoxifen (ng/mL) Plasma - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_pl_z_4_enx</b>	4-ENX (ng/mL) Plasma - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_pl_z_4_oht</b>	4-OHT (ng/mL) Plasma - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_pl_z_4oht</b>	4-4OHT (ng/mL) Plasma - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_pl_z_enx</b>	4-ENX (ng/mL) Plasma - [Drug Concentrations]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>conc_primary_breast</b>	Primary Breast - [Drug Concentrations]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 1="Right" 2="Left"
01. Principal	<b>conc_secondary_breast</b>	Secondary Breast - [Drug Concentrations]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 1="Right" 2="Left"
01. Principal	<b>conc_surg_type</b>	Surgery Type - [Drug Concentrations]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 1="Lumpectomy" 2="Mastectomy" 3="No tissue or no surgery"

## Section 28: Medication Compliance

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Class	Variable	Label	Description	Format Text
01. Principal	<b>comp_doses_expected</b>	Doses Expected - [Medication Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>comp_doses_taken_diary</b>	Doses Taken Per Diary - [Medication Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>comp_doses_taken_last_14days</b>	Doses Taken During The Last 14 Days - [Medication Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>comp_doses_taken_pharmacy</b>	Doses Taken Per Pharmacy - [Medication Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>comp_treatment</b>	Treatment Delivery Mode - [Medication Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 1="Oral" 2="Transdermal"



## Section 29: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	<b>conmed_comments1-27</b>	Comments - [Concomitant Medications]		Char
01. Principal	<b>conmed_continuing1-27</b>	Continuing - [Concomitant Medications]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes" 99="Unknown"
01. Principal	<b>conmed_dose1-27</b>	Medication Or Treatment Dose - [Concomitant Medications]		Char
01. Principal	<b>conmed_freq1-27</b>	Dose Frequency - [Concomitant Medications]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>conmed_freq_oth1-27</b>	Dose Frequency: Other, Specify - [Concomitant Medications]		Char
01. Principal	<b>conmed_name1-27</b>	Medication Or Treatment Name - [Concomitant Medications]		Char
01. Principal	<b>conmed_num</b>	Number Of Observations - [Concomitant Medications]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	<b>conmed_rep_date1-27</b>	Medication Reported Date - [Concomitant Medications]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	<b>conmed_start_date1-27</b>	Start Date - [Concomitant Medications]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>conmed_stop_date1-27</b>	Stop Date - [Concomitant Medications]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>conmed_units1-27</b>	Units - [Concomitant Medications]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>conmed_units_oth1-27</b>	Units: Other, Specify - [Concomitant Medications]		Char

## Section 30: Agent Interruption

Class	Variable	Label	Description	Format Text
01. Principal	<b>agent_amount_gel1-7</b>	Amount Of Agent Missed (# Of Gel Doses) - [Agent Interruption]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>agent_amount_pill1-7</b>	Amount Of Agent Missed (# Of Pills) - [Agent Interruption]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>agent_comments1-7</b>	Comments - [Agent Interruption]		Char
01. Principal	<b>agent_date1-7</b>	Start Date Of Interruption (Date Of First Dose Missed) - [Agent Interruption]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	<b>agent_num</b>	Number Of Agent Interruptions - [Agent Interruption]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	<b>agent_reason1-7</b>	Reason Stopped - [Agent Interruption]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 1="Investigator Decision Specify" 2="Participant Decision Specify" 3="Participant Forgot" 4="AE/SAE, Specify" 5="Other, Specify"
01. Principal	<b>agent_reason_other1-7</b>	Reason Stopped, Specify - [Agent Interruption]		Char
01. Principal	<b>agent_restart_date1-7</b>	If Restarted, Specify Date - [Agent Interruption]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>agent_restarted1-7</b>	Was Agent Restarted? - [Agent Interruption]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"

## Section 31: Agent Return And Compliance

Class	Variable	Label	Description	Format Text
01. Principal	<b>agrc_both</b>	Did Participant Apply Gel To Both Breasts? - [Agent Return And Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes" 99="Unknown"
01. Principal	<b>agrc_cap_missing_comments</b>	Amount Of Agent Missing For This Period, Comments - [Agent Return And Compliance]		Char
01. Principal	<b>agrc_cap_returned_comments</b>	Amount Of Agent Returned At This Visit, Comments - [Agent Return And Compliance]		Char
01. Principal	<b>agrc_capsules_missing</b>	Amount Of Agent Missing (# Of Capsules) - [Agent Return And Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>agrc_capsules_provided</b>	Amount Of Agent Provided At Previous Visit (# Of Capsules) - [Agent Return And Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	<b>agrc_capsules_returned</b>	Amount Of Agent Returned At This Visit (# Of Capsules) - [Agent Return And Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	<b>agrc_capsules_used</b>	Amount Of Agent Used During This Period (# Of Capsules) - [Agent Return And Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	<b>agrc_comments</b>	Comments - [Agent Return And Compliance]		Char
01. Principal	<b>agrc_compliant</b>	Is Participant Compliant (80% Or More Of Agent Used) With Protocol Intervention? - [Agent Return And Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes" 99="Unknown"
01. Principal	<b>agrc_disp_date</b>	Agent Dispensing Date - [Agent Return And Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	<b>agrc_disp_weight1-2</b>	Weight Of Gel Canister #2 At Dispensing (g) - [Agent Return And Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	<b>agrc_kit</b>	Kit Number - [Agent Return And Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>agrc_randomization</b>	Randomization Number - [Agent Return And Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	<b>agrc_reason_no</b>	Reason For Noncompliance - [Agent Return And Compliance]		Char
01. Principal	<b>agrc_ret_cap_on1-2</b>	Returned Gel Canister #2 Weighed With The Cap On? - [Agent Return And Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 99="Unknown"
01. Principal	<b>agrc_ret_date</b>	Agent Return Date - [Agent Return And Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	<b>agrc_ret_weight1-2</b>	Weight Of Returned Gel Canister #2 (g) - [Agent Return And Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"

## Section 32: Ductal Carcinoma In Situ

Class	Variable	Label	Description	Format Text
01. Principal	<b>dcis_ki67_li_v1</b>	Ki-67 Nuclear Antigen Labeling Index: Visit 1 (Baseline) - [Ductal Carcinoma In Situ]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>dcis_ki67_li_v2</b>	Ki-67 Nuclear Antigen Labeling Index: Visit 2 (Day Of Surgery) - [Ductal Carcinoma In Situ]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>dcis_ki67_neg_cells_v1</b>	Ki-67 Negative Cells: Visit 1 (Baseline) - [Ductal Carcinoma In Situ]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>dcis_ki67_neg_cells_v2</b>	Ki-67 Negative Cells: Visit 2 (Day Of Surgery) - [Ductal Carcinoma In Situ]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>dcis_ki67_pos_cells_v1</b>	Ki-67 Positive Cells: Visit 1 (Baseline) - [Ductal Carcinoma In Situ]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>dcis_ki67_pos_cells_v2</b>	Ki-67 Positive Cells: Visit 2 (Day Of Surgery) - [Ductal Carcinoma In Situ]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>dcis_total_cells_v1</b>	Total Cells: Visit 1 (Baseline) - [Ductal Carcinoma In Situ]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	<b>dcis_total_cells_v2</b>	Total Cells: Visit 2 (Day Of Surgery) - [Ductal Carcinoma In Situ]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"

## Section 33: Conservation Grossing

Class	Variable	Label	Description	Format Text
01. Principal	<b>congross_breast1-3</b>	Right Or Left Breast? - [Conservation Grossing]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" 1="Right" 2="Left"
01. Principal	<b>congross_comments1-3</b>	Comments - [Conservation Grossing]		Char
01. Principal	<b>congross_deep_height1-3</b>	Height (cm) - Deep Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>congross_deep_length1-3</b>	Length (cm) - Deep Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>congross_deep_weight1-3</b>	Total Weight (mg) - Deep Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>congross_deep_weight2_drug1-3</b>	Weight Of Drug Sample - Deep Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>congross_deep_weight2_hist1-3</b>	Weight Of Histology Sample - Deep Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>congross_deep_width1-3</b>	Width (cm) - Deep Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>congross_num</b>	Number of Observations - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	<b>congross_supf_height1-3</b>	Height (cm) - Superficial Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>congross_supf_length1-3</b>	Length (cm) - Superficial Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>congross_supf_weight1-3</b>	Total Weight (mg) - Superficial Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>congross_supf_weight1_drug1-3</b>	Weight Of Drug Sample - Superficial Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>congross_supf_weight1_hist1-3</b>	Weight Of Histology Sample - Superficial Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>congross_supf_width1-3</b>	Width (cm) - Superficial Sample - [Conservation Grossing]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"



## Section 34: Mastectomy Grossing Simplified

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgrosssim_breast_which</b>	Right Or Left Breast? - [Mastectomy Grossing Simplified]		.F="No Record For This Visit" 1="Right" 2="Left"
01. Principal	<b>mgrosssim_comments</b>	Comments - [Mastectomy Grossing Simplified]		Char
01. Principal	<b>mgrosssim_deep_deep_dist</b>	Deep Sample - Sample 2: Distance From Deep Surface (cm) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>mgrosssim_deep_drug_wt</b>	Deep Sample - Sample 2: Weight Of Drug Sample - Specimen A (mg) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>mgrosssim_deep_hist_wt</b>	Deep Sample - Sample 2: Weight Of Histology Sample - Specimen B (mg) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>mgrosssim_deep_lesion_dist</b>	Deep Sample - Sample 2: Distance From Lesion (cm) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>mgrosssim_deep_ss_dist</b>	Deep Sample - Sample 2: Distance From Superficial Surface (cm) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>mgrosssim_mast_ht</b>	Entire Mastectomy Specimen Dimensions: Height (cm) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit"
01. Principal	<b>mgrosssim_mast_len</b>	Entire Mastectomy Specimen Dimensions: Length (cm) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit"
01. Principal	<b>mgrosssim_mast_width</b>	Entire Mastectomy Specimen Dimensions: Width (cm) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit"
01. Principal	<b>mgrosssim_mast_wt</b>	Entire Mastectomy Specimen Weight (g) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgrosssim_supe rf_deep_dist</b>	Superficial Sample - Sample 1: Distance From Deep Surface (cm) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>mgrosssim_supe rf_drug_wt</b>	Superficial Sample - Sample 1: Weight Of Drug Sample - Specimen A (mg) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>mgrosssim_supe rf_hist_wt</b>	Superficial Sample - Sample 1: Weight Of Histology Sample - Specimen B (mg) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>mgrosssim_supe rf_lesion_dist</b>	Superficial Sample - Sample 1: Distance From Lesion (cm) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>mgrosssim_supe rf_ss_dist</b>	Superficial Sample - Sample 1: Distance From Superficial Surface (cm) - [Mastectomy Grossing Simplified]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>mgrosssim_tume sc</b>	Tumescence Used? - [Mastectomy Grossing Simplified]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

## Section 35: Mastectomy Grossing, NU, MSK

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgrossnumsk_a1_deep1-2</b>	Sample 1 (Slice A): Distance From Deep Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_a1_drug1-2</b>	Sample 1 (Slice A): Weight Of Drug Sample - Specimen A (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_a1_hist1-2</b>	Sample 1 (Slice A): Weight Of Histology Sample - Specimen B (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_a1_nip1-2</b>	Sample 1 (Slice A): Distance From Nipple (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_a1_ss1-2</b>	Sample 1 (Slice A): Distance From Superficial Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_a2_deep1-2</b>	Sample 2 (Slice A): Distance From Deep Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_a2_drug1-2</b>	Sample 2 (Slice A): Weight Of Drug Sample - Specimen A (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_a2_hist1-2</b>	Sample 2 (Slice A): Weight Of Histology Sample - Specimen B (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_a2_nip1-2</b>	Sample 2 (Slice A): Distance From Nipple (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_a2_ss1-2</b>	Sample 2 (Slice A): Distance From Superficial Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgrossnumsk_b3_deep1-2</b>	Sample 3 (Slice B): Distance From Deep Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_b3_drug1-2</b>	Sample 3 (Slice B): Weight Of Drug Sample - Specimen A (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_b3_hist1-2</b>	Sample 3 (Slice B): Weight Of Histology Sample - Specimen B (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_b3_nip1-2</b>	Sample 3 (Slice B): Distance From Nipple (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_b3_ss1-2</b>	Sample 3 (Slice B): Distance From Superficial Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_b4_deep1-2</b>	Sample 4 (Slice B): Distance From Deep Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_b4_drug1-2</b>	Sample 4 (Slice B): Weight Of Drug Sample - Specimen A (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_b4_hist1-2</b>	Sample 4 (Slice B): Weight Of Histology Sample - Specimen B (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_b4_nip1-2</b>	Sample 4 (Slice B): Distance From Nipple (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_b4_ss1-2</b>	Sample 4 (Slice B): Distance From Superficial Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_breast1-2</b>	Right Or Left Breast? - [Mastectomy Grossing, NU, MSK]		.F="No Record For This Visit" .N="N/A" 1="Right" 2="Left"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgrossnumsk_c5_deep1-2</b>	Sample 5 (Slice C): Distance From Deep Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_c5_drug1-2</b>	Sample 5 (Slice C): Weight Of Drug Sample - Specimen A (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_c5_hist1-2</b>	Sample 5 (Slice C): Weight Of Histology Sample - Specimen B (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_c5_nip1-2</b>	Sample 5 (Slice C): Distance From Nipple (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_c5_ss1-2</b>	Sample 5 (Slice C): Distance From Superficial Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_comments1-2</b>	Comments - [Mastectomy Grossing, NU, MSK]		Char
01. Principal	<b>mgrossnumsk_height1-2</b>	Entire Mastectomy Specimen Dimensions: Height (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_length1-2</b>	Entire Mastectomy Specimen Dimensions: Length (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_in7_deep1-2</b>	Sample 7 (Lymph Node): Distance From Deep Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_in7_drug1-2</b>	Sample 7 (Lymph Node): Weight Of Drug Sample - Specimen A (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>mgrossnumsk_in7_hist1-2</b>	Sample 7 (Lymph Node): Weight Of Histology Sample - Specimen B (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgrossnumsk_in7_nip1-2</b>	Sample 7 (Lymph Node): Distance From Nipple (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>mgrossnumsk_in7_ss1-2</b>	Sample 7 (Lymph Node): Distance From Superficial Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>mgrossnumsk_sllice1-2</b>	Number Of Slices - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_sllicea1-2</b>	Central Slice A Number - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_slliceb1-2</b>	Lateral Slice B Number - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_sllicec1-2</b>	Medial Slice C Number - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_thick1-2</b>	Average Slice Thickness (mm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_tum6_deep1-2</b>	Sample 6 (Tumor): Distance From Deep Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>mgrossnumsk_tum6_drug1-2</b>	Sample 6 (Tumor): Weight Of Drug Sample - Specimen A (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>mgrossnumsk_tum6_hist1-2</b>	Sample 6 (Tumor): Weight Of Histology Sample - Specimen B (mg) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>mgrossnumsk_tum6_nip1-2</b>	Sample 6 (Tumor): Distance From Nipple (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>mgrossnumsk_tum6_ss1-2</b>	Sample 6 (Tumor): Distance From Superficial Surface (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>mgrossnumsk_tumesc1-2</b>	Tumescence Used? - [Mastectomy Grossing, NU, MSK]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>mgrossnumsk_weight1-2</b>	Entire Mastectomy Specimen Weight (g) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>mgrossnumsk_width1-2</b>	Entire Mastectomy Specimen Dimensions: Width (cm) - [Mastectomy Grossing, NU, MSK]		Numeric .F="No Record For This Visit" .N="N/A"

## Section 36: Oncotype DCIS-Score

Class	Variable	Label	Description	Format Text
01. Principal	<b>surg_onc_10_year_risk</b>	Surgical 10 Year Risk Of Local Recurrence With Breast-Conserving Surgery Alone (Percent) - [Oncotype DCIS-Score]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>surg_onc_comment</b>	Comments - [Oncotype DCIS-Score]		Char
01. Principal	<b>surg_onc_er_score</b>	Surgical Oncotype Diagnosis Estrogen Score - [Oncotype DCIS-Score]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>surg_onc_pr_score</b>	Surgical Oncotype Diagnosis Progesterone Score - [Oncotype DCIS-Score]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>surg_onc_recur_score</b>	Surgical Recurrence Score Result - [Oncotype DCIS-Score]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>surg_onc_report_date</b>	Date Of Surgical Oncotype Diagnosis Report - [Oncotype DCIS-Score]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>surg_onc_specimen_date</b>	Date DCIS Post-Therapy Specimen Obtained - [Oncotype DCIS-Score]		SAS Date .F="No Record For This Visit" .M="Missing"



## Section 37: Oncotype Dx

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Class	Variable	Label	Description	Format Text
01. Principal	<b>onc_10yr_risk_pct</b>	10 Year Risk Of Local Recurrence With Breast-Conserving Surgery Alone (%) - [Oncotype Dx]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>onc_comments</b>	Comments - [Oncotype Dx]		Char
01. Principal	<b>onc_dcis_date</b>	Date DCIS Pre-Therapy Specimen Obtained - [Oncotype Dx]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>onc_er_score</b>	Estrogen Score - [Oncotype Dx]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>onc_pr_score</b>	Progesterone Score - [Oncotype Dx]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>onc_recurr_score</b>	Recurrence Score Result - [Oncotype Dx]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>onc_rep_date</b>	Date Of Report - [Oncotype Dx]		SAS Date .F="No Record For This Visit" .M="Missing"

## Section 38: Batch Shipment Specimen Inventory

Class	Variable	Label	Description	Format Text
01. Principal	<b>ship_comments1-3</b>	Comments - [Batch Shipment Specimen Inventory]		Char
01. Principal	<b>ship_date1-3</b>	Visit Date - [Batch Shipment Specimen Inventory]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ship_edta_buffy_num1-3</b>	Buffy Coat: Number Of Aliquots - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ship_edta_plasma_num1-3</b>	Plasma: Number Of Aliquots - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ship_nacit_plasma_num1-3</b>	Plasma: Number Of Aliquots - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ship_num</b>	Number of Observations - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit"
01. Principal	<b>ship_postdcis_block1-3</b>	Post-DCIS: Number Of Formalin-Fixed, Paraffin-Embedded (FFPE) Blocks - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ship_postdcis_slides1-3</b>	Post-DCIS: Number Of Slides - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ship_postdrug_cryo1-3</b>	Post-Drug: Number Of Cryovials - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ship_postfresh_block1-3</b>	Post-Fresh: Number Of FFPE Blocks - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ship_predcnblock1-3</b>	Pre-DCNB: Number Of FFPE Blocks - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>ship_predcnblock1-3</b>	Pre-DCNB: Number Of Slides - [Batch Shipment Specimen Inventory]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>ship_ship_date1-3</b>	Date Of Shipment - [Batch Shipment Specimen Inventory]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"

## Section 39: Participant Contact

Class	Variable	Label	Description	Format Text
01. Principal	<b>pcon_ae1-8</b>	Did The Participant Report Any Symptoms Or Adverse Events? - [Participant Contact]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes (complete AE)" 8="Too early to evaluate"
01. Principal	<b>pcon_comments 1-8</b>	Comments - [Participant Contact]		Char
01. Principal	<b>pcon_comp1-8</b>	Is The Participant Compliant With Protocol Intervention Per Telephone Conversation Or Email? - [Participant Contact]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes" 9="Unknown"
01. Principal	<b>pcon_date1-8</b>	Date - [Participant Contact]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>pcon_med1-8</b>	Were Any Changes In Concomitant Medications Reported? (Either New Medications Started Or Previous Medications Stopped?) - [Participant Contact]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes (complete ConMed form)" 8="Not applicable"

## Section 40: Off Study

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Class	Variable	Label	Description	Format Text
01. Principal	<b>off_agent_end_date</b>	Agent End Date - [Off Study]		SAS Date .M="Missing"
01. Principal	<b>off_comments</b>	Comments - [Off Study]		Char
01. Principal	<b>off_date</b>	Off Study Date - [Off Study]		SAS Date
01. Principal	<b>off_last_contact</b>	Date Of Last Contact - [Off Study]		SAS Date .M="Missing"
01. Principal	<b>off_reason</b>	Reason Off Study - [Off Study]		1="Adverse Event" 2="Death" 3="Disease Progression" 4="Lost to follow-up" 5="Other, specify" 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"
01. Principal	<b>off_reason_oth</b>	Reason Off Study Other: Specify - [Off Study]		Char