

NWU-2013-01-03 PERSON FILE

TABLE OF CONTENTS

Document Summary.....	3
NWU-2013-01-03 Person File	4
Section 1: Identifiers	4
Section 2: Agent Interruption	5
Section 3: Agent Return & Compliance	6
Section 4: Agent Compliance	7
Section 5: BESS	9
Section 6: Blood Chemisty	17
Section 7: Breast Cup Size.....	21
Section 8: Conmed	22
Section 9: Eligibility	24
Section 10: Enrollement	25
Section 11: Hormone Regimen	26
Section 12: Consent Form.....	27
Section 13: Mastectomy Grossing.....	28
Section 14: Medical History	32
Section 15: Menopausal Status	34
Section 16: Menstruation.....	35
Section 17: Off Study	36
Section 18: Participan Contact	37
Section 19: Participant Diary	39
Section 20: Physical Exam	40
Section 21: Pre-Enrollment.....	43
Section 22: Pregnancy Test.....	45

Section 23: Treatment Assignment Code	46
Section 24: Timepoints	47
Section 25: Tumor Characteristics - Baseline	48
Section 26: Tumor Characteristics - Surgery	49
Section 27: Unblinding	50
Section 28: Vital Signs	51
Section 29: Gene Expression	53
Section 30: Ki-67	60
Section 31: Plasma Concentration	61
Section 32: Serum Hormones	62
Section 33: Tissue Concentration	63
Section 34: Tissue Composition	64
Section 35: Dataset Accounting	65

Document Summary

Property	Value
Document Title	NWU-2013-01-03 Person File
Date Created	01/15/2020
For Dataset	prsn
Sections	35
Entries	594
Document Filename	dictionary_NWU-2013-01-03PersonFile.01152020.rtf

NWU-2013-01-03 Person File
01/15/2020
Dataset: prsn

NWU-2013-01-03 Person File

Section 1: Identifiers

Variable	Label	Description	Format Text
arm	Randomization Arm (Active Agent In Gel Or Pill)	Randomization Arm (Active Agent in Gel or Pill)	.N="Not Applicable" 1="Placebo Gel, Active Pill" 2="Active Gel, Placebo Pill"
participant_identifier	Participant Identifier	Participant Identifier	Char

Section 2: Agent Interruption

Variable	Label	Description	Format Text
amt_of_treatment_missed_cap1-4	Amount Of Treatment Missed (# Of Capsules)	The amount that describes how much of the agent was missing or not accounted for.	Num .N="Not Applicable"
amt_of_treatment_missed_gel1-4	Amount Of Treatment Missed (# Of Gel Doses, Where 1 Dose = Application)	The amount that describes how much of the agent was missing or not accounted for.	Num .M="Missing" .N="Not Applicable"
num_treatment_interruptions	Number Of Times Treatment Was Interrupted	Number of times treatment was interrupted	Num
treatment_interrupt_comments1-4	Treatment Interrupted Comments	the free text field for general notes.	Char
treatment_interrupt_date1-4	Start Date Of Interruption (Date Of First Dose Missed)	a date on which a treatment dose is temporarily stopped before a dose modification or continuation after addressing patient side effects.	SAS Date .N="Not Applicable"
treatment_interrupt_reason1-4	Treatment Interrupted Reason: Specify	The reason representing why the agent was stopped.	.N="Not Applicable" 1="AE/SAE, Specify" 2="Investigator decision, Specify" 3="Other, Specify" 4="Participant non-compliance"
treatment_interrupt_specify1-4	Treatment Interrupted Reason	The text that describes the reason the agent was stopped.	Char
treatment_restart_date1-4	Treatment Restart Date	The date the agent was restarted.	SAS Date .N="Not Applicable"
was_treatment_restarted1-4	Was Treatment Restarted?	Study Agent Continuation Indicator	.N="Not Applicable" 0="No" 1="Yes"

Section 3: Agent Return & Compliance

Variable	Label	Description	Format Text
agent_non_compliance_reason	If No, Reason For Noncompliance	the free text field for general notes.	Char
agent_pills_not_accounted	Amount Of Agent Missing/Not Accounted For This Period (# Of Capsules)	The amount that describes how much of the agent was missing or not accounted for.	Num .M="Missing"
agent_pills_provided_at_prev	Amount Of Agent Provided At Previous Visit (# Of Capsules)	The amount of agent that was provided at the last visit.	Num .M="Missing"
agent_pills_returned	Amount Of Agent Returned At This Visit (# Of Capsules)	The amount that describes how much of the agent was returned by the participant.	Num .M="Missing"
agent_pills_used	Amount Of Agent Used During This Period (# Of Capsules)	The amount that describes how much of the agent was actually taken.	Num .M="Missing"
agent_return_comments	Agent Returned Comments	The text that describes the reason the participant was noncompliant.	Char
agent_return_compliant	Is Participant Compliant (80% Or More Of Agent Used) With Protocol?	The indicator that represents whether the participant was compliant with the protocol intervention.	.M="Missing" 0="No" 1="Yes" 9="Unkown"
agent_return_dt	Agent Returned Visit Date	The date of the visit.	SAS Date .M="Missing"
agent_returned_gel_can_1_cap_on	Returned Gel Canister 1: Weighed With The Cap On?	Indication whether returned gel canister is weighed with the cap on.	.M="Missing" 0="No" 1="Yes" 9="Unkown"
agent_returned_gel_can_1_weight	Weight Of Returned Gel Canister 1 (g)	The weight value for the returned gel medication canister	Num .M="Missing"
agent_returned_gel_can_2_cap_on	Returned Gel Canister 2: Weighed With The Cap On?	Indication whether returned gel canister is weighed with the cap on.	.M="Missing" 0="No" 1="Yes" 9="Unkown"
agent_returned_gel_can_2_weight	Weight Of Returned Gel Canister 2 (g)	The weight value for the returned gel medication canister	Num .M="Missing"
agent_used_3_days_prior	Was Study Drug Taken For Each Of The 3 Days Prior To Surgery?	The yes/no/unknown response regarding whether a patient received the study agent prior to surgery.	.M="Missing" 0="No" 1="Yes" 9="Unkown"
agent_used_6_or_7_days	Was Study Drug Taken For 6/7 Days In The Last Week Of Therapy?	The yes/no/unknown response regarding whether a patient has received or taken the study agent within the last week of therapy.	.M="Missing" 0="No" 1="Yes" 9="Unkown"
agent_weight_gel_can_1	Weight Of Gel Canister 1, Pre-Study (g)	The weight value for the gel medication canister	Num .M="Missing"
agent_weight_gel_can_2	Weight Of Gel Canister 2, Pre-Study (g)	The weight value for the gel medication canister	Num .M="Missing"

Section 4: Agent Compliance

Variable	Label	Description	Format Text
actual_days_gel_used	Number Of Days Gel Reported As Applied Per Monitor Review Of Participant Log	Number of days gel reported as applied per Monitor Review of Participant Log	Num .N="Not Applicable"
actual_days_pill_taken	Number Of Days Agent Reported As Taken Per Monitor Review Of Participant Log	Number of days agent reported as taken per Monitor Review of Participant Log	Num .N="Not Applicable"
actual_gel_use	Actual Gel Used (g)	Actual Gel Used (g)	Num .M="Missing" .N="Not Applicable"
agent_compliance_comments	Compliance Notes	Compliance notes	Char
gel_compliance_by_diary	Gel Compliance Based On Diary	Gel Compliance Based on Diary	Num .N="Not Applicable"
gel_compliance_by_weight	Gel Compliance Based On Gel Weights	Gel Compliance Based on Gel Weights	Num .M="Missing" .N="Not Applicable"
overall_gel_compliant	Overall Compliant With Gel?	Overall Compliant with Gel?	.N="Not Applicable" 0="No" 1="Yes"
overall_pill_compliant	Overall Compliant With Pill?	Overall Compliant with Pill?	.N="Not Applicable" 0="No" 1="Yes"
pill_compliance_by_count	Pill Compliance Based On Pill Count	Pill Compliance Based on Pill Count	Num .N="Not Applicable"
pill_compliance_by_diary	Pill Compliance Based On Diary	Pill Compliance Based on Diary	Num .N="Not Applicable"
Projected_Days_on_Treatment	Projected Days On Treatment	Projected Days on Treatment	Num .N="Not Applicable"
projected_gel_use	Projected Gel Used (g)	Projected Gel Used (g)	Num .N="Not Applicable"
was_gel_compliance_79	Was Gel Compliance > 79%?	Was Gel Compliance > 79%?	.N="Not Applicable" 0="No" 1="Yes"
was_gel_taken_6_of_7	Was Gel Taken For Six Of The Last Seven Days Prior To Surgery?	Was Gel Taken for Six of the Last Seven Days Prior to Surgery?	.N="Not Applicable" 0="No" 1="Yes"
was_pill_compliance_79	Was Pill Compliance > 79%?	Was Pill Compliance > 79%?	.N="Not Applicable" 0="No" 1="Yes"

Variable	Label	Description	Format Text
was_pill_taken_6_of_7	Was Pill Taken For Six Of The Last Seven Days Prior To Surgery?	Was Pill Taken for Six of the Last Seven Days Prior to Surgery?	.N="Not Applicable" 0="No" 1="Yes"

Section 5: BESS

Variable	Label	Description	Format Text
bess_abdominal_pain1-3	BESS: Abdominal Pain	P22 Abdominal pain	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_avoidance_of_social1-3	BESS: Avoidance Of Social Affairs	P18 Avoidance of social affairs	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_back_pain_or_problems1-3	BESS: Back Pain Or Problems	P24 Back pain or problems	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_blind_spots_fuzzy_vision1-3	BESS: Blind Spots, Fuzzy Vision	P2 Blind spots, fuzzy vision	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_blurred_vision1-3	BESS: Blurred Vision	P26 Blurred vision	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_breast_sensitivity1-3	BESS: Breast Sensitivity/Tenderness	P5 Breast sensitivity/tenderness	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"

Variable	Label	Description	Format Text
bess_chest_pains1-3	BESS: Chest Pains	P7 Chest pains	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_cold_sweats1-3	BESS: Cold Sweats	V3 Cold sweats	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_constipation1-3	BESS: Constipation	P3 Constipation	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_cramps1-3	BESS: Cramps	P4 Cramps	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_date1-3	Bess Date	Visit date	SAS Date .M="Missing" .N="Not Applicable"
bess_decreased_appetite 1-3	BESS: Decreased Appetite	P12 Decreased appetite	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_diarrhea1-3	BESS: Diarrhea	Ga3 Diarrhea	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"

Variable	Label	Description	Format Text
bess_diff_with_bladder_laugh1-3	BESS: Difficulty With Bladder Control (When Laughing Or Crying)	B1 Difficulty with bladder control (when laughing or crying)	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_diff_with_bladder_other1-3	BESS: Difficulty With Bladder Control (At Other Times)	B2 Difficulty with bladder control (at other times)	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_difficulty_breathing1-3	BESS: Difficulty Breathing	P9 Difficulty breathing	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_difficulty_concentrating1-3	BESS: Difficulty Concentrating	C1 Difficulty concentrating	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_dizziness_faintness1-3	BESS: Dizziness, Faintness	P19 Dizziness, faintness	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_dry_mouth1-3	BESS: Dry Mouth	P10 Dry mouth	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_early_awakening1-3	BESS: Early Awakening	P21 Early awakening	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"

Variable	Label	Description	Format Text
bess_easily_distracted1-3	BESS: Easily Distracted	C2 Easily distracted	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_excitability1-3	BESS: Excitability	P14 Excitability	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_feeling_of_suffocation1-3	BESS: Feeling Of Suffocation	P13 Feeling of suffocation	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_forgetfulness1-3	BESS: Forgetfulness	C3 Forgetfulness	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_general_aches_and_pains1-3	BESS: General Aches And Pains	M3 General aches and pains	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_genital_itching1-3	BESS: Genital Itching/Irritation	Gy2 Genital itching/irritation	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_headaches1-3	BESS: Headaches	P1 Headaches	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"

Variable	Label	Description	Format Text
bess_hot_flashes1-3	BESS: Hot Flashes	V2 Hot flashes	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_joint_pain1-3	BESS: Joint Pain	M1 Joint pain	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_low_energy1-3	BESS: Low Energy	P25 Low energy	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_muscle_stiffness1-3	BESS: Muscle Stiffness	M2 Muscle stiffness	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_nausea1-3	BESS: Nausea	Ga2 Nausea	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_night_sweats1-3	BESS: Night Sweats	V1 Night sweats	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_num_visits	Number Of Visits Where Bess Questionnaire Was Completed	Number of visits where BESS questionnaire was completed	Num

Variable	Label	Description	Format Text
bess_numbness_tingling1-3	BESS: Numbness, Tingling	P20 Numbness, tingling	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_other_problems1-3	BESS: Any Other Problems?	P27 Any other problems?	Char
bess_pain_or_cramp_in_legs1-3	BESS: Pain Or Cramps In The Legs Or Feet	P23 Pain or cramps in the legs or feet	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_pain_with_intercourse1-3	BESS: Pain With Intercourse	D2 Pain with intercourse	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_ringing_in_ears1-3	BESS: Ringing In Ears	P6 Ringing in ears	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_short_temper1-3	BESS: Short Temper	P15 Short temper	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_swelling_of_hands_or_feet1-3	BESS: Swelling Of Hands Or Feet	P8 Swelling of hands or feet	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_tendency_to_take_naps1-3	BESS: Tendency To Take Naps; Stay In Bed	P16 Tendency to take naps; stay in bed	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"

Variable	Label	Description	Format Text
bess_tendency_toward_accidents1-3	BESS: Tendency Toward Accidents	P17 Tendency toward accidents	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_unhappy_with_appearance1-3	BESS: Unhappy With The Appearance Of My Body	W2 Unhappy with the appearance of my body	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_vaginal_bleeding1-3	BESS: Vaginal Bleeding Or Spotting	Gy3 Vaginal bleeding or spotting	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_vaginal_discharge1-3	BESS: Vaginal Discharge	Gy1 Vaginal discharge	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_vaginal_dryness1-3	BESS: Vaginal Dryness	D1 Vaginal dryness	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_vomiting1-3	BESS: Vomiting	Ga1 Vomiting	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"
bess_weight_gain1-3	BESS: Weight Gain	W1 Weight gain	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"

Variable	Label	Description	Format Text
bess_weight_loss1-3	BESS: Weight Loss	P11 Weight loss	.M="Missing" .N="Not Applicable" 0="Not at all" 1="Slightly" 2="Moderately" 3="Quite a bit" 4="Extremely" 9="Missing/blank/NA"

Section 6: Blood Chemisty

Variable	Label	Description	Format Text
blood_chem_alk_phos1-2	Alkaline Phosphatase - Result (U/L)	Result in U/L	Num .M="Missing" .N="Not Applicable"
blood_chem_alk_phos_or1-2	Alkaline Phosphatase - Out Of Range?	Out of Range?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_alk_phos_or_sig1-2	Alkaline Phosphatase - If Out Of Range, Is It Clinically Significant?	If out of range, is it clinically significant?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_bilirubin1-2	Total Bilirubin - Result (mg/dL)	Result in mg/dL	Num .M="Missing" .N="Not Applicable"
blood_chem_bilirubin_or1-2	Total Bilirubin - Out Of Range?	Out of Range?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_bilirubin_or_sig1-2	Total Bilirubin - If Out Of Range, Is It Clinically Significant?	If out of range, is it clinically significant?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_bun1-2	Bun - Result (mg/dL)	Result in mg/dL	Num .M="Missing" .N="Not Applicable"
blood_chem_bun_or1-2	Bun - Out Of Range?	Out of Range?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_bun_or_sig1-2	Bun - If Out Of Range, Is It Clinically Significant?	If out of range, is it clinically significant?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_comments1-2	Blood Chemistry Comments	Comments	Char
blood_chem_creatine1-2	Creatinine - Result (mg/dL)	Result in mg/dL	Num .M="Missing" .N="Not Applicable"
blood_chem_creatine_or1-2	Creatinine - Out Of Range?	Out of Range?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_creatine_or_sig1-2	Creatinine - If Out Of Range, Is It Clinically Significant?	If out of range, is it clinically significant?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Variable	Label	Description	Format Text
blood_chem_date1-2	Blood Chemistry Date	Visit date	SAS Date .M="Missing" .N="Not Applicable"
blood_chem_fasting1-2	Fasting?	Fasting?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
blood_chem_num_tests	Number Of Times Blood Chemistry Was Tested	Number of times blood chemistry was tested	Num
blood_chem_oth_test_1_oor1-2	Other Test 1 - Out Of Range?	An indicator that can be set or unset in order to signal whether the result lies outside the boundaries of the reference range.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_oth_test_1_oor_sig1-2	Other Test 1 - If Out Of Range, Is It Clinically Significant?	The indicator that represents the physician's assessment of clinical significance.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_oth_test_1_res1-2	Other Test 1 - Result	Numeric result of the laboratory analysis expressed as a number of 12 digits total, with 5 after the decimal.	Num .M="Missing" .N="Not Applicable"
blood_chem_oth_test_1_type1-2	Other Test 1 - Specify Other Test	Name of one optional lab test performed for patient assessment	.M="Missing" .N="Not Applicable" 1="Albumin, Plasma" 2="Anion Gap or Anion Gap (calc)" 3="Glucose" 4="Total Protein" 5="Sodium" 6="Glucose, Plasma" 7="Chloride, Plasma" 8="Carbon Dioxide" 9="Calcium"
blood_chem_oth_test_1_unit1-2	Other Test 1 - Units	The code that represents the unit of measure for the laboratory test result.	.M="Missing" .N="Not Applicable" 1="mg/dL" 2="MMOL/L" 3="meq/L" 4="g/dL"
blood_chem_oth_test_2_oor1-2	Other Test 2 - Out Of Range?	An indicator that can be set or unset in order to signal whether the result lies outside the boundaries of the reference range.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_oth_test_2_oor_sig1-2	Other Test 2 - If Out Of Range, Is It Clinically Significant?	The indicator that represents the physician's assessment of clinical significance.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_oth_test_2_res1-2	Other Test 2 - Result	Numeric result of the laboratory analysis expressed as a number of 12 digits total, with 5 after the decimal.	Num .M="Missing" .N="Not Applicable"

Variable	Label	Description	Format Text
blood_chem_oth_test_2_type1-2	Other Test 2 - Specify Other Test	Name of one optional lab test performed for patient assessment	.M="Missing" .N="Not Applicable" 1="Albumin, Plasma" 2="Anion Gap or Anion Gap (calc)" 3="Glucose" 4="Total Protein"
blood_chem_oth_test_2_unit1-2	Other Test 2 - Units	The code that represents the unit of measure for the laboratory test result.	.M="Missing" .N="Not Applicable" 1="mg/dL" 2="MMOL/L" 3="meq/L" 4="g/dL"
blood_chem_oth_test_3_oor1-2	Other Test 3 - Out Of Range?	An indicator that can be set or unset in order to signal whether the result lies outside the boundaries of the reference range.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_oth_test_3_oor_sig1-2	Other Test 3 - If Out Of Range, Is It Clinically Significant?	The indicator that represents the physician's assessment of clinical significance.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_oth_test_3_res1-2	Other Test 3 - Result	Numeric result of the laboratory analysis expressed as a number of 12 digits total, with 5 after the decimal.	Num .M="Missing" .N="Not Applicable"
blood_chem_oth_test_3_type1-2	Other Test 3 - Specify Other Test	Name of one optional lab test performed for patient assessment	.M="Missing" .N="Not Applicable" 1="Albumin, Plasma" 2="Anion Gap or Anion Gap (calc)" 3="Glucose" 4="Total Protein"
blood_chem_oth_test_3_unit1-2	Other Test 3 - Units	The code that represents the unit of measure for the laboratory test result.	.M="Missing" .N="Not Applicable" 1="mg/dL" 2="MMOL/L" 3="meq/L" 4="g/dL"
blood_chem_sgot_ast1-2	Sgot/Ast - Result (U/L)	Result in U/L	Num .M="Missing" .N="Not Applicable"
blood_chem_sgot_ast_or1-2	Sgot/Ast - Out Of Range?	Out of Range?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_sgot_ast_or_sig1-2	Sgot/Ast - If Out Of Range, Is It Clinically Significant?	If out of range, is it clinically significant?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_sgp_alt1-2	Sgp/Alt - Result (U/L)	Result in U/L	Num .M="Missing" .N="Not Applicable"

Variable	Label	Description	Format Text
blood_chem_sgp_alt_oor 1-2	Sgp/Alt - Out Of Range?	Out of Range?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
blood_chem_sgp_alt_oor _sig1-2	Sgp/Alt - If Out Of Range, Is It Clinically Significant?	If out of range, is it clinically significant?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Section 7: Breast Cup Size

Variable	Label	Description	Format Text
breast_cup_size	Breast Cup/Bust Size Verbatim	the free text field for general notes.	Char
breast_measure_comments	Breast Measurement Comments	Single or multiple letters referring to the size and volume of a breast, usually in reference to sizing a brassiere or undergarment.	Char
breast_measure_date	Breast Measurement Date	The date of the visit.	SAS Date .M="Missing" .N="Not Applicable"

Section 8: Conmed

Variable	Label	Description	Format Text
conmed1-9	Concomitant Medication Name	The name that describes the concomitant medication.	Char
conmed_comments1-9	Concomitant Medication Comments	the free text field for general notes.	Char
conmed_continuing1-9	Is The Participant Still Taking The Medication?	The indicator that describes if concomitant medication was continued.	.N="Not Applicable" 0="No" 1="Yes"
conmed_dose1-9	Concomitant Medication Dose	the numeric value for the amount of a medication which a patient is taking that is not part of protocol treatment.	Num .M="Missing" .N="Not Applicable"
conmed_freq1-9	Concomitant Medication Frequency	The number of occurrences of the concomitant medicine administered within a given time period.	.M="Missing" .N="Not Applicable" 1="BID" 2="OTH" 3="PRN" 4="Q6H" 5="Q8H" 6="QD" 7="QID" 8="TID" 9="4 times a day x 90 days" 10="Patient took one pill for one day" 11="As needed"
conmed_num_medications	Number Of Concomitant Medications Reported	Number of concomitant medications reported	Num
conmed_report_dt1-9	Concomitant Medication Reported Date	The date the concomitant medication was reported.	SAS Date .N="Not Applicable"
conmed_start_dt1-9	Concomitant Medication Started Date	The date the participant began taking the concomitant medication.	SAS Date .M="Missing" .N="Not Applicable"
conmed_stop_dt1-9	Concomitant Medication Ended Date	The date the participant stopped taking the concomitant medication.	SAS Date .N="Not Applicable"
conmed_units1-9	Concomitant Medication Units	All codes that represent dosage units of measure.	.M="Missing" .N="Not Applicable" 1="Oth" 2="Units" 3="Unk" 4="iu" 5="mg" 6="1 cap" 7="Oral Capsule" 8="Oral Tablet"
conmed_units_other1-9	Concomitant Medication Units Other Specifyh	The text that describes the dosage unit of measure.	.N="Not Applicable" 1="1 capsule/tablet"

Variable	Label	Description	Format Text
taking_conmed1-9	Was The Patient Taking Any Concomitant Medications?	the yes/no/unknown indicator to ask if a patient is taking any medication that is not part of protocol treatment (including medication prescribed for other medical conditions).	.N="Not Applicable" 0="No" 1="Yes"

Section 9: Eligibility

Variable	Label	Description	Format Text
eligibility_visit_date	Eligibility Date	Visit date	SAS Date .N="Not Applicable"
eligible	Is This Participant Eligible For Inclusion On This Protocol?	Is this participant eligible for inclusion on this protocol?	0="No" 1="Yes"

Section 10: Enrollement

Variable	Label	Description	Format Text
enrollment_agent_start_dt	Enrollment Agent Start Date	The start date for the administration of the intervention.	SAS Date .M="Missing" .N="Not Applicable"
enrollment_comments	Enrollment Comments	the free text field for general notes.	Char
enrollment_rand_dt	Enrollment Randomization Date	Date of a process used in therapeutic trials or other research endeavors for allocating experimental subjects, human or animal, between treatment and control groups, or among treatment groups.	SAS Date .N="Not Applicable"
enrollment_reg_dt	Enrollment Registration Date	Registration Date - The date the patient was enrolled on the protocol Enrollment Date - The date the participant is accepted into the study. The study site may also be notified to the treatment arm and Study Participant Identifier on this date.	SAS Date .N="Not Applicable"
enrollment_visit_dt	Enrollment Visit Date	The date of the visit.	SAS Date .N="Not Applicable"

Section 11: Hormone Regimen

Variable	Label	Description	Format Text
hormone_comments1-2	Hormone Comments	the free text field for general notes.	Char
hormone_contrac_phase1-2	If Contraceptive: Hormone Treatment Phase At Time Of Tissue Collection	Contraceptive hormone treatment phases at which tissue is collected.	.M="Missing" .N="Not Applicable" 1="Active Phase"
hormone_name1-2	Hormone Name	the name of the hormone therapy agent	Char
hormone_num_forms	Number Of Times Hormone Regimen Form Was Filled Out (1 Per Hormone Regimen)	Number of times hormone regimen form was filled out (1 per hormone regimen)	Num
hormone_postmen_phase1-2	If Postmenopausal: Hormone Treatment Phase At Time Of Tissue Collection	Postmenopausal hormone treatment phases at which tissue is collected	.M="Missing" .N="Not Applicable" 1="Not Cyclical"
hormone_tissue_colect_dt1-2	Hormone Tissue Collection Date	The date of the visit.	SAS Date .N="Not Applicable"
hormone_type1-2	Hormone Treatment Type	the type of current hormone therapy administered.	.N="Not Applicable" 1="Contraceptive" 2="Postmenopausal"

Section 12: Consent Form

Variable	Label	Description	Format Text
consent_date1-2	Consent Date	The date on which the patient/participant/legal representative agrees OR disagrees to participation in a protocol, treatment, or other activity by signing an informed consent document	SAS Date .N="Not Applicable"
consent_form_ver_date1-2	Consent Form Version Date	the date of the consent form version.	SAS Date .N="Not Applicable"
consent_form_version1-2	Consent Form Version	The version of the consent document in which the patient acknowledged participation on the protocol by signing the document.	Num .N="Not Applicable"
consent_IRB_approve_date1-2	Consent Form Irb Approval Start Date	The date the Central Institutional Review Board (CIRB) approved the document.	SAS Date .N="Not Applicable"
consent_num_forms_filled	Number Of Informed Consent Forms Completed	Number of informed consent forms completed	Num
consent_sample1-2	Did Participant Agree That Samples And Related Information May Be Kept In A Biobank For Use In Future Health Research?	The yes/no indicator for information related to a patient's consent to provide specimen(s) for future research and storage in a Biobank.	.N="Not Applicable" 0="No" 1="Yes"
consent_type1-2	Consent Type	An identifier specifying the type of consent document reviewed and/or approved, referencing a clinical study, specimen collection, or other research activity of which the candidate participant has been informed of the relevant medical facts and the risks involved.	.N="Not Applicable" 1="Study Participation"

Section 13: Mastectomy Grossing

Variable	Label	Description	Format Text
mast_date1-2	Mastectomy Date	The date of the visit.	SAS Date .N="Not Applicable"
mast_numBreastsBiopsied	Number Of Breasts Biopsied	Number of breasts biopsied	Num
mast_right_left1-2	Mastectomy: Right Or Left Breast	Side on which a mastectomy was performed.	.N="Not Applicable" 1="Left" 2="Right"
mast_tumescence_used1-2	Mastectomy: Tumescence Used	An indication whether a procedure is applied to make tissue to become swollen	.N="Not Applicable" 0="No" 1="Yes"
specimen_avg_slice_thickness1-2	Average Slice Thickness (mm)	Numeric value to describe the thickness of a slice to tissue taken from a biospecimen, measured in microns.	Num .N="Not Applicable"
specimen_height1-2	Specimen Height (cm)	The response regarding the vertical measurement or distance from the base to the top of a specimen that has been surgically resected.	Num .N="Not Applicable"
specimen_length1-2	Specimen Length (cm)	the linear extent or length of a the section of tissue surgically removed.	Num .N="Not Applicable"
specimen_num_slices1-2	Number Of Slices	Value to identify the number of 1 cm slices made from a specimen	Num .N="Not Applicable"
specimen_s1_a_deep_distance1-2	Specimen Sample 1 (Slice A): Distance From Deep Surface (cm)	A response for questions capturing the measured distance from the lesion to the deep surface	Num .N="Not Applicable"
specimen_s1_a_drug_weight1-2	Specimen Sample 1 (Slice A): Weight Of Drug Sample (mg)	Drug sample weight	Num .N="Not Applicable"
specimen_s1_a_hist_weight1-2	Specimen Sample 1 (Slice A): Weight Of Histology Sample (mg)	a numeric measure in grams for the weight of a sample of tissue or body fluid collected during an operative procedure.	Num .N="Not Applicable"
specimen_s1_a_nipple_distance1-2	Specimen Sample 1 (Slice A): Distance From Nipple (cm)	A response for questions capturing the measured distance from the lesion to the nipple in millimeters.	Num .N="Not Applicable"
specimen_s1_a_superficial_distance1-2	Specimen Sample 1 (Slice A): Distance From Superficial Surface (cm)	A response for questions capturing the measured distance from the lesion to the superficial surface	Num .N="Not Applicable"
specimen_s2_a_deep_distance1-2	Specimen Sample 2 (Slice A): Distance From Deep Surface (cm)	A response for questions capturing the measured distance from the lesion to the deep surface	Num .N="Not Applicable"
specimen_s2_a_drug_weight1-2	Specimen Sample 2 (Slice A): Weight Of Drug Sample (mg)	Drug sample weight	Num .N="Not Applicable"

Variable	Label	Description	Format Text
specimen_s2_a_hist_wgh t1-2	Specimen Sample 2 (Slice A): Weight Of Histology Sample (mg)	a numeric measure in grams for the weight of a sample of tissue or body fluid collected during an operative procedure.	Num .N="Not Applicable"
specimen_s2_a_nip_dist 1-2	Specimen Sample 2 (Slice A): Distance From Nipple (cm)	A response for questions capturing the measured distance from the lesion to the nipple in millimeters.	Num .N="Not Applicable"
specimen_s2_a_sup_dist 1-2	Specimen Sample 2 (Slice A): Distance From Superficial Surface (cm)	A response for questions capturing the measured distance from the lesion to the superficial surface	Num .N="Not Applicable"
specimen_s3_b_deep_di st1-2	Specimen Sample 3 (Slice B): Distance From Deep Surface (cm)	A response for questions capturing the measured distance from the lesion to the deep surface	Num .N="Not Applicable"
specimen_s3_b_drg_wgh t1-2	Specimen Sample 3 (Slice B): Weight Of Drug Sample (mg)	Drug sample weight	Num .N="Not Applicable"
specimen_s3_b_hist_wg ht1-2	Specimen Sample 3 (Slice B): Weight Of Histology Sample (mg)	a numeric measure in grams for the weight of a sample of tissue or body fluid collected during an operative procedure.	Num .N="Not Applicable"
specimen_s3_b_nip_dist 1-2	Specimen Sample 3 (Slice B): Distance From Nipple (cm)	A response for questions capturing the measured distance from the lesion to the nipple in millimeters.	Num .N="Not Applicable"
specimen_s3_b_sup_dist 1-2	Specimen Sample 3 (Slice B): Distance From Superficial Surface (cm)	A response for questions capturing the measured distance from the lesion to the superficial surface	Num .N="Not Applicable"
specimen_s4_b_deep_di st1-2	Specimen Sample 4 (Slice B): Distance From Deep Surface (cm)	A response for questions capturing the measured distance from the lesion to the deep surface	Num .N="Not Applicable"
specimen_s4_b_drg_wgh t1-2	Specimen Sample 4 (Slice B): Weight Of Drug Sample (mg)	Drug sample weight	Num .N="Not Applicable"
specimen_s4_b_hist_wg ht1-2	Specimen Sample 4 (Slice B): Weight Of Histology Sample (mg)	a numeric measure in grams for the weight of a sample of tissue or body fluid collected during an operative procedure.	Num .N="Not Applicable"
specimen_s4_b_nip_dist 1-2	Specimen Sample 4 (Slice B): Distance From Nipple (cm)	A response for questions capturing the measured distance from the lesion to the nipple in millimeters.	Num .N="Not Applicable"
specimen_s4_b_sup_dist 1-2	Specimen Sample 4 (Slice B): Distance From Superficial Surface (cm)	A response for questions capturing the measured distance from the lesion to the superficial surface	Num .N="Not Applicable"
specimen_s5_c_deep_dis t1-2	Specimen Sample 5 (Slice C): Distance From Deep Surface (cm)	A response for questions capturing the measured distance from the lesion to the deep surface	Num .N="Not Applicable"
specimen_s5_c_drg_wgh t1-2	Specimen Sample 5 (Slice C): Weight Of Drug Sample (mg)	Drug sample weight	Num .N="Not Applicable"
specimen_s5_c_hist_wgh t1-2	Specimen Sample 5 (Slice C): Weight Of Histology Sample (mg)	a numeric measure in grams for the weight of a sample of tissue or body fluid collected during an operative procedure.	Num .N="Not Applicable"

Variable	Label	Description	Format Text
specimen_s5_c_nip_dist1-2	Specimen Sample 5 (Slice C): Distance From Nipple (cm)	A response for questions capturing the measured distance from the lesion to the nipple in millimeters.	Num .N="Not Applicable"
specimen_s5_c_sup_dist1-2	Specimen Sample 5 (Slice C): Distance From Superficial Surface (cm)	A response for questions capturing the measured distance from the lesion to the superficial surface	Num .N="Not Applicable"
specimen_s6_deep_dist1-2	Specimen Sample 6 (Tumor): Distance From Deep Surface (cm)	A response for questions capturing the measured distance from the lesion to the deep surface	Num .N="Not Applicable"
specimen_s6_drg_wght1-2	Specimen Sample 6 (Tumor): Weight Of Drug Sample (mg)	Drug sample weight	Num .N="Not Applicable"
specimen_s6_hist_wght1-2	Specimen Sample 6 (Tumor): Weight Of Histology Sample (mg)	a numeric measure in grams for the weight of a sample of tissue or body fluid collected during an operative procedure.	Num .N="Not Applicable"
specimen_s6_nip_dist1-2	Specimen Sample 6 (Tumor): Distance From Nipple (cm)	A response for questions capturing the measured distance from the lesion to the nipple in millimeters.	Num .N="Not Applicable"
specimen_s6_sup_dist1-2	Specimen Sample 6 (Tumor): Distance From Superficial Surface (cm)	A response for questions capturing the measured distance from the lesion to the superficial surface	Num .N="Not Applicable"
specimen_s7_deep_dist1-2	Specimen Sample 7 (Lymph Node): Distance From Deep Surface (cm)	A response for questions capturing the measured distance from the lesion to the deep surface	Num .N="Not Applicable"
specimen_s7_drg_wght1-2	Specimen Sample 7 (Lymph Node): Weight Of Drug Sample (mg)	Drug sample weight	Num .N="Not Applicable"
specimen_s7_hist_wght1-2	Specimen Sample 7 (Lymph Node): Weight Of Histology Sample (mg)	a numeric measure in grams for the weight of a sample of tissue or body fluid collected during an operative procedure.	Num .N="Not Applicable"
specimen_s7_nip_dist1-2	Specimen Sample 7 (Lymph Node): Distance From Nipple (cm)	A response for questions capturing the measured distance from the lesion to the nipple in millimeters.	Num .N="Not Applicable"
specimen_s7_sup_dist1-2	Specimen Sample 7 (Lymph Node): Distance From Superficial Surface (cm)	A response for questions capturing the measured distance from the lesion to the superficial surface	Num .N="Not Applicable"
specimen_slice_a_num1-2	Slice A Number	Unique identifier for a specimen slice referenced by the dimensional cutting pattern.	Num .N="Not Applicable"
specimen_slice_b_num1-2	Slice B Number	Unique identifier for a specimen slice referenced by the dimensional cutting pattern.	Num .N="Not Applicable"
specimen_slice_c_num1-2	Slice C Number	Unique identifier for a specimen slice referenced by the dimensional cutting pattern.	Num .N="Not Applicable"
specimen_weight1-2	Specimen Weight	A numeric measure in grams for the weight of a sample of tissue or body fluid collected during an operative procedure.	Num .N="Not Applicable"

Variable	Label	Description	Format Text
specimen_width1-2	Specimen Width (cm)	The response regarding the width of a tissue specimen that has been surgically removed.	Num .N="Not Applicable"

Section 14: Medical History

Variable	Label	Description	Format Text
medhist_breast_comments_v1-2	Medical History: Breasts Comments	Breasts: Comments (required if abnormal)	Char
medhist_breast_v1-2	Medical History: Breasts	Breasts	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"
medhist_cardio_comments_v1-2	Medical History: Cardiovascular Comments	Cardiovascular: Comments (required if abnormal)	Char
medhist_cardio_v1-2	Medical History: Cardiovascular	Cardiovascular	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"
medhist_date_v1-2	Medical History Visit Date	Visit date	SAS Date .N="Not Applicable"
medhist_derma_comments_v1-2	Medical History: Dermatologic Comments	Dermatologic: Comments (required if abnormal)	Char
medhist_derma_v1-2	Medical History: Dermatologic	Dermatologic	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"
medhist_endo_comments_v1-2	Medical History: Endocrine/Metabolic Comments	Endocrine/Metabolic: Comments (required if abnormal)	Char
medhist_endo_v1-2	Medical History: Endocrine/Metabolic	Endocrine/Metabolic	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"
medhist_gastro_comments_v1-2	Medical History: Gastrointestinal Comments	Gastrointestinal: Comments (required if abnormal)	Char
medhist_gastro_v1-2	Medical History: Gastrointestinal	Gastrointestinal	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"
medhist_genit_comments_v1-2	Medical History: Genitourinary Comments	Genitourinary: Comments (required if abnormal)	Char
medhist_genit_v1-2	Medical History: Genitourinary	Genitourinary	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"
medhist_heent_comments_v1-2	Medical History: H/E/E/N/T Comments	H/E/E/N/T: Comments (required if abnormal)	Char
medhist_heent_v1-2	Medical History: H/E/E/N/T	H/E/E/N/T	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"

Variable	Label	Description	Format Text
medhist_hema_lymph_comments_v1-2	Medical History: Hematopoietic/Lymph Comments	Hematopoietic/Lymph: Comments (required if abnormal)	Char
medhist_hema_lymph_v1-2	Medical History: Hematopoietic/Lymph	Hematopoietic/Lymph	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"
medhist_muscskel_comments_v1-2	Medical History: Musculoskeletal Comments	Musculoskeletal: Comments (required if abnormal)	Char
medhist_muscskel_v1-2	Medical History: Musculoskeletal	Musculoskeletal	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"
medhist_neck_comments_v1-2	Medical History: Neck Comments	Neck: Comments (required if abnormal)	Char
medhist_neck_v1-2	Medical History: Neck	Neck	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"
medhist_neuro_comments_v1-2	Medical History: Neurologic Comments	Neurologic: Comments (required if abnormal)	Char
medhist_neuro_v1-2	Medical History: Neurologic	Neurologic	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"
medhist_num_visits	Number Of Visits With A Medical History Filled Out	Number of visits with a medical history filled out	Num
medhist_respiratory_comments_v1-2	Medical History: Respiratory Comments	Respiratory: Comments (required if abnormal)	Char
medhist_respiratory_v1-2	Medical History: Respiratory	Respiratory	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Assessed"

Section 15: Menopausal Status

Variable	Label	Description	Format Text
meno_comments	Menopause Status: Comments	the free text field for general notes.	Char
meno_has_ovary	Does The Participant Have At Least One Ovary?	the yes/no indicator whether one of the paired female reproductive glands containing the ova or germ cells is present.	.N="Not Applicable" 0="No" 1="Yes"
meno_hyster	Did The Patient Have A Hysterectomy?	the yes/no/unknown indicator that asks whether the patient had a hysterectomy.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
meno_last_period_6months_date	Date Of Last Menstrual Period (If Participant Had Period In Last 6 Months)	the date of the last period from onset of one menstrual bleeding (menstruation) to the next in an ovulating woman.	SAS Date .M="Missing" .N="Not Applicable"
meno_last_period_spont_date	Date Of Last Menstrual Period (If The Period Stopped Spontaneously)	the date of the last period from onset of one menstrual bleeding (menstruation) to the next in an ovulating woman.	SAS Date .M="Missing" .N="Not Applicable"
meno_over_55	Participant Over The Age Of 55?	the yes/no indicator that asks about the patient/participant's age.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
meno_period_6months	Has The Participant Had A Period In The Last 6 Months?	The yes/no response regarding whether the patient has had a menstrual cycle (sloughing of the endometrium in the absence of fertilization) within the past 6 months.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
meno_period_stop_spont	Did The Period Stop Spontaneously?	Determination of whether or not participant's menstrual periods have stopped	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
meno_stat	Menopause Status	the menopausal status of the patient/participant.	.N="Not Applicable" 1="Postmenopausal" 2="Premenopausal"
meno_stat_date	Menopause Status Visit Date	The date of the visit.	SAS Date .N="Not Applicable"
meno_why_period_stop	If No Hysterectomy, What Is The Reason For Stopping Periods?	Explanation of why menstrual periods ceased.	Char

Section 16: Menstruation

Variable	Label	Description	Format Text
menst_comments_v1-6	Menstruation: Other, Please Specify	An identifier used to describe a response other than one previously mentioned.	Char
menst_date_v1-6	Menstruation Questionnaire Date	The date of the visit.	SAS Date .N="Not Applicable"
menst_last_date_v1-6	Last Menstrual Period Date	The date of the last period from onset of one menstrual bleeding (menstruation) to the next in an ovulating woman.	SAS Date .M="Missing" .N="Not Applicable"
menst_num_visits	Number Of Visits Where A Menstruation Form Was Filled Out	Number of visits where a menstruation form was filled out	Num
menst_reason_no_last_date_v1-6	If No Last Menstrual Period Date, Specify Why	The response regarding the reason why the status of a patient's menstrual cycle was not reported.	.N="Not Applicable" 1="Information not obtainable" 2="Participant did not have period" 3="Other, please specify"

Section 17: Off Study

Variable	Label	Description	Format Text
off_study_agent_end_date	Agent End Date	The end date for the administration of the intervention.	SAS Date .M="Missing"
off_study_comments	Off Study: Comments	the free text field for general notes.	Char
off_study_last_cont_date	Date Of Last Contact	The date the participant was last seen or spoken to.	SAS Date
off_study_off_date	Date Off Study	The date when the patient/participant is removed from the protocol, i.e., is not being followed and will not be retreated.	SAS Date
off_study_other_spec	Reason Off Study Other, Specify	The text that describes the reason the participant went off study.	Char
off_study_reason	Reason Off Study	Choice of reasons for removing a patient/participant from a clinical trial.	1="Study Complete" 2="Adverse Event" 3="Ineligible" 4="Participant Withdrawal" 5="Physician Decision" 6="Other, specify"

Section 18: Participan Contact

Variable	Label	Description	Format Text
contact_ae_reported1-7	Did The Participant Report Any Symptoms Or Adverse Events?	A yes/no question that asks whether the participant reported any symptoms or adverse events.	Num .M="Missing" .N="Not Applicable" 0="No" 1="Yes (complete AE)" 2="Too early to evaluate"
contact_comments1-7	Contact Comments	the free text field for general notes.	Char
contact_compliant1-7	Is The Participant Compliant With Protocol Intervention Per Telephone Conversation Or Email?	The indicator that represents whether the participant was compliant with the protocol intervention.	Num .M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
contact_cont_reminders1-7	Does The Participant Want To Continue To Receive Email Or Text Message Reminders?	The yes/no/NA indicator related to patient contact consent.	Num .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
contact_cont_spec1-7	If Yes Please Specify Which Form Of Contact	Means by which an individual is contacted: e.g. phone, email, fax, address, etc.	Num .M="Missing" .N="Not Applicable" 1="Email" 2="Text"
contact_date1-7	Date Of Attempted Contact	The date the participant was contacted by the telephone.	SAS Date .M="Missing" .N="Not Applicable"
contact_med_changes1-7	Were Any Changes In Concomitant Medications Reported? Either New Medications Started Or Previous Medications Stopped?	A question that asks whether the participant reported any changes on concomitant medications.	Num .M="Missing" .N="Not Applicable" 0="No" 1="Yes (complete ConMed form)"
contact_num_attempts	Total Number Of Contact Attempts	Total number of contact attempts	Num
contact_result1-7	Contact Result	Means through which a patient/participant or family is contacted for follow-up or survival information.	Num .M="Missing" .N="Not Applicable" 1="Email contact with participant" 2="Left voicemail message" 3="Mobile text contact with participant" 4="No contact made (end this form; do not complete remaining questions)" 5="Spoke to family member" 6="Spoke to participant"

Variable	Label	Description	Format Text
contact_type1-7	Method Of Attempted Contact	Means by which an individual is contacted: e.g. phone, email, fax, address, etc.	Num .M="Missing" .N="Not Applicable" 1="Cell Phone" 2="Home Phone" 3="Work Phone" 4="Email"

Section 19: Participant Diary

Variable	Label	Description	Format Text
diary_comments	Participant Diary Comments	Comments	Char
diary_end_date	Participant Diary Last Date	End date of documents uploaded	SAS Date .N="Not Applicable"
diary_start_date	Participant Diary First Date	Start date of documents uploaded	SAS Date .N="Not Applicable"

Section 20: Physical Exam

Variable	Label	Description	Format Text
phys_ex_ab_comments_v1-3	Physical Exam Comments: Abdomen	Abdomen: Comments (required if abnormal)	Char
phys_ex_ab_v1-3	Physical Exam: Abdomen	Abdomen	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_appear_comments_v1-3	Physical Exam Comments: Appearance	Appearance: Comments (required if abnormal)	Char
phys_ex_appear_v1-3	Physical Exam: Appearance	Appearance	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_breast_comments_v1-3	Physical Exam Comments: Breasts	Breasts: Comments (required if abnormal)	Char
phys_ex_breast_v1-3	Physical Exam: Breasts	Breasts	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_chest_comments_v1-3	Physical Exam Comments: Chest	Chest: Comments (required if abnormal)	Char
phys_ex_chest_v1-3	Physical Exam: Chest	Chest	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_genital_comments_v1-3	Physical Exam Comments: Genitals	Genitalia: Comments (required if abnormal)	Char
phys_ex_genital_v1-3	Physical Exam: Genitals	Genitalia	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_heart_comments_v1-3	Physical Exam Comments: Heart	Heart: Comments (required if abnormal)	Char
phys_ex_heart_v1-3	Physical Exam: Heart	Heart	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_heent_comments_v1-3	Physical Exam Comments: H E E N T	H/E/E/N/T: Comments (required if abnormal)	Char
phys_ex_heent_v1-3	Physical Exam: H E E N T	H/E/E/N/T	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_lung_comments_v1-3	Physical Exam Comments: Lungs	Lungs: Comments (required if abnormal)	Char

Variable	Label	Description	Format Text
phys_ex_lung_v1-3	Physical Exam: Lungs	Lungs	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_lymph_comments_v1-3	Physical Exam Comments: Lymph Nodes	Lymph Nodes: Comments (required if abnormal)	Char
phys_ex_lymph_v1-3	Physical Exam: Lymph Nodes	Lymph Nodes	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_muscle_comments_v1-3	Physical Exam Comments: Musculoskeletal	Musculoskeletal: Comments (required if abnormal)	Char
phys_ex_muscle_v1-3	Physical Exam: Musculoskeletal	Musculoskeletal	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_neuro_comments_v1-3	Physical Exam Comments: Neurological	Neurological: Comments (required if abnormal)	Char
phys_ex_neuro_v1-3	Physical Exam: Neurological	Neurological	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_num_visits	Number Of Physical Exam Visits	Number of physical exam visits	Num
phys_ex_other_body_v1-3	Physical Exam: Other Body System	The text that describes the other specific organ system or body site.	Char
phys_ex_other_comments_v1-3	Physical Exam Comments: Other	Specify other body system/site: Comments (required if abnormal)	Char
phys_ex_other_v1-3	Physical Exam: Other	Other body system/site	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_pelvis_comments_v1-3	Physical Exam Comments: Pelvis	Pelvis: Comments (required if abnormal)	Char
phys_ex_pelvis_v1-3	Physical Exam: Pelvis	Pelvis	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_rectal_comments_v1-3	Physical Exam Comments: Rectal	Rectal: Comments (required if abnormal)	Char
phys_ex_rectal_v1-3	Physical Exam: Rectal	Rectal	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_skin_comments_v1-3	Physical Exam Comments: Skin	Skin: Comments (required if abnormal)	Char
phys_ex_skin_v1-3	Physical Exam: Skin	Skin	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_thyroid_comments_v1-3	Physical Exam Comments: Thyroid	Thyroid: Comments (required if abnormal)	Char

Variable	Label	Description	Format Text
phys_ex_thyroid_v1-3	Physical Exam: Thyroid	Thyroid	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
phys_ex_vascu_comments_v1-3	Physical Exam Comments: Vascular	Vascular: Comments (required if abnormal)	Char
phys_ex_vascu_v1-3	Physical Exam: Vascular	Vascular	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
physical_exam_date_v1-3	Physical Exam Date	Visit date	SAS Date .N="Not Applicable"

Section 21: Pre-Enrollment

Variable	Label	Description	Format Text
age_at_screening	Participant Age At Screening Visit 1 From Month Of Birth	Participant age at screening visit 1 from month of birth	Num
country	Participant Country	The code that represents the country where the addressee is located.	1="USA"
ethnicity	Participant Ethnicity	The text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories.	1="Hispanic or Latino" 2="Not Hispanic or Latino" 9="Not Reported"
gender	Participant Gender	Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles [Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.	1="Female"
preenrl_biopsy_laterality	Laterality Of Research Core Biopsy	The designation to identify a side of body from which a sample of tissue from the mammary organs was obtained for microscopic examination by a specialist in cellular function and changes.	.N="Not Applicable" 1="Left" 2="Right"
preenrl_comments	Comments	The free text field for general notes.	Char
preenrl_fail_reason	If No, Specify Primary Reason For Screen Failure	Text explanations the failure of an individual to meet screen requirements for a clinical trial.	.N="Not Applicable" 1="Did not meet eligibility criteria"
preenrl_has_breast_tumor	Does This Participant Have A Breast Tumor?	The preferred yes/no response to indicate if a carcinoma arising from the breast is present.	0="No" 1="Yes"
preenrl_has_screen_2_visit	Does This Participant Have A Screen 2 Visit?	An indication whether a participant has a second screen visit.	0="No" 1="Yes"
preenrl_institution	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in a clinical trial.	Char
preenrl_meet_req	Does This Participant Meet All Screening Criteria?	the yes/no/unknown indicator that asks the investigator to stipulate whether the patient is eligible for inclusion on this protocol.	0="No" 1="Yes"
preenrl_method_payment	Method Of Payment	Method of Payment	1="Managed Care/Medicare" 2="Private Insurance" 3="Medicare" 4="Medicare and Private Insurance" 5="Medicaid"

Variable	Label	Description	Format Text
preenrl_screen_1_date	Screen 1 Date	Date of an evaluation or assessment of an individual's eligibility to enter a clinical trial.	SAS Date
preenrl_screen_2_date	Screen 2 Date	Date of an evaluation or assessment of an individual's eligibility to enter a clinical trial.	SAS Date .N="Not Applicable"
race	Participant Race	The text for reporting information about race based on the Office of Management and Budget (OMB) categories.	1="White" 2="Black or African American" 3="Asian" 8="Unkown" 9="Not Reported"

Section 22: Pregnancy Test

Variable	Label	Description	Format Text
preg_test_comments_v1-3	Pregnancy Test Comments	The free text field for general notes.	Char
preg_test_num_tests	Number Of Pregnancy Tests	Number of pregnancy tests	Num
preg_test_results_v1-3	Pregnancy Test Results	The indicator pertaining to the result of a pregnancy test.	Num .N="Not Applicable" 1="Negative" 2="Not applicable, not female of child-bearing potential"
preg_test_visit_dt_v1-3	Pregnancy Test Date	The date of the visit.	SAS Date .N="Not Applicable"

Section 23: Treatment Assignment Code

Variable	Label	Description	Format Text
tactad_code1-2	Treatment Assignment Code	The date a coded value representing the start of a specific treatment has been assigned to be uniformly administered to a group of study subjects for separate statistical analysis	.N="Not Applicable" 0="TAC-0" 1="TAC1"
tactad_comments1-2	Treatment Assignment Code Comments	the free text field for general notes.	Char
tactad_num_codes	Number Of Treatment Assignment Mode	Number of treatment assignment mode	Num
tactad_start_date1-2	Treatment Assignment Code Start Date	A coded value representing a treatment assigned to be uniformly administered to a group of study subjects for separate statistical analysis.	SAS Date .N="Not Applicable"

Section 24: Timepoints

Variable	Label	Description	Format Text
tp_follow_up_comments	Time Point #5: Follow-Up Comments	Time Point #5: Follow-up comments	Char
tp_follow_up_end	Time Point #5 Follow-Up End Date	Time Point #5 Follow-Up	SAS Date .M="Missing"
tp_follow_up_start	Time Point #5 Follow-Up Start Date	Time Point #5 Follow-Up	SAS Date .M="Missing"
tp_intervention_comments	Time Point #2: Intervention Comments	Time Point #2: Intervention comments	Char
tp_intervention_end	Time Point #2 Intervention End Date	Time Point #2 Intervention	SAS Date .M="Missing"
tp_intervention_start	Time Point #2 Intervention Start Date	Time Point #2 Intervention	SAS Date .M="Missing"
tp_screening_visit_comments	Time Point #1: Screening Visits 1 And 2, Pregnancy Test Visit Comments	Time Point #1: Screening visits 1 and 2, pregnancy test visit comments	Char
tp_screening_visit_end	Time Point #1 Screening Visits 1 And 2, Pregnancy Test Visit End Date	Time Point #1 Screening Visits 1 and 2, Pregnancy Test Visit	SAS Date
tp_screening_visit_start	Time Point #1 Screening Visits 1 And 2, Pregnancy Test Visit Start Date	Time Point #1 Screening Visits 1 and 2, Pregnancy Test Visit	SAS Date .M="Missing"
tp_study_visit_1_comments	Time Point #3: Study Visit 1 Comments	Time Point #3: Study visit 1 comments	Char
tp_study_visit_1_end	Time Point #3 Study Visit 1 End Date	Time Point #3 Study Visit 1	SAS Date .M="Missing"
tp_study_visit_1_start	Time Point #3 Study Visit 1 Start Date	Time Point #3 Study Visit 1	SAS Date .M="Missing"
tp_study_visit_2_comments	Time Point #4: Study Visit 2 Comments	Time Point #4: Study visit 2 comments	Char
tp_study_visit_2_end	Time Point #4 Study Visit 2 End Date	Time Point #4 Study Visit 2	SAS Date .M="Missing"
tp_study_visit_2_start	Time Point #4 Study Visit 2 Start Date	Time Point #4 Study Visit 2	SAS Date .M="Missing"

Section 25: Tumor Characteristics - Baseline

Variable	Label	Description	Format Text
tumor_bl_comments1-3	Tumor At Baseline: Comments	The free text field for general notes.	Char
tumor_bl_date1-3	Tumor At Baseline: Visit Date	The date of the visit.	SAS Date .N="Not Applicable"
tumor_bl_estrogen1-3	Tumor At Baseline: Estrogen Receptor Status (% Pos Cells)	ER Positive results expressed as a percentage in numbers up to 3 characters with no decimal place.	Num .M="Missing" .N="Not Applicable"
tumor_bl_fish1-3	Tumor At Baseline: Fish	The results of fluorescence in situ hybridization (FISH) test.	.M="Missing" .N="Not Applicable" 1="Amplified" 2="Non-amplified" 3="Not done"
tumor_bl_her2_1-3	Tumor At Baseline: Her2 Status	The status of HER2/NEU by immunohistochemistry.	.M="Missing" .N="Not Applicable" 0="0" 1="1" 2="2" 3="3"
tumor_bl_hist1-3	Tumor At Baseline: Tumor Histology	Text term for the structural pattern of cancer cells used to define a microscopic diagnosis.	.N="Not Applicable" 1="DCIS" 2="Invasive Ductal" 3="Invasive Lobular" 4="Other, specify"
tumor_bl_hist_oth_spec1-3	Tumor At Baseline: Tumor Histology - Other Specify	The pathologic classification of the tumor not otherwise identified.	Char
tumor_bl_ki67_1-3	Tumor At Baseline: Ki 67 (% Pos Cells)	The numerical value that describes the percentage of cells staining positive for immunohistochemical assessment of Ki-67.	Num .M="Missing" .N="Not Applicable"
tumor_bl_nodal_staging1-3	Tumor At Baseline: Clinical Nodal Staging Based On Physical Exam Or Imaging	Extent of the regional lymph node involvement for the breast carcinoma based on evidence obtained from clinical assessment parameters determined prior to treatment.	.M="Missing" .N="Not Applicable" 1="No abnormal nodes" 2="Not Recorded/Unkown"
tumor_bl_num_tumors	Number Of Tumors At Baseline	Number of tumors at baseline	Num
tumor_bl_progesterone1-3	Tumor At Baseline: Progesterone Receptor Status (% Pos Cells)	Progesterone receptor level, expressed as % with numbers up to 3 characters with no decimal place.	Num .M="Missing" .N="Not Applicable"
tumor_bl_size1-3	Tumor At Baseline: Size Of Tumor At Initial Presentation (Based On Imaging Measurements)	the measurement of the primary tumor by the pathologist (For Breast Cancer use the maximum diameter of the invasive component; if multiple lesions, use the longest lesion).	Num .M="Missing" .N="Not Applicable"

Section 26: Tumor Characteristics - Surgery

Variable	Label	Description	Format Text
tumor_sur_comments1-3	Tumor At Surgery: Comments	The free text field for general notes.	Char
tumor_sur_date1-3	Tumor At Surgery: Visit Date	The date of the visit.	SAS Date .N="Not Applicable"
tumor_sur_estrogen1-3	Tumor At Surgery: Estrogen Receptor Status (% Pos Cells)	ER Positive results expressed as a percentage in numbers up to 3 characters with no decimal place.	Num .M="Missing" .N="Not Applicable"
tumor_sur_fish1-3	Tumor At Surgery: Fish	The results of fluorescence in situ hybridization (FISH) test.	.N="Not Applicable" 1="Amplified" 2="Non-amplified" 3="Not done"
tumor_sur_her2_1-3	Tumor At Surgery: Her2 Status	The status of HER2/NEU by immunohistochemistry.	.M="Missing" .N="Not Applicable" 0="0" 1="1" 2="2" 3="3"
tumor_sur_hist1-3	Tumor At Surgery: Tumor Histology	Text term for the structural pattern of cancer cells used to define a microscopic diagnosis.	.N="Not Applicable" 1="DCIS" 2="Invasive Ductal" 3="Invasive Lobular" 4="Other, specify"
tumor_sur_hist_oth_spec1-3	Tumor At Surgery: Tumor Histology - Other Specify	The pathologic classification of the tumor not otherwise identified.	Char
tumor_sur_ki67_1-3	Tumor At Surgery: Ki 67 (% Pos Cells)	The numerical value that describes the percentage of cells staining positive for immunohistochemical assessment of Ki-67.	Num .M="Missing" .N="Not Applicable"
tumor_sur_nodes_pos1-3	Tumor At Surgery: Number Of Nodes Positive	The number of lymph nodes involved with disease as determined by pathologic examination.	Num .N="Not Applicable"
tumor_sur_nodes_taken1-3	Tumor At Surgery: Number Of Nodes Taken	Numeric value for the quantity of lymph nodes removed from a person/patient.	Num .N="Not Applicable"
tumor_sur_num_tumors	Number Of Tumors At Surgery	Number of tumors at surgery	Num
tumor_sur_progesterone1-3	Tumor At Surgery: Progesterone Receptor Status (% Pos Cells)	Progesterone receptor level, expressed as % with numbers up to 3 characters with no decimal place.	Num .M="Missing" .N="Not Applicable"
tumor_sur_size1-3	Tumor At Surgery: Size Of Tumor At Surgery	The longest diameter for a tumor/lesion as determined by surgeon.	Num .M="Missing" .N="Not Applicable"

Section 27: Unblinding

Variable	Label	Description	Format Text
DCP_Protocol_Number	Dcp Protocol Number	DCP Protocol Number	Char
gel_dose	Gel Dose (mg Once A Day)	Gel Dose (mg once a Day)	Num .N="Not Applicable"
gel_type	Gel Type	Gel Type	Char
pill_dose	Caspule Dose (mg Once A Day)	Caspule Dose (mg once a Day)	Num .N="Not Applicable"
pill_type	Capsule Type	Capsule Type	Char
Registering_Consortium_Code	Registering Consortium Code	Registering Consortium Code	Char
Registering_Institution_Code	Registering Institution Code	Registering Institution Code	Char
Registering_Institution_Name	Registering Institution Name	Registering Institution Name	Char
treatment_assignment_code	Treatment Assignment Code (Tac)	Treatment Assignment Code (TAC)	Char
unblinding_comments	Unblinding Comments	Unblinding Comments	Char

Section 28: Vital Signs

Variable	Label	Description	Format Text
height_v1-3	Height (cm)	The number that describes the vertical distance of an individual.	Num .M="Missing" .N="Not Applicable"
vit_sig_bp_dias_v1-3	Blood Pressure Diastolic	The pressure of the blood against the artery walls during diastole (the relaxation phase).	Num .M="Missing" .N="Not Applicable"
vit_sig_bp_sys_v1-3	Blood Pressure Systolic	The pressure of the blood against the artery walls during systole (the contraction phase).	Num .M="Missing" .N="Not Applicable"
vit_sig_comments_v1-3	Vital Signs Comments	The free text field for general notes.	Char
vit_sig_num_visits	Number Of Times Vital Signs Taken	Number of times vital signs taken	Num
vit_sig_pulse_v1-3	Pulse	Numeric value to represent the measurement of the heart rate, which is the number of contractions (heart beats) expressed in "beats per minute" (bpm).	Num .M="Missing" .N="Not Applicable"
vit_sig_status_v1-3	Vital Signs Status	The ECOG functional performance status of the patient/participant.	.M="Missing" .N="Not Applicable" 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. Needs special assistance" 4="Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair." 5="Dead"
vit_sig_temperature_v1-3	Temperature (C)	The numeric value of a person's body temperature.	Num .M="Missing" .N="Not Applicable"
vit_sig_visit_date_v1-3	Vital Signs Visit Date	The date of the visit.	SAS Date .N="Not Applicable"

Variable	Label	Description	Format Text
weight_v1-3	Weight (kg)	The number that describes the vertical force exerted by the mass of an individual as a result of gravity.	Num .M="Missing" .N="Not Applicable"

Section 29: Gene Expression

Variable	Label	Description	Format Text
acat2_post	Endogenous Expression Of Acat2 Gene In Sample	ENDOGENOUS Expression of ACAT2 gene in sample	Num .N="Not Applicable"
acat2_pre	Endogenous Expression Of Acat2 Gene In Sample	ENDOGENOUS Expression of ACAT2 gene in sample	Num .N="Not Applicable"
adcy2_post	Endogenous Expression Of Adcy2 Gene In Sample	ENDOGENOUS Expression of ADCY2 gene in sample	Num .N="Not Applicable"
adcy2_pre	Endogenous Expression Of Adcy2 Gene In Sample	ENDOGENOUS Expression of ADCY2 gene in sample	Num .N="Not Applicable"
aspm_post	Endogenous Expression Of Aspn Gene In Sample	ENDOGENOUS Expression of ASPN gene in sample	Num .N="Not Applicable"
aspm_pre	Endogenous Expression Of Aspn Gene In Sample	ENDOGENOUS Expression of ASPN gene in sample	Num .N="Not Applicable"
atad3c_post	Endogenous Expression Of Atad3C Gene In Sample	ENDOGENOUS Expression of ATAD3C gene in sample	Num .N="Not Applicable"
atad3c_pre	Endogenous Expression Of Atad3C Gene In Sample	ENDOGENOUS Expression of ATAD3C gene in sample	Num .N="Not Applicable"
aurka_post	Endogenous Expression Of Aurka Gene In Sample	ENDOGENOUS Expression of AURKA gene in sample	Num .N="Not Applicable"
aurka_pre	Endogenous Expression Of Aurka Gene In Sample	ENDOGENOUS Expression of AURKA gene in sample	Num .N="Not Applicable"
bub1b_post	Endogenous Expression Of Bub1B Gene In Sample	ENDOGENOUS Expression of BUB1B gene in sample	Num .N="Not Applicable"
bub1b_pre	Endogenous Expression Of Bub1B Gene In Sample	ENDOGENOUS Expression of BUB1B gene in sample	Num .N="Not Applicable"
c19orf33_post	Endogenous Expression Of C19Orf33 Gene In Sample	ENDOGENOUS Expression of C19orf33 gene in sample	Num .N="Not Applicable"
c19orf33_pre	Endogenous Expression Of C19Orf33 Gene In Sample	ENDOGENOUS Expression of C19orf33 gene in sample	Num .N="Not Applicable"
cdc20_post	Endogenous Expression Of Cdc20 Gene In Sample	ENDOGENOUS Expression of CDC20 gene in sample	Num .N="Not Applicable"
cdc20_pre	Endogenous Expression Of Cdc20 Gene In Sample	ENDOGENOUS Expression of CDC20 gene in sample	Num .N="Not Applicable"
cdk1_post	Endogenous Expression Of Cdk1 Gene In Sample	ENDOGENOUS Expression of CDK1 gene in sample	Num .N="Not Applicable"
cdk1_pre	Endogenous Expression Of Cdk1 Gene In Sample	ENDOGENOUS Expression of CDK1 gene in sample	Num .N="Not Applicable"
cep55_post	Endogenous Expression Of Cep55 Gene In Sample	ENDOGENOUS Expression of CEP55 gene in sample	Num .N="Not Applicable"
cep55_pre	Endogenous Expression Of Cep55 Gene In Sample	ENDOGENOUS Expression of CEP55 gene in sample	Num .N="Not Applicable"
cybrd1_post	Endogenous Expression Of Cybrd1 Gene In Sample	ENDOGENOUS Expression of CYBRD1 gene in sample	Num .N="Not Applicable"

Variable	Label	Description	Format Text
cybrd1_pre	Endogenous Expression Of Cybrd1 Gene In Sample	ENDOGENOUS Expression of CYBRD1 gene in sample	Num .N="Not Applicable"
ect2_post	Endogenous Expression Of Ect2 Gene In Sample	ENDOGENOUS Expression of ECT2 gene in sample	Num .N="Not Applicable"
ect2_pre	Endogenous Expression Of Ect2 Gene In Sample	ENDOGENOUS Expression of ECT2 gene in sample	Num .N="Not Applicable"
erbb2_post	Endogenous Expression Of Erbb2 Gene In Sample	ENDOGENOUS Expression of ERBB2 gene in sample	Num .N="Not Applicable"
erbb2_pre	Endogenous Expression Of Erbb2 Gene In Sample	ENDOGENOUS Expression of ERBB2 gene in sample	Num .N="Not Applicable"
erbb4_post	Endogenous Expression Of Erbb4 Gene In Sample	ENDOGENOUS Expression of ERBB4 gene in sample	Num .N="Not Applicable"
erbb4_pre	Endogenous Expression Of Erbb4 Gene In Sample	ENDOGENOUS Expression of ERBB4 gene in sample	Num .N="Not Applicable"
esr1_post	Endogenous Expression Of Esr1 Gene In Sample	ENDOGENOUS Expression of ESR1 gene in sample	Num .N="Not Applicable"
esr1_pre	Endogenous Expression Of Esr1 Gene In Sample	ENDOGENOUS Expression of ESR1 gene in sample	Num .N="Not Applicable"
fads2_post	Endogenous Expression Of Fads2 Gene In Sample	ENDOGENOUS Expression of FADS2 gene in sample	Num .N="Not Applicable"
fads2_pre	Endogenous Expression Of Fads2 Gene In Sample	ENDOGENOUS Expression of FADS2 gene in sample	Num .N="Not Applicable"
gene_sample_id_post	Identifier Assigned To Sample ID	Identifier assigned to sample ID	Char
gene_sample_id_pre	Identifier Assigned To Sample ID	Identifier assigned to sample ID	Char
gpd1_post	Endogenous Expression Of Gpd1 Gene In Sample	ENDOGENOUS Expression of GPD1 gene in sample	Num .N="Not Applicable"
gpd1_pre	Endogenous Expression Of Gpd1 Gene In Sample	ENDOGENOUS Expression of GPD1 gene in sample	Num .N="Not Applicable"
grb7_post	Endogenous Expression Of Grb7 Gene In Sample	ENDOGENOUS Expression of GRB7 gene in sample	Num .N="Not Applicable"
grb7_pre	Endogenous Expression Of Grb7 Gene In Sample	ENDOGENOUS Expression of GRB7 gene in sample	Num .N="Not Applicable"
gusb_post	Housekeeping Control, Expression Of Gusb Gene In Sample	HOUSEKEEPING control, Expression of GUSB gene in sample	Num .N="Not Applicable"
gusb_pre	Housekeeping Control, Expression Of Gusb Gene In Sample	HOUSEKEEPING control, Expression of GUSB gene in sample	Num .N="Not Applicable"
hist1h3f_post	Endogenous Expression Of Hist1H3F Gene In Sample	ENDOGENOUS Expression of HIST1H3F gene in sample	Num .N="Not Applicable"
hist1h3f_pre	Endogenous Expression Of Hist1H3F Gene In Sample	ENDOGENOUS Expression of HIST1H3F gene in sample	Num .N="Not Applicable"
hist1h3g_post	Endogenous Expression Of Hist1H3G Gene In Sample	ENDOGENOUS Expression of HIST1H3G gene in sample	Num .N="Not Applicable"
hist1h3g_pre	Endogenous Expression Of Hist1H3G Gene In Sample	ENDOGENOUS Expression of HIST1H3G gene in sample	Num .N="Not Applicable"

Variable	Label	Description	Format Text
hist1h3j_post	Endogenous Expression Of Hist1H3J Gene In Sample	ENDOGENOUS Expression of HIST1H3J gene in sample	Num .N="Not Applicable"
hist1h3j_pre	Endogenous Expression Of Hist1H3J Gene In Sample	ENDOGENOUS Expression of HIST1H3J gene in sample	Num .N="Not Applicable"
hist2h3a_post	Endogenous Expression Of Hist2H3A Gene In Sample	ENDOGENOUS Expression of HIST2H3A gene in sample	Num .N="Not Applicable"
hist2h3a_pre	Endogenous Expression Of Hist2H3A Gene In Sample	ENDOGENOUS Expression of HIST2H3A gene in sample	Num .N="Not Applicable"
hist2h3c_post	Endogenous Expression Of Hist2H3C Gene In Sample	ENDOGENOUS Expression of HIST2H3C gene in sample	Num .N="Not Applicable"
hist2h3c_pre	Endogenous Expression Of Hist2H3C Gene In Sample	ENDOGENOUS Expression of HIST2H3C gene in sample	Num .N="Not Applicable"
hprt1_post	Housekeeping Control, Expression Of Hprt1 Gene In Sample	HOUSEKEEPING control, Expression of HPRT1 gene in sample	Num .N="Not Applicable"
hprt1_pre	Housekeeping Control, Expression Of Hprt1 Gene In Sample	HOUSEKEEPING control, Expression of HPRT1 gene in sample	Num .N="Not Applicable"
ifi6_post	Endogenous Expression Of Ifi6 Gene In Sample	ENDOGENOUS Expression of IFI6 gene in sample	Num .N="Not Applicable"
ifi6_pre	Endogenous Expression Of Ifi6 Gene In Sample	ENDOGENOUS Expression of IFI6 gene in sample	Num .N="Not Applicable"
isg15_post	Endogenous Expression Of Isg15 Gene In Sample	ENDOGENOUS Expression of ISG15 gene in sample	Num .N="Not Applicable"
isg15_pre	Endogenous Expression Of Isg15 Gene In Sample	ENDOGENOUS Expression of ISG15 gene in sample	Num .N="Not Applicable"
kif2c_post	Endogenous Expression Of Kif2C Gene In Sample	ENDOGENOUS Expression of KIF2C gene in sample	Num .N="Not Applicable"
kif2c_pre	Endogenous Expression Of Kif2C Gene In Sample	ENDOGENOUS Expression of KIF2C gene in sample	Num .N="Not Applicable"
kifc1_post	Endogenous Expression Of Kifc1 Gene In Sample	ENDOGENOUS Expression of KIFC1 gene in sample	Num .N="Not Applicable"
kifc1_pre	Endogenous Expression Of Kifc1 Gene In Sample	ENDOGENOUS Expression of KIFC1 gene in sample	Num .N="Not Applicable"
l1cam_post	Endogenous Expression Of L1Cam Gene In Sample	ENDOGENOUS Expression of L1CAM gene in sample	Num .N="Not Applicable"
l1cam_pre	Endogenous Expression Of L1Cam Gene In Sample	ENDOGENOUS Expression of L1CAM gene in sample	Num .N="Not Applicable"
med1_post	Endogenous Expression Of Med1 Gene In Sample	ENDOGENOUS Expression of MED1 gene in sample	Num .N="Not Applicable"
med1_pre	Endogenous Expression Of Med1 Gene In Sample	ENDOGENOUS Expression of MED1 gene in sample	Num .N="Not Applicable"
mgp_post	Endogenous Expression Of Mgp Gene In Sample	ENDOGENOUS Expression of MGP gene in sample	Num .N="Not Applicable"
mgp_pre	Endogenous Expression Of Mgp Gene In Sample	ENDOGENOUS Expression of MGP gene in sample	Num .N="Not Applicable"
mki67_post	Endogenous Expression Of Mki67 Gene In Sample	ENDOGENOUS Expression of MKI67 gene in sample	Num .N="Not Applicable"

NWU-2013-01-03 Person File

01/15/2020

Dataset: prsn

Variable	Label	Description	Format Text
mki67_pre	Endogenous Expression Of Mki67 Gene In Sample	ENDOGENOUS Expression of MKI67 gene in sample	Num .N="Not Applicable"
mybl2_post	Endogenous Expression Of Mybl2 Gene In Sample	ENDOGENOUS Expression of MYBL2 gene in sample	Num .N="Not Applicable"
mybl2_pre	Endogenous Expression Of Mybl2 Gene In Sample	ENDOGENOUS Expression of MYBL2 gene in sample	Num .N="Not Applicable"
neg_a_post	Custom Designed RNA Spike As Negative Control For Assay Quality Control A	Custom designed RNA SPIKE as negative control for assay quality control A	Num .N="Not Applicable"
neg_a_pre	Custom Designed RNA Spike As Negative Control For Assay Quality Control A	Custom designed RNA SPIKE as negative control for assay quality control A	Num .N="Not Applicable"
neg_b_post	Custom Designed RNA Spike As Negative Control For Assay Quality Control B	Custom designed RNA SPIKE as negative control for assay quality control B	Num .N="Not Applicable"
neg_b_pre	Custom Designed RNA Spike As Negative Control For Assay Quality Control B	Custom designed RNA SPIKE as negative control for assay quality control B	Num .N="Not Applicable"
neg_c_post	Custom Designed RNA Spike As Negative Control For Assay Quality Control C	Custom designed RNA SPIKE as negative control for assay quality control C	Num .N="Not Applicable"
neg_c_pre	Custom Designed RNA Spike As Negative Control For Assay Quality Control C	Custom designed RNA SPIKE as negative control for assay quality control C	Num .N="Not Applicable"
neg_d_post	Custom Designed RNA Spike As Negative Control For Assay Quality Control D	Custom designed RNA SPIKE as negative control for assay quality control D	Num .N="Not Applicable"
neg_d_pre	Custom Designed RNA Spike As Negative Control For Assay Quality Control D	Custom designed RNA SPIKE as negative control for assay quality control D	Num .N="Not Applicable"
neg_e_post	Custom Designed RNA Spike As Negative Control For Assay Quality Control E	Custom designed RNA SPIKE as negative control for assay quality control E	Num .N="Not Applicable"
neg_e_pre	Custom Designed RNA Spike As Negative Control For Assay Quality Control E	Custom designed RNA SPIKE as negative control for assay quality control E	Num .N="Not Applicable"
neg_f_post	Custom Designed RNA Spike As Negative Control For Assay Quality Control F	Custom designed RNA SPIKE as negative control for assay quality control F	Num .N="Not Applicable"
neg_f_pre	Custom Designed RNA Spike As Negative Control For Assay Quality Control F	Custom designed RNA SPIKE as negative control for assay quality control F	Num .N="Not Applicable"
neg_g_post	Custom Designed RNA Spike As Negative Control For Assay Quality Control G	Custom designed RNA SPIKE as negative control for assay quality control G	Num .N="Not Applicable"
neg_g_pre	Custom Designed RNA Spike As Negative Control For Assay Quality Control G	Custom designed RNA SPIKE as negative control for assay quality control G	Num .N="Not Applicable"
neg_h_post	Custom Designed RNA Spike As Positive Control For Assay Quality Control A	Custom designed RNA SPIKE as positive control for assay quality control A	Num .N="Not Applicable"

NWU-2013-01-03 Person File

01/15/2020

Dataset: prsn

Variable	Label	Description	Format Text
neg_h_pre	Custom Designed RNA Spike As Positive Control For Assay Quality Control A	Custom designed RNA SPIKE as positive control for assay quality control A	Num .N="Not Applicable"
pgk1_post	Housekeeping Control, Expression Of Pgk1 Gene In Sample	HOUSEKEEPING control, Expression of PGK1 gene in sample	Num .N="Not Applicable"
pgk1_pre	Housekeeping Control, Expression Of Pgk1 Gene In Sample	HOUSEKEEPING control, Expression of PGK1 gene in sample	Num .N="Not Applicable"
pgr_post	Endogenous Expression Of Pgr Gene In Sample	ENDOGENOUS Expression of PGR gene in sample	Num .N="Not Applicable"
pgr_pre	Endogenous Expression Of Pgr Gene In Sample	ENDOGENOUS Expression of PGR gene in sample	Num .N="Not Applicable"
plk1_post	Endogenous Expression Of Plk1 Gene In Sample	ENDOGENOUS Expression of PLK1 gene in sample	Num .N="Not Applicable"
plk1_pre	Endogenous Expression Of Plk1 Gene In Sample	ENDOGENOUS Expression of PLK1 gene in sample	Num .N="Not Applicable"
pos_a_post	Custom Designed RNA Spike As Positive Control For Assay Quality Control B	Custom designed RNA SPIKE as positive control for assay quality control B	Num .N="Not Applicable"
pos_a_pre	Custom Designed RNA Spike As Positive Control For Assay Quality Control B	Custom designed RNA SPIKE as positive control for assay quality control B	Num .N="Not Applicable"
pos_b_post	Custom Designed RNA Spike As Positive Control For Assay Quality Control C	Custom designed RNA SPIKE as positive control for assay quality control C	Num .N="Not Applicable"
pos_b_pre	Custom Designed RNA Spike As Positive Control For Assay Quality Control C	Custom designed RNA SPIKE as positive control for assay quality control C	Num .N="Not Applicable"
pos_c_post	Custom Designed RNA Spike As Positive Control For Assay Quality Control D	Custom designed RNA SPIKE as positive control for assay quality control D	Num .N="Not Applicable"
pos_c_pre	Custom Designed RNA Spike As Positive Control For Assay Quality Control D	Custom designed RNA SPIKE as positive control for assay quality control D	Num .N="Not Applicable"
pos_d_post	Custom Designed RNA Spike As Positive Control For Assay Quality Control E	Custom designed RNA SPIKE as positive control for assay quality control E	Num .N="Not Applicable"
pos_d_pre	Custom Designed RNA Spike As Positive Control For Assay Quality Control E	Custom designed RNA SPIKE as positive control for assay quality control E	Num .N="Not Applicable"
pos_e_post	Custom Designed RNA Spike As Positive Control For Assay Quality Control F	Custom designed RNA SPIKE as positive control for assay quality control F	Num .N="Not Applicable"
pos_e_pre	Custom Designed RNA Spike As Positive Control For Assay Quality Control F	Custom designed RNA SPIKE as positive control for assay quality control F	Num .N="Not Applicable"
pos_f_post	Custom Designed RNA Spike As Positive Control For Assay Quality Control G	Custom designed RNA SPIKE as positive control for assay quality control G	Num .N="Not Applicable"

Variable	Label	Description	Format Text
pos_f_pre	Custom Designed RNA Spike As Positive Control For Assay Quality Control G	Custom designed RNA SPIKE as positive control for assay quality control G	Num .N="Not Applicable"
psmd3_post	Endogenous Expression Of Psm3 Gene In Sample	ENDOGENOUS Expression of PSMD3 gene in sample	Num .N="Not Applicable"
psmd3_pre	Endogenous Expression Of Psm3 Gene In Sample	ENDOGENOUS Expression of PSMD3 gene in sample	Num .N="Not Applicable"
pttg1_post	Endogenous Expression Of Pttg1 Gene In Sample	ENDOGENOUS Expression of PTTG1 gene in sample	Num .N="Not Applicable"
pttg1_pre	Endogenous Expression Of Pttg1 Gene In Sample	ENDOGENOUS Expression of PTTG1 gene in sample	Num .N="Not Applicable"
rad54l_post	Endogenous Expression Of Rad54L Gene In Sample	ENDOGENOUS Expression of RAD54L gene in sample	Num .N="Not Applicable"
rad54l_pre	Endogenous Expression Of Rad54L Gene In Sample	ENDOGENOUS Expression of RAD54L gene in sample	Num .N="Not Applicable"
rbp4_post	Endogenous Expression Of Rbp4 Gene In Sample	ENDOGENOUS Expression of RBP4 gene in sample	Num .N="Not Applicable"
rbp4_pre	Endogenous Expression Of Rbp4 Gene In Sample	ENDOGENOUS Expression of RBP4 gene in sample	Num .N="Not Applicable"
rrm2_post	Endogenous Expression Of Rrm2 Gene In Sample	ENDOGENOUS Expression of RRM2 gene in sample	Num .N="Not Applicable"
rrm2_pre	Endogenous Expression Of Rrm2 Gene In Sample	ENDOGENOUS Expression of RRM2 gene in sample	Num .N="Not Applicable"
sec14l2_post	Endogenous Expression Of Sec14L2 Gene In Sample	ENDOGENOUS Expression of SEC14L2 gene in sample	Num .N="Not Applicable"
sec14l2_pre	Endogenous Expression Of Sec14L2 Gene In Sample	ENDOGENOUS Expression of SEC14L2 gene in sample	Num .N="Not Applicable"
slc1a1_post	Endogenous Expression Of Slc1A1 Gene In Sample	ENDOGENOUS Expression of SLC1A1 gene in sample	Num .N="Not Applicable"
slc1a1_pre	Endogenous Expression Of Slc1A1 Gene In Sample	ENDOGENOUS Expression of SLC1A1 gene in sample	Num .N="Not Applicable"
stc2_post	Endogenous Expression Of Stc2 Gene In Sample	ENDOGENOUS Expression of STC2 gene in sample	Num .N="Not Applicable"
stc2_pre	Endogenous Expression Of Stc2 Gene In Sample	ENDOGENOUS Expression of STC2 gene in sample	Num .N="Not Applicable"
syt9_post	Endogenous Expression Of Syt9 Gene In Sample	ENDOGENOUS Expression of SYT9 gene in sample	Num .N="Not Applicable"
syt9_pre	Endogenous Expression Of Syt9 Gene In Sample	ENDOGENOUS Expression of SYT9 gene in sample	Num .N="Not Applicable"
tfap2b_post	Endogenous Expression Of Tfp2B Gene In Sample	ENDOGENOUS Expression of TFAP2B gene in sample	Num .N="Not Applicable"
tfap2b_pre	Endogenous Expression Of Tfp2B Gene In Sample	ENDOGENOUS Expression of TFAP2B gene in sample	Num .N="Not Applicable"
top2a_post	Endogenous Expression Of Top2A Gene In Sample	ENDOGENOUS Expression of TOP2A gene in sample	Num .N="Not Applicable"
top2a_pre	Endogenous Expression Of Top2A Gene In Sample	ENDOGENOUS Expression of TOP2A gene in sample	Num .N="Not Applicable"

Variable	Label	Description	Format Text
ubd_post	Endogenous Expression Of Ubd Gene In Sample	ENDOGENOUS Expression of UBD gene in sample	Num .N="Not Applicable"
ubd_pre	Endogenous Expression Of Ubd Gene In Sample	ENDOGENOUS Expression of UBD gene in sample	Num .N="Not Applicable"
ube2c_post	Endogenous Expression Of Ube2C Gene In Sample	ENDOGENOUS Expression of UBE2C gene in sample	Num .N="Not Applicable"
ube2c_pre	Endogenous Expression Of Ube2C Gene In Sample	ENDOGENOUS Expression of UBE2C gene in sample	Num .N="Not Applicable"

Section 30: Ki-67

Variable	Label	Description	Format Text
halo_scored1-4	Scored (HALO)	Scored (HALO)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
he_annotations1-4	Annotations (HE)	Annotations (HE)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
he_stained1-4	Stained HE	Stained HE	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
ihc_stained1-4	Stained IHC	Stained IHC	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
ki67_comments1-4	Ki67 Comments	Ki-67 Comments	Char
ki67_img_tag1-4	Image Tag	Image Tag	Char
ki67_path_comments1-4	He Pathologist Comments	HE Pathologist Comments	Char
stain_2_pos_nuclei_cell1-4	% Stain 2 Positive Nuclei Cells	% Stain 2 Positive Nuclei Cells	Num .M="Missing" .N="Not Applicable"
total_cells1-4	Total Cells	Total Cells	Num .M="Missing" .N="Not Applicable"
tumor_grade1-4	Tumor Grade (Pathologist Report)	Tumor Grade (Pathologist Report)	Num .M="Missing" .N="Not Applicable"
tumor_group1-4	Group	Group	Char

Section 31: Plasma Concentration

Variable	Label	Description	Format Text
plasma_cdb_4124	Plasma Concentration Cdb 4124	CDB-4124	Num .N="Not Applicable"
plasma_cdb_4453	Plasma Concentration Cdb 4453	CDB-4453	Num .N="Not Applicable"
plasma_sample_id	Plasma Concentration Sample ID	Sample ID	Char

Section 32: Serum Hormones

Variable	Label	Description	Format Text
serum_e2_1-2	Serum E2 Mean (12 - 1070 pg/mL)	E2 (12 - 1070 pg/mL) mean	Num .N="Not Applicable"
serum_fsh1-2	Serum Fsh Mean (0.1 - 170 mIU/mL)	FSH (0.1 - 170 mIU/mL) mean	Num .N="Not Applicable"
serum_num_saples	Number Of Serum Samples Taken	Number of serum samples taken	Num
serum_p4_1-2	Serum P4 Mean (0.2 - 40 ng/mL)	P4 (0.2 - 40 ng/mL) mean	Num .N="Not Applicable"
serum_sample_id1-2	Serum Sample ID	Sample ID	Char

Section 33: Tissue Concentration

Variable	Label	Description	Format Text
tissue_cdb_4124_i1-14	Cdb-4124 (ng/g) Initial	CDB-4124 (ng/g) Initial	Num .M="Missing" .N="Not Applicable"
tissue_cdb_4124_r1-14	Cdb-4124 (ng/g) Repeat (If Initial Concentration >=5 ng/g, Repeat)	CDB-4124 (ng/g) Repeat (if initial concentration >=5 ng/g, repeat)	Num .M="Missing" .N="Not Applicable"
tissue_cdb_4453_i1-14	Cdb-4453 (ng/g) Initial	CDB-4453 (ng/g) Initial	Num .M="Missing" .N="Not Applicable"
tissue_cdb_4453_r1-14	Cdb-4453 (ng/g) Repeat	CDB-4453 (ng/g) Repeat	Num .M="Missing" .N="Not Applicable"
tissue_location1-14	Tissue Sample Location	Tissue sample location	.M="Missing" .N="Not Applicable" 1="R1" 2="R2" 3="R3" 4="R4" 5="R5" 6="R6" 7="R7" 8="L1" 9="L2" 10="L3" 11="L4" 12="L5" 13="L6" 14="L7"
tissue_num_samples	Number Of Tissue Concentration Samples	Number of tissue concentration samples	Num
tissue_sample_id1-14	Tissue Sample ID	Tissue sample id	Char
tissue_sample_total_weight1-14	Total Weight (g)	Total Weight (g)	Num .M="Missing" .N="Not Applicable"
tissue_weight_i1-14	Weight For Extraction (g) Initial	Weight For Extraction (g) Initial	Num .M="Missing" .N="Not Applicable"
tissue_weight_r1-14	Weight For Extraction (g) Repeat	Weight for extraction (g) Repeat	Num .M="Missing" .N="Not Applicable"

Section 34: Tissue Composition

Variable	Label	Description	Format Text
tissue_comp_adpi1-14	Adipose Percentage Of Tissue Area As Determined By Algorithm	Adipose percentage of tissue area as determined by algorithm	Num .N="Not Applicable"
tissue_comp_epith1-14	Epithelium Percentage Of Tissue Area As Determined By Algorithm	Epithelium percentage of tissue area as determined by algorithm	Num .N="Not Applicable"
tissue_comp_img_id1-14	Image ID Assigned By Eslide Manager Upon Scanning	Image ID assigned by eSlide Manager upon scanning	Num .N="Not Applicable"
tissue_comp_num_samples	Number Of Tissue Composition Samples	Number of tissue composition samples	Num
tissue_comp_nwu_id1-14	Northwestern ID Assigned By Lab Member Based On Slide Label	Northwestern ID assigned by lab member based on slide label	Char
tissue_comp_stroma1-14	Stroma Percentage Of Tissue Area As Determined By Algorithm	Stroma percentage of tissue area as determined by algorithm	Num .N="Not Applicable"
tissue_comp_tisarea1-14	Total Tissue Area Of Analysis (mm ²)	Total tissue area of analysis (mm ²)	Num .N="Not Applicable"

Section 35: Dataset Accounting

Variable	Label	Description	Format Text
in_agentcompliance	In Agent Compliance Dataset	In Agent Compliance Dataset	0="Not in dataset" 1="In dataset"
in_agint	In Agent Interruption Dataset	In Agent Interruption Dataset	0="Not in dataset" 1="In dataset"
in_agrc	In Agent Return & Compliance Dataset	In Agent Return & Compliance Dataset	0="Not in dataset" 1="In dataset"
in_bess	In Bess Dataset	In BESS Dataset	0="Not in dataset" 1="In dataset"
in_bldchm	In Blood Chemistry Dataset	In Blood Chemistry Dataset	0="Not in dataset" 1="In dataset"
in_breastcupsize	In Breast Cup Size Dataset	In Breast Cup Size Dataset	0="Not in dataset" 1="In dataset"
in_conmed	In Concomitant Medications Dataset	In Concomitant Medications Dataset	0="Not in dataset" 1="In dataset"
in_elig	In Eligibility Dataset	In Eligibility Dataset	0="Not in dataset" 1="In dataset"
in_enrl	In Enrollment Dataset	In Enrollment Dataset	0="Not in dataset" 1="In dataset"
in_geneexpression	In Gene Expression Dataset	In Gene Expression Dataset	0="Not in dataset" 1="In dataset"
in_hormregph	In Hormone Regimen Dataset	In Hormone Regimen Dataset	0="Not in dataset" 1="In dataset"
in_icf	In Informed Consent Form Dataset	In Informed Consent Form Dataset	0="Not in dataset" 1="In dataset"
in_ki67	In Ki-67 Dataset	In Ki-67 Dataset	0="Not in dataset" 1="In dataset"
in_mastgross	In Mastectomy Grossing Dataset	In Mastectomy Grossing Dataset	0="Not in dataset" 1="In dataset"
in_medhx	In Medical History Dataset	In Medical History Dataset	0="Not in dataset" 1="In dataset"
in_menost	In Menopausal Status Dataset	In Menopausal Status Dataset	0="Not in dataset" 1="In dataset"
in_menst	In Menstruation Dataset	In Menstruation Dataset	0="Not in dataset" 1="In dataset"
in_offst	In Off Study Dataset	In Off Study Dataset	0="Not in dataset" 1="In dataset"
in_parcntct	In Participant Contact Form Dataset	In Participant Contact Form Dataset	0="Not in dataset" 1="In dataset"
in_pardiarysrcdocs	In Participant Diary Source Dataset	In Participant Diary Source Dataset	0="Not in dataset" 1="In dataset"
in_physex	In Physical Exam Dataset	In Physical Exam Dataset	0="Not in dataset" 1="In dataset"

Variable	Label	Description	Format Text
in_plasmaconcentration	In Plasma Concentration Dataset	In Plasma Concentration Dataset	0="Not in dataset" 1="In dataset"
in_preenrl	In Pre-Enrollment Dataset	In Pre-Enrollment Dataset	0="Not in dataset" 1="In dataset"
in_pregt	In Pregnancy Test Dataset	In Pregnancy Test Dataset	0="Not in dataset" 1="In dataset"
in_serumhormones	In Serum Hormones Dataset	In Serum Hormones Dataset	0="Not in dataset" 1="In dataset"
in_tactad	In Treatment Assignment Code Dataset	In Treatment Assignment Code Dataset	0="Not in dataset" 1="In dataset"
in_timepoints	In Time Points Dataset	In Time Points Dataset	0="Not in dataset" 1="In dataset"
in_tissuecomposition	In Tissue Composition Dataset	In Tissue Composition Dataset	0="Not in dataset" 1="In dataset"
in_tissueconcentration	In Tissue Concentration Dataset	In Tissue Concentration Dataset	0="Not in dataset" 1="In dataset"
in_tumcharsbl	In Tumor Characteristics At Baseline Dataset	In Tumor Characteristics at Baseline Dataset	0="Not in dataset" 1="In dataset"
in_tumcharssurg	In Tumor Characteristics At Surgery Dataset	In Tumor Characteristics at Surgery Dataset	0="Not in dataset" 1="In dataset"
in_unblinding	In Unblinding Dataset	In Unblinding Dataset	0="Not in dataset" 1="In dataset"
in_vitsig	In Vital Signs Dataset	In Vital Signs Dataset	0="Not in dataset" 1="In dataset"