

MDA2014-04-02 - Enhanced Person Data Dictionary

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Document Summary

Property	Value
Document Title	MDA2014-04-02 - Enhanced Person: Data Dictionary
Date Created	05/09/2022
Sections	35
Entries	871
Document Filename	dictionary_enhanced_prsn.rtf

MDA2014-04-02 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	Accession	Accession		Numeric
01. Principal	build_dt	Build Date		SAS Date
01. Principal	MRNO	Participant ID		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	arm	Study Arm		.R="Not Randomized" 1="NeuVax (1000 ug nelipepimut-S + 250 ug GM-CSF)" 2="GM-CSF Only (250 ug)"

Section 3: Demographics

Class	Variable	Label	Description	Format Text
01. Principal	ethnicity	Ethnicity		1="Hispanic or Latino" 2="Not Hispanic or Latino" 3="Unknown" 4="Not Reported"
01. Principal	gender	Gender		2="Female"
01. Principal	race	Race		1="White" 2="Black or African American" 4="Asian" 6="Unknown" 7="Not Reported"
01. Principal	race_eth	Race + Ethnicity		1="White, Non-Hispanic" 2="Black, Non-Hispanic" 3="Hispanic" 5="Asian" 7="Unknown" 8="Not Reported"

Section 4: Registration

Class	Variable	Label	Description	Format Text
01. Principal	reg_consent_bank	OK To Bank Samples For Future Research - [Registration]		0="No" 1="Yes"
01. Principal	reg_consent_contact	OK To Contact For Results From Studies - [Registration]		.M="Missing" 0="No" 1="Yes"
01. Principal	reg_consent_dt	Date Informed Consent Signed - [Registration]		SAS Date
01. Principal	reg_consent_genetic	Use Specimen For Genetic Research - [Registration]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	reg_consent_ppt	OK To Contact For Participation In Future Research - [Registration]		0="No" 1="Yes"
01. Principal	reg_dt	Date Of Registration - [Registration]		SAS Date
01. Principal	reg_institution	Institution - [Registration]		1="Dana Farber Cancer Institute" 2="M. D. Anderson Cancer Center" 3="Thomas Jefferson University Hospital"
01. Principal	reg_pay_method	Payment Method - [Registration]		1="Private Insurance" 8="Medicare And Private Insurance"
01. Principal	reg_tac0	Treatment Assignment Code TAC0 Signed Informed Consent - [Registration]		1="Yes"
01. Principal	reg_version	Version Of Informed Consent - [Registration]		Char
01. Principal	reg_version_dt	Version Date Of Informed Consent - [Registration]		SAS Date .M="Missing"
01. Principal	reg_visit_dt	Visit Date - [Registration]		SAS Date .M="Missing"

Section 5: Medical History

Class	Variable	Label	Description	Format Text
01. Principal	medhist_allerdrug_cmnt	Comments - Allergic/Drug Sensitivity - [Medical History]		Char
01. Principal	medhist_allerdrug_finding	Finding - Allergic/Drug Sensitivity - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medhist_breast_cmnt	Comments - Breasts - [Medical History]		Char
01. Principal	medhist_breast_finding	Finding - Breasts - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medhist_cardio_cmnt	Comments - Cardiovascular - [Medical History]		Char
01. Principal	medhist_cardio_finding	Finding - Cardiovascular - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medhist_derma_cmnt	Comments - Dermatologic - [Medical History]		Char
01. Principal	medhist_derma_finding	Finding - Dermatologic - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medhist_endomehta_cmnt	Comments - Endocrine/Metabolic - [Medical History]		Char
01. Principal	medhist_endomehta_finding	Finding - Endocrine/Metabolic - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medhist_gastro_cmnt	Comments - Gastrointestinal - [Medical History]		Char
01. Principal	medhist_gastro_finding	Finding - Gastrointestinal - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medhist_genit_cmnt	Comments - Genitourinary - [Medical History]		Char
01. Principal	medhist_genit_finding	Finding - Genitourinary - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"

Class	Variable	Label	Description	Format Text
01. Principal	medhist_heent_cmnt	Comments - H/E/E/N/T - [Medical History]		Char
01. Principal	medhist_heent_finding	Finding - H/E/E/N/T - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medhist_hemalymp_cmnt	Comments - Hematopoietic/Lymph - [Medical History]		Char
01. Principal	medhist_hemalymp_finding	Finding - Hematopoietic/Lymph - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medhist_muscskel_cmnt	Comments - Musculoskeletal - [Medical History]		Char
01. Principal	medhist_muscskel_finding	Finding - Musculoskeletal - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medhist_neck_cmnt	Comments - Neck - [Medical History]		Char
01. Principal	medhist_neck_finding	Finding - Neck - [Medical History]		.R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	medhist_neuro_cmnt	Comments - Neurologic - [Medical History]		Char
01. Principal	medhist_neuro_finding	Finding - Neurologic - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	medhist_oth_cmnt	Comments - Other Body System - [Medical History]		Char
01. Principal	medhist_oth_finding	Finding - Other Body System - [Medical History]		.N="N/A" .R="Not Randomized" 2="Abnormal"
01. Principal	medhist_oth_sys	Type - Other Body System - [Medical History]		Char
01. Principal	medhist_resp_cmnt	Comments - Respiratory - [Medical History]		Char
01. Principal	medhist_resp_finding	Finding - Respiratory - [Medical History]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"

Section 6: Reproductive History

Class	Variable	Label	Description	Format Text
01. Principal	reprohist_1stbirth_age	Age At First Live Birth - [Reproductive History]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	reprohist_last_period_dt	Date Of Last Menstrual Period - [Reproductive History]		SAS Date .M="Missing" .R="Not Randomized" .U="Unknown"
01. Principal	reprohist_menarche_age	Age At Menarche - [Reproductive History]		Numeric .M="Missing" .R="Not Randomized" .U="Unknown"
01. Principal	reprohist_meno_age	Age At Menopause - [Reproductive History]		Numeric .M="Missing" .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	reprohist_meno_cause	Was Menopause - [Reproductive History]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Naturally-induced" 2="Surgically-induced" 3="Chemically-induced"
01. Principal	reprohist_num_children	Number Of Children - [Reproductive History]		Numeric .R="Not Randomized"
01. Principal	reprohist_visit_dt	Visit Date - [Reproductive History]		SAS Date .R="Not Randomized"

Section 7: Breast Cancer History

Class	Variable	Label	Description	Format Text
01. Principal	brncrhist_dxd1-3	Diagnosis Date - History # - [Breast Cancer History]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	brncrhist_grade1-3	Grade - History # - [Breast Cancer History]		Char
01. Principal	brncrhist_hist_type1-3	Histology Type - History # - [Breast Cancer History]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Ductal Carcinoma in Situ"
01. Principal	brncrhist_horm_rec_dt1-3	Hormone Reception Date - History # - [Breast Cancer History]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	brncrhist_horm_rec_type1-3	Hormone Reception Type - History # - [Breast Cancer History]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Estrogen Receptor" 2="Progesterone Receptor" 3="HER2"
01. Principal	brncrhist_largest_dim_size1-3	Size (cm) of Largest Dimension - History # - [Breast Cancer History]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	brncrhist_location1-3	Location - History # - [Breast Cancer History]		.N="N/A" .R="Not Randomized" 1="Left" 2="Right"
01. Principal	brncrhist_m_stage1-3	M Stage - History # - [Breast Cancer History]		Char
01. Principal	brncrhist_method1-3	Method - History # - [Breast Cancer History]		.M="Missing" .N="N/A" .R="Not Randomized" 1="IHC" 2="Nuclear Staining"
01. Principal	brncrhist_n_stage1-3	N Stage - History # - [Breast Cancer History]		Char
01. Principal	brncrhist_num	Number Of History Records - [Breast Cancer History]		Numeric .R="Not Randomized"
01. Principal	brncrhist_othspec1-3	Specific Other Method - History # - [Breast Cancer History]		Char
01. Principal	brncrhist_result1-3	Result - History # - [Breast Cancer History]		.M="Missing" .N="N/A" .R="Not Randomized" 0="Negative" 1="Positive"

Class	Variable	Label	Description	Format Text
01. Principal	brcncrhist_t_stag e1-3	T Stage - History # - [Breast Cancer History]		Char

Section 8: Family History

Class	Variable	Label	Description	Format Text
01. Principal	famhist_age_at_dx1-8	Age At Diagnosis - Cancer # - [Family History]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	famhist_cancer_hist	Does Participant Have A Family History Of Breast Or Any Other Cancer? - [Family History]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	famhist_cancer_type1-8	Cancer Type - Cancer # - [Family History]		Char
01. Principal	famhist_comments1-8	Comments - Cancer # - [Family History]		Char
01. Principal	famhist_num	Number Of Cancers In Family's History - [Family History]		Numeric .R="Not Randomized"
01. Principal	famhist_relation1-8	Relation To Participant - Cancer # - [Family History]		Char

Section 9: Previous Therapy

Class	Variable	Label	Description	Format Text
01. Principal	prvthrpj_adj_or_neo1-6	Adjuvant or Neo-Adjuvant? - Therapy # - [Previous Therapy]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Adjuvant" 2="Neo-Adjuvant"
01. Principal	prvthrpj_began_dt1-6	Date Began - Therapy # - [Previous Therapy]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	prvthrpj_breast_comments	Comments About Previous Breast Surgery - [Previous Therapy]		Char
01. Principal	prvthrpj_breast_response	Previous Breast Surgery? - [Previous Therapy]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	prvthrpj_chemo_comments	Comments About Previous Chemotherapy - [Previous Therapy]		Char
01. Principal	prvthrpj_chemo_response	Previous Chemotherapy? - [Previous Therapy]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	prvthrpj_comments1-6	Comments - Therapy # - [Previous Therapy]		Char
01. Principal	prvthrpj_complete_dt1-6	Date Completed - Therapy # - [Previous Therapy]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	prvthrpj_details1-6	Therapy Details - Therapy # - [Previous Therapy]		Char
01. Principal	prvthrpj_horm_comments	Comments About Previous Hormonal Therapy - [Previous Therapy]		Char
01. Principal	prvthrpj_horm_response	Previous Hormonal Therapy? - [Previous Therapy]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	prvthrpj_num	Number Of Previous Therapies - [Previous Therapy]		Numeric .R="Not Randomized"
01. Principal	prvthrpj_rad_comments	Comments About Previous Radiation Therapy - [Previous Therapy]		Char

Class	Variable	Label	Description	Format Text
01. Principal	prvthry_rad_response	Previous Radiation Therapy? - [Previous Therapy]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	prvthry_type1-6	Therapy Type - Therapy # - [Previous Therapy]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Chemotherapy" 2="Radiation Therapy" 3="Hormonal Therapy" 4="Breast Surgery"
01. Principal	prvthry_visit_dt	Visit Date - [Previous Therapy]		SAS Date .R="Not Randomized"

Section 10: HLA-A2 Blood Sample

Class	Variable	Label	Description	Format Text
01. Principal	hlabld_sample_num	Sample Number - [HLA-A2 Blood Sample]		Char
01. Principal	hlabld_time	Time Obtained - [HLA-A2 Blood Sample]		SAS Time .R="Not Randomized"
01. Principal	hlabld_visit_dt	Visit Date - [HLA-A2 Blood Sample]		SAS Date .R="Not Randomized"

Section 11: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	bsymp_comments1-9	Comments - Symptom # - [Baseline Symptoms]		Char
01. Principal	bsymp_grade1-9	Grade - Symptom # - [Baseline Symptoms]		.M="Missing" .N="N/A" .R="Not Randomized" 1="1 (Mild)" 2="2 (Moderate)"
01. Principal	bsymp_num	Number Of Baseline Symptoms - [Baseline Symptoms]		Numeric .R="Not Randomized"
01. Principal	bsymp_onset_dt1-9	Onset Date - Symptom # - [Baseline Symptoms]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	bsymp_symp_desc1-9	Symptom Description - Symptom # - [Baseline Symptoms]		Char

Section 12: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	phys_attrib_abdom_cmnt_v1	Abdomen - Comments - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	phys_attrib_abdom_cmnt_v6	Abdomen - Comments - Visit 6 (Final Follow-Up) - [Physical Exam]		Char
01. Principal	phys_attrib_abdom_finding_ex	Abdomen - Finding - Extra Visit - [Physical Exam]		.N="N/A" .R="Not Randomized" 1="Normal"
01. Principal	phys_attrib_abdom_finding_v1	Abdomen - Finding - Visit 1 (Baseline) - [Physical Exam]		.M="Missing" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_abdom_finding_v6	Abdomen - Finding - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_appear_cmnt_v1	Appearance - Comments - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	phys_attrib_appear_cmnt_v6	Appearance - Comments - Visit 6 (Final Follow-Up) - [Physical Exam]		Char
01. Principal	phys_attrib_appear_finding_ex	Appearance - Finding - Extra Visit - [Physical Exam]		.N="N/A" .R="Not Randomized" 1="Normal"
01. Principal	phys_attrib_appear_finding_v1	Appearance - Finding - Visit 1 (Baseline) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_appear_finding_v6	Appearance - Finding - Visit 6 (Final Follow-Up) - [Physical Exam]		.N="N/A" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_bmi_ex	BMI - Extra Visit - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_bmi_v1	BMI - Visit 1 (Baseline) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_bmi_v6	BMI - Visit 6 (Final Follow-Up) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	phys_attrib_bp_dia_ex	Diastolic BP (mm Hg) - Extra Visit - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_bp_dia_v1	Diastolic BP (mm Hg) - Visit 1 (Baseline) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_bp_dia_v6	Diastolic BP (mm Hg) - Visit 6 (Final Follow-Up) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_bp_sys_ex	Systolic BP (mm Hg) - Extra Visit - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_bp_sys_v1	Systolic BP (mm Hg) - Visit 1 (Baseline) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_bp_sys_v6	Systolic BP (mm Hg) - Visit 6 (Final Follow-Up) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_breast_cmnt_v1	Breasts - Comments - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	phys_attrib_breast_cmnt_v6	Breasts - Comments - Visit 6 (Final Follow-Up) - [Physical Exam]		Char
01. Principal	phys_attrib_breast_finding_ex	Breasts - Finding - Extra Visit - [Physical Exam]		.N="N/A" .R="Not Randomized" 2="Abnormal"
01. Principal	phys_attrib_breast_finding_v1	Breasts - Finding - Visit 1 (Baseline) - [Physical Exam]		.R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	phys_attrib_breast_finding_v6	Breasts - Finding - Visit 6 (Final Follow-Up) - [Physical Exam]		.N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	phys_attrib_ecog_ex	ECOG Performance Status - Extra Visit - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_ecog_v1	ECOG Performance Status - Visit 1 (Baseline) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_ecog_v6	ECOG Performance Status - Visit 6 (Final Follow-Up) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_heart_cmnt_v1	Heart - Comments - Visit 1 (Baseline) - [Physical Exam]		Char

Class	Variable	Label	Description	Format Text
01. Principal	phys_attrib_heart_cmnt_v6	Heart - Comments - Visit 6 (Final Follow-Up) - [Physical Exam]		Char
01. Principal	phys_attrib_heart_finding_ex	Heart - Finding - Extra Visit - [Physical Exam]		.N="N/A" .R="Not Randomized" 1="Normal"
01. Principal	phys_attrib_heart_finding_v1	Heart - Finding - Visit 1 (Baseline) - [Physical Exam]		.M="Missing" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_heart_finding_v6	Heart - Finding - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_heart_cmnt_v1	H/E/E/N/T - Comments - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	phys_attrib_heart_cmnt_v6	H/E/E/N/T - Comments - Visit 6 (Final Follow-Up) - [Physical Exam]		Char
01. Principal	phys_attrib_heart_finding_ex	H/E/E/N/T - Finding - Extra Visit - [Physical Exam]		.N="N/A" .R="Not Randomized" 1="Normal"
01. Principal	phys_attrib_heart_finding_v1	H/E/E/N/T - Finding - Visit 1 (Baseline) - [Physical Exam]		.M="Missing" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_heart_finding_v6	H/E/E/N/T - Finding - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_height_ex	Height (cm) - Extra Visit - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_height_v1	Height (cm) - Visit 1 (Baseline) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_height_v6	Height (cm) - Visit 6 (Final Follow-Up) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_lung_cmnt_v1	Lung - Comments - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	phys_attrib_lung_cmnt_v6	Lung - Comments - Visit 6 (Final Follow-Up) - [Physical Exam]		Char
01. Principal	phys_attrib_lung_finding_ex	Lung - Finding - Extra Visit - [Physical Exam]		.N="N/A" .R="Not Randomized" 1="Normal"

Class	Variable	Label	Description	Format Text
01. Principal	phys_attrib_lung_finding_v1	Lung - Finding - Visit 1 (Baseline) - [Physical Exam]		.M="Missing" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_lung_finding_v6	Lung - Finding - Visit 6 (Final Follow-Up) - [Physical Exam]		.N="N/A" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_lymph_cmnt_v1	Lymph - Comments - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	phys_attrib_lymph_cmnt_v6	Lymph - Comments - Visit 6 (Final Follow-Up) - [Physical Exam]		Char
01. Principal	phys_attrib_lymph_finding_ex	Lymph - Finding - Extra Visit - [Physical Exam]		.N="N/A" .R="Not Randomized" 1="Normal"
01. Principal	phys_attrib_lymph_finding_v1	Lymph - Finding - Visit 1 (Baseline) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	phys_attrib_lymph_finding_v6	Lymph - Finding - Visit 6 (Final Follow-Up) - [Physical Exam]		.N="N/A" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_no_bmi_ex	BMI Not Obtained - Extra Visit - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False"
01. Principal	phys_attrib_no_bmi_v1	BMI Not Obtained - Visit 1 (Baseline) - [Physical Exam]		.R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_bmi_v6	BMI Not Obtained - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_bp_ex	Blood Pressure Not Obtained - Extra Visit - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False"
01. Principal	phys_attrib_no_bp_v1	Blood Pressure Not Obtained - Visit 1 (Baseline) - [Physical Exam]		.R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_bp_v6	Blood Pressure Not Obtained - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_height_ex	Height Not Obtained - Extra Visit - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False"

Class	Variable	Label	Description	Format Text
01. Principal	phys_attrib_no_height_v1	Height Not Obtained - Visit 1 (Baseline) - [Physical Exam]		.R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_height_v6	Height Not Obtained - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_pulse_ex	Pulse Rate Not Obtained - Extra Visit - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False"
01. Principal	phys_attrib_no_pulse_v1	Pulse Rate Not Obtained - Visit 1 (Baseline) - [Physical Exam]		.R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_pulse_v6	Pulse Rate Not Obtained - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_resp_ex	Respiration Rate Not Obtained - Extra Visit - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False"
01. Principal	phys_attrib_no_resp_v1	Respiration Rate Not Obtained - Visit 1 (Baseline) - [Physical Exam]		.R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_resp_v6	Respiration Rate Not Obtained - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_temp_ex	Temperature Not Obtained - Extra Visit - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False"
01. Principal	phys_attrib_no_temp_v1	Temperature Not Obtained - Visit 1 (Baseline) - [Physical Exam]		.R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_temp_v6	Temperature Not Obtained - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_weight_ex	Weight Not Obtained - Extra Visit - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False"
01. Principal	phys_attrib_no_weight_v1	Weight Not Obtained - Visit 1 (Baseline) - [Physical Exam]		.R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_no_weight_v6	Weight Not Obtained - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_attrib_pulse_ex	Pulse Rate - Extra Visit - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	phys_attrib_pulse_v1	Pulse Rate - Visit 1 (Baseline) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_pulse_v6	Pulse Rate - Visit 6 (Final Follow-Up) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_resp_ex	Respiration Rate - Extra Visit - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_resp_v1	Respiration Rate - Visit 1 (Baseline) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_resp_v6	Respiration Rate - Visit 6 (Final Follow-Up) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_skin_cmnt_v1	Skin - Comments - Visit 1 (Baseline) - [Physical Exam]		Char
01. Principal	phys_attrib_skin_cmnt_v6	Skin - Comments - Visit 6 (Final Follow-Up) - [Physical Exam]		Char
01. Principal	phys_attrib_skin_finding_ex	Skin - Finding - Extra Visit - [Physical Exam]		.N="N/A" .R="Not Randomized" 1="Normal"
01. Principal	phys_attrib_skin_finding_v1	Skin - Finding - Visit 1 (Baseline) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Assessed"
01. Principal	phys_attrib_skin_finding_v6	Skin - Finding - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Normal" 3="Not Assessed"
01. Principal	phys_attrib_temp_ex	Temperature - Extra Visit - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_temp_units_ex	Temperature Unit - Extra Visit - [Physical Exam]		.M="Missing" .R="Not Randomized" 1="°C"
01. Principal	phys_attrib_temp_units_v1	Temperature Unit - Visit 1 (Baseline) - [Physical Exam]		.M="Missing" .R="Not Randomized" 1="°C" 2="°F"
01. Principal	phys_attrib_temp_units_v6	Temperature Unit - Visit 6 (Final Follow-Up) - [Physical Exam]		.M="Missing" .R="Not Randomized" 1="°C"
01. Principal	phys_attrib_temp_v1	Temperature - Visit 1 (Baseline) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	phys_attrib_temp_v6	Temperature - Visit 6 (Final Follow-Up) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_visit_dt_ex	Visit Date - Extra Visit - [Physical Exam]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_visit_dt_v1	Visit Date - Visit 1 (Baseline) - [Physical Exam]		SAS Date .R="Not Randomized"
01. Principal	phys_attrib_visit_dt_v6	Visit Date - Visit 6 (Final Follow-Up) - [Physical Exam]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_weight_ex	Weight (kg) - Extra Visit - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_weight_v1	Weight (kg) - Visit 1 (Baseline) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_attrib_weight_v6	Weight (kg) - Visit 6 (Final Follow-Up) - [Physical Exam]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phys_oth_bodysys_v1_1-2	Other Body System - Name - Visit 1 (Baseline) - System # - [Physical Exam]		Char
01. Principal	phys_oth_bodysys_v6	Other Body System - Name - Visit 6 (Final Follow-Up) - [Physical Exam]		Char
01. Principal	phys_oth_comments_v1_1-2	Other Body System - Comments - Visit 1 (Baseline) - System # - [Physical Exam]		Char
01. Principal	phys_oth_comments_v6	Other Body System - Comments - Visit 6 (Final Follow-Up) - [Physical Exam]		Char
01. Principal	phys_oth_finding_v1_1-2	Other Body System - Finding - Visit 1 (Baseline) - System # - [Physical Exam]		.N="N/A" .R="Not Randomized" 2="Abnormal"
01. Principal	phys_oth_finding_v6	Other Body System - Finding - Visit 6 (Final Follow-Up) - [Physical Exam]		.N="N/A" .R="Not Randomized" 2="Abnormal"
01. Principal	phys_oth_num_v1	Number Of Other Body Systems Examined - Visit 1 (Baseline) - [Physical Exam]		Numeric .R="Not Randomized"
01. Principal	phys_oth_num_v6	Number Of Other Body Systems Examined - Visit 6 (Final Follow-Up) - [Physical Exam]		Numeric .R="Not Randomized"

Section 13: Pregnancy Tests

Class	Variable	Label	Description	Format Text
01. Principal	preg_num	Number Of Pregnancy Tests Taken - [Pregnancy Tests]		Numeric .R="Not Randomized"
01. Principal	preg_result1-6	Result - Test # - [Pregnancy Tests]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Not Obtained" 3="Negative"
01. Principal	preg_rsn_not_col1-6	Reason Not Collected - Test # - [Pregnancy Tests]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Participant Is Female And Not Of Childbearing Potential"
01. Principal	preg_spec_dt1-6	Date Specimen Collected - Test # - [Pregnancy Tests]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	preg_test_type1-6	Test Type - Test # - [Pregnancy Tests]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Urine" 2="Serum"

Section 14: Cardiac Assessment

Class	Variable	Label	Description	Format Text
01. Principal	cardiac_comments_ex	Comments - Extra - [Cardiac Assessment]		Char
01. Principal	cardiac_comments_v1	Comments - Visit 1 (Baseline) - [Cardiac Assessment]		Char
01. Principal	cardiac_comments_v5	Comments - Visit 5 (Post-Vaccination Follow-Up) - [Cardiac Assessment]		Char
01. Principal	cardiac_ejection_fraction_ex	Ejection Fraction - Extra - [Cardiac Assessment]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	cardiac_ejection_fraction_v1	Ejection Fraction - Visit 1 (Baseline) - [Cardiac Assessment]		Numeric .R="Not Randomized"
01. Principal	cardiac_ejection_fraction_v5	Ejection Fraction - Visit 5 (Post-Vaccination Follow-Up) - [Cardiac Assessment]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	cardiac_num	Number Of Cardiac Assessments Completed - [Cardiac Assessment]		Numeric .R="Not Randomized"
01. Principal	cardiac_perform_dt_ex	Date Performed - Extra - [Cardiac Assessment]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	cardiac_perform_dt_v1	Date Performed - Visit 1 (Baseline) - [Cardiac Assessment]		SAS Date .R="Not Randomized"
01. Principal	cardiac_perform_dt_v5	Date Performed - Visit 5 (Post-Vaccination Follow-Up) - [Cardiac Assessment]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	cardiac_ultrasound_result_ex	Result - Extra - [Cardiac Assessment]		.N="N/A" .R="Not Randomized" 1="Normal"
01. Principal	cardiac_ultrasound_result_v1	Result - Visit 1 (Baseline) - [Cardiac Assessment]		.R="Not Randomized" 1="Normal"
01. Principal	cardiac_ultrasound_result_v5	Result - Visit 5 (Post-Vaccination Follow-Up) - [Cardiac Assessment]		.M="Missing" .R="Not Randomized" 1="Normal"

Section 15: Specimen Shipping

Class	Variable	Label	Description	Format Text
01. Principal	num_specimens_ex	Number Of Specimens Shipped - Extra Visit - [Specimen Shipping]		Numeric .R="Not Randomized"
01. Principal	num_specimens_v2	Number Of Specimens Shipped - Visit 2 (Vaccination 1) - [Specimen Shipping]		Numeric .R="Not Randomized"
01. Principal	num_specimens_v4	Number Of Specimens Shipped - Visit 4 (Surgery) - [Specimen Shipping]		Numeric .R="Not Randomized"
01. Principal	num_specimens_v5	Number Of Specimens Shipped - Visit 5 (Post-Inoculation) - [Specimen Shipping]		Numeric .R="Not Randomized"
01. Principal	num_specimens_v6	Number Of Specimens Shipped - Visit 6 (Final Follow-Up) - [Specimen Shipping]		Numeric .R="Not Randomized"
01. Principal	specship_blood_id_ex_1-4	Blood Specimen ID - Specimen 4 - Extra Visit - [Specimen Shipping]		Char
01. Principal	specship_blood_id_v2_1-4	Blood Specimen ID - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		Char
01. Principal	specship_blood_id_v4_1-3	Blood Specimen ID - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		Char
01. Principal	specship_blood_id_v5_1-2	Blood Specimen ID - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		Char
01. Principal	specship_blood_id_v6_1-2	Blood Specimen ID - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		Char
01. Principal	specship_checked_ex_1-4	Checked - Specimen 4 - Extra Visit - [Specimen Shipping]		.M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	specship_checked_v2_1-4	Checked - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		.N="N/A" .R="Not Randomized" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	specship_checked_v4_1-3	Checked - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		.N="N/A" .R="Not Randomized" 1="True"
01. Principal	specship_checked_v5_1-2	Checked - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		.N="N/A" .R="Not Randomized" 1="True"
01. Principal	specship_checked_v6_1-2	Checked - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		.N="N/A" .R="Not Randomized" 1="True"
01. Principal	specship_col_dte_ex_1-4	Date Collected - Specimen 4 - Extra Visit - [Specimen Shipping]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_col_dte_v2_1-4	Date Collected - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_col_dte_v4_1-3	Date Collected - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_col_dte_v5_1-2	Date Collected - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_col_dte_v6_1-2	Date Collected - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_col_time_ex_1-4	Time Collected - Specimen 4 - Extra Visit - [Specimen Shipping]		SAS Time .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_col_time_v2_1-4	Time Collected - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		SAS Time .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_col_time_v4_1-3	Time Collected - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		SAS Time .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_col_time_v5_1-2	Time Collected - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		SAS Time .N="N/A" .R="Not Randomized"
01. Principal	specship_col_time_v6_1-2	Time Collected - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		SAS Time .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	specship_num_blue_tops_ex_1-4	Number Of Blue Tiger Tops If Less Than 5 Quantity - Specimen 4 - Extra Visit - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_blue_tops_v2_1-4	Number Of Blue Tiger Tops If Less Than 5 Quantity - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_blue_tops_v4_1-3	Number Of Blue Tiger Tops If Less Than 5 Quantity - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_blue_tops_v5_1-2	Number Of Blue Tiger Tops If Less Than 5 Quantity - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_blue_tops_v6_1-2	Number Of Blue Tiger Tops If Less Than 5 Quantity - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_red_tops_ex_1-4	Number Of Red Tiger Tops If Not 1 - Specimen 4 - Extra Visit - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_red_tops_v2_1-4	Number Of Red Tiger Tops If Not 1 - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_red_tops_v4_1-3	Number Of Red Tiger Tops If Not 1 - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_red_tops_v5_1-2	Number Of Red Tiger Tops If Not 1 - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_red_tops_v6_1-2	Number Of Red Tiger Tops If Not 1 - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	specship_num_slides_ex_1-4	Number Of Unstained Slides If Not 10 - Specimen 4 - Extra Visit - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_slides_v2_1-4	Number Of Unstained Slides If Not 10 - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_slides_v4_1-3	Number Of Unstained Slides If Not 10 - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_slides_v5_1-2	Number Of Unstained Slides If Not 10 - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_num_slides_v6_1-2	Number Of Unstained Slides If Not 10 - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	specship_rcv_dt_ex_1-4	Date Received - Specimen 4 - Extra Visit - [Specimen Shipping]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_rcv_dt_v2_1-4	Date Received - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_rcv_dt_v4_1-3	Date Received - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_rcv_dt_v5_1-2	Date Received - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_rcv_dt_v6_1-2	Date Received - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_reference_ex_1-4	Reference - Specimen 4 - Extra Visit - [Specimen Shipping]		Char
01. Principal	specship_reference_v2_1-4	Reference - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		Char
01. Principal	specship_reference_v4_1-3	Reference - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		Char

Class	Variable	Label	Description	Format Text
01. Principal	specship_referen ce_v5_1-2	Reference - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		Char
01. Principal	specship_referen ce_v6_1-2	Reference - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		Char
01. Principal	specship_ship_d t_ex_1-4	Date Shipped - Specimen 4 - Extra Visit - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_ship_d t_v2_1-4	Date Shipped - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_ship_d t_v4_1-3	Date Shipped - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_ship_d t_v5_1-2	Date Shipped - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_ship_d t_v6_1-2	Date Shipped - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_state_e x_1-4	Cold/Frozen/Other - Specimen 4 - Extra Visit - [Specimen Shipping]		.N="N/A" .R="Not Randomized" 2="Frozen" 3="Other"
01. Principal	specship_state_v 2_1-4	Cold/Frozen/Other - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Cold" 3="Other"
01. Principal	specship_state_v 4_1-3	Cold/Frozen/Other - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Cold" 3="Other"
01. Principal	specship_state_v 5_1-2	Cold/Frozen/Other - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Cold" 3="Other"
01. Principal	specship_state_v 6_1-2	Cold/Frozen/Other - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Cold" 3="Other"

Class	Variable	Label	Description	Format Text
01. Principal	specship_tissue_id_ex_1-4	Tissue Specimen ID - Specimen 4 - Extra Visit - [Specimen Shipping]		Char
01. Principal	specship_tissue_id_v2_1-4	Tissue Specimen ID - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		Char
01. Principal	specship_tissue_id_v4_1-3	Tissue Specimen ID - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		Char
01. Principal	specship_tissue_id_v5_1-2	Tissue Specimen ID - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		Char
01. Principal	specship_tissue_id_v6_1-2	Tissue Specimen ID - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		Char
01. Principal	specship_tst_num_ex_1-4	Number Of Tubes, Slides or Tissue - Specimen 4 - Extra Visit - [Specimen Shipping]		.M="Missing" .N="N/A" .R="Not Randomized" 1="5 Blue Tiger Tops" 2="1 Red Tiger Top" 3="10 Unstained Slides And 1 H And E"
01. Principal	specship_tst_num_v2_1-4	Number Of Tubes, Slides or Tissue - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		.N="N/A" .R="Not Randomized" 1="5 Blue Tiger Tops" 2="1 Red Tiger Top" 3="10 Unstained Slides And 1 H And E" 4="Tissue"
01. Principal	specship_tst_num_v4_1-3	Number Of Tubes, Slides or Tissue - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		.N="N/A" .R="Not Randomized" 1="5 Blue Tiger Tops" 2="1 Red Tiger Top" 3="10 Unstained Slides And 1 H And E"
01. Principal	specship_tst_num_v5_1-2	Number Of Tubes, Slides or Tissue - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		.N="N/A" .R="Not Randomized" 1="5 Blue Tiger Tops" 2="1 Red Tiger Top"
01. Principal	specship_tst_num_v6_1-2	Number Of Tubes, Slides or Tissue - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		.N="N/A" .R="Not Randomized" 1="5 Blue Tiger Tops" 2="1 Red Tiger Top"
01. Principal	specship_verif_dt_ex_1-4	Date Verified - Specimen 4 - Extra Visit - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_verif_dt_v2_1-4	Date Verified - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	specship_verif_d t_v4_1-3	Date Verified - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_verif_d t_v5_1-2	Date Verified - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_verif_d t_v6_1-2	Date Verified - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_visit_dt _ex_1-4	Visit Date - Specimen 4 - Extra Visit - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_visit_dt _v2_1-4	Visit Date - Specimen 4 - Visit 2 (Vaccination 1) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_visit_dt _v4_1-3	Visit Date - Specimen 3 - Visit 4 (Surgery) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_visit_dt _v5_1-2	Visit Date - Specimen 2 - Visit 5 (Post-Inoculation) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	specship_visit_dt _v6_1-2	Visit Date - Specimen 2 - Visit 6 (Final Follow-Up) - [Specimen Shipping]		SAS Date .N="N/A" .R="Not Randomized"

Section 16: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	conmed_continuing1-18	Continuing - Medication # - [Concomitant Medications]		.N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	conmed_dose1-18	Dose - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_freq1-18	Frequency - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_name1-18	Medication - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_num	Number Of Medications Taken - [Concomitant Medications]		Numeric .R="Not Randomized"
01. Principal	conmed_oth_freq1-18	Other Frequency - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_oth_units1-18	Other Units - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_reason1-18	Reason - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_report_dt1-18	Medication Reported Date - Medication # - [Concomitant Medications]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	conmed_start_dt1-18	Start Date - Medication # - [Concomitant Medications]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	conmed_stop_dt1-18	Stop Date - Medication # - [Concomitant Medications]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	conmed_units1-18	Units - Medication # - [Concomitant Medications]		Char

Section 17: Eligibility Verification

Class	Variable	Label	Description	Format Text
01. Principal	elig_comments	Comments - [Eligibility Verification]		Char
01. Principal	elig_rand_criteria	Meets Randomization Criteria? - [Eligibility Verification]		0="No" 1="Yes"
01. Principal	elig_verif_dt	Verified on Date - [Eligibility Verification]		SAS Date .M="Missing"
01. Principal	elig_verif_status	Verification Status - [Eligibility Verification]		.M="Missing" 0="Ineligible" 1="Confirmed" 2="Pending"

Section 18: Inclusion Criteria

Class	Variable	Label	Description	Format Text
01. Principal	incl_clinchem	Is Clinical Chemistry Less Than 2x Normal Upper Limit Of Normal Range? - [Inclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	incl_comply	Is The Participant Willing To Comply With All Study Interventions And Follow-Up Procedures? - [Inclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	incl_consent	Does The Participant Have The Ability To Understand And The Willingness To Sign A Written Informed Consent Document? - [Inclusion Criteria]		.R="Not Randomized" 1="Yes"
01. Principal	incl_dcis	Does The Participant Have A Diagnosis Of Dcis Made By Core Needle Biopsy? - [Inclusion Criteria]		.R="Not Randomized" 1="Yes"
01. Principal	incl_ecog	Is The ECOG Performance Status 0 Or 1 (Karnofsky >60%)? - [Inclusion Criteria]		.M="Missing" .R="Not Randomized" 1="Yes"
01. Principal	incl_eject_fract	A Normal Ejection Fraction, As Defined By The Participant's Institution. - [Inclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	incl_fem18	Is The Participant Female >18 Years Of Age, Pre Or Post-Menopausal? - [Inclusion Criteria]		.R="Not Randomized" 1="Yes"
01. Principal	incl_hla_a2	Is The Participant HLA-A2 Positive? - [Inclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	incl_rad_abn	Does The Participant Have An Area Of Radiographic Abnormality Measuring At Least 1 cm. - [Inclusion Criteria]		.N="N/A" .R="Not Randomized" 1="Yes"

Section 19: Exclusion Criteria

Class	Variable	Label	Description	Format Text
01. Principal	excl_autoimmune	Does The Participant Have Any Autoimmune Diseases Including Or Any Other Medical Conditions That, In The Opinion Of The Investigator, Would Compromise The Subject's Safety? - [Exclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	excl_bcanc	Does The Participant Have Invasive Breast Cancer? Areas Of Microinvasion Or Suspicious For Microinvasion On Core Biopsy Is Allowed. - [Exclusion Criteria]		.R="Not Randomized" 0="No"
01. Principal	excl_bilateral	Does The Participant Have Bilateral Breast Malignancy Or An Unconfirmed, Nonmalignant But Suspicious Mass In The Opposite Breast To Include Atypical Ductal Hyperplasia? - [Exclusion Criteria]		.N="N/A" .R="Not Randomized" 0="No"
01. Principal	excl_concurr_trt	Is The Participant Taking Concurrent Treatment With Other Investigational Agent - [Exclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	excl_dcis	Does The Participant Have A History Of Prior Ductal Carcinoma In Situ (DCIS) Treated Within The Past Two Years? Patients Completing All Treatment For A Previous Diagnosis Of DCIS Over Two...? - [Exclusion Criteria]		.M="Missing" .N="N/A" .R="Not Randomized" 0="No"
01. Principal	excl_dcis_lcis	Does The Participant Have A History Of Prior Ductal Carcinoma In Situ (DCIS)? Prior Lobular Carcinoma In Situ (LCIS) Is Allowed - [Exclusion Criteria]		.F="No Record For This Visit" .R="Not Randomized" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	excl_hiv_hep	Does The Participant Have A Known History Of Or Known Active Infection With Human Immunodeficiency Virus (HIV), Hepatitis B Or Hepatitis C? - [Exclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	excl_hypersens	Does The Participant Have A Known Hypersensitivity To GM-CSF, Yeast-Derived Products, Or Any Component Of The GM-CSF Product (E.G. Mannitol) - [Exclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	excl_illness	Does The Participant Have Uncontrolled Intercurrent Illness Including, But Not Limited To, Ongoing Or Active Infection, Symptomatic Congestive Heart Failure, Unstable Angina Pectoris, Cardiac Arrhythmia...? - [Exclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	excl_immune_def	Does The Participant Have Known Immune Deficiency Diseases Such As Immunoglobulin Deficiency Or Immunosuppressive Therapy That Might Interfere With Appropriate Immune Response? - [Exclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	excl_immunotherapy	Has The Participant Had Any Recent Or Planned Immunotherapy - [Exclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	excl_lcis	Prior Lobular Carcinoma In Situ (LCIS) Is Allowed - [Exclusion Criteria]		.M="Missing" .N="N/A" .R="Not Randomized" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	excl_neuvax_aller	Does The Participant Have A History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To NeuVax? - [Exclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	excl_nonb_malign	Does The Participant Have A History Of Non-Breast Malignancy Within 5 Years Prior To Randomization, Except Curatively Treated Superficial Bladder Cancer, Carcinoma In Situ Of The Cervix (Stage 0 - 1)...? - [Exclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	excl_preg	Is The Participant Pregnant, Unwilling To Use Adequate Contraception During Study Treatment Duration Or Breastfeeding. - [Exclusion Criteria]		.M="Missing" .N="N/A" .R="Not Randomized" 0="No"
01. Principal	excl_prior_bcanc	History Of Prior Breast Cancer Treated Within The Past Two Years. Patients Completing All Breast Cancer-Specific Treatment Over Two Years Prior To The Current Diagnosis Are Eligible. - [Exclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	excl_steroid_imm	Is The Patient On Chronic Steroid Therapy Or Other Immunosuppressive Therapy Except For Topical Or Inhaled Steroids Known To Have Low Systemic Absorption? - [Exclusion Criteria]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Section 20: Randomization

Class	Variable	Label	Description	Format Text
01. Principal	rand_dt	Date Participant Randomized - [Randomization]		SAS Date .R="Not Randomized"
01. Principal	rand_eligible	Is Participant Eligible For Inclusion In The Protocol - [Randomization]		0="No" 1="Yes"
01. Principal	rand_hla_a2	HLA A2 Status - [Randomization]		.M="Missing" 0="Negative" 1="Positive"
01. Principal	rand_not_applicable	Not Applicable - [Randomization]		0="False" 1="True"
01. Principal	rand_num	Randomization Number - [Randomization]		Char
01. Principal	rand_obtain_dt	Date Obtained - [Randomization]		SAS Date .M="Missing"
01. Principal	rand_tac1-2	TAC2 (Vaccine Group Neli pepimut-S Peptide1000 mcg And GM-CSF 250 mcg ID x2 Vaccinations 2 Weeks Apart Prior To Surgery) - [Randomization]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	rand_tac1b	TAC1B (GM-CSF Only Group: GM-CSF 250 mcg ID x3 Vaccinations 2 Weeks Apart Prior To Surgery) - [Randomization]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	rand_tac2b	TAC2B (GM-CSF Only Group: GM-CSF 250 mcg ID x2 Vaccinations 2 Weeks Apart Prior To Surgery) - [Randomization]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Section 21: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_num	Number Of Adverse Events The Participant Experienced During The Study - [Adverse Events]		Numeric .R="Not Randomized"

Section 22: Symptom Assessment

Class	Variable	Label	Description	Format Text
01. Principal	sympas_arthra_comment_v1-6	Arthralgias - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_arthra_end_dt_v1-6	Arthralgias - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_arthra_grade_v1-6	Arthralgias - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_arthra_onset_dt_v1-6	Arthralgias - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_arthra_response_v1-6	Arthralgias - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False"
01. Principal	sympas_backp_comment_v1-6	Back Pain - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_backp_end_dt_v1-6	Back Pain - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_backp_grade_v1-6	Back Pain - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_backp_onset_dt_v1-6	Back Pain - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_backp_response_v1-6	Back Pain - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False"
01. Principal	sympas_bonep_comment_v1-6	Bone Pain - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_bonep_end_dt_v1-6	Bone Pain - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	sympas_bonep_grade_v1-6	Bone Pain - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_bonep_onset_dt_v1-6	Bone Pain - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_bonep_response_v1-6	Bone Pain - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False"
01. Principal	sympas_ery_edema_comment_v1-6	Erythema/Edema - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_ery_edema_end_dt_v1-6	Erythema/Edema - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_ery_edema_grade_v1-6	Erythema/Edema - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_ery_edema_onset_dt_v1-6	Erythema/Edema - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_ery_edema_response_v1-6	Erythema/Edema - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	sympas_fatigue_comment_v1-6	Fatigue - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_fatigue_end_dt_v1-6	Fatigue - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_fatigue_grade_v1-6	Fatigue - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_fatigue_onset_dt_v1-6	Fatigue - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_fatigue_response_v1-6	Fatigue - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	sympas_fever_comment_v1-6	Fever - Comment - Visit # - [Symptom Assessment]		Char

Class	Variable	Label	Description	Format Text
01. Principal	sympas_fever_end_dt_v1-6	Fever - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_fever_grade_v1-6	Fever - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_fever_onset_dt_v1-6	Fever - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_fever_response_v1-6	Fever - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False"
01. Principal	sympas_headache_comment_v1-6	Headache - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_headache_end_dt_v1-6	Headache - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_headache_grade_v1-6	Headache - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_headache_onset_dt_v1-6	Headache - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_headache_response_v1-6	Headache - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	sympas_induration_comment_v1-6	Induration - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_induration_end_dt_v1-6	Induration - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_induration_grade_v1-6	Induration - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_induration_onset_dt_v1-6	Induration - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	sympas_indur_response_v1-6	Induration - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	sympas_malaise_comment_v1-6	Malaise - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_malaise_end_dt_v1-6	Malaise - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_malaise_grade_v1-6	Malaise - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_malaise_onset_dt_v1-6	Malaise - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_malaise_response_v1-6	Malaise - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False"
01. Principal	sympas_myalgias_comment_v1-6	Myalgias - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_myalgias_end_dt_v1-6	Myalgias - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_myalgias_grade_v1-6	Myalgias - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_myalgias_onset_dt_v1-6	Myalgias - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_myalgias_response_v1-6	Myalgias - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	sympas_nausea_comment_v1-6	Nausea - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_nausea_end_dt_v1-6	Nausea - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_nausea_grade_v1-6	Nausea - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	sympas_nausea_onset_dt_v1-6	Nausea - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_nausea_response_v1-6	Nausea - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False"
01. Principal	sympas_oth_comment_v1-6	Other Symptom - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_oth_end_dt_v1-6	Other Symptom - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	sympas_oth_grade_v1-6	Other Symptom - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	sympas_oth_onset_dt_v1-6	Other Symptom - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	sympas_oth_response_v1-6	Other Symptom - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	sympas_oth_symptom_v1-6	Other Symptom - Symptom - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_pruritus_comment_v1-6	Pruritus - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_pruritus_end_dt_v1-6	Pruritus - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_pruritus_grade_v1-6	Pruritus - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_pruritus_onset_dt_v1-6	Pruritus - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_pruritus_response_v1-6	Pruritus - Response - Visit # - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	sympas_visit_dt_v1-6	Visit Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	sympas_vomiting_comment_v1-6	Vomiting - Comment - Visit # - [Symptom Assessment]		Char
01. Principal	sympas_vomiting_end_dt_v1-6	Vomiting - End Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_vomiting_grade_v1-6	Vomiting - Grade - Visit # - [Symptom Assessment]		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_vomiting_onset_dt_v1-6	Vomiting - Onset Date - Visit # - [Symptom Assessment]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	sympas_vomiting_response_v1-6	Vomiting - Response - Visit 1 (Baseline) - [Symptom Assessment]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False"

Section 23: Telephone Contact

Class	Variable	Label	Description	Format Text
01. Principal	tele_ae1-4	Did The Participant Report Any Symptoms Or Adverse Events? - Contact # - [Telephone Contact]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tele_conmed1-4	Were Any Changes In Concomitant Medication Reported? - Contact # - [Telephone Contact]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tele_contact_dt1-4	Date Of Telephone Contact - Contact # - [Telephone Contact]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	tele_contact_num	Number Of Times Contacted By Telephone - [Telephone Contact]		Numeric .R="Not Randomized"
01. Principal	tele_on_agent1-4	Is The Participant Currently On Study Agent? - Contact # - [Telephone Contact]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Section 24: Off Study

Class	Variable	Label	Description	Format Text
01. Principal	offstudy_agent_end_dt	Agent End Date - [Off Study]		SAS Date .M="Missing"
01. Principal	offstudy_dt	Off Study Date - [Off Study]		SAS Date
01. Principal	offstudy_form_dt	Form Date - [Off Study]		SAS Date .M="Missing"
01. Principal	offstudy_last_contact_dt	Date Of Last Contact - [Off Study]		SAS Date
01. Principal	offstudy_na	Not Applicable - [Off Study]		0="False" 1="True"
01. Principal	offstudy_no_ae	Participant Did Not Have Any Adverse Events - [Off Study]		0="False" 1="True"
01. Principal	offstudy_no_agent	Check This Box If The Participant Did Not Have Any Agent - [Off Study]		0="False" 1="True"
01. Principal	offstudy_no_conmed	Participant Did Not Take Any Concomitant Meds - [Off Study]		0="False" 1="True"
01. Principal	offstudy_rsn	Off Study Reason - [Off Study]		3="Disease Progression" 5="Ineligible" 7="Participant Withdrawal" 10="Protocol Defined Follow-Up Completed" 11="Other, Specify"
01. Principal	offstudy_rsn_exp	Reason Explanation - [Off Study]		Char

Section 25: Inoculation

Class	Variable	Label	Description	Format Text
01. Principal	inoc_admin_time1-5	Time Administered - Inoculation # - [Inoculation]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_bp_lower1-5	Blood Pressure L - Inoculation # - [Inoculation]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	inoc_bp_lower15_1-5	Blood Pressure (Lower) 15 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_bp_lower30_1-5	Blood Pressure (Lower) 30 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	inoc_bp_upper15_1-5	Blood Pressure (Upper) 15 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_bp_upper30_1-5	Blood Pressure (Upper) 30 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	inoc_cycle1-5	Inoculation Cycle - Inoculation # - [Inoculation]		Char
01. Principal	inoc_dose_reduction1-5	Indication For Dose Reduction From Previous Inoculation - Inoculation # - [Inoculation]		.M="Missing" .N="N/A" .R="Not Randomized" 0="No"
01. Principal	inoc_dth_100mcg_nelip1-5	DTH 100mcg Nelipepimut S Peptide - Inoculation # - [Inoculation]		Char
01. Principal	inoc_gm_csf_brand1-5	GM CSF Brand - Inoculation # - [Inoculation]		Char
01. Principal	inoc_gm_csf_dose1-5	If Dose Reduction List Dose Of GM-CSF From Last Inoculation - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	inoc_gm_csf_exp_dt1-5	GM CSF Expiration - Inoculation # - [Inoculation]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_gm_csf_lot 1-5	GM CSF Lot - Inoculation # - [Inoculation]		Char
01. Principal	inoc_gm_csf_mcg1-5	mcg GM CSF - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_healthmed_change1-5	Change In Current Health Status Or Medication - Inoculation # - [Inoculation]		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	inoc_immediate_reaction1-5	Immediate Local Or Systemic Reactions - Inoculation # - [Inoculation]		.N="N/A" .R="Not Randomized" 0="None" 1="Yes"
01. Principal	inoc_num	Number Of Inoculation Visits - [Inoculation]		Numeric .R="Not Randomized"
01. Principal	inoc_peptide_dose1-5	If Dose Reduction List Dose Of Peptide From Last Inoculation - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_peptide_mcg1-5	mcg Nelipepimut S Peptide - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_peptide_mcg_only1-5	mcg GM CSF Only - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_photo30_1-5	Photograph 30 Minutes Within Monitoring Period - Inoculation # - [Inoculation]		.F="No Record For This Visit" .R="Not Randomized" 1="True"
01. Principal	inoc_pre_bp_sys 1-5	Pre-Inoculation Systolic Blood Pressure - Inoculation # - [Inoculation]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	inoc_pre_pulse1-5	Pre-Inoculation Pulse Rate - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_pre_resp1-5	Pre-Inoculation Respiration Rate - Inoculation # - [Inoculation]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	inoc_pre_temp1-5	Pre-Inoculation Temperature - Inoculation # - [Inoculation]		Numeric .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	inoc_pre_temp_unit1-5	Pre-Inoculation Temperature Unit - Inoculation # - [Inoculation]		.N="N/A" .R="Not Randomized" 1="°C" 2="°F"
01. Principal	inoc_pre_time1-5	Pre-Inoculation Time - Inoculation # - [Inoculation]		SAS Time .N="N/A" .R="Not Randomized"
01. Principal	inoc_pre_time15_1-5	Time 15 Minutes After Inoculation - Inoculation # - [Inoculation]		SAS Time .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_pre_time30_1-5	Time 30 Minutes After Inoculation - Inoculation # - [Inoculation]		SAS Time .N="N/A" .R="Not Randomized"
01. Principal	inoc_pulse15_1-5	Pulse Rate 15 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_pulse30_1-5	Pulse Rate 30 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	inoc_resp15_1-5	Respiration Rate 15 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_resp30_1-5	Respiration Rate 30 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	inoc_site1-5	Site - Inoculation # - [Inoculation]		Char
01. Principal	inoc_temp15_1-5	Temperature 15 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_temp30_1-5	Temperature 30 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_temp_unit15_1-5	Temperature Unit 15 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	inoc_temp_unit30_1-5	Temperature Unit 30 Minutes After Inoculation - Inoculation # - [Inoculation]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	inoc_verif_dt1-5	Verified Date - Inoculation # - [Inoculation]		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	inoc_visit_dt1-5	Visit Date - Inoculation # - [Inoculation]		SAS Date .N="N/A" .R="Not Randomized"

Section 26: Surgical Resection

Class	Variable	Label	Description	Format Text
01. Principal	resec_dcis	Is DCIS Present - [Surgical Resection]		.R="Not Randomized" 0="False" 1="True"
01. Principal	resec_dcis_inv	Is DCIS Present with Invasive Cancer - [Surgical Resection]		.R="Not Randomized" 0="False" 1="True"
01. Principal	resec_grade	Grade - [Surgical Resection]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	resec_grade_inv	Grade (Invasive Cancer) - [Surgical Resection]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	resec_laterality	Laterality - [Surgical Resection]		.R="Not Randomized" 1="Right Breast" 2="Left Breast"
01. Principal	resec_margin	Margin Status - [Surgical Resection]		.M="Missing" .R="Not Randomized" 0="Negative (Clear)" 1="Positive"
01. Principal	resec_margin_inv	Margin Status (Invasive Cancer) - [Surgical Resection]		.M="Missing" .R="Not Randomized" 0="Negative (Clear)" 1="Positive"
01. Principal	resec_proc_type	Type Of Procedure - [Surgical Resection]		.R="Not Randomized" 1="Lumpectomy" 2="Partial Mastectomy" 3="Mastectomy"
01. Principal	resec_size	Size - [Surgical Resection]		Numeric .M="Missing" .R="Not Randomized" .U="Unknown"
01. Principal	resec_size_inv	Size (Invasive Cancer) - [Surgical Resection]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	resec_visit_dt	Visit Date - [Surgical Resection]		SAS Date .R="Not Randomized"

Section 27: Post-Inoculation

Class	Variable	Label	Description	Format Text
01. Principal	pinoc_all_sites_mgd1-6	All Sites Merged 1 - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_and_site_pair_a1-6	And Site Pair A - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_arthra_grade1-6	Arthralgias Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_backp_grade1-6	Back Pain Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_bonep_grade1-6	Bone Pain Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_booster_time1-6	Booster Time - # - [Post-Inoculation]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	pinoc_chills_grade1-6	Chills Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_cycle1-6	Inoculation Cycle - # - [Post-Inoculation]		Char
01. Principal	pinoc_dth_e75_1-6	DTH Measurements E75 - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_dth_meas_e75_1-6	DTH Measurements E75 x - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	pinoc_ery_edema1-6	Erythema Edema Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_eval_time1-6	Evaluation Time - # - [Post-Inoculation]		Char
01. Principal	pinoc_evaluation1-6	Evaluation - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Local Reaction (48-72 Hours After Placement)" 2="Researcher Measured" 3="Self-Reported" 4="N/A"
01. Principal	pinoc_exp_arthra1-6	Expected Arthralgias - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_exp_backp1-6	Expected Back Pain - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_exp_bonep1-6	Expected Bone Pain - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_exp_chills1-6	Expected Chills - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_exp_ery_edema1-6	Expected Erythema Edema - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_exp_fatigue1-6	Expected Fatigue - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_exp_fever1-6	Expected Fever - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_exp_headache1-6	Expected Headache - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	pinoc_exp_induration1-6	Expected Induration - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_exp_malaise1-6	Expected Malaise - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_exp_myalgias1-6	Expected Myalgias - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	pinoc_exp_nausea1-6	Expected Nausea - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_exp_other1-6	Expected Other - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_exp_pruritus1-6	Expected Pruritus - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_exp_systemic1-6	Expected Systemic - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_exp_vomiting1-6	Expected Vomiting - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_fatigue_grade1-6	Fatigue Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_fda_rpt1-6	If Yes Was FDA Report Written - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	pinoc_fever_grade1-6	Fever Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	pinoc_headache_grade1-6	Headache Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_indur_grade1-6	Induration Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_irb_notified1-6	Local IRB notified - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	pinoc_local_ae1-6	Local AE None - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="None"
01. Principal	pinoc_malaise_grade1-6	Malaise Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_myalgias_grade1-6	Myalgias Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_nausea_grade1-6	Nausea Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_num	Number Of Post-Inoculations - [Post-Inoculation]		Numeric .R="Not Randomized"
01. Principal	pinoc_oth_local_ae_grade1-6	Other Local AE Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_oth_systemic1-6	Other Systemic - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_photograph1-5	Photograph - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	pinoc_pi_notified1-6	PI Notified - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	pinoc_pruritus_grade1-6	Pruritus Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_rel_arthra1-6	Related Arthralgias - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_rel_backp1-6	Related Back Pain - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_rel_bonep1-6	Related Bone Pain - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_rel_chills1-6	Related Chills - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_rel_ery_ed1-6	Related Erythema Edema - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_rel_fatigue1-6	Related Fatigue - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	pinoc_rel_fever1-6	Related Fever - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_rel_headache1-6	Related Headache - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_rel_induration1-6	Related Induration - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	pinoc_rel_malaise1-6	Related Malaise - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_rel_myalgias1-6	Related Myalgias - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	pinoc_rel_nausea1-6	Related Nausea - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_rel_other1-6	Related Other - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_rel_pruritus1-6	Related Pruritus - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="True"
01. Principal	pinoc_rel_systemic1-6	Related Systemic - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_rel_vomiting1-6	Related Vomiting - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_researcher_meas_na1-6	NA Researcher Measured - # - [Post-Inoculation]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Yes"
01. Principal	pinoc_sae1-6	Any Of The Above Events Serious - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False"
01. Principal	pinoc_self_rpt_meas1-6	Self Reported Measured - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1=">= 10 cm x 10 cm"
01. Principal	pinoc_self_rpt_meas_na1-6	Self Reported Measured NA - # - [Post-Inoculation]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	pinoc_site1_med 1_1-6	Site 1 Medial 1 - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_site2_med 1_1-6	Site 2 Medial 1 - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_site3_med 1_1-6	Site 3 Medial 1 - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_site4_med 1_1-6	Site 4 Medial 1 - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_site_pair_ a1-6	Site Pair A - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_site_pair_ a_mgd1_1-6	Site Pair A Merged 1 - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_spec_oth_ loc_ae1-6	Specify Other Local AE - # - [Post-Inoculation]		Char
01. Principal	pinoc_systemic_ ae1-6	None Systemic AE - # - [Post-Inoculation]		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No"
01. Principal	pinoc_systemic_ spec1-6	Specify Systemic - # - [Post-Inoculation]		Char
01. Principal	pinoc_time2_1-6	Time 2 - # - [Post-Inoculation]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_verif_dt1-6	Verified Date - # - [Post-Inoculation]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_visit_dt1-6	Visit Date - # - [Post-Inoculation]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	pinoc_vomiting_grade1-6	Vomiting Grade - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_x_1b1-6	x 1B - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_x_2b1-6	x 2B - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_x_3b1-6	x 3B - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_x_4b1-6	x 4B - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_x_all_mgd1-6	x All Merge2 - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_x_sb2_mgd1-6	x SB2 Merge - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pinoc_x_sb_mgd1-6	x SB Merge - # - [Post-Inoculation]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Section 28: Post-Surgery Radiation Therapy

Class	Variable	Label	Description	Format Text
01. Principal	psrad_aes	AEs - [Post-Surgery Radiation Therapy]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	psrad_boost	Boost? - [Post-Surgery Radiation Therapy]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No Boost" 1="Boost"
01. Principal	psrad_boost_beg_in_dt	Boost - Date Began - [Post-Surgery Radiation Therapy]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	psrad_boost_complete_dt	Boost - Date Completed - [Post-Surgery Radiation Therapy]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	psrad_boost_fractions	Boost - Fractions - [Post-Surgery Radiation Therapy]		Char
01. Principal	psrad_boost_total_dose	Boost - Total Dose - [Post-Surgery Radiation Therapy]		Char
01. Principal	psrad_comments	Rad Therapy Comments - [Post-Surgery Radiation Therapy]		Char
01. Principal	psrad_det_comments	Rad Therapy Details Comments - [Post-Surgery Radiation Therapy]		Char
01. Principal	psrad_exter_begin_dt	External/Intraoperative - Date Began - [Post-Surgery Radiation Therapy]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	psrad_exter_complete_dt	External/Intraoperative - Date Completed - [Post-Surgery Radiation Therapy]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	psrad_exter_complete_na	External/Intraoperative - Date Completed NA - [Post-Surgery Radiation Therapy]		.F="No Record For This Visit" .R="Not Randomized" 0="False"
01. Principal	psrad_exter_fractions	External/Intraoperative - Fractions - [Post-Surgery Radiation Therapy]		Char

Class	Variable	Label	Description	Format Text
01. Principal	psrad_exter_intra	External Or Intraoperative? - [Post-Surgery Radiation Therapy]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="External"
01. Principal	psrad_exter_total_dose	External/Intraoperative - Total Dose - [Post-Surgery Radiation Therapy]		Char
01. Principal	psrad_laterality	Laterality - [Post-Surgery Radiation Therapy]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Right" 2="Left"
01. Principal	psrad_received	Did The Participant Receive Radiation Therapy - [Post-Surgery Radiation Therapy]		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	psrad_site	Site - [Post-Surgery Radiation Therapy]		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Partial Breast" 2="Whole Breast"
01. Principal	psrad_visit_dt	Visit Date - [Post-Surgery Radiation Therapy]		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 29: Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alkphos_clinsig_v1	Alkaline Phosphate - Clinically Significant - Visit 1 (Baseline) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_alkphos_clinsig_v4	Alkaline Phosphate - Clinically Significant - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_alkphos_cmnt_v1	Alkaline Phosphate - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_alkphos_cmnt_v4	Alkaline Phosphate - Comments - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_alkphos_fasting_v1	Alkaline Phosphate - Fasting - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	bldchem_alkphos_fasting_v4	Alkaline Phosphate - Fasting - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_alkphos_not_obt_v1	Alkaline Phosphate - Not Obtained - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No"
01. Principal	bldchem_alkphos_not_obt_v4	Alkaline Phosphate - Not Obtained - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_alkphos_oor_v1	Alkaline Phosphate - Out Of Range - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_alkphos_oor_v4	Alkaline Phosphate - Out Of Range - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_alkphos_rslt_v1	Alkaline Phosphate - Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_alkphos_rslt_v4	Alkaline Phosphate - Result - Visit 4 (Surgery) - [Blood Chemistry]		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alkphos_units_v1	Alkaline Phosphate - Units - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_alkphos_units_v4	Alkaline Phosphate - Units - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_bili_clin_sig_v1	Total Bilirubin - Clinically Significant - Visit 1 (Baseline) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_bili_clin_sig_v4	Total Bilirubin - Clinically Significant - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_bili_comments_v1	Total Bilirubin - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_bili_comments_v4	Total Bilirubin - Comments - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_bili_fasting_v1	Total Bilirubin - Fasting - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	bldchem_bili_fasting_v4	Total Bilirubin - Fasting - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_bili_not_obt_v1	Total Bilirubin - Not Obtained - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No"
01. Principal	bldchem_bili_not_obt_v4	Total Bilirubin - Not Obtained - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bili_oor_v1	Total Bilirubin - Out Of Range - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bili_oor_v4	Total Bilirubin - Out Of Range - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_bili_rslt_v1	Total Bilirubin - Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_bili_rslt_v4	Total Bilirubin - Result - Visit 4 (Surgery) - [Blood Chemistry]		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bili_units_v1	Total Bilirubin - Units - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_bili_units_v4	Total Bilirubin - Units - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_clinsig_v1	BUN - Clinically Significant - Visit 1 (Baseline) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_bun_clinsig_v4	BUN - Clinically Significant - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_bun_comments_v1	BUN - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_comments_v4	BUN - Comments - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_bun_fasting_v1	BUN - Fasting - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	bldchem_bun_fasting_v4	BUN - Fasting - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_bun_not_obt_v1	BUN - Not Obtained - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No"
01. Principal	bldchem_bun_not_obt_v4	BUN - Not Obtained - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bun_out_of_range_v1	BUN - Out Of Range - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bun_out_of_range_v4	BUN - Out Of Range - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_bun_result_v1	BUN - Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_bun_result_v4	BUN - Result - Visit 4 (Surgery) - [Blood Chemistry]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldchem_bun_units_v1	BUN - Units - Visit 1 (Baseline) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bun_units_v4	BUN - Units - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_creat_clinsig_v1	Creatinine - Clinically Significant - Visit 1 (Baseline) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_creat_clinsig_v4	Creatinine - Clinically Significant - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_creat_comments_v1	Creatinine - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_creat_comments_v4	Creatinine - Comments - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_creat_fasting_v1	Creatinine - Fasting - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	bldchem_creat_fasting_v4	Creatinine - Fasting - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_creat_not_obt_v1	Creatinine - Not Obtained - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No"
01. Principal	bldchem_creat_not_obt_v4	Creatinine - Not Obtained - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_creat_out_of_range_v1	Creatinine - Out Of Range - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_creat_out_of_range_v4	Creatinine - Out Of Range - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_creat_result_v1	Creatinine - Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_creat_result_v4	Creatinine - Result - Visit 4 (Surgery) - [Blood Chemistry]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldchem_creat_units_v1	Creatinine - Units - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_creat_units_v4	Creatinine - Units - Visit 4 (Surgery) - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_lactate_clinsig_v1	Lactate Dehydrogenase - Clinically Significant - Visit 1 (Baseline) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_lactate_clinsig_v4	Lactate Dehydrogenase - Clinically Significant - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_lactate_cmnt_v1	Lactate Dehydrogenase - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_lactate_cmnt_v4	Lactate Dehydrogenase - Comments - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_lactate_fasting_v1	Lactate Dehydrogenase - Fasting - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	bldchem_lactate_fasting_v4	Lactate Dehydrogenase - Fasting - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_lactate_not_obt_v1	Lactate Dehydrogenase - Not Obtained - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_lactate_not_obt_v4	Lactate Dehydrogenase - Not Obtained - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_lactate_oor_v1	Lactate Dehydrogenase - Out Of Range - Visit 1 (Baseline) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_lactate_oor_v4	Lactate Dehydrogenase - Out Of Range - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_lactate_rslt_v1	Lactate Dehydrogenase - Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_lactate_rslt_v4	Lactate Dehydrogenase - Result - Visit 4 (Surgery) - [Blood Chemistry]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldchem_lactate_units_v1	Lactate Dehydrogenase - Units - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_lactate_units_v4	Lactate Dehydrogenase - Units - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_sgot_ast_clinsig_v1	SGOT/AST - Clinically Significant - Visit 1 (Baseline) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgot_ast_clinsig_v4	SGOT/AST - Clinically Significant - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_sgot_ast_cmnt_v1	SGOT/AST - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_sgot_ast_cmnt_v4	SGOT/AST - Comments - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_sgot_ast_fasting_v1	SGOT/AST - Fasting - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	bldchem_sgot_ast_fasting_v4	SGOT/AST - Fasting - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_sgot_ast_not_obt_v1	SGOT/AST - Not Obtained - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No"
01. Principal	bldchem_sgot_ast_not_obt_v4	SGOT/AST - Not Obtained - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgot_ast_oor_v1	SGOT/AST - Out Of Range - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgot_ast_oor_v4	SGOT/AST - Out Of Range - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sgot_ast_rslt_v1	SGOT/AST - Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .R="Not Randomized"
01. Principal	bldchem_sgot_ast_rslt_v4	SGOT/AST - Result - Visit 4 (Surgery) - [Blood Chemistry]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldchem_sgot_ast_units_v1	SGOT/AST - Units - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_sgot_ast_units_v4	SGOT/AST - Units - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_alt_clinsig_v1	SGPT/ALT - Clinically Significant - Visit 1 (Baseline) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_alt_clinsig_v4	SGPT/ALT - Clinically Significant - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	bldchem_sgpt_alt_cmnt_v1	SGPT/ALT - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_alt_cmnt_v4	SGPT/ALT - Comments - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_alt_fasting_v1	SGPT/ALT - Fasting - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	bldchem_sgpt_alt_fasting_v4	SGPT/ALT - Fasting - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_sgpt_alt_not_obt_v1	SGPT/ALT - Not Obtained - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No"
01. Principal	bldchem_sgpt_alt_not_obt_v4	SGPT/ALT - Not Obtained - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_alt_oor_v1	SGPT/ALT - Out Of Range - Visit 1 (Baseline) - [Blood Chemistry]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_alt_oor_v4	SGPT/ALT - Out Of Range - Visit 4 (Surgery) - [Blood Chemistry]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bldchem_sgpt_alt_rslt_v1	SGPT/ALT - Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_sgpt_al t_rsit_v4	SGPT/ALT - Result - Visit 4 (Surgery) - [Blood Chemistry]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldchem_sgpt_al t_units_v1	SGPT/ALT - Units - Visit 1 (Baseline) - [Blood Chemistry]		Char
01. Principal	bldchem_sgpt_al t_units_v4	SGPT/ALT - Units - Visit 4 (Surgery) - [Blood Chemistry]		Char
01. Principal	bldchem_spec_d t_v1	Specimen Collection Date - Visit 1 (Baseline) - [Blood Chemistry]		SAS Date .R="Not Randomized"
01. Principal	bldchem_spec_d t_v4	Specimen Collection Date - Visit 4 (Surgery) - [Blood Chemistry]		SAS Date .M="Missing" .R="Not Randomized"

Section 30: Hematology Lab Tests

Class	Variable	Label	Description	Format Text
01. Principal	hema_labs_anc_clinsig_v1	Absolute Neutrophil Count - Clinically Significant - Visit 1 (Baseline) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_anc_clinsig_v4	Absolute Neutrophil Count - Clinically Significant - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_anc_cmnt_v1	Absolute Neutrophil Count - Comments - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_anc_cmnt_v4	Absolute Neutrophil Count - Comments - Visit 4 (Surgery) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_anc_fasting_v1	Absolute Neutrophil Count - Fasting - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_labs_anc_fasting_v4	Absolute Neutrophil Count - Fasting - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_labs_anc_not_obt_v1	Absolute Neutrophil Count - Not Obtained - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No"
01. Principal	hema_labs_anc_not_obt_v4	Absolute Neutrophil Count - Not Obtained - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_anc_oor_v1	Absolute Neutrophil Count - Out Of Range - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_labs_anc_oor_v4	Absolute Neutrophil Count - Out Of Range - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_labs_anc_result_v1	Absolute Neutrophil Count - Result - Visit 1 (Baseline) - [Hematology Lab Tests]		Numeric .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_labs_anc_rslt_v4	Absolute Neutrophil Count - Result - Visit 4 (Surgery) - [Hematology Lab Tests]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	hema_labs_anc_units_v1	Absolute Neutrophil Count - Units - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_anc_units_v4	Absolute Neutrophil Count - Units - Visit 4 (Surgery) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_hemat_clinsig_v1	Hematocrit - Clinically Significant - Visit 1 (Baseline) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_hemat_clinsig_v4	Hematocrit - Clinically Significant - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_hemat_cmnt_v1	Hematocrit - Comments - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_hemat_cmnt_v4	Hematocrit - Comments - Visit 4 (Surgery) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_hemat_fasting_v1	Hematocrit - Fasting - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_labs_hemat_fasting_v4	Hematocrit - Fasting - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_labs_hemat_not_obt_v1	Hematocrit - Not Obtained - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No"
01. Principal	hema_labs_hemat_not_obt_v4	Hematocrit - Not Obtained - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_hemat_oor_v1	Hematocrit - Out Of Range - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_labs_hemat_oor_v4	Hematocrit - Out Of Range - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_hemat_rslt_v1	Hematocrit - Result - Visit 1 (Baseline) - [Hematology Lab Tests]		Numeric .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_labs_hemat_rslt_v4	Hematocrit - Result - Visit 4 (Surgery) - [Hematology Lab Tests]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	hema_labs_hemat_units_v1	Hematocrit - Units - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_hemat_units_v4	Hematocrit - Units - Visit 4 (Surgery) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_hemo_clinsig_v1	Hemoglobin - Clinically Significant - Visit 1 (Baseline) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_hemo_clinsig_v4	Hemoglobin - Clinically Significant - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_hemo_cmnt_v1	Hemoglobin - Comments - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_hemo_cmnt_v4	Hemoglobin - Comments - Visit 4 (Surgery) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_hemo_fasting_v1	Hemoglobin - Fasting - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_labs_hemo_fasting_v4	Hemoglobin - Fasting - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_labs_hemo_not_obt_v1	Hemoglobin - Not Obtained - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No"
01. Principal	hema_labs_hemo_not_obt_v4	Hemoglobin - Not Obtained - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_hemo_oor_v1	Hemoglobin - Out Of Range - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_labs_hemo_oor_v4	Hemoglobin - Out Of Range - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_labs_hemo_rslt_v1	Hemoglobin - Result - Visit 1 (Baseline) - [Hematology Lab Tests]		Numeric .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_labs_hemo_rslt_v4	Hemoglobin - Result - Visit 4 (Surgery) - [Hematology Lab Tests]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	hema_labs_hemo_units_v1	Hemoglobin - Units - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_hemo_units_v4	Hemoglobin - Units - Visit 4 (Surgery) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_plate_clinsig_v1	Platelets - Clinically Significant - Visit 1 (Baseline) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_plate_clinsig_v4	Platelets - Clinically Significant - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_plate_cmnt_v1	Platelets - Comments - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_plate_cmnt_v4	Platelets - Comments - Visit 4 (Surgery) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_plate_fasting_v1	Platelets - Fasting - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_labs_plate_fasting_v4	Platelets - Fasting - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_labs_plate_not_obt_v1	Platelets - Not Obtained - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No"
01. Principal	hema_labs_plate_not_obt_v4	Platelets - Not Obtained - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_plate_oor_v1	Platelets - Out Of Range - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_labs_plate_oor_v4	Platelets - Out Of Range - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_plate_rslt_v1	Platelets - Result - Visit 1 (Baseline) - [Hematology Lab Tests]		Numeric .R="Not Randomized"
01. Principal	hema_labs_plate_rslt_v4	Platelets - Result - Visit 4 (Surgery) - [Hematology Lab Tests]		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_labs_plate_units_v1	Platelets - Units - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_plate_units_v4	Platelets - Units - Visit 4 (Surgery) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_rbc_clinsig_v1	Red Blood Cells - Clinically Significant - Visit 1 (Baseline) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_rbc_clinsig_v4	Red Blood Cells - Clinically Significant - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_rbc_cmnt_v1	Red Blood Cells - Comments - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_rbc_cmnt_v4	Red Blood Cells - Comments - Visit 4 (Surgery) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_rbc_fasting_v1	Red Blood Cells - Fasting - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_labs_rbc_fasting_v4	Red Blood Cells - Fasting - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_labs_rbc_not_obt_v1	Red Blood Cells - Not Obtained - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No"
01. Principal	hema_labs_rbc_not_obt_v4	Red Blood Cells - Not Obtained - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_rbc_oor_v1	Red Blood Cells - Out Of Range - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No"
01. Principal	hema_labs_rbc_oor_v4	Red Blood Cells - Out Of Range - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_rbc_result_v1	Red Blood Cells - Result - Visit 1 (Baseline) - [Hematology Lab Tests]		Numeric .R="Not Randomized"
01. Principal	hema_labs_rbc_result_v4	Red Blood Cells - Result - Visit 4 (Surgery) - [Hematology Lab Tests]		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	hema_labs_rbc_units_v1	Red Blood Cells - Units - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_rbc_units_v4	Red Blood Cells - Units - Visit 4 (Surgery) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_spec_dt_v1	Specimen Collection Date - Visit 1 (Baseline) - [Hematology Lab Tests]		SAS Date .R="Not Randomized"
01. Principal	hema_labs_spec_dt_v4	Specimen Collection Date - Visit 4 (Surgery) - [Hematology Lab Tests]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	hema_labs_wbc_clinsig_v1	White Blood Cells - Clinically Significant - Visit 1 (Baseline) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_wbc_clinsig_v4	White Blood Cells - Clinically Significant - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_wbc_cmnt_v1	White Blood Cells - Comments - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_wbc_cmnt_v4	White Blood Cells - Comments - Visit 4 (Surgery) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_wbc_fasting_v1	White Blood Cells - Fasting - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_labs_wbc_fasting_v4	White Blood Cells - Fasting - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_labs_wbc_not_obt_v1	White Blood Cells - Not Obtained - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No"
01. Principal	hema_labs_wbc_not_obt_v4	White Blood Cells - Not Obtained - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_labs_wbc_oor_v1	White Blood Cells - Out Of Range - Visit 1 (Baseline) - [Hematology Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_labs_wbc_oor_v4	White Blood Cells - Out Of Range - Visit 4 (Surgery) - [Hematology Lab Tests]		.M="Missing" .R="Not Randomized" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hema_labs_wbc_rslt_v1	White Blood Cells - Result - Visit 1 (Baseline) - [Hematology Lab Tests]		Numeric .R="Not Randomized"
01. Principal	hema_labs_wbc_rslt_v4	White Blood Cells - Result - Visit 4 (Surgery) - [Hematology Lab Tests]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	hema_labs_wbc_units_v1	White Blood Cells - Units - Visit 1 (Baseline) - [Hematology Lab Tests]		Char
01. Principal	hema_labs_wbc_units_v4	White Blood Cells - Units - Visit 4 (Surgery) - [Hematology Lab Tests]		Char

Section 31: Hematology Differential

Class	Variable	Label	Description	Format Text
01. Principal	hema_diff_bands_clinsig_v1	Bands % - Clinically Significant - Visit 1 (Baseline) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_diff_bands_clinsig_v4	Bands % - Clinically Significant - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized"
01. Principal	hema_diff_bands_cmnt_v1	Bands % - Comments - Visit 1 (Baseline) - [Hematology Differential]		Char
01. Principal	hema_diff_bands_cmnt_v4	Bands % - Comments - Visit 4 (Surgery) - [Hematology Differential]		Char
01. Principal	hema_diff_bands_fasting_v1	Bands % - Fasting - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_diff_bands_fasting_v4	Bands % - Fasting - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_diff_bands_not_obt_v1	Bands % - Not Obtained - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 1="Yes"
01. Principal	hema_diff_bands_not_obt_v4	Bands % - Not Obtained - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 1="Yes"
01. Principal	hema_diff_bands_oor_v1	Bands % - Out Of Range - Visit 1 (Baseline) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_bands_oor_v4	Bands % - Out Of Range - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hema_diff_bands_rslt_v1	Bands % - Result - Visit 1 (Baseline) - [Hematology Differential]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	hema_diff_bands_rslt_v4	Bands % - Result - Visit 4 (Surgery) - [Hematology Differential]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	hema_diff_baso_clinsig_v1	Basophils % - Clinically Significant - Visit 1 (Baseline) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_baso_clinsig_v4	Basophils % - Clinically Significant - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_baso_cmnt_v1	Basophils % - Comments - Visit 1 (Baseline) - [Hematology Differential]		Char
01. Principal	hema_diff_baso_cmnt_v4	Basophils % - Comments - Visit 4 (Surgery) - [Hematology Differential]		Char
01. Principal	hema_diff_baso_fasting_v1	Basophils % - Fasting - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_diff_baso_fasting_v4	Basophils % - Fasting - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_diff_baso_not_obt_v1	Basophils % - Not Obtained - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No"
01. Principal	hema_diff_baso_not_obt_v4	Basophils % - Not Obtained - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_baso_oor_v1	Basophils % - Out Of Range - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hema_diff_baso_oor_v4	Basophils % - Out Of Range - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_baso_rslt_v1	Basophils % - Result - Visit 1 (Baseline) - [Hematology Differential]		Numeric .R="Not Randomized"
01. Principal	hema_diff_baso_rslt_v4	Basophils % - Result - Visit 4 (Surgery) - [Hematology Differential]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	hema_diff_eosin_clinsig_v1	Eosinophils % - Clinically Significant - Visit 1 (Baseline) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_eosin_clinsig_v4	Eosinophils % - Clinically Significant - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_eosin_cmnt_v1	Eosinophils % - Comments - Visit 1 (Baseline) - [Hematology Differential]		Char
01. Principal	hema_diff_eosin_cmnt_v4	Eosinophils % - Comments - Visit 4 (Surgery) - [Hematology Differential]		Char
01. Principal	hema_diff_eosin_fasting_v1	Eosinophils % - Fasting - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_diff_eosin_fasting_v4	Eosinophils % - Fasting - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_diff_eosin_not_obt_v1	Eosinophils % - Not Obtained - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No"
01. Principal	hema_diff_eosin_not_obt_v4	Eosinophils % - Not Obtained - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hema_diff_eosin_oor_v1	Eosinophils % - Out Of Range - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_diff_eosin_oor_v4	Eosinophils % - Out Of Range - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_eosin_rslt_v1	Eosinophils % - Result - Visit 1 (Baseline) - [Hematology Differential]		Numeric .R="Not Randomized"
01. Principal	hema_diff_eosin_rslt_v4	Eosinophils % - Result - Visit 4 (Surgery) - [Hematology Differential]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	hema_diff_lymph_o_clinsig_v1	Lymphocytes % - Clinically Significant - Visit 1 (Baseline) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_lymph_o_clinsig_v4	Lymphocytes % - Clinically Significant - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_lymph_o_cmnt_v1	Lymphocytes % - Comments - Visit 1 (Baseline) - [Hematology Differential]		Char
01. Principal	hema_diff_lymph_o_cmnt_v4	Lymphocytes % - Comments - Visit 4 (Surgery) - [Hematology Differential]		Char
01. Principal	hema_diff_lymph_o_fasting_v1	Lymphocytes % - Fasting - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_diff_lymph_o_fasting_v4	Lymphocytes % - Fasting - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_diff_lymph_o_not_obt_v1	Lymphocytes % - Not Obtained - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hema_diff_lymph_o_not_obt_v4	Lymphocytes % - Not Obtained - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_lymph_o_oor_v1	Lymphocytes % - Out Of Range - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_diff_lymph_o_oor_v4	Lymphocytes % - Out Of Range - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_diff_lymph_o_rslt_v1	Lymphocytes % - Result - Visit 1 (Baseline) - [Hematology Differential]		Numeric .R="Not Randomized"
01. Principal	hema_diff_lymph_o_rslt_v4	Lymphocytes % - Result - Visit 4 (Surgery) - [Hematology Differential]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	hema_diff_mono_clinsig_v1	Monocytes % - Clinically Significant - Visit 1 (Baseline) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_mono_clinsig_v4	Monocytes % - Clinically Significant - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_mono_cmnt_v1	Monocytes % - Comments - Visit 1 (Baseline) - [Hematology Differential]		Char
01. Principal	hema_diff_mono_cmnt_v4	Monocytes % - Comments - Visit 4 (Surgery) - [Hematology Differential]		Char
01. Principal	hema_diff_mono_fasting_v1	Monocytes % - Fasting - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No" 2="Unknown"
01. Principal	hema_diff_mono_fasting_v4	Monocytes % - Fasting - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	hema_diff_mono_not_obt_v1	Monocytes % - Not Obtained - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No"
01. Principal	hema_diff_mono_not_obt_v4	Monocytes % - Not Obtained - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_mono_oor_v1	Monocytes % - Out Of Range - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_diff_mono_oor_v4	Monocytes % - Out Of Range - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_diff_mono_rslt_v1	Monocytes % - Result - Visit 1 (Baseline) - [Hematology Differential]		Numeric .R="Not Randomized"
01. Principal	hema_diff_mono_rslt_v4	Monocytes % - Result - Visit 4 (Surgery) - [Hematology Differential]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	hema_diff_neutro_clinsig_v1	Neutrophils % - Clinically Significant - Visit 1 (Baseline) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_neutro_clinsig_v4	Neutrophils % - Clinically Significant - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_neutro_cmnt_v1	Neutrophils % - Comments - Visit 1 (Baseline) - [Hematology Differential]		Char
01. Principal	hema_diff_neutro_cmnt_v4	Neutrophils % - Comments - Visit 4 (Surgery) - [Hematology Differential]		Char
01. Principal	hema_diff_neutro_fasting_v1	Neutrophils % - Fasting - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No" 2="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	hema_diff_neutro_fasting_v4	Neutrophils % - Fasting - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Unknown"
01. Principal	hema_diff_neutro_not_obt_v1	Neutrophils % - Not Obtained - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized"
01. Principal	hema_diff_neutro_not_obt_v1	Neutrophils % - Not Obtained - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No"
01. Principal	hema_diff_neutro_not_obt_v4	Neutrophils % - Not Obtained - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing"
01. Principal	hema_diff_neutro_not_obt_v4	Neutrophils % - Not Obtained - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	hema_diff_neutro_oor_v1	Neutrophils % - Out Of Range - Visit 1 (Baseline) - [Hematology Differential]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_diff_neutro_oor_v4	Neutrophils % - Out Of Range - Visit 4 (Surgery) - [Hematology Differential]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	hema_diff_neutro_rslt_v1	Neutrophils % - Result - Visit 1 (Baseline) - [Hematology Differential]		Numeric .R="Not Randomized"
01. Principal	hema_diff_neutro_rslt_v4	Neutrophils % - Result - Visit 4 (Surgery) - [Hematology Differential]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	hema_diff_spec_dt_v1	Specimen Collection Date - Visit 1 (Baseline) - [Hematology Differential]		SAS Date .R="Not Randomized"
01. Principal	hema_diff_spec_dt_v4	Specimen Collection Date - Visit 4 (Surgery) - [Hematology Differential]		SAS Date .M="Missing" .R="Not Randomized"

Section 32: Dextramer Measures Trellis Plots

Class	Variable	Label	Description	Format Text
01. Principal	dex_day1-4	Day - # - [Dextramer Measures Trellis Plots]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	dex_id	ID - [Dextramer Measures Trellis Plots]		Char
01. Principal	dex_net_val_e75_1-4	E75 Net Value - # - [Dextramer Measures Trellis Plots]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	dex_net_val_flu1-4	Flu Net Value - # - [Dextramer Measures Trellis Plots]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	dex_surg_day	Day Of Surgery - [Dextramer Measures Trellis Plots]		Numeric .R="Not Randomized"

Section 33: Patient Encounter Comments

Class	Variable	Label	Description	Format Text
01. Principal	pt_encntr_comments1-2	Comments - Encounter # - [Patient Encounter Comments]		Char
01. Principal	pt_encntr_measure_dt1-2	Date Measured - Encounter # - [Patient Encounter Comments]		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	pt_encntr_num	Number Of Encounters - [Patient Encounter Comments]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	pt_encntr_type1-2	Encounter Type - Encounter # - [Patient Encounter Comments]		.F="No Record For This Visit" .R="Not Randomized" 2="Inoculation" 6="Telephone Consult" 7="Other"
01. Principal	pt_encntr_verification_dt1-2	Verification Date - Encounter # - [Patient Encounter Comments]		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 34: Comments

Class	Variable	Label	Description	Format Text
01. Principal	cmnt_comments 1-8	Comments - Comment # - [Comments]		Char
01. Principal	cmnt_field_name 1-8	Field Name - Comment # - [Comments]		Char
01. Principal	cmnt_form_code 1-8	Form Code - Comment # - [Comments]		Char
01. Principal	cmnt_form_dt1-8	Form Date - Comment # - [Comments]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	cmnt_num	Number Of Comments - [Comments]		Numeric .F="No Record For This Visit" .R="Not Randomized"

Section 35: Verification

Class	Variable	Label	Description	Format Text
01. Principal	verif_dt	Date Of Investigator's Signature - [Verification]		SAS Date