

MAY2013-02-02 - Enhanced Person Data Dictionary

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MAY2013-02-02 - Enhanced Person: Data Dictionary

Section 1: Identifier

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

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	build_dt	Build Date		SAS Date
01. Principal	rave_id	Rave ID		Numeric
01. Principal	site	Site		1="Mayo Clinic (MN026)" 2="Mayo Clinic in Florida (FL080)" 3="Massachusetts General Hospital Cancer Center (MA034)" 4="Mount Sinai Hospital (NY021)" 5="Cleveland Clinic Foundation (OH027)" 6="Case Western Reserve University (OH029)"

Section 3: Demography

Class	Variable	Label	Description	Format Text
01. Principal	country	Country Of Residence - [Demography]		1="US"
01. Principal	ethnicity	Ethnicity - [Demography]		1="Hispanic or Latino" 2="Not Hispanic Or Latino" 3="Not reported" 4="Unknown"
01. Principal	gender	Gender - [Demography]		1="Female" 2="Male"
01. Principal	payment	Method Of Payment - [Demography]		1="Private Insurance" 2="Private Insurance And Medicare" 3="Medicare" 4="Medicare And Medicaid" 5="Medicaid" 6="Other" 7="Unknown"
01. Principal	race	Race - [Demography]		1="White" 2="Black or African American" 3="Native Hawaiian or Other Pacific Islander" 4="Asian" 5="American Indian or Alaska Native" 6="Not reported (Participant refused or not available)" 7="Unknown (Participant unsure)"

Section 4: Eligibility Checklist (Pre-Registration)

Class	Variable	Label	Description	Format Text
01. Principal	cl_prereg_added_to_research	Registration Office Personnel Will Automatically Register Participants Separately To The Translational Research Components Of The Study - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_age	Age - [Eligibility Checklist (Pre-Registration)]		Numeric
01. Principal	cl_prereg_auth_c a	Participant Has Given Permission To Collect And Store Blood And Tissue For Future Use In Research To Learn About, Prevent, Treat Or Cure Cancer - [Eligibility Checklist (Pre-Registration)]		0="No" 1="Yes"
01. Principal	cl_prereg_auth_o th	Participant Has Given Permission To Collect And Store Blood And Tissue For Future Use In Research About Other Health Problems - [Eligibility Checklist (Pre-Registration)]		0="No" 1="Yes"
01. Principal	cl_prereg_auth_o ut	Participant Has Given Permission To Send Blood And/Or Tissue Sample(s) To Researchers At An Outside Institution - [Eligibility Checklist (Pre-Registration)]		0="No" 1="Yes"
01. Principal	cl_prereg_auth_r es	Participant Has Given Permission To His/Her Doctor To Contact Them In The Future To Ask Them To Take Part In More Research - [Eligibility Checklist (Pre-Registration)]		0="No" 1="Yes"
01. Principal	cl_prereg_case_ detail_id	Case Number - [Eligibility Checklist (Pre-Registration)]		Numeric

Class	Variable	Label	Description	Format Text
01. Principal	cl_prereg_consent_dt	Date Informed Consent Signed - [Eligibility Checklist (Pre-Registration)]		SAS Date
01. Principal	cl_prereg_consent_form	Consent Form Signed And Dated - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_cpn_supervision	All Trial Activities Must Be Conducted At A CPN Member Institution Under The Supervision Of A CPN Physician - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_ctep_arm	TAC/TAD Code - [Eligibility Checklist (Pre-Registration)]		0="TAC-0" 1="TAC-1 (Erlotinib 50 mg Po Q am X 7 Days [Empty Stomach])" 2="TAC-1B (Non-Surgical Cohort B: Erlotinib 50mg Po Qam X 7 Days [Empty Stomach])" 3="TAC-2A (Surgical Cohort A: Erlotinib 25mg Po Qam X 7 Days [Empty Stomach])" 4="TAC-2B (Non-Surgical Cohort B: Erlotinib 25mg Po Qam X 7 Days [Empty Stomach])" 5="TAC1 (Erlotinib 75 Mg Po Q Am X 7 Days [Empty Stomach])"
01. Principal	cl_prereg_date_mod	Date Modified - [Eligibility Checklist (Pre-Registration)]		SAS Date
01. Principal	cl_prereg_dc_num	Protocol Number - [Eligibility Checklist (Pre-Registration)]		Char
01. Principal	cl_prereg_do_baseline_evals	Baseline (Screening) Evaluations Must Be Completed Within The Guidelines Specified On The Schedule Of Events - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_enroll_dt	Enrollment Date - [Eligibility Checklist (Pre-Registration)]		SAS Date
01. Principal	cl_prereg_eres_num	ERES Number - [Eligibility Checklist (Pre-Registration)]		Char
01. Principal	cl_prereg_excl_comorbidity	Uncontrolled Intercurrent Illness That Would Limit Compliance With Study Requirements - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	cl_prereg_excl_cyp3a4_inducers	Use Of CYP3A4 Inducers - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_excl_cyp3a4_inhibitors	Use Of Potent CYP3A4 Inhibitors - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_excl_diagnosis_of_hiv	Participants With A Known Diagnosis Of HIV - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_excl_erlotinib_allergy	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Erlotinib (Tarceva) - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_excl_med_necessary	Participants Who Cannot Have Their Warfarin, Lovenox, Plavix, Or Other Comparable Medications Held For Percutaneous Or Transjugular Liver Biopsy And Surgery If So Indicated - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_excl_path_report	Non-Surgical Cohort Only: Pathology Report From Clinical Liver Biopsy Demonstrates No Histologic Abnormalities Associated With Chronic Hepatitis, Steatohepatitis, Fibrosis, Or Cirrhosis - [Eligibility Checklist (Pre-Registration)]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	cl_prereg_excl_ph_altering_drug	Participants Who Regularly (>=2 Times Per Week) Use Drugs That Alter The pH Of The GI Tract - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	cl_prereg_excl_prior_erlotinib	Any Prior Treatment With Erlotinib Or Other Agent Whose Primary Mechanism Of Action Is Known To Inhibit EGFR - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_hipaa_dt	Date Of Authorization - [Eligibility Checklist (Pre-Registration)]		SAS Date .M="Missing"
01. Principal	cl_prereg_incl_18_or_older	Age >=18 Years - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_incl_avoid_pregnancy	Willingness To Use Adequate Contraception To Avoid Pregnancy Or Impregnation Until 2 Weeks After Discontinuing Study Agent - [Eligibility Checklist (Pre-Registration)]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	cl_prereg_incl_fibros_or_cirrhosis	Individuals With A Clinical Diagnosis Fibrosis Or Cirrhosis Of The Liver - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_incl_informed_consent	Ability To Understand And The Willingness To Sign A Written Informed Consent Document - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_incl_liver_biopsy	Able To Undergo: A. Percutaneous Or Transjugular Biopsy Of Cirrhotic Liver At Least 7 Days Prior To Liver Resection (Surgical Cohort), OR B. A Biopsy Of The Cirrhotic Liver (Non-Surgical Cohort) - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_incl_not_preg_brst_fed	Not Pregnant Or Breast Feeding - [Eligibility Checklist (Pre-Registration)]		.M="Missing" .N="N/A" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	cl_prereg_incl_provide_blood	Willingness To Provide Mandatory Blood Specimens As Specified In The Protocol - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_incl_stop_tobacco_use	Willingness To Discontinue Smoking During The Study Two Weeks Prior To Beginning The Study And Willingness To Not Smoke While Taking Study Medication - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_incl_tissue_consent	Willingness To Authorize Collection Of Tissue From Surgically-Resected Liver Or Clinical Liver Biopsy For Analyses Specified In The Protocol - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_phi_use_auth	Existence Of Authorization For Use And Disclosure Of Protected Health Information (USA Institutions Only) - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_pielig	Is The Participant Eligible For Inclusion On This Study? - [Eligibility Checklist (Pre-Registration)]		0="No" 1="Yes"
01. Principal	cl_prereg_prev_id	Has The Participant Been Pre-Registered Previously To This Study? - Yes: Prior Participant CPN ID Number - [Eligibility Checklist (Pre-Registration)]		Char
01. Principal	cl_prereg_previus	Has The Participant Been Pre-Registered Previously To This Study? - [Eligibility Checklist (Pre-Registration)]		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	cl_prereg_screening_done	Screening And On-Study Evaluations Must Be Completed Within The Guidelines Specified On The Schedule Of Events - [Eligibility Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	cl_prereg_study_id	Study ID - [Eligibility Checklist (Pre-Registration)]		Numeric
01. Principal	cl_prereg_version	Version Number - [Eligibility Checklist (Pre-Registration)]		Numeric

Section 5: Screening

Class	Variable	Label	Description	Format Text
01. Principal	screen_comments	Comments - [Screening]		Char
01. Principal	screen_dt	Completion Date - [Screening]		SAS Date
01. Principal	screen_elig	Does Participant Meet Screening Criteria? - [Screening]		0="No" 1="Yes"
01. Principal	screen_inelig_reason	Which Screening Criteria Not Met? - [Screening]		.M="Missing" 1="Investigator decision" 2="Phospho-EGFR negative" 3="Patient decision" 4="Did not meet eligibility criteria" 5="Other"
01. Principal	screen_inelig_reason_spec	Which Screening Criteria Not Met? - Specify - [Screening]		Char

Section 6: Eligibility Checklist (Registration)

Class	Variable	Label	Description	Format Text
01. Principal	cl_reg_alt	ALT/SGPT (U/L) - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	cl_reg_alt_unl	ALT/SGPT UNL (U/L) - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	cl_reg_ast	AST/SGOT (U/L) - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	cl_reg_ast_unl	AST/SGOT UNL (U/L) - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	cl_reg_case_detail_id	Case Number - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit"
01. Principal	cl_reg_creat	Creatinine (mg/dL) - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	cl_reg_creat_unl	Creatinine UNL (mg/dL) - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	cl_reg_ctep_arm	TAC/TAD Code - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" 0="TAC-0" 1="TAC-1 (Erlotinib 50 mg Po Q am X 7 Days [Empty Stomach])" 2="TAC-1B (Non-Surgical Cohort B: Erlotinib 50mg Po Qam X 7 Days [Empty Stomach])" 3="TAC-2A (Surgical Cohort A: Erlotinib 25mg Po Qam X 7 Days [Empty Stomach])" 4="TAC-2B (Non-Surgical Cohort B: Erlotinib 25mg Po Qam X 7 Days [Empty Stomach])" 5="TAC1 (Erlotinib 75 Mg Po Q Am X 7 Days [Empty Stomach])"
01. Principal	cl_reg_date_mod	Date Modified - [Eligibility Checklist (Registration)]		SAS Date .F="No Record For This Visit"
01. Principal	cl_reg_dc_num	Protocol Number - [Eligibility Checklist (Registration)]		Char
01. Principal	cl_reg_dose_level	Dose Level - [Eligibility Checklist (Registration)]		-1="50 mg/day" -2="25 mg/day" .F="No Record For This Visit" 0="75 mg/day" 1="100 mg/day" 2="150 mg/day"
01. Principal	cl_reg_enroll_dt	Enrollment Date - [Eligibility Checklist (Registration)]		SAS Date .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	cl_reg_eres_num	ERES Number - [Eligibility Checklist (Registration)]		Char
01. Principal	cl_reg_excl_biop_not_done	Surgical Cohort (Cohort A Only): Percutaneous Or Transjugular Biopsy Incomplete Or Not Performed - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	cl_reg_excl_oth_agent	Receiving Any Other Investigational Agents <=6 Months Prior To Registration - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	cl_reg_group	Grouping Factor - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" 1="Dose Escalation/De-Escalation Cohort" 2="Dose Expansion Cohort"
01. Principal	cl_reg_incl_ast_alt	AST (SGOT) And ALT (SGPT) <=5 X Institutional ULN - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	cl_reg_incl_creat_le_1pt5	Creatinine <=1.5 X Institutional ULN - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	cl_reg_incl_ecog_01	ECOG Performance Status - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	cl_reg_incl_inr_le_1pt5	INR <=1.5 - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	cl_reg_incl_norm_org_func	Participants Must Have Normal Organ And Marrow Function - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	cl_reg_incl_plt_ge50	Platelets >=50 B/L (10^9/L) - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	cl_reg_incl_pos_phoso_egfr	Non-Surgical Cohort Only: Positive Phospho-EGFR Assessment (>=100 Stained Pixels) From Tissue Obtained From Previous Clinical Liver Biopsy - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	cl_reg_incl_preint_biop_samp	Pre-Intervention Biopsy Sample Collected - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	cl_reg_incl_tbili_e_3x_uln	Total Bilirubin <=3 X Institutional ULN - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	cl_reg_inr	INR - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	cl_reg_int_within_14days	Intervention Cannot Begin Prior To Registration And Must Begin <=14 Days From Registration - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	cl_reg_is_ppt_elig	Is The Participant Eligible For Inclusion On This Study? - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	cl_reg_perf_stat_01	ECOG Performance Status - [Eligibility Checklist (Registration)]		.F="No Record For This Visit" 0="Fully Active, Able To Carry On All Pre-Disease Performance Without Restriction" 1="Restricted In Physically Strenuous Activity But Ambulatory And Able To Carry Out Work Of A Light Or Sedentary Nature, E.G., Light House Work, Office Work"
01. Principal	cl_reg_plt_ge_50	Platelets (>=50) - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	cl_reg_study_id	Study ID - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit"
01. Principal	cl_reg_tot_bili	Total Bilirubin - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	cl_reg_tot_bili_unl	Total Bilirubin UNL - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	cl_reg_version	Version Number - [Eligibility Checklist (Registration)]		Numeric .F="No Record For This Visit"

Section 7: Medical/Surgical History

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_body_sys1-48	Body System/Site - # - [Medical/Surgical History]		.F="No Record For This Visit" .N="N/A" 1="Abdomen" 2="Breasts" 3="Cardiovascular" 4="Dermatologic" 5="Endocrine/Metabolic" 6="Gastrointestinal" 7="Genitourinary" 8="HEENT" 9="Hematopoietic/Lymph Node(s)" 10="Immune" 11="Musculoskeletal" 12="Neck" 13="Neurologic" 14="Other" 15="Pelvis" 16="Psychologic" 17="Respiratory" 18="Skin"
01. Principal	medsurg_body_sys_oth1-48	Other Body System/Site - # - [Medical/Surgical History]		Char
01. Principal	medsurg_comments	Comments - [Medical/Surgical History]		Char
01. Principal	medsurg_description1-48	Description - # - [Medical/Surgical History]		Char
01. Principal	medsurg_dx_dt1-48	Date Of Diagnosis/Surgery - # - [Medical/Surgical History]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	medsurg_med_hx_dt	Medical History Date - [Medical/Surgical History]		SAS Date .F="No Record For This Visit"
01. Principal	medsurg_num	Total Number Of Observations - [Medical/Surgical History]		Numeric .F="No Record For This Visit"

Section 8: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	bsymp_comments	Comments - [Baseline Symptoms]		Char
01. Principal	bsymp_description1-6	Symptom Description - # - [Baseline Symptoms]		Char
01. Principal	bsymp_eval_dt1-6	Evaluation Date - # - [Baseline Symptoms]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	bsymp_grade1-6	Grade - # - [Baseline Symptoms]		.F="No Record For This Visit" .N="N/A" 0="Absent Adverse Event" 1="Mild Adverse Event" 2="Moderate Adverse Event" 3="Severe Adverse Event" 4="Life-threatening Adverse Event" 5="Death Related to Adverse Event"
01. Principal	bsymp_num	Total Number Of Observations - [Baseline Symptoms]		Numeric .F="No Record For This Visit"
01. Principal	bsymp_onset_dt1-6	Onset Date - # - [Baseline Symptoms]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	bsymp_symp_comments1-6	Comments - # - [Baseline Symptoms]		Char

Section 9: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	phyexam_abdn_abn_spec_v0/phyexam_abdn_abn_spec_v2	Abdomen - Status: Abnormal - Specify - Visit # - [Physical Exam]		Char
01. Principal	phyexam_abdn_status_v0/phyexam_abdn_status_v2	Abdomen - Status - Visit # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phyexam_allergy_spec_v0/phyexam_allergy_spec_v2	Does The Participant Have Any Allergies? (Specify) - Visit # - [Physical Exam]		Char
01. Principal	phyexam_any_allergies_v0/phyexam_any_allergies_v2	Does The Participant Have Any Allergies? - Visit # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	phyexam_appr_abn_spec_v0/phyexam_appr_abn_spec_v2	Appearance - Status: Abnormal - Specify - Visit # - [Physical Exam]		Char
01. Principal	phyexam_appr_status_v0/phyexam_appr_status_v2	Appearance - Status - Visit # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phyexam_body_temp_v0/phyexam_body_temp_v2	Body Temperature (C) - Visit # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	phyexam_bp_diastolic_v0/phyexam_bp_diastolic_v2	Diastolic Blood Pressure (mmHg) - Visit # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	phyexam_bp_systolic_v0/phyexam_bp_systolic_v2	Systolic Blood Pressure (mmHg) - Visit # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	phyexam_card_abn_spec_v0/phyexam_card_abn_spec_v2	Cardiovascular - Status: Abnormal - Specify - Visit # - [Physical Exam]		Char
01. Principal	phyexam_card_status_v0/phyexam_card_status_v2	Cardiovascular - Status - Visit # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal" 3="Not Examined"

Class	Variable	Label	Description	Format Text
01. Principal	phyexam_cig_his t_v0/phyexam_ci g_hist_v2	Cigarette History - Visit # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" 1="Current smoker" 2="Quit/former smoker" 3="Never smoked"
01. Principal	phyexam_comme nts_v0/phyexam_ comments_v2	Comments - Visit # - [Physical Exam]		Char
01. Principal	phyexam_eval_dt _v0/phyexam_ev al_dt_v2	Evaluation Date - Visit # - [Physical Exam]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	phyexam_height _v0/phyexam_hei ght_v2	Height (cm) - Visit # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	phyexam_musc_ abn_spec_v0/phy exam_musc_abn_ _spec_v2	Musculoskeletal - Status: Abnormal - Specify - Visit # - [Physical Exam]		Char
01. Principal	phyexam_musc_ status_v0/phyexa m_musc_status_ v2	Musculoskeletal - Status - Visit # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phyexam_pulse_ rate_v0/phyexam _pulse_rate_v2	Pulse Rate - Visit # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	phyexam_resp_a bn_spec_v0/phye xam_resp_abn_s pec_v2	Respiratory - Status: Abnormal - Specify - Visit # - [Physical Exam]		Char
01. Principal	phyexam_resp_s tatus_v0/phyexa m_resp_status_v 2	Respiratory - Status - Visit # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phyexam_skin_a bn_spec_v0/phye xam_skin_abn_s pec_v2	Skin - Status: Abnormal - Specify - Visit # - [Physical Exam]		Char
01. Principal	phyexam_skin_st atus_v0/phyexam _skin_status_v2	Skin - Status - Visit # - [Physical Exam]		.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phyexam_weight _v0/phyexam_we ight_v2	Weight (kg) - Visit # - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing"

Section 10: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	conmed_comments1-24	Comments - # - [Concomitant Medications]		Char
01. Principal	conmed_continuing1-24	Continuing - # - [Concomitant Medications]		.N="N/A" .U="Unknown" 0="No" 1="Yes"
01. Principal	conmed_dose1-24	Dose - # - [Concomitant Medications]		Numeric .M="Missing" .N="N/A"
01. Principal	conmed_end_dt1-24	Stop Date - # - [Concomitant Medications]		SAS Date .M="Missing" .N="N/A"
01. Principal	conmed_freq1-24	Frequency - # - [Concomitant Medications]		Char

Class	Variable	Label	Description	Format Text
01. Principal	conmed_indication1-24	Indication - # - [Concomitant Medications]		.M="Missing" .N="N/A" 1="Accelerate Hematopoietic Recovery" 2="Acidity" 3="Adrenal Suppression" 4="Allergic Reaction" 5="Allergy" 6="Alopecia" 7="Anemia" 8="Anesthesia" 9="Anorexia" 10="Anti-Angina" 11="Anticoagulation" 12="Antipsychotic" 13="Anxiety" 14="Apheresis" 15="Appetite" 16="Arrhythmia" 17="Arthralgia" 18="Arthritis" 19="Ascites" 20="Asthma" 21="Attention Deficit Disorder" 22="Attention Deficit Hyperactivity Disorder (ADHD)" 23="Benign Prostatic Hyperplasia" 24="Bipolar Disorder" 25="Birth Control" 26="Blepharitis (Eyelid Inflammation)" 27="Bloating" 28="Bony Disease" 29="Bronchitis" 30="Bronchospasm" 31="Bursitis" 32="Cardiac" 33="Cellulitis" 34="Chronic Obstructive Pulmonary Disease (COPD)" 35="Cmv Therapy" 36="Cns Disease" 37="Complicating Disease Or Condition" 38="Congestion" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] conmed_indication1-24			[...continued] 39="Conjunctivitis" 40="Constipation" 41="Contrast Study" 42="Cough" 43="Dehydration" 44="Depression" 45="Dermatitis" 46="Diabetes" 47="Diarrhea" 48="Dry Skin" 49="Dyspepsia" 50="Dysphagia" 51="Dyspnea" 52="Dysuria" 53="Earache" 54="Edema" 55="Electrolyte Imbalance" 56="Empirical Coverage" 57="Engraftment" 58="Epiphora (Watery Eyes)" 59="Epistaxis" 60="Erectile Dysfunction" 61="Erythema" 62="Esophagitis" 63="Extrapyramidal" 64="Eye Redness" 65="Fatigue" 66="Fever" 67="Fever W/Low WBC" 68="Flatulence" 69="Flu Symptoms" 70="Fluid Overload" 71="Fluid Retention" 72="Gastric Ulcer" 73="Gastritis" 74="Gastroesophageal Reflux Disease" 75="Gastrointestinal Distress" 76="GI Decontamination" 77="Glaucoma" 78="Gout" 79="Granulocytopenia" 80="Gvhd Prophylaxis" 81="Gvhd Therapy" 82="Hand Foot Syndrome (HFS)" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] conmed_indication1-24			[...continued] 83="Headache" 84="Hemolytic Urem Syndrome" 85="Hemorrhage" 86="Hemorrhoids" 87="Heparin Reversal" 88="Hepatic Lab Abnormality" 89="Hiatal Hernia" 90="Hiccoughs" 91="HIV" 92="Hormonal Manipulation" 93="Hot Flashes" 94="Hypercalcemia" 95="Hypercholesterolemia" 96="Hyperglycemia" 97="Hyperkalemia" 98="Hyperlipidemia" 99="Hyperparathyroidism" 100="Hypertension" 101="Hyperthyroidism" 102="Hyperuricemia" 103="Hypoalbuminemia" 104="Hypocalcemia" 105="Hypokalemia" 106="Hypomagnesemia" 107="Hypophosphatemia" 108="Hypotension" 109="Hypothyroidism" 110="Hypoxia" 111="Immunosuppression" 112="Indigestion" 113="Induce Sedation" 114="Infection" 115="Inflammation" 116="Injection Site Reaction" 117="Insomnia" 118="Itching" 119="Keratitis Sicca (Dry Eyes)" 120="Lactose Intolerance" 121="Leg Cramps" 122="Line Occlusion" 123="Line Patency" 124="Local Anesthesia" 125="Macular Degeneration" 126="Malignancy" 127="Malignant Hyperthermia" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] conmed_indication1-24			[...continued] 128="Menopausal Symptoms" 129="Metabolic Imbalance" 130="Mood" 131="Mouth Sores" 132="Mucositis" 133="Muscle Spasm" 134="Myalgia" 135="Myasthenia Gravis" 136="Nail Changes" 137="Narcolepsy" 138="Nasal Symptom" 139="Nausea" 140="Nausea And Vomiting" 141="Neuropathy" 142="Neutropenia" 143="Nutrition" 144="Osteoporosis" 145="Pain" 146="Palliation" 147="Pancreatic Insufficiency" 148="Parkinson's Disease" 149="Partial Thromboplastin Time (PTT) Prolongation" 150="Periodontal Disease" 151="Petechiae" 152="Pharyngitis" 153="Phlebitis" 154="Pleural Effusion" 155="Pneumonitis" 156="Port Occlusion" 157="Post Traumatic Stress Disorder" 158="Posttreatment" 159="Prechemotherapy" 160="Preprocedure/Diagnostic Testing" 161="Pretreatment" 162="Prophylaxis" 163="Pruritus" 164="Pseudogout" 165="Psoriasis" 166="Pulmonary Embolus" 167="Rash" 168="Rectal Bleeding" 169="Reflux" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] conmed_indication1-24			[...continued] 170="Renal/Urinary" 171="Replacement" 172="Respiratory Distress/Dyspnea" 173="Restless Leg Syndrome" 174="Restlessness" 175="Rhinitis" 176="Rhinorrhea" 177="Rigors" 178="Scabies" 179="Seizures" 180="Sinusitis" 181="Skin Irritation" 182="Sleep" 183="Sleep Apnea" 184="Smoking Cessation" 185="Stomach Cramps" 186="Stomatitis" 187="Supplement" 188="Thrombocytopenia" 189="Thrombus" 190="Thrush" 191="Tremors" 192="Urinary" 193="Urticaria" 194="Vaginal Dryness" 195="Vascular Access" 196="Vasodilatation (Flush)" 197="Venous Thrombosis" 198="Vertigo" 199="Vitamins" 200="Vomiting" 201="Weight Gain" 202="Weight Loss" 203="Wheezing" 204="Xerosis" 205="Xerostomia" 999="Other Specify"
01. Principal	conmed_name1-24	Medication Name - # - [Concomitant Medications]		Char
01. Principal	conmed_num	Total Number Of Medications - [Concomitant Medications]		Numeric
01. Principal	conmed_start_dt1-24	Start Date - # - [Concomitant Medications]		SAS Date .N="N/A"
01. Principal	conmed_taking_any1-24	Is The Participant Taking Any Concomitant Medications? - # - [Concomitant Medications]		.M="Missing" .N="N/A" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	conmed_units1-24	Units - # - [Concomitant Medications]		Char

Section 11: Participant Status (Baseline)

Class	Variable	Label	Description	Format Text
01. Principal	event_bsl_ae_assess	Were Adverse Events Assessed During This Reporting Period? - [Participant Status (Baseline)]		.F="No Record For This Visit" 0="No" 1="Yes and reportable adverse events occurred" 2="Yes but no reportable adverse events occurred"
01. Principal	event_bsl_cod	Cause Of Death (Primary Cause Of Death) - [Participant Status (Baseline)]		.F="No Record For This Visit" .M="Missing" 1="Drug-Related" 2="Unknown" 3="Other"
01. Principal	event_bsl_cod_spec	Cause Of Death: Other - Specify - [Participant Status (Baseline)]		Char
01. Principal	event_bsl_com	Comments - [Participant Status (Baseline)]		Char
01. Principal	event_bsl_contact_dt	Contact Date - [Participant Status (Baseline)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	event_bsl_death_dt	Death Date - [Participant Status (Baseline)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	event_bsl_med_hist	Did The Participant Have Any Relevant Medical/Surgical History To Report? - [Participant Status (Baseline)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	event_bsl_phys_exam	Was The Overall Physical Exam Performed? - [Participant Status (Baseline)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	event_bsl_pre_int_symp	Were There Any Pre-Intervention Symptoms? - [Participant Status (Baseline)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	event_bsl_protocol_int	Will The Patient Proceed To Protocol Intervention For The First Visit? - [Participant Status (Baseline)]		.F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	event_bsl_vital_status	Participant Vital Status - [Participant Status (Baseline)]		.F="No Record For This Visit" .M="Missing" 1="Alive" 2="Dead"

Section 12: Agent Intervention

Class	Variable	Label	Description	Format Text
01. Principal	agent_int_admin1-13	Was Agent Administered? - # - [Agent Intervention]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	agent_int_comments	Comments - [Agent Intervention]		Char
01. Principal	agent_int_compliant1-13	Is The Participant Compliant With Protocol Intervention? - # - [Agent Intervention]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	agent_int_dose1-13	Erlotinib Dose (mg) - # - [Agent Intervention]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	agent_int_dose_dt1-13	Dose Date - # - [Agent Intervention]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	agent_int_dose_tm1-13	Dose Time - # - [Agent Intervention]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	agent_int_fasting1-13	Fasting - # - [Agent Intervention]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	agent_int_last_meal_dt1-13	Last Meal Date - # - [Agent Intervention]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	agent_int_last_meal_tm1-13	Last Meal Time - # - [Agent Intervention]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	agent_int_num	Number Of Observations - [Agent Intervention]		Numeric .F="No Record For This Visit"
01. Principal	agent_int_num_hrs_meal1-13	Number Of Hours Since Last Meal - # - [Agent Intervention]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	agent_int_start_dt1-13	Date Agent Started - # - [Agent Intervention]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	agent_int_stop_dt1-13	Date Agent Stopped - # - [Agent Intervention]		SAS Date .F="No Record For This Visit" .N="N/A"

Section 13: Pregnancy Test

Class	Variable	Label	Description	Format Text
01. Principal	pregres_comments	Comments - [Pregnancy Test]		Char
01. Principal	pregres_result	Result - [Pregnancy Test]		.F="No Record For This Visit" 0="Negative" 1="Positive" 2="Not obtained" 3="Not applicable/not female of child-bearing potential"
01. Principal	pregres_spec_col_dt	Date Specimen Collected - [Pregnancy Test]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	pregres_spec_type	Type Of Specimen - [Pregnancy Test]		.F="No Record For This Visit" .M="Missing" 1="Urine" 2="Serum"

Section 14: Specimen Collection (Blood)

Class	Variable	Label	Description	Format Text
01. Principal	specbld_comments_v0/specbld_comments_v2	Comments - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	specbld_grn_col_dt_v0/specbld_grn_col_dt_v2	Na Heparin (Green Top) - Date Specimen Collected - Visit # - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	specbld_grn_collected_v0/specbld_grn_collected_v2	Na Heparin (Green Top) - Was Specimen Collected? - Visit # - [Specimen Collection (Blood)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	specbld_grn_not_col_rsn_v0/specbld_grn_not_col_rsn_v2	Na Heparin (Green Top) - Not Collected Reason - Visit # - [Specimen Collection (Blood)]		.F="No Record For This Visit" .N="N/A" 1="Sample not required" 2="Not available" 3="Patient refusal" 4="Institution error" 5="Institution won't release" 6="Facility will not release block" 7="Other"
01. Principal	specbld_grn_num_v0/specbld_grn_num_v2	Na Heparin (Green Top) - Number Of Specimens Collected - Visit # - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	specbld_grn_rsn_oth_v0/specbld_grn_rsn_oth_v2	Na Heparin (Green Top) - Not Collected Reason - Other (Specify) - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	specbld_grn_ship_dt_v0/specbld_grn_ship_dt_v2	Na Heparin (Green Top) - Date Specimen Shipped - Visit # - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	specbld_how_stored_v0/specbld_how_stored_v2	If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? - Visit # - [Specimen Collection (Blood)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="Not Stored Per Protocol" 1="Stored Per Protocol"
01. Principal	specbld_prp_col_dt_v0/specbld_prp_col_dt_v2	EDTA (Purple Top) - Date Specimen Collected - Visit # - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	specbld_prp_collected_v0/specbld_prp_collected_v2	EDTA (Purple Top) - Was Specimen Collected? - Visit # - [Specimen Collection (Blood)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	specbld_prp_not_col_rsn_v0/specbld_prp_not_col_rsn_v2	EDTA (Purple Top) - Not Collected Reason - Visit # - [Specimen Collection (Blood)]		.F="No Record For This Visit" .N="N/A" 1="Sample not required" 2="Not available" 3="Patient refusal" 4="Institution error" 5="Institution won't release" 6="Facility will not release block" 7="Other"
01. Principal	specbld_prp_num_v0/specbld_prp_num_v2	EDTA (Purple Top) - Number Of Specimens Collected - Visit # - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	specbld_prp_rsn_oth_v0/specbld_prp_rsn_oth_v2	EDTA (Purple Top) - Not Collected Reason - Other (Specify) - Visit # - [Specimen Collection (Blood)]		Char
01. Principal	specbld_prp_ship_dt_v0/specbld_prp_ship_dt_v2	EDTA (Purple Top) - Date Specimen Shipped - Visit # - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	specbld_red_col_dt_v0/specbld_red_col_dt_v2	Red Top - Date Specimen Collected - Visit # - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	specbld_red_collected_v0/specbld_red_collected_v2	Red Top - Was Specimen Collected? - Visit # - [Specimen Collection (Blood)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	specbld_red_not_col_rsn_v0/specbld_red_not_col_rsn_v2	Red Top - Not Collected Reason - Visit # - [Specimen Collection (Blood)]		.F="No Record For This Visit" .N="N/A" 1="Sample not required" 2="Not available" 3="Patient refusal" 4="Institution error" 5="Institution won't release" 6="Facility will not release block" 7="Other"
01. Principal	specbld_red_num_v0/specbld_red_num_v2	Red Top - Number Of Specimens Collected - Visit # - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	specbld_red_rsn_oth_v0/specbld_red_rsn_oth_v2	Red Top - Not Collected Reason - Other (Specify) - Visit # - [Specimen Collection (Blood)]		Char

Class	Variable	Label	Description	Format Text
01. Principal	specbld_red_ship_dt_v0/specbld_red_ship_dt_v2	Red Top - Date Specimen Shipped - Visit # - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"

Section 15: Specimen Collection (Tissue - Baseline)

Class	Variable	Label	Description	Format Text
01. Principal	spectis_bl_comments	Comments - [Specimen Collection (Tissue - Baseline)]		Char
01. Principal	spectis_bl_form_bl_col_dt	Liver Biopsy - Formalin - Baseline - Date Specimen Collected - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"
01. Principal	spectis_bl_form_bl_col_tm	Liver Biopsy - Formalin - Baseline - Time Specimen Collected - [Specimen Collection (Tissue - Baseline)]		SAS Time .M="Missing"
01. Principal	spectis_bl_form_bl_collected	Liver Biopsy - Formalin - Baseline - Was Specimen Collected? - [Specimen Collection (Tissue - Baseline)]		0="No" 1="Yes"
01. Principal	spectis_bl_form_bl_not_col_rsn	Liver Biopsy - Formalin - Baseline - Not Collected Reason - [Specimen Collection (Tissue - Baseline)]		.M="Missing" 1="Sample not required" 2="Not available" 3="Patient refusal" 4="Institution error" 5="Institution won't release" 6="Facility will not release block" 7="Other"
01. Principal	spectis_bl_form_bl_num	Liver Biopsy - Formalin - Baseline - Number Of Specimens Collected - [Specimen Collection (Tissue - Baseline)]		Numeric .M="Missing"
01. Principal	spectis_bl_form_bl_par_blocks	Liver Biopsy - Formalin - Baseline - Paraffin Blocks - [Specimen Collection (Tissue - Baseline)]		Numeric .M="Missing"
01. Principal	spectis_bl_form_bl_par_emb_dt	Liver Biopsy - Formalin - Baseline - Date Of Paraffin Embedding - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"
01. Principal	spectis_bl_form_bl_par_emb_tm	Liver Biopsy - Formalin - Baseline - Time Of Paraffin Embedding - [Specimen Collection (Tissue - Baseline)]		SAS Time .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	spectis_bl_form_bl_rsn_oth	Liver Biopsy - Formalin - Baseline - Not Collected Reason - Other (Specify) - [Specimen Collection (Tissue - Baseline)]		Char
01. Principal	spectis_bl_form_bl_sect_dt	Liver Biopsy - Formalin - Baseline - Date Of Sectioning - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"
01. Principal	spectis_bl_form_bl_sect_tm	Liver Biopsy - Formalin - Baseline - Time Of Sectioning - [Specimen Collection (Tissue - Baseline)]		SAS Time .M="Missing"
01. Principal	spectis_bl_form_bl_ship_dt	Liver Biopsy - Formalin - Baseline - Date Specimen Shipped - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"
01. Principal	spectis_bl_form_eg_col_dt	Liver Biopsy - Formalin - Eligibility - Date Specimen Collected - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"
01. Principal	spectis_bl_form_eg_col_tm	Liver Biopsy - Formalin - Eligibility - Time Specimen Collected - [Specimen Collection (Tissue - Baseline)]		SAS Time .M="Missing"
01. Principal	spectis_bl_form_eg_collected	Liver Biopsy - Formalin - Eligibility - Was Specimen Collected? - [Specimen Collection (Tissue - Baseline)]		0="No" 1="Yes"
01. Principal	spectis_bl_form_eg_not_col_rsn	Liver Biopsy - Formalin - Eligibility - Not Collected Reason - [Specimen Collection (Tissue - Baseline)]		.M="Missing" 1="Sample not required" 2="Not available" 3="Patient refusal" 4="Institution error" 5="Institution won't release" 6="Facility will not release block" 7="Other"
01. Principal	spectis_bl_form_eg_num	Liver Biopsy - Formalin - Eligibility - Number Of Specimens Collected - [Specimen Collection (Tissue - Baseline)]		Numeric .M="Missing"
01. Principal	spectis_bl_form_eg_par_blocks	Liver Biopsy - Formalin - Eligibility - Paraffin Blocks - [Specimen Collection (Tissue - Baseline)]		Numeric .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	spectis_bl_form_eg_par_emb_dt	Liver Biopsy - Formalin - Eligibility - Date Of Paraffin Embedding - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"
01. Principal	spectis_bl_form_eg_par_emb_tm	Liver Biopsy - Formalin - Eligibility - Time Of Paraffin Embedding - [Specimen Collection (Tissue - Baseline)]		SAS Time .M="Missing"
01. Principal	spectis_bl_form_eg_rsn_oth	Liver Biopsy - Formalin - Eligibility - Not Collected Reason - Other (Specify) - [Specimen Collection (Tissue - Baseline)]		Char
01. Principal	spectis_bl_form_eg_sect_dt	Liver Biopsy - Formalin - Eligibility - Date Of Sectioning - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"
01. Principal	spectis_bl_form_eg_sect_tm	Liver Biopsy - Formalin - Eligibility - Time Of Sectioning - [Specimen Collection (Tissue - Baseline)]		SAS Time .M="Missing"
01. Principal	spectis_bl_form_eg_ship_dt	Liver Biopsy - Formalin - Eligibility - Date Specimen Shipped - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"
01. Principal	spectis_bl_how_stored	If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? - [Specimen Collection (Tissue - Baseline)]		.M="Missing" .N="N/A" 0="Not Stored Per Protocol" 1="Stored Per Protocol"
01. Principal	spectis_bl_how_stored_spec	If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? (Specify) - [Specimen Collection (Tissue - Baseline)]		Char
01. Principal	spectis_bl_rna_col_dt	Liver Biopsy - RNAlater - Baseline - Date Specimen Collected - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"
01. Principal	spectis_bl_rna_col_tm	Liver Biopsy - RNAlater - Baseline - Time Specimen Collected - [Specimen Collection (Tissue - Baseline)]		SAS Time .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	spectis_bl_rna_collected	Liver Biopsy - RNAlater - Baseline - Was Specimen Collected? - [Specimen Collection (Tissue - Baseline)]		0="No" 1="Yes"
01. Principal	spectis_bl_rna_not_col_rsn	Liver Biopsy - RNAlater - Baseline - Not Collected Reason - [Specimen Collection (Tissue - Baseline)]		.M="Missing" 1="Sample not required" 2="Not available" 3="Patient refusal" 4="Institution error" 5="Institution won't release" 6="Facility will not release block" 7="Other"
01. Principal	spectis_bl_rna_num	Liver Biopsy - RNAlater - Baseline - Number Of Specimens Collected - [Specimen Collection (Tissue - Baseline)]		Numeric .M="Missing"
01. Principal	spectis_bl_rna_par_blocks	Liver Biopsy - RNAlater - Baseline - Paraffin Blocks - [Specimen Collection (Tissue - Baseline)]		Numeric .M="Missing"
01. Principal	spectis_bl_rna_par_emb_dt	Liver Biopsy - RNAlater - Baseline - Date Of Paraffin Embedding - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"
01. Principal	spectis_bl_rna_par_emb_tm	Liver Biopsy - RNAlater - Baseline - Time Of Paraffin Embedding - [Specimen Collection (Tissue - Baseline)]		SAS Time .M="Missing"
01. Principal	spectis_bl_rna_rsn_oth	Liver Biopsy - RNAlater - Baseline - Not Collected Reason - Other (Specify) - [Specimen Collection (Tissue - Baseline)]		Char
01. Principal	spectis_bl_rna_section_dt	Liver Biopsy - RNAlater - Baseline - Date Of Sectioning - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"
01. Principal	spectis_bl_rna_section_tm	Liver Biopsy - RNAlater - Baseline - Time Of Sectioning - [Specimen Collection (Tissue - Baseline)]		SAS Time .M="Missing"
01. Principal	spectis_bl_rna_ship_dt	Liver Biopsy - RNAlater - Baseline - Date Specimen Shipped - [Specimen Collection (Tissue - Baseline)]		SAS Date .M="Missing"

Section 16: Specimen Collection (Tissue - Post-Intervention)

Class	Variable	Label	Description	Format Text
01. Principal	spectis_pi_comments	Comments - [Specimen Collection (Tissue - Post-Intervention)]		Char
01. Principal	spectis_pi_how_stored	If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? - [Specimen Collection (Tissue - Post-Intervention)]		.F="No Record For This Visit" .N="N/A" 0="Not Stored Per Protocol" 1="Stored Per Protocol"
01. Principal	spectis_pi_how_stored_spec	If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? (Specify) - [Specimen Collection (Tissue - Post-Intervention)]		Char
01. Principal	spectis_pi_lb_form_col_dt	Liver Biopsy - Formalin - Date Specimen Collected - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_form_col_tm	Liver Biopsy - Formalin - Time Specimen Collected - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_form_collected	Liver Biopsy - Formalin - Was Specimen Collected? - [Specimen Collection (Tissue - Post-Intervention)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	spectis_pi_lb_form_not_col_rsn	Liver Biopsy - Formalin - Not Collected Reason - [Specimen Collection (Tissue - Post-Intervention)]		.F="No Record For This Visit" .M="Missing" 1="Sample not required" 2="Not available" 3="Patient refusal" 4="Institution error" 5="Institution won't release" 6="Facility will not release block" 7="Other"

Class	Variable	Label	Description	Format Text
01. Principal	spectis_pi_lb_for m_num	Liver Biopsy - Formalin - Number Of Specimens Collected - [Specimen Collection (Tissue - Post-Intervention)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_for m_par_blocks	Liver Biopsy - Formalin - Paraffin Blocks - [Specimen Collection (Tissue - Post-Intervention)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_for m_par_emb_dt	Liver Biopsy - Formalin - Date Of Paraffin Embedding - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_for m_par_emb_tm	Liver Biopsy - Formalin - Time Of Paraffin Embedding - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_for m_rsn_oth	Liver Biopsy - Formalin - Not Collected Reason - Other (Specify) - [Specimen Collection (Tissue - Post-Intervention)]		Char
01. Principal	spectis_pi_lb_for m_sect_dt	Liver Biopsy - Formalin - Date Of Sectioning - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_for m_sect_tm	Liver Biopsy - Formalin - Time Of Sectioning - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_for m_ship_dt	Liver Biopsy - Formalin - Date Specimen Shipped - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_rn a_col_dt	Liver Biopsy - RNAlater - Date Specimen Collected - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_rn a_col_tm	Liver Biopsy - RNAlater - Time Specimen Collected - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	spectis_pi_lb_rna_collected	Liver Biopsy - RNAlater - Was Specimen Collected? - [Specimen Collection (Tissue - Post-Intervention)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	spectis_pi_lb_rna_not_col_rsn	Liver Biopsy - RNAlater - Not Collected Reason - [Specimen Collection (Tissue - Post-Intervention)]		.F="No Record For This Visit" .M="Missing" 1="Sample not required" 2="Not available" 3="Patient refusal" 4="Institution error" 5="Institution won't release" 6="Facility will not release block" 7="Other"
01. Principal	spectis_pi_lb_rna_num	Liver Biopsy - RNAlater - Number Of Specimens Collected - [Specimen Collection (Tissue - Post-Intervention)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_rna_par_blocks	Liver Biopsy - RNAlater - Paraffin Blocks - [Specimen Collection (Tissue - Post-Intervention)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_rna_par_emb_dt	Liver Biopsy - RNAlater - Date Of Paraffin Embedding - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_rna_par_emb_tm	Liver Biopsy - RNAlater - Time Of Paraffin Embedding - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_rna_rsn_oth	Liver Biopsy - RNAlater - Not Collected Reason - Other (Specify) - [Specimen Collection (Tissue - Post-Intervention)]		Char
01. Principal	spectis_pi_lb_rna_sect_dt	Liver Biopsy - RNAlater - Date Of Sectioning - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lb_rna_sect_tm	Liver Biopsy - RNAlater - Time Of Sectioning - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	spectis_pi_lb_rna_ship_dt	Liver Biopsy - RNAlater - Date Specimen Shipped - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_for_m_col_dt	Liver Resection Specimen - Formalin - Date Specimen Collected - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_for_m_col_tm	Liver Resection Specimen - Formalin - Time Specimen Collected - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_for_m_collected	Liver Resection Specimen - Formalin - Was Specimen Collected? - [Specimen Collection (Tissue - Post-Intervention)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	spectis_pi_lr_for_m_not_col_rsn	Liver Resection Specimen - Formalin - Not Collected Reason - [Specimen Collection (Tissue - Post-Intervention)]		.F="No Record For This Visit" .M="Missing" 1="Sample not required" 2="Not available" 3="Patient refusal" 4="Institution error" 5="Institution won't release" 6="Facility will not release block" 7="Other"
01. Principal	spectis_pi_lr_for_m_num	Liver Resection Specimen - Formalin - Number Of Specimens Collected - [Specimen Collection (Tissue - Post-Intervention)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_for_m_par_blocks	Liver Resection Specimen - Formalin - Paraffin Blocks - [Specimen Collection (Tissue - Post-Intervention)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_for_m_par_emb_dt	Liver Resection Specimen - Formalin - Date Of Paraffin Embedding - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_for_m_par_emb_tm	Liver Resection Specimen - Formalin - Time Of Paraffin Embedding - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	spectis_pi_lr_for m_rsn_oth	Liver Resection Specimen - Formalin - Not Collected Reason - Other (Specify) - [Specimen Collection (Tissue - Post-Intervention)]		Char
01. Principal	spectis_pi_lr_for m_sect_dt	Liver Resection Specimen - Formalin - Date Of Sectioning - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_for m_sect_tm	Liver Resection Specimen - Formalin - Time Of Sectioning - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_for m_ship_dt	Liver Resection Specimen - Formalin - Date Specimen Shipped - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_rna _col_dt	Liver Resection Specimen - RNAlater - Date Specimen Collected - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_rna _col_tm	Liver Resection Specimen - RNAlater - Time Specimen Collected - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_rna _collected	Liver Resection Specimen - RNAlater - Was Specimen Collected? - [Specimen Collection (Tissue - Post-Intervention)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	spectis_pi_lr_rna _not_col_rsn	Liver Resection Specimen - RNAlater - Not Collected Reason - [Specimen Collection (Tissue - Post-Intervention)]		.F="No Record For This Visit" .M="Missing" 1="Sample not required" 2="Not available" 3="Patient refusal" 4="Institution error" 5="Institution won't release" 6="Facility will not release block" 7="Other"
01. Principal	spectis_pi_lr_rna _num	Liver Resection Specimen - RNAlater - Number Of Specimens Collected - [Specimen Collection (Tissue - Post-Intervention)]		Numeric .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	spectis_pi_lr_rna _par_blocks	Liver Resection Specimen - RNAlater - Paraffin Blocks - [Specimen Collection (Tissue - Post-Intervention)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_rna _par_emb_dt	Liver Resection Specimen - RNAlater - Date Of Paraffin Embedding - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_rna _par_emb_tm	Liver Resection Specimen - RNAlater - Time Of Paraffin Embedding - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_rna _rsn_oth	Liver Resection Specimen - RNAlater - Not Collected Reason - Other (Specify) - [Specimen Collection (Tissue - Post-Intervention)]		Char
01. Principal	spectis_pi_lr_rna _sect_dt	Liver Resection Specimen - RNAlater - Date Of Sectioning - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_rna _sect_tm	Liver Resection Specimen - RNAlater - Time Of Sectioning - [Specimen Collection (Tissue - Post-Intervention)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	spectis_pi_lr_rna _ship_dt	Liver Resection Specimen - RNAlater - Date Specimen Shipped - [Specimen Collection (Tissue - Post-Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"

Section 17: Participant Status (Intervention)

Class	Variable	Label	Description	Format Text
01. Principal	event_tx_ae_assess	Were Adverse Events Assessed During This Reporting Period? - [Participant Status (Intervention)]		.F="No Record For This Visit" 0="No" 1="Yes and reportable adverse events occurred" 2="Yes but no reportable adverse events occurred"
01. Principal	event_tx_com	Comments - [Participant Status (Intervention)]		Char
01. Principal	event_tx_contact_dt	Contact Date - [Participant Status (Intervention)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	event_tx_phys_exam	Was The Overall Physical Exam Performed? - [Participant Status (Intervention)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	event_tx_post_int_eval	Will The Participant Continue To The Post-Intervention Evaluation? - [Participant Status (Intervention)]		.F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	event_tx_vital_status	Participant Vital Status - [Participant Status (Intervention)]		.F="No Record For This Visit" .M="Missing" 1="Alive" 2="Dead"

Section 18: Expedited Reporting

Class	Variable	Label	Description	Format Text
01. Principal	aer_ae_attrib	What Is The Attribution To The Study Medication? - [Expedited Reporting]		.F="No Record For This Visit" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probably" 5="Definite"
01. Principal	aer_ae_comments	Comments - [Expedited Reporting]		Char
01. Principal	aer_ae_grade	Grade - [Expedited Reporting]		.F="No Record For This Visit" 0="Absent Adverse Event" 1="Mild Adverse Event" 2="Moderate Adverse Event" 3="Severe Adverse Event" 4="Life-threatening Adverse Event" 5="Death Related to Adverse Event"
01. Principal	aer_ae_notify_dt	Date Made Aware Of Events - [Expedited Reporting]		SAS Date .F="No Record For This Visit"
01. Principal	aer_ae_term	Adverse Event Term (CTCAE V4.0) - [Expedited Reporting]		Numeric .F="No Record For This Visit"
01. Principal	aer_aer_form	Is This An Adverse Event Report Form? - [Expedited Reporting]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	aer_amendment_num	Amendment Number - [Expedited Reporting]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	aer_attachment	Attached Report - [Expedited Reporting]		Char
01. Principal	aer_death_prog	Was Death Due To Progression? - [Expedited Reporting]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	aer_format_type	Report Format - [Expedited Reporting]		.F="No Record For This Visit" 1="MedWatch" 2="AdEERs" 3="Other"
01. Principal	aer_format_type_spec	Report Format - Specify - [Expedited Reporting]		Char
01. Principal	aer_in_hospital	Hospitalization - [Expedited Reporting]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	aer_occur_dt	Date Of First Occurrence Of Adverse Event - [Expedited Reporting]		SAS Date .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	aer_ppt_dead	Has Patient Died? - [Expedited Reporting]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	aer_ticket_num	Ticket Number - [Expedited Reporting]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	aer_visit	Visit Number - [Expedited Reporting]		Numeric .F="No Record For This Visit" .M="Missing"

Section 19: Phone Call Compliance

Class	Variable	Label	Description	Format Text
01. Principal	phone_ae_reported1-2	Were Any Adverse Events Reported? - # - [Phone Call Compliance]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	phone_call_attempt_dt1-2	Date Follow-Up Phone Call Attempted - # - [Phone Call Compliance]		SAS Date .F="No Record For This Visit"
01. Principal	phone_call_attempted1-2	Was A Follow-Up Phone Call Attempted? - # - [Phone Call Compliance]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	phone_call_completed1-2	Was A Follow-Up Phone Call Completed? - # - [Phone Call Compliance]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	phone_call_completed_dt1-2	Date Follow-Up Phone Call Completed - # - [Phone Call Compliance]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	phone_com1-2	Comments - # - [Phone Call Compliance]		Char
01. Principal	phone_conmeds_reported1-2	Any Changes To Concomitant Medications Reported? - # - [Phone Call Compliance]		.F="No Record For This Visit" 0="No" 1="Yes"

Section 20: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_num	Number Of Adverse Events Experienced During The Study - [Adverse Events]		Numeric

Section 21: Post-Intervention Evaluation

Class	Variable	Label	Description	Format Text
01. Principal	pi_eval_ae	Were Adverse Events Assessed During This Reporting Period? - [Post-Intervention Evaluation]		.F="No Record For This Visit" 0="No" 1="Yes but no reportable adverse events occurred" 2="Yes and reportable adverse events occurred"
01. Principal	pi_eval_comments	Comments - [Post-Intervention Evaluation]		Char
01. Principal	pi_eval_contact_dt	Contact Date - [Post-Intervention Evaluation]		SAS Date .F="No Record For This Visit"
01. Principal	pi_eval_last_fup	Has The Participant Completed Their Last Follow-Up Visit? - [Post-Intervention Evaluation]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	pi_eval_physical	Was The Overall Physical Exam Performed? - [Post-Intervention Evaluation]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	pi_eval_vital_status	Participant Vital Status - [Post-Intervention Evaluation]		.F="No Record For This Visit" 1="Alive" 2="Dead"
01. Principal	pi_eval_wiwi	Did The Participant Complete The Was It Worth It (WIWI) Questionnaire? - [Post-Intervention Evaluation]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	pi_eval_wiwi_dt	Was It Worth It Questionnaire Date Completed - [Post-Intervention Evaluation]		SAS Date .F="No Record For This Visit" .M="Missing"

Section 22: Was It Worth It? Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	wiwi_experience	Overall, How Was Your Experience Of Participating In This Research Study? - [Was It Worth It? Questionnaire]		.F="No Record For This Visit" 1="Better than I expected" 2="The same as I expected" 3="Worse than I expected"
01. Principal	wiwi_improve	If There Was One Thing That Could Have Been Done To Improve Your Experience In This Research Study, What Would It Be? - [Was It Worth It? Questionnaire]		Char
01. Principal	wiwi_no_assesment_reason	Reason Assesment Was Not Completed - [Was It Worth It? Questionnaire]		.F="No Record For This Visit" 1="Patient refusal: patient reported physical reason" 2="Patient refusal: patient reported mental/emotional reason" 3="Patient refusal: patient said did not like content of questions" 4="Patient refusal: patient did not give a reason" 5="Patient refusal: other, specify" 6="Unable to accommodate disability or language needs, specify" 7="Not administered: staff unavailable" 8="Not administered: staff did not give/offer assessment to patient" 9="Not administered: staff misinterpreted protocol" 10="Not administered: copy of form not available" 11="Other, specify"
01. Principal	wiwi_ppt_again	If You Had To Do It Over, Would You Participate In This Research Study Again? - [Was It Worth It? Questionnaire]		.F="No Record For This Visit" 0="No" 1="Yes" 2="Uncertain"
01. Principal	wiwi_qol	Overall, Did Your Quality Of Life Change By Participating In This Research Study? - [Was It Worth It? Questionnaire]		.F="No Record For This Visit" 1="It improved" 2="It stayed the same" 3="It got worse"
01. Principal	wiwi_recommend	Would You Recommend Participating In This Research Study To Others? - [Was It Worth It? Questionnaire]		.F="No Record For This Visit" 0="No" 1="Yes" 2="Uncertain"

Class	Variable	Label	Description	Format Text
01. Principal	wiwi_talk	Would You Like To Talk To Someone About Your Concerns? - [Was It Worth It? Questionnaire]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	wiwi_worthwhile	Was It Worthwhile For You To Participate In This Research Study? - [Was It Worth It? Questionnaire]		.F="No Record For This Visit" 0="No" 1="Yes" 2="Uncertain"

Section 23: Off Study

Class	Variable	Label	Description	Format Text
01. Principal	end_at_agent_stopped_dt	Date Agent Stopped - [Off Study]		SAS Date .M="Missing"
01. Principal	end_at_comment	Comments - [Off Study]		Char
01. Principal	end_at_end_at_comment	Off Treatment Reason Other, Specify - [Off Study]		Char
01. Principal	end_at_last_contact_dt	Date Of Last Contact - [Off Study]		SAS Date
01. Principal	end_at_off_study_dt	Off Study Date - [Off Study]		SAS Date
01. Principal	end_at_reason	Off Study Reason - [Off Study]		1="Adverse event" 2="Death" 3="Ineligible (includes screen failures)" 4="Physician decision" 5="Study complete"

Section 24: Supporting Documentation

Class	Variable	Label	Description	Format Text
01. Principal	supdoc_assess_dt_v0_1-8	Date Of Assessment - Visit 0 (Baseline) - # - [Supporting Documentation]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	supdoc_assess_dt_v2_1-4	Date Of Assessment - Visit 2 (Post-Intervention) - # - [Supporting Documentation]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	supdoc_attachm ent_v0_1-8	Attachment - Visit 0 (Baseline) - # - [Supporting Documentation]		Char
01. Principal	supdoc_attachm ent_v2_1-4	Attachment - Visit 2 (Post-Intervention) - # - [Supporting Documentation]		Char
01. Principal	supdoc_commen ts_v0_1-8	Comments - Visit 0 (Baseline) - # - [Supporting Documentation]		Char
01. Principal	supdoc_commen ts_v2_1-4	Comments - Visit 2 (Post-Intervention) - # - [Supporting Documentation]		Char
01. Principal	supdoc_num_v0/ supdoc_num_v2	Total Number Of Observations - [Supporting Documentation]		Numeric .F="No Record For This Visit"
01. Principal	supdoc_type_sp ec_v0_1-8	Report Type (Specify) - Visit 0 (Baseline) - # - [Supporting Documentation]		Char
01. Principal	supdoc_type_sp ec_v2_1-4	Report Type (Specify) - Visit 2 (Post-Intervention) - # - [Supporting Documentation]		Char
01. Principal	supdoc_type_v0_1-8	Report Type - Visit 0 (Baseline) - # - [Supporting Documentation]		.F="No Record For This Visit" .N="N/A" 1="Laboratory report" 2="Clinic note" 3="Other"
01. Principal	supdoc_type_v2_1-4	Report Type - Visit 2 (Post-Intervention) - # - [Supporting Documentation]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Laboratory report" 2="Clinic note" 3="Other"

Section 25: Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	lrc_alk_pho_csig_v0/lrc_alk_pho_csig_v2	Alkaline Phosphatase - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_alk_pho_done_v0/lrc_alk_pho_done_v2	Alkaline Phosphatase - Was Lab Specimen Collected? - Visit # - [Blood Chemistry]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrc_alk_pho_oor_v0/lrc_alk_pho_oor_v2	Alkaline Phosphatase - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_alk_pho_units_v0/lrc_alk_pho_units_v2	Alkaline Phosphatase - Units - Visit # - [Blood Chemistry]		Char
01. Principal	lrc_alk_pho_val_v0/lrc_alk_pho_val_v2	Alkaline Phosphatase - Lab Value - Visit # - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrc_als_ami_csig_v0/lrc_als_ami_csig_v2	Alanine Aminotransferase (ALT or SGPT) - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_als_ami_done_v0/lrc_als_ami_done_v2	Alanine Aminotransferase (ALT or SGPT) - Was Lab Specimen Collected? - Visit # - [Blood Chemistry]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrc_als_ami_oor_v0/lrc_als_ami_oor_v2	Alanine Aminotransferase (ALT or SGPT) - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_als_ami_units_v0/lrc_als_ami_units_v2	Alanine Aminotransferase (ALT or SGPT) - Units - Visit # - [Blood Chemistry]		Char
01. Principal	lrc_als_ami_val_v0/lrc_als_ami_val_v2	Alanine Aminotransferase (ALT or SGPT) - Lab Value - Visit # - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrc_asp_ami_csig_v0/lrc_asp_ami_csig_v2	Aspartate Aminotransferase (AST or SGOT) - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	lrc_asp_ami_done_v0/lrc_asp_ami_done_v2	Aspartate Aminotransferase (AST or SGOT) - Was Lab Specimen Collected? - Visit # - [Blood Chemistry]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrc_asp_ami_oor_v0/lrc_asp_ami_oor_v2	Aspartate Aminotransferase (AST or SGOT) - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_asp_ami_units_v0/lrc_asp_ami_units_v2	Aspartate Aminotransferase (AST or SGOT) - Units - Visit # - [Blood Chemistry]		Char
01. Principal	lrc_asp_ami_val_v0/lrc_asp_ami_val_v2	Aspartate Aminotransferase (AST or SGOT) - Lab Value - Visit # - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrc_bil_tot_csig_v0/lrc_bil_tot_csig_v2	Bilirubin Total - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_bil_tot_done_v0/lrc_bil_tot_done_v2	Bilirubin Total - Was Lab Specimen Collected? - Visit # - [Blood Chemistry]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrc_bil_tot_oor_v0/lrc_bil_tot_oor_v2	Bilirubin Total - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_bil_tot_units_v0/lrc_bil_tot_units_v2	Bilirubin Total - Units - Visit # - [Blood Chemistry]		Char
01. Principal	lrc_bil_tot_val_v0/lrc_bil_tot_val_v2	Bilirubin Total - Lab Value - Visit # - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrc_bld_ure_nit_csig_v0/lrc_bld_ure_nit_csig_v2	Blood Urea Nitrogen (BUN) - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_bld_ure_nit_done_v0/lrc_bld_ure_nit_done_v2	Blood Urea Nitrogen (BUN) - Was Lab Specimen Collected? - Visit # - [Blood Chemistry]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrc_bld_ure_nit_oor_v0/lrc_bld_ure_nit_oor_v2	Blood Urea Nitrogen (BUN) - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_bld_ure_nit_units_v0/lrc_bld_ure_nit_units_v2	Blood Urea Nitrogen (BUN) - Units - Visit # - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	lrc_bld_ure_nit_val_v0/lrc_bld_ure_nit_val_v2	Blood Urea Nitrogen (BUN) - Lab Value - Visit # - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrc_calc_csig_v0/lrc_calc_csig_v2	Calcium - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_calc_done_v0/lrc_calc_done_v2	Calcium - Was Lab Specimen Collected? - Visit # - [Blood Chemistry]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrc_calc_oor_v0/lrc_calc_oor_v2	Calcium - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_calc_units_v0/lrc_calc_units_v2	Calcium - Units - Visit # - [Blood Chemistry]		Char
01. Principal	lrc_calc_val_v0/lrc_calc_val_v2	Calcium - Lab Value - Visit # - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrc_comments_v0/lrc_comments_v2	Comments - Visit # - [Blood Chemistry]		Char
01. Principal	lrc_crea_phos_csig_v0/lrc_crea_phos_csig_v2	Creatine Phosphokinase (CPK) - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_crea_phos_done_v0/lrc_crea_phos_done_v2	Creatine Phosphokinase (CPK) - Was Lab Specimen Collected? - Visit # - [Blood Chemistry]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrc_crea_phos_oor_v0/lrc_crea_phos_oor_v2	Creatine Phosphokinase (CPK) - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_crea_phos_units_v0/lrc_crea_phos_units_v2	Creatine Phosphokinase (CPK) - Units - Visit # - [Blood Chemistry]		Char
01. Principal	lrc_crea_phos_val_v0/lrc_crea_phos_val_v2	Creatine Phosphokinase (CPK) - Lab Value - Visit # - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrc_creat_csig_v0/lrc_creat_csig_v2	Creatinine - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_creat_done_v0/lrc_creat_done_v2	Creatinine - Was Lab Specimen Collected? - Visit # - [Blood Chemistry]		.F="No Record For This Visit" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	lrc_creat_oor_v0/ lrc_creat_oor_v2	Creatinine - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_creat_units_v0/ lrc_creat_units_v2	Creatinine - Units - Visit # - [Blood Chemistry]		Char
01. Principal	lrc_creat_val_v0/ lrc_creat_val_v2	Creatinine - Lab Value - Visit # - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrc_fasting_v0/lrc_fasting_v2	Fasting - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .U="Unknown" 0="No" 1="Yes"
01. Principal	lrc_sample_col_dt_v0/ lrc_sample_col_dt_v2	Sample Collection Date - Visit # - [Blood Chemistry]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	lrc_tot_prot_csig_v0/ lrc_tot_prot_csig_v2	Total Protein - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_tot_prot_done_v0/ lrc_tot_prot_done_v2	Total Protein - Was Lab Specimen Collected? - Visit # - [Blood Chemistry]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrc_tot_prot_oor_v0/ lrc_tot_prot_oor_v2	Total Protein - Out Of Range - Visit # - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrc_tot_prot_units_v0/ lrc_tot_prot_units_v2	Total Protein - Units - Visit # - [Blood Chemistry]		Char
01. Principal	lrc_tot_prot_val_v0/ lrc_tot_prot_val_v2	Total Protein - Lab Value - Visit # - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing"

Section 26: Hematology

Class	Variable	Label	Description	Format Text
01. Principal	lrh_baso_csig_v0 /lrh_baso_csig_v2	Basophils - Clinically Significant - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_baso_done_v0 /lrh_baso_done_v2	Basophils - Was Lab Specimen Collected? - Visit # - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrh_baso_oor_v0 /lrh_baso_oor_v2	Basophils - Out Of Range - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_baso_units_v0 /lrh_baso_units_v2	Basophils - Units - Visit # - [Hematology]		Char
01. Principal	lrh_baso_val_v0 /rh_baso_val_v2	Basophils - Lab Value - Visit # - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrh_comments_v0 /lrh_comments_v2	Comments - Visit # - [Hematology]		Char
01. Principal	lrh_eosino_csig_v0 /lrh_eosino_csig_v2	Eosinophils - Clinically Significant - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_eosino_done_v0 /lrh_eosino_done_v2	Eosinophils - Was Lab Specimen Collected? - Visit # - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrh_eosino_oor_v0 /lrh_eosino_oor_v2	Eosinophils - Out Of Range - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_eosino_units_v0 /lrh_eosino_units_v2	Eosinophils - Units - Visit # - [Hematology]		Char
01. Principal	lrh_eosino_val_v0 /lrh_eosino_val_v2	Eosinophils - Lab Value - Visit # - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrh_hematocrit_csig_v0 /lrh_hematocrit_csig_v2	Hematocrit - Clinically Significant - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_hematocrit_done_v0 /lrh_hematocrit_done_v2	Hematocrit - Was Lab Specimen Collected? - Visit # - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrh_hematocrit_oor_v0 /lrh_hematocrit_oor_v2	Hematocrit - Out Of Range - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	lrh_hematocrit_u nits_v0/lrh_hema tocrit_units_v2	Hematocrit - Units - Visit # - [Hematology]		Char
01. Principal	lrh_hematocrit_v al_v0/lrh_hemato crit_val_v2	Hematocrit - Lab Value - Visit # - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrh_hematoglob_ csig_v0/lrh_hema toglob_csig_v2	Hemoglobin - Clinically Significant - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_hematoglob_ done_v0/lrh_hem atoglob_done_v2	Hemoglobin - Was Lab Specimen Collected? - Visit # - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrh_hematoglob_ oor_v0/lrh_hemat oglob_oor_v2	Hemoglobin - Out Of Range - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_hematoglob_ units_v0/lrh_hem atoglob_units_v2	Hemoglobin - Units - Visit # - [Hematology]		Char
01. Principal	lrh_hematoglob_ val_v0/lrh_hemat oglob_val_v2	Hemoglobin - Lab Value - Visit # - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrh_lympho_csig_ _v0/lrh_lympho_ csig_v2	Lymphocytes - Clinically Significant - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_lympho_done_ _v0/lrh_lympho_ done_v2	Lymphocytes - Was Lab Specimen Collected? - Visit # - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrh_lympho_oor_ v0/lrh_lympho_o or_v2	Lymphocytes - Out Of Range - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_lympho_units_ _v0/lrh_lympho_ units_v2	Lymphocytes - Units - Visit # - [Hematology]		Char
01. Principal	lrh_lympho_val_ v0/lrh_lympho_v al_v2	Lymphocytes - Lab Value - Visit # - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrh_mono_csig_v 0/lrh_mono_csig_ _v2	Monocytes - Clinically Significant - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_mono_done_ v0/lrh_mono_don e_v2	Monocytes - Was Lab Specimen Collected? - Visit # - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrh_mono_oor_v0 /lrh_mono_oor_v 2	Monocytes - Out Of Range - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	lrh_mono_units_v0/lrh_mono_units_v2	Monocytes - Units - Visit # - [Hematology]		Char
01. Principal	lrh_mono_val_v0/lrh_mono_val_v2	Monocytes - Lab Value - Visit # - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrh_neutro_csig_v0/lrh_neutro_csig_v2	Neutrophils (ANC) - Clinically Significant - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_neutro_done_v0/lrh_neutro_done_v2	Neutrophils (ANC) - Was Lab Specimen Collected? - Visit # - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrh_neutro_oor_v0/lrh_neutro_oor_v2	Neutrophils (ANC) - Out Of Range - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_neutro_units_v0/lrh_neutro_units_v2	Neutrophils (ANC) - Units - Visit # - [Hematology]		Char
01. Principal	lrh_neutro_val_v0/lrh_neutro_val_v2	Neutrophils (ANC) - Lab Value - Visit # - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrh_plat_csig_v0/lrh_plat_csig_v2	Platelets - Clinically Significant - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_plat_done_v0/lrh_plat_done_v2	Platelets - Was Lab Specimen Collected? - Visit # - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrh_plat_oor_v0/lrh_plat_oor_v2	Platelets - Out Of Range - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_plat_units_v0/lrh_plat_units_v2	Platelets - Units - Visit # - [Hematology]		Char
01. Principal	lrh_plat_val_v0/lrh_plat_val_v2	Platelets - Lab Value - Visit # - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrh_rbc_csig_v0/lrh_rbc_csig_v2	Red Blood Cells (RBC) - Clinically Significant - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_rbc_done_v0/lrh_rbc_done_v2	Red Blood Cells (RBC) - Was Lab Specimen Collected? - Visit # - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrh_rbc_oor_v0/lrh_rbc_oor_v2	Red Blood Cells (RBC) - Out Of Range - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	lrh_rbc_units_v0/ lrh_rbc_units_v2	Red Blood Cells (RBC) - Units - Visit # - [Hematology]		Char
01. Principal	lrh_rbc_val_v0/lr h_rbc_val_v2	Red Blood Cells (RBC) - Lab Value - Visit # - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lrh_sample_col_ dt_v0/lrh_sample _col_dt_v2	Sample Collection Date - Visit # - [Hematology]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	lrh_wbc_csig_v0/ lrh_wbc_csig_v2	White Blood Cells (WBC) - Clinically Significant - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_wbc_done_v0 /lrh_wbc_done_v 2	White Blood Cells (WBC) - Was Lab Specimen Collected? - Visit # - [Hematology]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lrh_wbc_oor_v0/l rh_wbc_oor_v2	White Blood Cells (WBC) - Out Of Range - Visit # - [Hematology]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lrh_wbc_units_v0 /lrh_wbc_units_v 2	White Blood Cells (WBC) - Units - Visit # - [Hematology]		Char
01. Principal	lrh_wbc_val_v0/lr h_wbc_val_v2	White Blood Cells (WBC) - Lab Value - Visit # - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing"

Section 27: Other Lab Tests

Class	Variable	Label	Description	Format Text
01. Principal	lro_alb_serum_csig_v0/lro_alb_serum_csig_v2	Albumin - Clinically Significant - Visit # - [Other Lab Tests]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lro_alb_serum_done_v0/lro_alb_serum_done_v2	Albumin - Was Lab Specimen Collected? - Visit # - [Other Lab Tests]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lro_alb_serum_oor_v0/lro_alb_serum_oor_v2	Albumin - Out Of Range - Visit # - [Other Lab Tests]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lro_alb_serum_units_v0/lro_alb_serum_units_v2	Albumin - Units - Visit # - [Other Lab Tests]		Char
01. Principal	lro_alb_serum_val_v0/lro_alb_serum_val_v2	Albumin - Lab Value - Visit # - [Other Lab Tests]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lro_comments_v0/lro_comments_v2	Comments - Visit # - [Other Lab Tests]		Char
01. Principal	lro_hcv_pos_v0/lro_hcv_pos_v2	Is The Patient HCV Positive? - Visit # - [Other Lab Tests]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lro_hcv_rna_dt_v0/lro_hcv_rna_dt_v2	Date HCV RNA Test Was Performed - Visit # - [Other Lab Tests]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	lro_hep_b_surf_ant_v0/lro_hep_b_surf_ant_v2	Hepatitis B Surface Antigen - Visit # - [Other Lab Tests]		.F="No Record For This Visit" 0="Negative" 1="Positive" 2="Not Done"
01. Principal	lro_hepc_virus_rna_csig_v0/lro_hepc_virus_rna_csig_v2	Hepatitis C Virus RNA Quantitative IU/mL - Clinically Significant - Visit # - [Other Lab Tests]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lro_hepc_virus_rna_done_v0/lro_hepc_virus_rna_done_v2	Hepatitis C Virus RNA Quantitative IU/mL - Was Lab Specimen Collected? - Visit # - [Other Lab Tests]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lro_hepc_virus_rna_oor_v0/lro_hepc_virus_rna_oor_v2	Hepatitis C Virus RNA Quantitative IU/mL - Out Of Range - Visit # - [Other Lab Tests]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	lro_hepc_virus_rna_units_v0/lro_hepc_virus_rna_units_v2	Hepatitis C Virus RNA Quantitative IU/mL - Units - Visit # - [Other Lab Tests]		Char
01. Principal	lro_hepc_virus_rna_val_v0/lro_hepc_virus_rna_val_v2	Hepatitis C Virus RNA Quantitative IU/mL - Lab Value - Visit # - [Other Lab Tests]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lro_inr_pro_time_csig_v0/lro_inr_pro_time_csig_v2	International Normalized Ratio (INR) Prothrombin Time - Clinically Significant - Visit # - [Other Lab Tests]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lro_inr_pro_time_done_v0/lro_inr_pro_time_done_v2	International Normalized Ratio (INR) Prothrombin Time - Was Lab Specimen Collected? - Visit # - [Other Lab Tests]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	lro_inr_pro_time_oor_v0/lro_inr_pro_time_oor_v2	International Normalized Ratio (INR) Prothrombin Time - Out Of Range - Visit # - [Other Lab Tests]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	lro_inr_pro_time_units_v0/lro_inr_pro_time_units_v2	International Normalized Ratio (INR) Prothrombin Time - Units - Visit # - [Other Lab Tests]		Char
01. Principal	lro_inr_pro_time_val_v0/lro_inr_pro_time_val_v2	International Normalized Ratio (INR) Prothrombin Time - Lab Value - Visit # - [Other Lab Tests]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	lro_sample_col_dt_v0/lro_sample_col_dt_v2	Sample Collection Date - Visit # - [Other Lab Tests]		SAS Date .F="No Record For This Visit" .M="Missing"

Section 28: Non-Surgical

Class	Variable	Label	Description	Format Text
01. Principal	nonsurg_comments	Comments - [Non-Surgical]		Char
01. Principal	nonsurg_egfr_pos	Was The Phospho-EGFR Staining Positive? - [Non-Surgical]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	nonsurg_pos_pix_num	Was The Phospho-EGFR Staining Positive?: Yes - Number Of Positive Pixels - [Non-Surgical]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	nonsurg_supporting_doc	Attached Supporting Documentation - [Non-Surgical]		Char

Section 29: Phospho-EGFR Staining

Class	Variable	Label	Description	Format Text
01. Principal	phospho_attachment_v0/phospho_attachment_v2	Attached Supporting Documentation - Visit # - [Phospho-EGFR Staining]		Char
01. Principal	phospho_comments_v0/phospho_comments_v2	Comments - Visit # - [Phospho-EGFR Staining]		Char
01. Principal	phospho_evaluable_v0/phospho_evaluable_v2	Was The Patient Evaluable? - Visit # - [Phospho-EGFR Staining]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	phospho_num_portal_tracts_v0/phospho_num_portal_tracts_v2	Total Number Of Portal Tracts In Sample - Visit # - [Phospho-EGFR Staining]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	phospho_pixel_ratio_v0/phospho_pixel_ratio_v2	Ratio Of Positive/Total Pixels (%) - Visit # - [Phospho-EGFR Staining]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	phospho_pos_pixel_num_v0/phospho_pos_pixel_num_v2	Positive Pixels - Visit # - [Phospho-EGFR Staining]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	phospho_rsn_no_t_eval_oth_v0/phospho_rsn_not_eval_oth_v2	Was The Patient Evaluable?: No - Specify: Other - Specify - Visit # - [Phospho-EGFR Staining]		Char
01. Principal	phospho_rsn_no_t_eval_v0/phospho_rsn_not_eval_v2	Was The Patient Evaluable?: No - Specify - Visit # - [Phospho-EGFR Staining]		.F="No Record For This Visit" .M="Missing" 1="No positive pixels" 2="Insufficient tissue" 3="Assay failed" 4="Specimen lost" 5="Other, specify"
01. Principal	phospho_tot_pixel_num_v0/phospho_tot_pixel_num_v2	Total Pixels - Visit # - [Phospho-EGFR Staining]		Numeric .F="No Record For This Visit" .M="Missing"

Section 30: Phospho-EGFR Staining (Additional)

Class	Variable	Label	Description	Format Text
01. Principal	phosadd_attach ment_dt_v0	Attached Supporting Documentation Date - Visit 0 (Baseline) - [Phospho-EGFR Staining (Additional)]		SAS Date .F="No Record For This Visit"
01. Principal	phosadd_attach ment_dt_v2_1-2	Attached Supporting Documentation Date - Visit 2 (Post-Intervention) - # - [Phospho-EGFR Staining (Additional)]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	phosadd_attach ment_v0	Attached Supporting Documentation - Visit 0 (Baseline) - [Phospho-EGFR Staining (Additional)]		Char
01. Principal	phosadd_attach ment_v2_1-2	Attached Supporting Documentation - Visit 2 (Post-Intervention) - # - [Phospho-EGFR Staining (Additional)]		Char
01. Principal	phosadd_comme nts	Comments - [Phospho-EGFR Staining (Additional)]		Char
01. Principal	phosadd_evalua ble_v0	Was The Patient Evaluable? - Visit 0 (Baseline) - [Phospho-EGFR Staining (Additional)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	phosadd_evalua ble_v2_1-2	Was The Patient Evaluable? - Visit 2 (Post-Intervention) - # - [Phospho-EGFR Staining (Additional)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	phosadd_num_p ortal_tracts_v0	Total Number Of Portal Tracts In Sample - Visit 0 (Baseline) - [Phospho-EGFR Staining (Additional)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	phosadd_num_p ortal_tracts_v2_1 -2	Total Number Of Portal Tracts In Sample - Visit 2 (Post-Intervention) - # - [Phospho-EGFR Staining (Additional)]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	phosadd_pixel_r atio_v0	Ratio Of Positive/Total Pixels (%) - Visit 0 (Baseline) - [Phospho-EGFR Staining (Additional)]		Numeric .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	phosadd_pixel_ratio_v2_1-2	Ratio Of Positive/Total Pixels (%) - Visit 2 (Post-Intervention) - # - [Phospho-EGFR Staining (Additional)]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	phosadd_pos_pixel_num_v0	Positive Pixels - Visit 0 (Baseline) - [Phospho-EGFR Staining (Additional)]		Numeric .F="No Record For This Visit"
01. Principal	phosadd_pos_pixel_num_v2_1-2	Positive Pixels - Visit 2 (Post-Intervention) - # - [Phospho-EGFR Staining (Additional)]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	phosadd_rsn_not_eval_v0	Was The Patient Evaluable? - No: Specify - Visit 0 (Baseline) - [Phospho-EGFR Staining (Additional)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="No positive pixels" 2="Insufficient tissue" 3="Assay failed" 4="Specimen lost" 5="Other, specify"
01. Principal	phosadd_rsn_not_eval_v2_1-2	Was The Patient Evaluable? - No: Specify - Visit 2 (Post-Intervention) - # - [Phospho-EGFR Staining (Additional)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="No positive pixels" 2="Insufficient tissue" 3="Assay failed" 4="Specimen lost" 5="Other, specify"
01. Principal	phosadd_tot_pixel_num_v0	Total Pixels - Visit 0 (Baseline) - [Phospho-EGFR Staining (Additional)]		Numeric .F="No Record For This Visit"
01. Principal	phosadd_tot_pixel_num_v2_1-2	Total Pixels - Visit 2 (Post-Intervention) - # - [Phospho-EGFR Staining (Additional)]		Numeric .F="No Record For This Visit" .N="N/A"

Section 31: Biomarkers

Class	Variable	Label	Description	Format Text
01. Principal	biomarker_assay_dt1-5	Assay Date - # - [Biomarkers]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	biomarker_concentration1-5	Concentration (ng/mL) - # - [Biomarkers]		Numeric .F="No Record For This Visit" .L="<LLOQ (1.00)" .N="N/A"
01. Principal	biomarker_custom_id1-5	Custom ID - # - [Biomarkers]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	biomarker_dilution1-5	Dilution Factor - # - [Biomarkers]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	biomarker_hour_nominal1-5	Hour Nominal - # - [Biomarkers]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	biomarker_num	Total Number of Observations - [Biomarkers]		Numeric .F="No Record For This Visit"
01. Principal	biomarker_run_id1-5	Run ID - # - [Biomarkers]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	biomarker_visit1-5	Visit - # - [Biomarkers]		.F="No Record For This Visit" .N="N/A" 0="Baseline" 2="Post-Intervention"

Section 32: Analysis

Class	Variable	Label	Description	Format Text
01. Principal	analysis_eval	Evaluable For Primary Endpoint - [Analysis]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	analysis_pct_change_avg	Percent Change In Average Ratio (%) (Rounded To Nearest 10th) - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_change_med	Percent Change In Median Ratio (%) (Rounded To Nearest 10th) - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_change_min	Smallest Percent Change In Ratio (%) From Pre-Intervention To Post-Intervention (Rounded To Nearest 10th) - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_change_pre1_post1-3	Percent Change In Ratio (%) From Pre-Intervention Sample 1 To Post-Intervention Sample # - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_change_pre2_post1-3	Percent Change In Ratio (%) From Pre-Intervention Sample 2 To Post-Intervention Sample # - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_changen_avg	Percent Change In Average Ratio (%) - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_changen_med	Percent Change In Median Ratio (%) - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_changen_min	Smallest Percent Change In Ratio (%) From Pre-Intervention To Post-Intervention - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_changen_pre1_post1-3	Percent Change In Ratio (%) From Pre-Intervention Sample 1 To Post-Intervention Sample 3 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	analysis_pct_change_pre2_post1-3	Percent Change In Ratio (%) From Pre-Intervention Sample 2 To Post-Intervention Sample 3 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_ratio_post1-3	Post-Intervention Ratio (%): Sample 3 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_ratio_postavg	Post-Intervention Ratio (%): Average - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_ratio_pre1-2	Pre-Intervention Ratio (%): Sample 2 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pct_ratio_preavg	Pre-Intervention Ratio (%): Average - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pos_pixels_post1-3	Post-Intervention Positive Pixels: Sample 3 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_pos_pixels_pre1-2	Pre-Intervention Positive Pixels: Sample 2 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	analysis_response_avg	Response For Average - [Analysis]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	analysis_response_best	Best Response - [Analysis]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	analysis_response_med	Response For Median - [Analysis]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	analysis_response_pre1_post1-3	Response For Pre-Intervention Sample 1 To Post-Intervention Sample 3 - [Analysis]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	analysis_response_pre2_post1-3	Response For Pre-Intervention Sample 2 To Post-Intervention Sample 3 - [Analysis]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	analysis_surgical_cohort	Surgical Cohort - [Analysis]		.F="No Record For This Visit" 1="Surgical Cohort" 2="Non-Surgical Cohort"
01. Principal	analysis_tot_pixels_post1-3	Post-Intervention Total Pixels: Sample 3 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	analysis_tot_pix_pre1-2	Pre-Intervention Total Pixels: Sample 2 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"