

# MAY2013-02-02 - Enhanced Person Data Dictionary

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## Document Summary

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## MAY2013-02-02 - Enhanced Person: Data Dictionary

### Section 1: Identifier

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

## Section 2: Study-wide

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Class	Variable	Label	Description	Format Text
01. Principal	<b>build_dt</b>	Build Date		SAS Date
01. Principal	<b>PROJECT</b>	Protocol		Char
01. Principal	<b>rave_id</b>	Rave ID		Numeric
01. Principal	<b>site</b>	Site		1="Case Western Reserve University" 2="Cleveland Clinic Foundation" 3="Massachusetts General Hospital Cancer Center" 4="Mayo Clinic" 5="Mayo Clinic In Florida" 6="Mount Sinai Hospital"
01. Principal	<b>site_number</b>	Site Number		1="FL080" 2="MA034" 3="MN026" 4="NY021" 5="OH027" 6="OH029"

## Section 3: Analysis

Class	Variable	Label	Description	Format Text
01. Principal	<b>analysis_age</b>	Age - [Analysis]		Numeric .F="No Record For This Visit"
01. Principal	<b>analysis_bmi</b>	BMI - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_cighist</b>	Cigarette History - [Analysis]		.F="No Record For This Visit" 1="Current Smoker" 2="Quit/Former Smoker" 3="Never Smoked"
01. Principal	<b>analysis_ctep_arm</b>	TAC/TAD Code - [Analysis]		.F="No Record For This Visit" 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	<b>analysis_dose_cohort</b>	Dose Cohort - [Analysis]		Numeric .F="No Record For This Visit"
01. Principal	<b>analysis_dose_level</b>	Dose Level (mg/day) - [Analysis]		Numeric .F="No Record For This Visit"
01. Principal	<b>analysis_ethnicity</b>	Ethnicity - [Analysis]		.F="No Record For This Visit" 1="Hispanic Or Latino" 2="Not Hispanic Or Latino" 3="Not Reported" 4="Unknown"
01. Principal	<b>analysis_eval</b>	Evaluable For Primary Endpoint - [Analysis]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>analysis_off_study_reason</b>	Off Study Reason - [Analysis]		.F="No Record For This Visit" 1="Adverse Event" 2="Physician Decision" 3="Study Complete"
01. Principal	<b>analysis_pct_change_avg</b>	Percent Change In Average Ratio (PCT) (rounded to nearest 10th) - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_change_med</b>	Percent Change In Median Ratio (PCT) (rounded to nearest 10th) - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>analysis_pct_changec_min</b>	Smallest Percent Change In Ratio (PCT) From Pre-Intervention To Post-Intervention (rounded to nearest 10th) - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_changec_pre1_post1-3</b>	Percent Change In Ratio (PCT) From Pre-Intervention Sample 1 To Post-Intervention Sample # - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_changec_pre2_post1-3</b>	Percent Change In Ratio (PCT) From Pre-Intervention Sample 2 To Post-Intervention Sample # - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_changen_avg</b>	Percent Change In Average Ratio (PCT) - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_changen_med</b>	Percent Change In Median Ratio (PCT) - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_changen_min</b>	Smallest Percent Change In Ratio (PCT) From Pre-Intervention To Post-Intervention - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_changen_pre1_post1-3</b>	Percent Change In Ratio (PCT) From Pre-Intervention Sample 1 To Post-Intervention Sample 3 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_changen_pre2_post1-3</b>	Percent Change In Ratio (PCT) From Pre-Intervention Sample 2 To Post-Intervention Sample 3 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_ratio_post1-3</b>	Post-Intervention Ratio (PCT): Sample 3 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_ratio_postavg</b>	Post-Intervention Ratio (PCT): Average - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_ratio_pre1-2</b>	Pre-Intervention Ratio (PCT): Sample 2 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pct_ratio_preavg</b>	Pre-Intervention Ratio (PCT): Average - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>analysis_pos_pix_post1-3</b>	Post-Intervention Positive Pixels: Sample 3 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_pos_pix_pre1-2</b>	Pre-Intervention Positive Pixels: Sample 2 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_race</b>	Race - [Analysis]		.F="No Record For This Visit" 1="White" 2="Black Or African American" 3="Asian" 4="Not Reported"
01. Principal	<b>analysis_reg_dt</b>	Registration Date - [Analysis]		SAS Date .F="No Record For This Visit"
01. Principal	<b>analysis_response_avg</b>	Response For Average - [Analysis]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>analysis_response_best</b>	Best Response - [Analysis]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>analysis_response_med</b>	Response For Median - [Analysis]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>analysis_response_pre1_post1-3</b>	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	<b>analysis_response_pre2_post1-3</b>	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	<b>analysis_sex</b>	Sex - [Analysis]		.F="No Record For This Visit" 1="Female" 2="Male"
01. Principal	<b>analysis_surgical_cohort</b>	Surgical Cohort - [Analysis]		Numeric .F="No Record For This Visit"
01. Principal	<b>analysis_tot_pix_post1-3</b>	Post-Intervention Total Pixels: Sample 3 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>analysis_tot_pix_pre1-2</b>	Pre-Intervention Total Pixels: Sample 2 - [Analysis]		Numeric .F="No Record For This Visit" .M="Missing"



## Section 4: Demography

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Class	Variable	Label	Description	Format Text
01. Principal	<b>country</b>	Country Of Residence - [Demographics]		1="US"
01. Principal	<b>ethnicity</b>	Ethnicity - [Demographics]		1="Hispanic or Latino" 2="Not Hispanic Or Latino" 3="Not reported" 4="Unknown"
01. Principal	<b>form_oid</b>	Form OID - [Demographics]		Char
01. Principal	<b>gender</b>	Gender - [Demographics]		1="Female" 2="Male"
01. Principal	<b>payment</b>	Method Of Payment - [Demographics]		1="Private Insurance" 2="Private Insurance And Medicare" 3="Medicare" 4="Medicare And Medicaid" 5="Medicaid" 6="Other" 7="Unknown"
01. Principal	<b>race</b>	Race - [Demographics]		1="White" 2="Black Or African American" 3="Asian" 4="Not Reported" 5="Unknown"

## Section 5: Medical/Surgical History

Class	Variable	Label	Description	Format Text
01. Principal	<b>medsurg_body_sys1-49</b>	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	<b>medsurg_body_sys_oth1-49</b>	Other (Body) System/Site Text - [Medical/Surgical History]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Auditory" 2="Bariatric Surgery" 3="Bone" 4="Chest Pain" 5="Cobalamin Deficiency" 6="Diagnosis" 7="Digestive System" 8="Dizziness" 9="General" 10="Hepatobiliary" 11="Hyperlipidemia" 12="Hypertensive Disorder" 13="Iron Deficiency Anemia" 14="Liver" 15="Liver Pathology" 16="Morbid Obesity" 17="Nodules On Ct Chest" 18="Pyelonephritis" 19="Severe Obesity (Bmi >=40)" 20="Surgery" 21="Vitamin D Deficiency" 22="Weight" 23="Abdominal Surgery" 24="Abdominal Wound Infection" 25="Alcohol Use" 26="Hematologic" 27="Hepatobiliary" 28="Hypophosphatemia" 29="Metabolism And Nutrition Disorders" 30="Nutrition" 31="Plasma Electrolytes" 32="Reproductive"

Class	Variable	Label	Description	Format Text
01. Principal	<b>medsurg_com</b>	Comments - [Medical/Surgical History]		Char
01. Principal	<b>medsurg_cycle1-49</b>	Visit Number - [Medical/Surgical History]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>medsurg_de_scri pt1-49</b>	DE Comments - [Medical/Surgical History]		Char
01. Principal	<b>medsurg_dx_dt1-49</b>	Date Of Diagnosis/Surgery - [Medical/Surgical History]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>medsurg_med_h x_dt1-49</b>	Medical History Date - [Medical/Surgical History]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>medsurg_num</b>	Number Of Observations - [Medical/Surgical History]		Numeric .F="No Record For This Visit"

## Section 6: Pregnancy: Test Result

Class	Variable	Label	Description	Format Text
01. Principal	<b>pregres_cycle_ex</b>	Visit Number - Visit extra - [Pregnancy: Test Result]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>pregres_cycle_v1</b>	Visit Number - Visit 0 - [Pregnancy: Test Result]		Numeric .F="No Record For This Visit"
01. Principal	<b>pregres_num</b>	Number Of Observations - [Pregnancy: Test Result]		Numeric .F="No Record For This Visit"
01. Principal	<b>pregres_preg_test_ex</b>	Result - Visit extra - [Pregnancy: Test Result]		.F="No Record For This Visit" .N="N/A" 1="Negative" 2="Not applicable/not female of child-bearing potential" 3="Not obtained"
01. Principal	<b>pregres_preg_test_v1</b>	Result - Visit 0 - [Pregnancy: Test Result]		.F="No Record For This Visit" 1="Negative" 2="Not applicable/not female of child-bearing potential" 3="Not obtained"
01. Principal	<b>pregres_spec_colldt_ex</b>	Date Specimen Collected - Visit extra - [Pregnancy: Test Result]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>pregres_spec_colldt_v1</b>	Date Specimen Collected - Visit 0 - [Pregnancy: Test Result]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>pregres_spec_type_ex</b>	Type Of Specimen - Visit extra - [Pregnancy: Test Result]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Serum" 2="Urine"
01. Principal	<b>pregres_spec_type_v1</b>	Type Of Specimen - Visit 0 - [Pregnancy: Test Result]		.F="No Record For This Visit" .M="Missing" 1="Serum" 2="Urine"

## Section 7: Checklist (Pre-Registration)

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

Class	Variable	Label	Description	Format Text
01. Principal	<b>cl_prereg_consent_form</b>	Consent Form Signed And Dated - [Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_consntdt</b>	Date Informed Consent Signed - [Checklist (Pre-Registration)]		SAS Date
01. Principal	<b>cl_prereg_CPN_supervision</b>	All Trial Activities Must Be Conducted At A CPN Member Institution Under The Supervision Of A CPN Physician - [Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_ctep_arm</b>	TAC/TAD Code - [Checklist (Pre-Registration)]		Char
01. Principal	<b>cl_prereg_date_mod</b>	Date Modified - [Checklist (Pre-Registration)]		Numeric
01. Principal	<b>cl_prereg_dc_num</b>	Protocol Number - [Checklist (Pre-Registration)]		Char
01. Principal	<b>cl_prereg_do_baseline_evals</b>	Baseline (Screening) Evaluations Must Be Completed Within The Guidelines Specified On The Schedule Of Events - [Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_EnrollDT</b>	Enrollment Date - [Checklist (Pre-Registration)]		SAS Date
01. Principal	<b>cl_prereg_eresnum</b>	ERES Number - [Checklist (Pre-Registration)]		Char
01. Principal	<b>cl_prereg_excl_comorbidity</b>	exclusion 004: Uncontrolled Intercurrent Illness Including, But Not Limited To, Ongoing Or Active Infection, Symptomatic Congestive Heart Failure, Unstable Angina Pectoris, Or Psychiatric Illness/Social Situations That Would Limit Compliance With Study Re		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>cl_prereg_excl_cyp3a4_inducers</b>	exclusion 006: Use Of CYP3A4 Inducers Such As Rifampicin, Rifabutin, Rifapentine, Phenytoin, Carbamazepine, Phenobarbital, And St. John`s Wort - [Checklist (Pre-Registration)]		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_excl_cyp3a4_inhibitors</b>	exclusion 005: Use Of Potent CYP3A4 Inhibitors, Such As Ketoconazole, Atazanavir, Clarithromycin, Indinavir, Itraconazole, Nefazondone, Nelfinavir, Ritonavir, Saquinavir, Telithromycin, Troleandomycin, Voriconazole And Grapefruit Or Grapefruit Juice - [Ch		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_excl_diagnosis_of_hiv</b>	exclusion 002: Participants With A Known Diagnosis Of HIV. Note: An HIV Screening Test Does Not Have To Be Performed To Evaluate This Criterion - [Checklist (Pre-Registration)]		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_excl_erlotinib_allergy</b>	exclusion 007: History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Erlotinib (Tarceva.SR.nS) - [Checklist (Pre-Registration)]		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_excl_med_necessary</b>	Participants Who Cannot Have Their Warfarin, Lovenox, Plavix, Or Other Comparable Medications Held For Percutaneous Or Transjugular Liver Biopsy And Surgery If So Indicated - [Checklist (Pre-Registration)]		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>cl_prereg_excl_path_report</b>	Non-Surgical Cohort Only: Pathology Report From Clinical Liver Biopsy (If A Surgical Cohort (Se - [Checklist (Pre-Registration)])		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_excl_ph_altering_drug</b>	Participants Who Regularly (>=2 Times Per Week) Use Drugs That Alter The pH Of The GI Tract, Such As Proton Pump Inhibitors (PPI) And Antacids. Exceptions: Individuals Who Use Prescription PPIs And Have Approval From Their Primary Health Care Provider To		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_excl_prior_erlotinib</b>	Non-Surgical Cohort Only: Pathology Report From Clinical Liver Biopsy (If A Surgical Cohort (Se - [Checklist (Pre-Registration)])		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_form</b>	Form - [Checklist (Pre-Registration)]		Numeric
01. Principal	<b>cl_prereg_hipaa_dt</b>	Date Of Authorization (mm/dd/yyyy) - [Checklist (Pre-Registration)]		SAS Date .M="Missing"
01. Principal	<b>cl_prereg_incl_18_or_older</b>	inclu 002: Age >=18 Years. Note: Because No Dosing Or Adverse Event Data Are Currently Available On The Use Of Erlotinib (Tarceva.SR.nS) In Participants <18 Years Of Age, Children Are Excluded From This Study But May Be Eligible For Future Pediatric Trial		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_incl_avoid_pregnancy</b>	inclu 005: Willingness To Use Adequate Contraception To Avoid Pregnancy Or Impregnation Until 2 Weeks After Discontinuing Study Agent. If Not A Woman Of Childbearing Potential (Select NA) - [Checklist (Pre-Registration)]"		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"



Class	Variable	Label	Description	Format Text
01. Principal	<b>cl_prereg_incl_fibros_or_cirrhos</b>	inclu 001: Individuals With A Clinical Diagnosis Fibrosis Or Cirrhosis Of The Liver (No More Than Child-Pugh Classification A; Child-Pugh-Turcotte Score Of 6 Or Less) Who Have: A. An Indication For Surgical Liver Resection, OR B. A Clinical Liver Biopsy (		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_incl_informed_consent</b>	Ability To Understand And The Willingness To Sign A Written Informed Consent Document - [Checklist (Pre-Registration)]"		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_incl_liver_biop</b>	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) - [Checklist (Pre-Registration)]"		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_incl_not_preg_brst_fed</b>	Not Pregnant Or Breast Feeding. Note: The Effects Of Erlotinib (Tarceva.SR.nS) On The Developing Human Fetus At The Recommended Therapeutic Dose Are Unknown. For This Reason, Women Of Childbearing Potential And Men Must Agree To Use Adequate Contraceptio		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_incl_provide_blood</b>	Willingness To Provide Mandatory Blood Specimens As Specified In The Protocol - [Checklist (Pre-Registration)]"		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>cl_prereg_incl_stop_tobacco_use</b>	Willingness To Discontinue Smoking During The Study Two Weeks Prior To Beginning The Study And Willingness To Not Smoke While Taking Study Medication - [Checklist (Pre-Registration)]"		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_incl_tissue_consent</b>	Willingness To Authorize Collection Of Tissue From Surgically-Resected Liver Or Clinical Liver Biopsy For Analyses Specified In The Protocol - [Checklist (Pre-Registration)]"		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_phi_use_auth</b>	Existence Of Authorization For Use And Disclosure Of Protected Health Information (USA Institutions Only). If Not A USA Institution (Select NA) - [Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_pielig</b>	Is The Participant Eligible For Inclusion On This Study? - [Checklist (Pre-Registration)]		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_prev_id</b>	If Yes: Prior Participant CPN ID Number - [Checklist (Pre-Registration)]		Char
01. Principal	<b>cl_prereg_previous</b>	Has The Participant Been Pre-Registered Previously To This Study? - [Checklist (Pre-Registration)]		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_screening_done</b>	Screening And On-Study Evaluations Must Be Completed Within The Guidelines Specified On The Schedule Of Events - [Checklist (Pre-Registration)]		.M="Missing" 0="No" 1="Yes"
01. Principal	<b>cl_prereg_studyid</b>	Study ID - [Checklist (Pre-Registration)]		Numeric
01. Principal	<b>cl_prereg_version</b>	Version Number - [Checklist (Pre-Registration)]		Numeric

## Section 8: Registration Eligibility Checklist

Class	Variable	Label	Description	Format Text
01. Principal	<b>cl_reg_alt</b>	ALT/SGPT (U/L) - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>cl_reg_alt_unl</b>	ALT/SGPT UNL (U/L) - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>cl_reg_Arm</b>	Treatment Arm - [Registration Eligibility Checklist]		.F="No Record For This Visit" 1="Cohort A (Surgical Cohort)" 2="Cohort B (Non-Surgical Cohort)"
01. Principal	<b>cl_reg_ast</b>	AST/SGOT (U/L) - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>cl_reg_ast_unl</b>	AST/SGOT UNL (U/L) - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>cl_reg_case_detail_id</b>	Case Number - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit"
01. Principal	<b>cl_reg_creat</b>	Creatinine (mg/dL) - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>cl_reg_creatunl</b>	Creatinine UNL (mg/dL) - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>cl_reg_ctep_arm</b>	TAC/TAD Code - [Registration Eligibility Checklist]		.F="No Record For This Visit" 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	<b>cl_reg_date_mod</b>	Date Modified - [Registration Eligibility Checklist]		SAS Date .F="No Record For This Visit"
01. Principal	<b>cl_reg_dc_num</b>	Protocol Number - [Registration Eligibility Checklist]		Char
01. Principal	<b>cl_reg_doselevl</b>	Dose Level (+2, +1, 0, -1, -2) - [Registration Eligibility Checklist]		.F="No Record For This Visit" 1="-1" 2="-2" 3="0"
01. Principal	<b>cl_reg_EnrollDT</b>	Enrollment Date - [Registration Eligibility Checklist]		SAS Date .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	<b>cl_reg_eresnum</b>	ERES Number - [Registration Eligibility Checklist]		Char
01. Principal	<b>cl_reg_excl_biop_notdone</b>	Surgical Cohort (Cohort A Only): Percutaneous Or Transjugular Biopsy Incomplete Or Not Performed. If Not A Surgical Cohort (Select NA) - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_excl_oth_agent</b>	Receiving Any Other Investigational Agents <=6 Months Prior To Registration - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_form</b>	Form - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit"
01. Principal	<b>cl_reg_group</b>	Group: 1=Dose Escalation/De-Escalation Cohort 2=Expansion Cohort - [Registration Eligibility Checklist]		.F="No Record For This Visit" 1="Dose Escalation/De-Escalation Cohort" 2="Dose Expansion Cohort"
01. Principal	<b>cl_reg_incl_ast_alt</b>	AST (SGOT) And ALT (SGPT) <=5 X Institutional ULN - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_incl_creat_le_1pt5</b>	Creatinine <=1.5 X Institutional ULN - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_incl_ecog_01</b>	ECOG Performance Status 0 Or 1 (Appendix A) - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_incl_inr_le_1pt5</b>	INR <=1.5 - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_incl_norm_org_func</b>	Participants Must Have Normal Organ And Marrow Function As Defined Below - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_incl_plt_ge50</b>	Platelets >=50 B/L (10^9/L) - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>cl_reg_incl_pos_phoso_egfr</b>	Non-Surgical Cohort Only: Positive Phospho-EGFR Assessment ( $\geq 100$ Stained Pixels, See Section 7.3) From Tissue Obtained From Previous Clinical Liver Biopsy. <P> If Not A Non-Surgical Cohort </> (Select NA) </> - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_incl_preint_biopsamp</b>	Pre-Intervention Biopsy Sample Collected - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_incl_tbili_1e_3x_uln</b>	Total Bilirubin $\leq 3$ X Institutional ULN - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_inr</b>	INR (Decimal Use Available With Entry, If Needed - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>cl_reg_int_within_14days</b>	Intervention Cannot Begin Prior To Registration And Must Begin $\leq 14$ Days From Registration - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_is_ppt_elig</b>	Is The Participant Eligible For Inclusion On This Study? - [Registration Eligibility Checklist]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>cl_reg_perf_stat_01</b>	ECOG Performance Status 0 Or 1 - [Registration Eligibility Checklist]		.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	<b>cl_reg_plt_ge_50</b>	Platelets ( $\geq 50$ ) - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>cl_reg_studyid</b>	Study ID - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit"
01. Principal	<b>cl_reg_tbiliunl</b>	Total Bilirubin UNL - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>cl_reg_tot_bili</b>	Total Bilirubin - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>cl_reg_version</b>	Version Number - [Registration Eligibility Checklist]		Numeric .F="No Record For This Visit"

## Section 9: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	<b>conmed_com1-24</b>	Comments - [Concomitant Medications]		Char
01. Principal	<b>conmed_conmed1-24</b>	Is The Participant Taking Any Concomitant Medications? - [Concomitant Medications]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>conmed_conmed_name1-24</b>	Medication Name - [Concomitant Medications]		Char
01. Principal	<b>conmed_cont1-24</b>	Continuing - [Concomitant Medications]		.N="N/A" 0="No" 1="Yes" 9="Unknown"
01. Principal	<b>conmed_dose1-24</b>	Dose - [Concomitant Medications]		Numeric .M="Missing" .N="N/A"
01. Principal	<b>conmed_enddt1-24</b>	Stop Date - [Concomitant Medications]		SAS Date .M="Missing" .N="N/A"
01. Principal	<b>conmed_folder_instance_name1-24</b>	Dataset Folder Name - [Concomitant Medications]		Char
01. Principal	<b>conmed_freq1-24</b>	Frequency - [Concomitant Medications]		Char
01. Principal	<b>conmed_freq_sp1-24</b>	Frequency (Specify) - [Concomitant Medications]		Char
01. Principal	<b>conmed_indicatn1-24</b>	Indication - [Concomitant Medications]		Numeric .M="Missing" .N="N/A"
01. Principal	<b>conmed_num</b>	Number Of Observations - [Concomitant Medications]		Numeric
01. Principal	<b>conmed_strtdt1-24</b>	Start Date - [Concomitant Medications]		SAS Date .N="N/A"
01. Principal	<b>conmed_units1-24</b>	Units - [Concomitant Medications]		Char

## Section 10: Participant Status: Baseline

Class	Variable	Label	Description	Format Text
01. Principal	<b>event_bsl_ae_assess</b>	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	<b>event_bsl_cod</b>	Cause Of Death (Primary Cause Of Death) - [Participant Status: Baseline]		.F="No Record For This Visit" .M="Missing" 1="Other"
01. Principal	<b>event_bsl_cod_ssp</b>	If Other Cause Of Death, Specify - [Participant Status: Baseline]		.F="No Record For This Visit" .M="Missing" 1="Hepatic Failure"
01. Principal	<b>event_bsl_com</b>	Comments - [Participant Status: Baseline]		Char
01. Principal	<b>event_bsl_contact_dt</b>	Contact Date - [Participant Status: Baseline]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>event_bsl_death_dt</b>	Death Date - [Participant Status: Baseline]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>event_bsl_med_hist</b>	Did The Participant Have Any Relevant Medical/Surgical History To Report? - [Participant Status: Baseline]		.F="No Record For This Visit" 0="No" 1="Yes" 99="Not Applicable"
01. Principal	<b>event_bsl_phys_exam</b>	Was The Overall Physical Exam Performed? - [Participant Status: Baseline]		.F="No Record For This Visit" 0="No" 1="Yes" 99="Not Applicable"
01. Principal	<b>event_bsl_pre_int_symp</b>	Were There Any Pre-Intervention Symptoms? - [Participant Status: Baseline]		.F="No Record For This Visit" 0="No" 1="Yes" 99="Not Applicable"
01. Principal	<b>event_bsl_protocol_int</b>	Will The Patient Proceed To Protocol Intervention For The First Visit? (Check One) - [Participant Status: Baseline]		.F="No Record For This Visit" 0="No" 1="Yes" 99="Not Applicable"
01. Principal	<b>event_bsl_target_days</b>	Target Days From Baseline - [Participant Status: Baseline]		Numeric .F="No Record For This Visit"



Class	Variable	Label	Description	Format Text
01. Principal	<b>event_bsl_visit_num</b>	Visit Number - [Participant Status: Baseline]		Numeric .F="No Record For This Visit"
01. Principal	<b>event_bsl_vital_stat</b>	Participant Vital Status - [Participant Status: Baseline]		.F="No Record For This Visit" .M="Missing" 1="Alive" 2="Dead"

## Section 11: Specimen Collection (Blood)

Class	Variable	Label	Description	Format Text
01. Principal	<b>bldspc_com_v0/bldspc_com_v2</b>	Comments - Visit 2 - [Specimen Collection (Blood)]		Char
01. Principal	<b>bldspc_grn_spccol_v0/bldspc_grn_spccol_v2</b>	(Green Top) Na Heparin - Date Specimen Collected - Visit 2 - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>bldspc_grn_spcnum_v0/bldspc_grn_spcnum_v2</b>	(Green Top) Na Heparin - Number Of Specimens Collected - Visit 2 - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>bldspc_grn_spcshp_v0/bldspc_grn_spcshp_v2</b>	(Green Top) Na Heparin - Date Specimen Shipped - Visit 2 - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>bldspc_grn_spcsub_v0/bldspc_grn_spcsub_v2</b>	(Green Top) Na Heparin - Was Specimen Collected? - Visit 2 - [Specimen Collection (Blood)]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes" 99="Not Applicable"
01. Principal	<b>bldspc_grn_spcnyp_v0/bldspc_grn_spcnyp_v2</b>	(Green Top) Na Heparin - Specimen Type - Visit 2 - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>bldspc_how_stored_v0/bldspc_how_stored_v2</b>	If Samples Were Not Shipped On The Day Of Collection, How Were The Specimens Stored? - Visit 2 - [Specimen Collection (Blood)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Stored Per Protocol" 2="Not Applicable"
01. Principal	<b>bldspc_prp_spccol_v0/bldspc_prp_spccol_v2</b>	(Purple Top) EDTA - Date Specimen Collected - Visit 2 - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>bldspc_prp_spcnum_v0/bldspc_prp_spcnum_v2</b>	(Purple Top) EDTA - Number Of Specimens Collected - Visit 2 - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>bldspc_prp_spcshp_v0/bldspc_prp_spcshp_v2</b>	(Purple Top) EDTA - Date Specimen Shipped - Visit 2 - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bldspc_prp_spcsub_v0/bldspc_prp_spcsub_v2</b>	(Purple Top) EDTA - Was Specimen Collected? - Visit 2 - [Specimen Collection (Blood)]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes" 99="Not Applicable"
01. Principal	<b>bldspc_prp_spc_typ_v0/bldspc_prp_spc_typ_v2</b>	(Purple Top) EDTA - Specimen Type - Visit 2 - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .N="N/A" 1="Whole Blood"
01. Principal	<b>bldspc_red_spc_col_v0/bldspc_red_spc_col_v2</b>	(Red Top) - Date Specimen Collected - Visit 2 - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>bldspc_red_spc_num_v0/bldspc_red_spc_num_v2</b>	(Red Top) - Number Of Specimens Collected - Visit 2 - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>bldspc_red_spcshp_v0/bldspc_red_spcshp_v2</b>	(Red Top) - Date Specimen Shipped - Visit 2 - [Specimen Collection (Blood)]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>bldspc_red_spcsub_v0/bldspc_red_spcsub_v2</b>	(Red Top) - Was Specimen Collected? - Visit 2 - [Specimen Collection (Blood)]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes" 99="Not Applicable"
01. Principal	<b>bldspc_red_spc_typ_v0/bldspc_red_spc_typ_v2</b>	(Red Top) - Specimen Type - Visit 2 - [Specimen Collection (Blood)]		Numeric .F="No Record For This Visit" .N="N/A" 1="Whole Blood"

## Section 12: Specimen Collection (BSL)

Class	Variable	Label	Description	Format Text
01. Principal	<b>bslspc_com</b>	Comments - [Specimen Collection (BSL)]		Char
01. Principal	<b>bslspc_cycle</b>	Visit Number - [Specimen Collection (BSL)]		Numeric
01. Principal	<b>bslspc_formalin_baseline_block</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Paraffin Blocks - [Specimen Collection (BSL)]		Numeric .M="Missing"
01. Principal	<b>bslspc_formalin_baseline_coldt</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Date Specimen Collected - [Specimen Collection (BSL)]		SAS Date .M="Missing"
01. Principal	<b>bslspc_formalin_baseline_coltm</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Time Specimen Collected (Hh:Nn:Rr) - [Specimen Collection (BSL)]		SAS Time .M="Missing"
01. Principal	<b>bslspc_formalin_baseline_parafdt</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Date Of Paraffin Embedding - [Specimen Collection (BSL)]		SAS Date .M="Missing"
01. Principal	<b>bslspc_formalin_baseline_paraftm</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Time Of Paraffin Embedding (Hh:Nn:Rr) - [Specimen Collection (BSL)]		SAS Time .M="Missing"
01. Principal	<b>bslspc_formalin_baseline_sectdt</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Date Of Sectioning - [Specimen Collection (BSL)]		SAS Date .M="Missing"
01. Principal	<b>bslspc_formalin_baseline_secttm</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Time Of Sectioning (Hh:Nn:Rr) - [Specimen Collection (BSL)]		SAS Time .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bslspc_formalin_baseline_shipdt</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Date Specimen Shipped - [Specimen Collection (BSL)]		SAS Date .M="Missing"
01. Principal	<b>bslspc_formalin_baseline_spcnum</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Number Of Specimens Collected - [Specimen Collection (BSL)]		SAS Time .M="Missing"
01. Principal	<b>bslspc_formalin_baseline_spcrsn</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Not Collected Reason - [Specimen Collection (BSL)]		Char
01. Principal	<b>bslspc_formalin_baseline_spcrsp</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Not Collected Reason - Other (Specify) - [Specimen Collection (BSL)]		Char
01. Principal	<b>bslspc_formalin_baseline_subm</b>	Container Or Additive (Formalin) - Time Point (Baseline) - Was Specimen Collected? - [Specimen Collection (BSL)]		0="No" 1="Yes" 99="Not Applicable"
01. Principal	<b>bslspc_RNAlater_baseline_block</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Paraffin Blocks - [Specimen Collection (BSL)]		Numeric .M="Missing"
01. Principal	<b>bslspc_RNAlater_baseline_coldt</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Date Specimen Collected - [Specimen Collection (BSL)]		SAS Date .M="Missing"
01. Principal	<b>bslspc_RNAlater_baseline_coltm</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Time Specimen Collected (Hh:Nn:Rr) - [Specimen Collection (BSL)]		SAS Time .M="Missing"
01. Principal	<b>bslspc_RNAlater_baseline_parafdt</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Date Of Paraffin Embedding - [Specimen Collection (BSL)]		SAS Date .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bslspc_RNAlater _baseline_praftm</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Time Of Paraffin Embedding (Hh:Nn:Rr) - [Specimen Collection (BSL)]		SAS Time .M="Missing"
01. Principal	<b>bslspc_RNAlater _baseline_sectdt</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Date Of Sectioning - [Specimen Collection (BSL)]		SAS Date .M="Missing"
01. Principal	<b>bslspc_RNAlater _baseline_secttm</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Time Of Sectioning (Hh:Nn:Rr) - [Specimen Collection (BSL)]		SAS Time .M="Missing"
01. Principal	<b>bslspc_RNAlater _baseline_shipdt</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Date Specimen Shipped - [Specimen Collection (BSL)]		SAS Date .M="Missing"
01. Principal	<b>bslspc_RNAlater _baseline_spcnum</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Number Of Specimens Collected - [Specimen Collection (BSL)]		Numeric .M="Missing"
01. Principal	<b>bslspc_RNAlater _baseline_spcrsn</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Not Collected Reason - [Specimen Collection (BSL)]		Char
01. Principal	<b>bslspc_RNAlater _baseline_spcrsp</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Not Collected Reason - Other (Specify) - [Specimen Collection (BSL)]		Char
01. Principal	<b>bslspc_RNAlater _baseline_subm</b>	Container Or Additive (RNAlater) - Time Point (Baseline) - Was Specimen Collected? - [Specimen Collection (BSL)]		0="No" 1="Yes" 99="Not Applicable"
01. Principal	<b>bslspc_RNAlater _elig_block</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Paraffin Blocks - [Specimen Collection (BSL)]		Numeric .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>bslspc_RNAlater_elig_coldt</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Date Specimen Collected - [Specimen Collection (BSL)]		SAS Date .M="Missing"
01. Principal	<b>bslspc_RNAlater_elig_coltm</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Time Specimen Collected (Hh:Nn:Rr) - [Specimen Collection (BSL)]		SAS Time .M="Missing"
01. Principal	<b>bslspc_RNAlater_elig_parafdt</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Date Of Paraffin Embedding - [Specimen Collection (BSL)]		SAS Date .M="Missing"
01. Principal	<b>bslspc_RNAlater_elig_paraftm</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Time Of Paraffin Embedding (Hh:Nn:Rr) - [Specimen Collection (BSL)]		SAS Time .M="Missing"
01. Principal	<b>bslspc_RNAlater_elig_sectdt</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Date Of Sectioning - [Specimen Collection (BSL)]		SAS Date .M="Missing"
01. Principal	<b>bslspc_RNAlater_elig_secttm</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Time Of Sectioning (Hh:Nn:Rr) - [Specimen Collection (BSL)]		SAS Time .M="Missing"
01. Principal	<b>bslspc_RNAlater_elig_shipdt</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Date Specimen Shipped - [Specimen Collection (BSL)]		SAS Date .M="Missing"
01. Principal	<b>bslspc_RNAlater_elig_spcnum</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Number Of Specimens Collected - [Specimen Collection (BSL)]		Numeric .M="Missing"
01. Principal	<b>bslspc_RNAlater_elig_spcrsn</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Not Collected Reason - [Specimen Collection (BSL)]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>bslspc_RNAlater_elig_spcrsp</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Not Collected Reason - Other (Specify) - [Specimen Collection (BSL)]		Char
01. Principal	<b>bslspc_RNAlater_elig_subm</b>	Container Or Additive (RNAlater) - Time Point (Eligibility) - Was Specimen Collected? - [Specimen Collection (BSL)]		0="No" 1="Yes" 99="Not Applicable"
01. Principal	<b>bslspc_store</b>	If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? - [Specimen Collection (BSL)]		.M="Missing" .N="Not Applicable" 1="Stored per protocol" 2="Not stored per protocol"
01. Principal	<b>bslspc_store_sp</b>	If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? (Specify) - [Specimen Collection (BSL)]		Char
01. Principal	<b>bslspc_type</b>	Specimen Type - [Specimen Collection (BSL)]		1="Liver biopsy (2 Cores)"



## Section 13: Supporting Documentation (BSL)

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Class	Variable	Label	Description	Format Text
01. Principal	<b>sdbsl_attach1-8</b>	Attachment - Record 8 - [Supporting Documentation (BSL)]		Char
01. Principal	<b>sdbsl_com1-8</b>	Comments - Record 8 - [Supporting Documentation (BSL)]		Char
01. Principal	<b>sdbsl_cycle1-8</b>	Visit Number - Record 8 - [Supporting Documentation (BSL)]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>sdbsl_dt1-8</b>	Date Of Assessment - Record 8 - [Supporting Documentation (BSL)]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>sdbsl_num</b>	Number of Observations - [Supporting Documentation (BSL)]		Numeric .F="No Record For This Visit"
01. Principal	<b>sdbsl_type1-8</b>	Report Type - Record 8 - [Supporting Documentation (BSL)]		Char
01. Principal	<b>sdbsl_type_sp1-8</b>	Report Type (Specify) - Record 8 - [Supporting Documentation (BSL)]		Char

## Section 14: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	<b>phyexam_allergy_hx_ex</b>	Does The Participant Have Any Allergies? - Visit extra - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>phyexam_allergy_hx_v0/phyexam_allergyhx_v2</b>	Does The Participant Have Any Allergies? - Visit 2 - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>phyexam_allergy_spec_ex</b>	Does The Participant Have Any Allergies? (Specify) - Visit extra - [Physical Exam]		Char
01. Principal	<b>phyexam_allergy_spec_v0/phyexam_allergyspec_v2</b>	Does The Participant Have Any Allergies? (Specify) - Visit 2 - [Physical Exam]		Char
01. Principal	<b>phyexam_bodtemp_ex</b>	Body Temperature (C) - Visit extra - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phyexam_bodtemp_v0/phyexam_bodtemp_v2</b>	Body Temperature (C) - Visit 2 - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phyexam_cighist_ex</b>	Cigarette History - Visit extra - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Current smoker" 2="Never smoked" 3="Quit/former smoker"
01. Principal	<b>phyexam_cighist_v0/phyexam_cighist_v2</b>	Cigarette History - Visit 2 - [Physical Exam]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Current smoker" 2="Never smoked" 3="Quit/former smoker"
01. Principal	<b>phyexam_comments_ex</b>	Comments - Visit extra - [Physical Exam]		Char
01. Principal	<b>phyexam_comments_v0/phyexam_comments_v2</b>	Comments - Visit 2 - [Physical Exam]		Char
01. Principal	<b>phyexam_diastolic_ex</b>	Diastolic Blood Pressure (mmHg) - Visit extra - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>phyexam_diastolic_v0/phyexam_diastolic_v2</b>	Diastolic Blood Pressure (mmHg) - Visit 2 - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phyexam_evaldt_ex</b>	Evaluation Date - Visit extra - [Physical Exam]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phyexam_evaldt_v0/phyexam_evaldt_v2</b>	Evaluation Date - Visit 2 - [Physical Exam]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>phyexam_height_ex</b>	Height - Visit extra - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phyexam_height_v0/phyexam_height_v2</b>	Height - Visit 2 - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phyexam_pulse_ex</b>	Pulse Rate - Visit extra - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phyexam_pulse_v0/phyexam_pulse_v2</b>	Pulse Rate - Visit 2 - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phyexam_systolic_ex</b>	Systolic Blood Pressure (mmHg) - Visit extra - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phyexam_systolic_v0/phyexam_systolic_v2</b>	Systolic Blood Pressure (mmHg) - Visit 2 - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phyexam_weight_ex</b>	Weight - Visit extra - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phyexam_weight_v0/phyexam_weight_v2</b>	Weight - Visit 2 - [Physical Exam]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

## Section 15: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	<b>symptm_com1-6</b>	Comments - Record 6 - [Baseline Symptoms]		Char
01. Principal	<b>symptm_eval_dt1-6</b>	Evaluation Date - Record 6 - [Baseline Symptoms]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>symptm_num</b>	Number of Observations - [Baseline Symptoms]		Numeric .F="No Record For This Visit"
01. Principal	<b>symptm_symp_com1-6</b>	Comments - Record 6 - [Baseline Symptoms]		Char
01. Principal	<b>symptm_symp_desc1-6</b>	Symptom Description (Verbatim Term) - Record 6 - [Baseline Symptoms]		Char
01. Principal	<b>symptm_symp_grade1-6</b>	Grade - Record 6 - [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	<b>symptm_symp_onset_dt1-6</b>	Onset Date - Record 6 - [Baseline Symptoms]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>symptm_visit_num</b>	Visit Number - [Baseline Symptoms]		.F="No Record For This Visit" 0="Baseline"

## Section 16: Biomarkers

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Class	Variable	Label	Description	Format Text
01. Principal	<b>biomarker_assay1-5</b>	Biomarker Assay - [Biomarkers]		Numeric .F="No Record For This Visit"
01. Principal	<b>biomarker_concentration1-5</b>	Biomarker Concentration - [Biomarkers]		Numeric .F="No Record For This Visit" .L="<LLOQ (1.00)"
01. Principal	<b>biomarker_custom_id1-5</b>	Biomarker Custom ID - [Biomarkers]		Numeric .F="No Record For This Visit"
01. Principal	<b>biomarker_dilution1-5</b>	Biomarker Dilution - [Biomarkers]		Numeric .F="No Record For This Visit"
01. Principal	<b>biomarker_hour_nominal1-5</b>	Biomarker Hour Nominal - [Biomarkers]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>biomarker_num</b>	Number of Observations - [Biomarkers]		Numeric .F="No Record For This Visit"
01. Principal	<b>biomarker_run_id1-5</b>	Biomarker Run ID - [Biomarkers]		Numeric .F="No Record For This Visit"
01. Principal	<b>biomarker_visit1-5</b>	Biomarker Visit - [Biomarkers]		.F="No Record For This Visit" 1="Baseline" 2="Post Intervention"

## Section 17: Screening

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Class	Variable	Label	Description	Format Text
01. Principal	<b>screen_com</b>	Comments - [Screening]		Char
01. Principal	<b>screen_cycle</b>	Visit Number - [Screening]		Numeric
01. Principal	<b>screen_elig</b>	Does Participant Meet Screening Criteria? - [Screening]		0="No" 1="Yes"
01. Principal	<b>screen_inelig_rsn</b>	If No, Which Screening Criteria Not Met? - [Screening]		.M="Missing" 1="Did not meet other eligibility criteria" 2="Investigator decision" 3="Patient decision" 4="Phospho-EGFR negative"
01. Principal	<b>screen_inelig_rsn_sp</b>	Specify - [Screening]		Char
01. Principal	<b>screen_scrn_dt</b>	Screen Completion Date - [Screening]		SAS Date

## Section 18: Subject Enrollment

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Class	Variable	Label	Description	Format Text
01. Principal	<b>subjenrl_current_site</b>	Current Site CTEP ID - [Subject Enrollment]		Char
01. Principal	<b>subjenrl_enrl_site</b>	Enrolling Site CTEP ID - [Subject Enrollment]		Char
01. Principal	<b>subjenrl_form_oid</b>	Form OID - [Subject Enrollment]		Char
01. Principal	<b>subjenrl_group_data</b>	Registering Membership - [Subject Enrollment]		1="Case Western Reserve University" 2="Cleveland Clinic Foundation" 3="Massachusetts General Hospital Cancer Center" 4="Mayo Clinic" 5="Mayo Clinic In Florida" 6="Mount Sinai Medical Center"
01. Principal	<b>subjenrl_partic_enrol_dt</b>	Enrollment Date - [Subject Enrollment]		SAS Date
01. Principal	<b>subjenrl_partic_enrol_tm</b>	Enrollment Time - [Subject Enrollment]		SAS Time
01. Principal	<b>subjenrl_pt_id</b>	Participant ID - [Subject Enrollment]		Char
01. Principal	<b>subjenrl_src_app</b>	Source Application - [Subject Enrollment]		1="REMOTE_REGISTRATION"

## Section 19: Supporting Documentation

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Class	Variable	Label	Description	Format Text
01. Principal	<b>supdoc_attach1-4</b>	Attachment - Record 4 - [Supporting Documentation]		Char
01. Principal	<b>supdoc_cycle1-4</b>	Visit Number - Record 4 - [Supporting Documentation]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>supdoc_dt1-4</b>	Date Of Assessment - Record 4 - [Supporting Documentation]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>supdoc_type1-4</b>	Report Type - Record 4 - [Supporting Documentation]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Clinic note" 2="Laboratory report" 3="Other"
01. Principal	<b>supdoc_type_sp1-4</b>	Report Type (Specify) - Record 4 - [Supporting Documentation]		Char



## Section 20: Phospho-EGFR Staining

Class	Variable	Label	Description	Format Text
01. Principal	<b>phosadd_com_v0/phosadd_com_v2/phosadd_com_v9</b>	Comments - Visit # Missing - [Phospho-EGFR Staining]		Char
01. Principal	<b>phosadd_cycle_v0/phosadd_cycle_v2/phosadd_cycle_v9</b>	Visit - Visit # Missing - [Phospho-EGFR Staining]		.F="No Record For This Visit" .N="N/A" 0="Visit 0" 1="Visit # Missing" 2="Visit 2"
01. Principal	<b>phosadd_eval_pp_egfr_v0/phosadd_eval_pp_egfr_v2/phosadd_eval_pp_egfr_v9</b>	Was The Patient Evaluable? - Visit # Missing - [Phospho-EGFR Staining]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>phosadd_num</b>	Number Of Observations - [Phospho-EGFR Staining]		Numeric .F="No Record For This Visit"
01. Principal	<b>phosadd_num_portal_tracts_v0/phosadd_num_portal_tracts_v2/phosadd_num_portal_tracts_v9</b>	Total Number Of Portal Tracts In Sample - Visit # Missing - [Phospho-EGFR Staining]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phosadd_pixel_ratio_v0/phosadd_pixel_ratio_v2/phosadd_pixel_ratio_v9</b>	Ratio Of Positive/Total Pixels (PCT) - Visit # Missing - [Phospho-EGFR Staining]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>phosadd_pos_pixel_num_v0/phosadd_pos_pixel_num_v2/phosadd_pos_pixel_num_v9</b>	Positive Pixels - Visit # Missing - [Phospho-EGFR Staining]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>phosadd_pp_egfr_report_dt_v0/phosadd_pp_egfr_report_dt_v2/phosadd_pp_egfr_report_dt_v9</b>	Date - Visit # Missing - [Phospho-EGFR Staining]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>phosadd_pp_egfr_report_v0/phosadd_pp_egfr_report_v2/phosadd_pp_egfr_report_v9</b>	Supporting Documentation Attachment - Visit # Missing - [Phospho-EGFR Staining]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>phosadd_reason_not_elig_v0/phosadd_reason_not_elig_v2/phosadd_reason_not_elig_v9</b>	(If No), Specify - Visit # Missing - [Phospho-EGFR Staining]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Insufficient tissue"
01. Principal	<b>phosadd_tot_pixel_num_v0/phosadd_tot_pixel_num_v2/phosadd_tot_pixel_num_v9</b>	Total Pixels - Visit # Missing - [Phospho-EGFR Staining]		Numeric .F="No Record For This Visit" .N="N/A"

## Section 21: Phospho-EGFR (Navigation)

Class	Variable	Label	Description	Format Text
01. Principal	<b>phospho_com_v1-2</b>	Comments - Visit 2 - [Phospho-EGFR (Navigation)]		Char
01. Principal	<b>phospho_cycle_v1-2</b>	Visit Number - Visit 2 - [Phospho-EGFR (Navigation)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phospho_eval_pp_egfr_v1-2</b>	Was The Patient Evaluable? - Visit 2 - [Phospho-EGFR (Navigation)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>phospho_num</b>	Number Of Observations - [Phospho-EGFR (Navigation)]		Numeric .F="No Record For This Visit"
01. Principal	<b>phospho_num_portal_tracts_v1-2</b>	Total Number Of Portal Tracts In Sample - Visit 2 - [Phospho-EGFR (Navigation)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phospho_other_spell_v1-2</b>	If Other, Specify - Visit 2 - [Phospho-EGFR (Navigation)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phospho_pixel_ratio_v1-2</b>	Ratio Of Positive/Total Pixels (PCT) - Visit 2 - [Phospho-EGFR (Navigation)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phospho_pos_pixel_num_v1-2</b>	Positive Pixels - Visit 2 - [Phospho-EGFR (Navigation)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>phospho_pp_egfr_report_v1-2</b>	Supporting Documentation Attachment - Visit 2 - [Phospho-EGFR (Navigation)]		Char
01. Principal	<b>phospho_reason_not_elig_v1-2</b>	(If No), Specify - Visit 2 - [Phospho-EGFR (Navigation)]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="No positive pixels" 2="Other specify"
01. Principal	<b>phospho_tot_pixel_num_v1-2</b>	Total Pixels - Visit 2 - [Phospho-EGFR (Navigation)]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

## Section 22: Agent Intervention

Class	Variable	Label	Description	Format Text
01. Principal	<b>protdata_agent1-13</b>	Agent Name - [Agent Intervention]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="Erlotinib"
01. Principal	<b>protdata_agent_start_dt1-13</b>	Date Agent Started - [Agent Intervention]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>protdata_agent_stop_dt1-13</b>	Date Agent Stopped - [Agent Intervention]		SAS Date .F="No Record For This Visit" .N="N/A"
01. Principal	<b>protdata_com1-13</b>	Comments - [Agent Intervention]		Char
01. Principal	<b>protdata_comply1-13</b>	Is The Participant Compliant With Protocol Intervention? (Check One) - [Agent Intervention]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>protdata_cycle1-13</b>	Visit Number - [Agent Intervention]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>protdata_dose1-13</b>	Dose - [Agent Intervention]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>protdata_dose_dt1-13</b>	Dose Date - [Agent Intervention]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>protdata_dose_num1-13</b>	Agent Dose Number - [Agent Intervention]		Numeric .F="No Record For This Visit" .N="N/A"
01. Principal	<b>protdata_fasting1-13</b>	Fasting - [Agent Intervention]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>protdata_last_meal_dt1-13</b>	Last Meal Date - [Agent Intervention]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>protdata_last_meal_time1-13</b>	Last Meal Time (Hours:Minutes:AM Or PM) - [Agent Intervention]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>protdata_num</b>	Number Of Observations - [Agent Intervention]		Numeric .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	<b>protdata_num_hrs_meal1-13</b>	Number Of Hours Since Last Meal - [Agent Intervention]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>protdata_rx_admin1-13</b>	Was Agent Administered? - [Agent Intervention]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>protdata_rx_units1-13</b>	Units - [Agent Intervention]		Char
01. Principal	<b>protdata_start_time1-13</b>	Dose Time (Hours:Minutes:AM Or PM) - [Agent Intervention]		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A"

## Section 23: Post-Intervention Evaluation

Class	Variable	Label	Description	Format Text
01. Principal	<b>protintr_ae_asse ss</b>	Were Adverse Events Assessed During This Reporting Period? - [Post-Intervention Evaluation]		Char
01. Principal	<b>protintr_contact_ dt</b>	Contact Date - [Post-Intervention Evaluation]		SAS Date .F="No Record For This Visit"
01. Principal	<b>protintr_cycle</b>	Visit Number - [Post-Intervention Evaluation]		Numeric .F="No Record For This Visit"
01. Principal	<b>protintr_fu_stat</b>	Participant Vital Status - [Post-Intervention Evaluation]		.F="No Record For This Visit" 1="Alive" 2="Dead" 3="Unknown" 4="Unspecified"
01. Principal	<b>protintr_last_fu</b>	Has The Participant Completed Their Last Follow-Up Visit? - [Post-Intervention Evaluation]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>protintr_phys_pe rf</b>	Was The Overall Physical Exam Performed? - [Post-Intervention Evaluation]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>protintr_qolcomp</b>	Did The Participant Complete The Was It Worth It (WIWI) Questionnaire? - [Post-Intervention Evaluation]		.F="No Record For This Visit" 1="Yes" 2="No" 3="Not applicable"
01. Principal	<b>protintr_qolcomp _dt</b>	Was It Worth It Questionnaire Date Completed - [Post-Intervention Evaluation]		SAS Date .F="No Record For This Visit" .M="Missing"

## Section 24: Non Surgical

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Class	Variable	Label	Description	Format Text
01. Principal	<b>nonsurg_com</b>	Comments - [Non Surgical]		Char
01. Principal	<b>nonsurg_egfr_pos</b>	Was The Phospho-EGFR Staining Positive? - [Non Surgical]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>nonsurg_phospho</b>	Supporting Documentation Attachment (Non-Surgical) - [Non Surgical]		Char
01. Principal	<b>nonsurg_pos_pix_num</b>	(If Yes), Number Of Positive Pixels - [Non Surgical]		Numeric .F="No Record For This Visit" .M="Missing"

## Section 25: Phone Call Compliance

Class	Variable	Label	Description	Format Text
01. Principal	<b>phone_ae_reported1-2</b>	Were Any Adverse Events Reported? - [Phone Call Compliance]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>phone_call_attempt_dt1-2</b>	Date Follow-Up Phone Call Attempted - [Phone Call Compliance]		SAS Date .F="No Record For This Visit"
01. Principal	<b>phone_call_completed1-2</b>	Was A Follow-Up Phone Call Completed? - [Phone Call Compliance]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>phone_call_completed_dt1-2</b>	Date Follow-Up Phone Call Completed - [Phone Call Compliance]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>phone_com1-2</b>	Comments - [Phone Call Compliance]		Char
01. Principal	<b>phone_cycle1-2</b>	Visit Number - [Phone Call Compliance]		Numeric .F="No Record For This Visit"
01. Principal	<b>phone_fu_call1</b>	Was A Follow-Up Phone Call Attempted? - [Phone Call Compliance]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>phone_fu_ph_call2</b>	Was A Follow-Up Phone Call Attempted? - [Phone Call Compliance]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>phone_report_concom_meds1-2</b>	Did The Participant Report Any Changes To Concomitant Medications? - [Phone Call Compliance]		.F="No Record For This Visit" 0="No" 1="Yes"



## Section 26: Participant Status: Intervention

Class	Variable	Label	Description	Format Text
01. Principal	<b>event_tx_ae_ess</b>	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	<b>event_tx_com</b>	Comments - [Participant Status: Intervention]		Char
01. Principal	<b>event_tx_contact_dt</b>	Contact Date - [Participant Status: Intervention]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>event_tx_phys_exam</b>	Was The Overall Physical Exam Performed? - [Participant Status: Intervention]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>event_tx_post_int_eval</b>	Will The Participant Continue To The Post-Intervention Evaluation? - [Participant Status: Intervention]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 99="Unknown"
01. Principal	<b>event_tx_visit_num</b>	Visit Number - [Participant Status: Intervention]		Numeric .F="No Record For This Visit"
01. Principal	<b>event_tx_vital_status</b>	Participant Vital Status - [Participant Status: Intervention]		.F="No Record For This Visit" .M="Missing" 1="Alive" 2="Dead"

## Section 27: Treatment Assignment

Class	Variable	Label	Description	Format Text
01. Principal	<b>trtassign_arm1-2</b>	Treatment Arm - [Treatment Assignment]		.M="Missing" .N="N/A" 1="A"
01. Principal	<b>trtassign_arm_assignment_dt1-2</b>	Date Of Intervention/Treatment Assignment - [Treatment Assignment]		SAS Date .N="N/A"
01. Principal	<b>trtassign_event_desc1-2</b>	Event Description - [Treatment Assignment]		.N="N/A" 1="Pre-Registration" 2="Registration/Randomization"
01. Principal	<b>trtassign_event_tm1-2</b>	Event Time - [Treatment Assignment]		SAS Time .N="N/A"
01. Principal	<b>trtassign_form_oid1-2</b>	Form OID - [Treatment Assignment]		.N="N/A" 1="PID3285336_V1_0"
01. Principal	<b>trtassign_registration_step_num1-2</b>	Registration Step - [Treatment Assignment]		Numeric .N="N/A"

## Section 28: Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	<b>lrc_alk_pho_serum_csig_v0/lrc_alk_pho_serum_csig_v2</b>	Alkaline Phosphatase Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_alk_pho_serum_done_v0/lrc_alk_pho_serum_done_v2</b>	Alkaline Phosphatase Serum - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_alk_pho_serum_range_v0/lrc_alk_pho_serum_range_v2</b>	Alkaline Phosphatase Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_alk_pho_serum_units_v0/lrc_alk_pho_serum_units_v2</b>	Alkaline Phosphatase Serum - Lab Test - Units - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 1="UL" 2="[U]/L" 3="[iU]/L" 4="g/dL" 5="mg/dL"
01. Principal	<b>lrc_alk_pho_serum_val_v0/lrc_alk_pho_serum_val_v2</b>	Alkaline Phosphatase Serum - Lab Value - Visit 2 - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrc_als_ami_serum_csig_v0/lrc_als_ami_serum_csig_v2</b>	Alanine Aminotransferase (ALT or SGPT) Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_als_ami_serum_done_v0/lrc_als_ami_serum_done_v2</b>	Alanine Aminotransferase (ALT or SGPT) Serum - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_als_ami_serum_range_v0/lrc_als_ami_serum_range_v2</b>	Alanine Aminotransferase (ALT or SGPT) Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_als_ami_serum_units_v0/lrc_als_ami_serum_units_v2</b>	Alanine Aminotransferase (ALT or SGPT) Serum - Lab Test - Units - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 1="UL" 2="[U]/L" 3="[iU]/L" 4="g/dL" 5="mg/dL"

Class	Variable	Label	Description	Format Text
01. Principal	<b>lrc_als_ami_serum_val_v0/lrc_als_ami_serum_val_v2</b>	Alanine Aminotransferase (ALT or SGPT) Serum - Lab Value - Visit 2 - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrc_asp_ami_serum_csig_v0/lrc_asp_ami_serum_csig_v2</b>	Aspartate Aminotransferase (AST or SGOT) Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_asp_ami_serum_done_v0/lrc_asp_ami_serum_done_v2</b>	Aspartate Aminotransferase (AST or SGOT) Serum - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_asp_ami_serum_range_v0/lrc_asp_ami_serum_range_v2</b>	Aspartate Aminotransferase (AST or SGOT) Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_asp_ami_serum_units_v0/lrc_asp_ami_serum_units_v2</b>	Aspartate Aminotransferase (AST or SGOT) Serum - Lab Test - Units - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 1="UL" 2="[U]/L" 3="[iU]/L" 4="g/dL" 5="mg/dL"
01. Principal	<b>lrc_asp_ami_serum_val_v0/lrc_asp_ami_serum_val_v2</b>	Aspartate Aminotransferase (AST or SGOT) Serum - Lab Value - Visit 2 - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrc_bil_tot_serum_csig_v0/lrc_bil_tot_serum_csig_v2</b>	Bilirubin Total Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_bil_tot_serum_done_v0/lrc_bil_tot_serum_done_v2</b>	Bilirubin Total Serum - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_bil_tot_serum_range_v0/lrc_bil_tot_serum_range_v2</b>	Bilirubin Total Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_bil_tot_serum_units_v0/lrc_bil_tot_serum_units_v2</b>	Bilirubin Total Serum - Lab Test - Units - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="UL" 2="[U]/L" 3="[iU]/L" 4="g/dL" 5="mg/dL"

Class	Variable	Label	Description	Format Text
01. Principal	<b>lrc_bil_tot_serum_val_v0/lrc_bil_tot_serum_val_v2</b>	Bilirubin Total Serum - Lab Value - Visit 2 - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrc_bld_ure_nit_serum_csig_v0/lrc_bld_ure_nit_serum_csig_v2</b>	Blood Urea Nitrogen (BUN) Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_bld_ure_nit_serum_done_v0/lrc_bld_ure_nit_serum_done_v2</b>	Blood Urea Nitrogen (BUN) Serum - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_bld_ure_nit_serum_range_v0/lrc_bld_ure_nit_serum_range_v2</b>	Blood Urea Nitrogen (BUN) Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_bld_ure_nit_serum_units_v0/lrc_bld_ure_nit_serum_units_v2</b>	Blood Urea Nitrogen (BUN) Serum - Lab Test - Units - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="UL" 2="[U]/L" 3="[iU]/L" 4="g/dL" 5="mg/dL"
01. Principal	<b>lrc_bld_ure_nit_serum_val_v0/lrc_bld_ure_nit_serum_val_v2</b>	Blood Urea Nitrogen (BUN) Serum - Lab Value - Visit 2 - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrc_calc_serum_csig_v0/lrc_calc_serum_csig_v2</b>	Calcium Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_calc_serum_done_v0/lrc_calc_serum_done_v2</b>	Calcium Serum - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_calc_serum_range_v0/lrc_calc_serum_range_v2</b>	Calcium Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_calc_serum_units_v0/lrc_calc_serum_units_v2</b>	Calcium Serum - Lab Test - Units - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 1="UL" 2="[U]/L" 3="[iU]/L" 4="g/dL" 5="mg/dL"
01. Principal	<b>lrc_calc_serum_val_v0/lrc_calc_serum_val_v2</b>	Calcium Serum - Lab Value - Visit 2 - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>lrc_com_v0/lrc_com_v2</b>	Comments - Visit 2 - [Blood Chemistry]		Char
01. Principal	<b>lrc_crea_phos_serum_csig_v0/lrc_crea_phos_serum_csig_v2</b>	Creatine Phosphokinase (CPK) Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_crea_phos_serum_done_v0/lrc_crea_phos_serum_done_v2</b>	Creatine Phosphokinase (CPK) Serum - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_crea_phos_serum_range_v0/lrc_crea_phos_serum_range_v2</b>	Creatine Phosphokinase (CPK) Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_crea_phos_serum_units_v0/lrc_crea_phos_serum_units_v2</b>	Creatine Phosphokinase (CPK) Serum - Lab Test - Units - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 1="UL" 2="[U]/L" 3="[iU]/L" 4="g/dL" 5="mg/dL"
01. Principal	<b>lrc_crea_phos_serum_val_v0/lrc_crea_phos_serum_val_v2</b>	Creatine Phosphokinase (CPK) Serum - Lab Value - Visit 2 - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrc_creat_serum_csig_v0/lrc_creat_serum_csig_v2</b>	Creatinine Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_creat_serum_done_v0/lrc_creat_serum_done_v2</b>	Creatinine Serum - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_creat_serum_range_v0/lrc_creat_serum_range_v2</b>	Creatinine Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_creat_serum_units_v0/lrc_creat_serum_units_v2</b>	Creatinine Serum - Lab Test - Units - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="UL" 2="[U]/L" 3="[iU]/L" 4="g/dL" 5="mg/dL"
01. Principal	<b>lrc_creat_serum_val_v0/lrc_creat_serum_val_v2</b>	Creatinine Serum - Lab Value - Visit 2 - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>lrc_fasting_v0/lrc_fasting_v2</b>	Fasting - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" 1="Yes" 2="No" 3="Unknown"
01. Principal	<b>lrc_tot_prot_serum_csig_v0/lrc_tot_prot_serum_csig_v2</b>	Total Protein Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_tot_prot_serum_done_v0/lrc_tot_prot_serum_done_v2</b>	Total Protein Serum - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_tot_prot_serum_range_v0/lrc_tot_prot_serum_range_v2</b>	Total Protein Serum - Out Of Range - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrc_tot_prot_serum_units_v0/lrc_tot_prot_serum_units_v2</b>	Total Protein Serum - Lab Test - Units - Visit 2 - [Blood Chemistry]		.F="No Record For This Visit" .N="N/A" 1="UL" 2="[U]/L" 3="[iU]/L" 4="g/dL" 5="mg/dL"
01. Principal	<b>lrc_tot_prot_serum_val_v0/lrc_tot_prot_serum_val_v2</b>	Total Protein Serum - Lab Value - Visit 2 - [Blood Chemistry]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrc_visit_num</b>	Visit Number - [Blood Chemistry]		.F="No Record For This Visit" 0="Baseline" 2="Post Intervention Evaluation"

## Section 29: Blood Chemistry, Other

Class	Variable	Label	Description	Format Text
01. Principal	<b>lro_alb_serum_csig_v0/lro_alb_serum_csig_v2</b>	Albumin Serum - Clinically Significant - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lro_alb_serum_done_v0/lro_alb_serum_done_v2</b>	Albumin Serum - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" .N="N/A" 1="Negative" 2="Not done" 3="Positive"
01. Principal	<b>lro_alb_serum_range_v0/lro_alb_serum_range_v2</b>	Albumin Serum - Out Of Range - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lro_alb_serum_units_v0/lro_alb_serum_units_v2</b>	Albumin Serum - Lab Test - Units - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="IU/mL" 2="g/dL"
01. Principal	<b>lro_alb_serum_val_v0/lro_alb_serum_val_v2</b>	Albumin Serum - Lab Value - Visit 2 - [Blood Chemistry, Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lro_com_v0/lro_com_v2</b>	Comments - Visit 2 - [Blood Chemistry, Other]		Char
01. Principal	<b>lro_hcv_pos_v0/lro_hcv_pos_v2</b>	Is The Patient HCV Positive? - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lro_hcv_rna_dt_v0/lro_hcv_rna_dt_v2</b>	Date HCV RNA Test Was Performed (dd MMM yyyy) - Visit 2 - [Blood Chemistry, Other]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lro_hep_b_done_v0/lro_hep_b_done_v2</b>	Hepatitis B Surface Antigen - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" 1="Negative" 2="Not done" 3="Positive"
01. Principal	<b>lro_hepc_virus_rna_csig_v0/lro_hepc_virus_rna_csig_v2</b>	Hepatitis C Virus RNA Quantitative IU/mL Serum - Clinically Significant - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"



Class	Variable	Label	Description	Format Text
01. Principal	<b>Iro_hepc_virus_rna_done_v0/Iro_hepc_virus_rna_done_v2</b>	Hepatitis C Virus RNA Quantitative IU/mL Serum - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" .N="N/A" 1="Negative" 2="Not done" 3="Positive"
01. Principal	<b>Iro_hepc_virus_rna_range_v0/Iro_hepc_virus_rna_range_v2</b>	Hepatitis C Virus RNA Quantitative IU/mL Serum - Out Of Range - Visit 2 - [Blood Chemistry, Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>Iro_hepc_virus_rna_units_v0/Iro_hepc_virus_rna_units_v2</b>	Hepatitis C Virus RNA Quantitative IU/mL Serum - Lab Test - Units - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="IU/mL" 2="g/dL"
01. Principal	<b>Iro_hepc_virus_rna_val_v0/Iro_hepc_virus_rna_val_v2</b>	Hepatitis C Virus RNA Quantitative IU/mL Serum - Lab Value - Visit 2 - [Blood Chemistry, Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>Iro_inr_pro_time_blood_csig_v0/Iro_inr_pro_time_blood_csig_v2</b>	International Normalized Ratio (INR) Prothrombin Time Blood - Clinically Significant - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>Iro_inr_pro_time_blood_done_v0/Iro_inr_pro_time_blood_done_v2</b>	International Normalized Ratio (INR) Prothrombin Time Blood - Was Lab Specimen Collected? - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" .N="N/A" 1="Negative" 2="Not done" 3="Positive"
01. Principal	<b>Iro_inr_pro_time_blood_range_v0/Iro_inr_pro_time_blood_range_v2</b>	International Normalized Ratio (INR) Prothrombin Time Blood - Out Of Range - Visit 2 - [Blood Chemistry, Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>Iro_inr_pro_time_blood_units_v0/Iro_inr_pro_time_blood_units_v2</b>	International Normalized Ratio (INR) Prothrombin Time Blood - Lab Test - Units - Visit 2 - [Blood Chemistry, Other]		.F="No Record For This Visit" .M="Missing" .N="N/A" 1="IU/mL" 2="g/dL"
01. Principal	<b>Iro_inr_pro_time_blood_val_v0/Iro_inr_pro_time_blood_val_v2</b>	International Normalized Ratio (INR) Prothrombin Time Blood - Lab Value - Visit 2 - [Blood Chemistry, Other]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>Iro_sample_collection_dt_v0/Iro_sample_collection_dt_v2</b>	Sample Collection Date - Visit 2 - [Blood Chemistry, Other]		SAS Date .F="No Record For This Visit" .M="Missing"

## Section 30: Hematology

Class	Variable	Label	Description	Format Text
01. Principal	<b>lrh_baso_blood_csig_v0/lrh_baso_blood_csig_v2</b>	Basophils # Blood - Clinically Significant - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_baso_blood_done_v0/lrh_baso_blood_done_v2</b>	Basophils # Blood - Was Lab Specimen Collected? - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>lrh_baso_blood_range_v0/lrh_baso_blood_range_v2</b>	Basophils # Blood - Out Of Range - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_baso_blood_units_v0/lrh_baso_blood_units_v2</b>	Basophils # Blood - Lab Test - Units - Visit 2 - [Hematology]		.F="No Record For This Visit" .N="N/A" 1="%" 2="10^12Cells/L" 3="10^3/uL" 4="10^6/uL" 5="10^9Cells/L" 6="K/uL" 7="M/uL" 8="g/dL" 9="mg/dL"
01. Principal	<b>lrh_baso_blood_val_v0/lrh_baso_blood_val_v2</b>	Basophils # Blood - Lab Value - Visit 2 - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrh_com_v0/lrh_com_v2</b>	Comments - Visit 2 - [Hematology]		Char
01. Principal	<b>lrh_eosino_blood_csig_v0/lrh_eosino_blood_csig_v2</b>	Eosinophils # Blood - Clinically Significant - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_eosino_blood_done_v0/lrh_eosino_blood_done_v2</b>	Eosinophils # Blood - Was Lab Specimen Collected? - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>lrh_eosino_blood_range_v0/lrh_eosino_blood_range_v2</b>	Eosinophils # Blood - Out Of Range - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>lrh_eosino_blood_units_v0/lrh_eosino_blood_units_v2</b>	Eosinophils # Blood - Lab Test - Units - Visit 2 - [Hematology]		.F="No Record For This Visit" .N="N/A" 1="%" 2="10^12Cells/L" 3="10^3/uL" 4="10^6/uL" 5="10^9Cells/L" 6="K/uL" 7="M/uL" 8="g/dL" 9="mg/dL"
01. Principal	<b>lrh_eosino_blood_val_v0/lrh_eosino_blood_val_v2</b>	Eosinophils # Blood - Lab Value - Visit 2 - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrh_hematocrit_blood_csig_v0/lrh_hematocrit_blood_csig_v2</b>	Hematocrit % Blood - Clinically Significant - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_hematocrit_blood_done_v0/lrh_hematocrit_blood_done_v2</b>	Hematocrit % Blood - Was Lab Specimen Collected? - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Misssing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>lrh_hematocrit_blood_range_v0/lrh_hematocrit_blood_range_v2</b>	Hematocrit % Blood - Out Of Range - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_hematocrit_blood_units_v0/lrh_hematocrit_blood_units_v2</b>	Hematocrit % Blood - Lab Test - Units - Visit 2 - [Hematology]		.F="No Record For This Visit" .N="N/A" 1="%" 2="10^12Cells/L" 3="10^3/uL" 4="10^6/uL" 5="10^9Cells/L" 6="K/uL" 7="M/uL" 8="g/dL" 9="mg/dL"
01. Principal	<b>lrh_hematocrit_blood_val_v0/lrh_hematocrit_blood_val_v2</b>	Hematocrit % Blood - Lab Value - Visit 2 - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrh_hematoglob_blood_csig_v0/lrh_hematoglob_blood_csig_v2</b>	Hemoglobin Blood - Clinically Significant - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_hematoglob_blood_done_v0/lrh_hematoglob_blood_done_v2</b>	Hemoglobin Blood - Was Lab Specimen Collected? - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Misssing" .N="Not Applicable" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>lrh_hematoglob_blood_range_v0/lrh_hematoglob_blood_range_v2</b>	Hemoglobin Blood - Out Of Range - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_hematoglob_blood_units_v0/lrh_hematoglob_blood_units_v2</b>	Hemoglobin Blood - Lab Test - Units - Visit 2 - [Hematology]		.F="No Record For This Visit" .N="N/A" 1="%" 2="10^12Cells/L" 3="10^3/uL" 4="10^6/uL" 5="10^9Cells/L" 6="K/uL" 7="M/uL" 8="g/dL" 9="mg/dL"
01. Principal	<b>lrh_hematoglob_blood_val_v0/lrh_hematoglob_blood_val_v2</b>	Hemoglobin Blood - Lab Value - Visit 2 - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrh_lympho_blood_csig_v0/lrh_lympho_blood_csig_v2</b>	Lymphocytes # Blood - Clinically Significant - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_lympho_blood_done_v0/lrh_lympho_blood_done_v2</b>	Lymphocytes # Blood - Was Lab Specimen Collected? - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>lrh_lympho_blood_range_v0/lrh_lympho_blood_range_v2</b>	Lymphocytes # Blood - Out Of Range - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_lympho_blood_units_v0/lrh_lympho_blood_units_v2</b>	Lymphocytes # Blood - Lab Test - Units - Visit 2 - [Hematology]		.F="No Record For This Visit" .N="N/A" 1="%" 2="10^12Cells/L" 3="10^3/uL" 4="10^6/uL" 5="10^9Cells/L" 6="K/uL" 7="M/uL" 8="g/dL" 9="mg/dL"
01. Principal	<b>lrh_lympho_blood_val_v0/lrh_lympho_blood_val_v2</b>	Lymphocytes # Blood - Lab Value - Visit 2 - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrh_mono_blood_csig_v0/lrh_mono_blood_csig_v2</b>	Monocytes # Blood - Clinically Significant - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>lrh_mono_blood_done_v0/lrh_mono_blood_done_v2</b>	Monocytes # Blood - Was Lab Specimen Collected? - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Misssing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>lrh_mono_blood_range_v0/lrh_mono_blood_range_v2</b>	Monocytes # Blood - Out Of Range - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_mono_blood_units_v0/lrh_mono_blood_units_v2</b>	Monocytes # Blood - Lab Test - Units - Visit 2 - [Hematology]		.F="No Record For This Visit" .N="N/A" 1="%" 2="10^12Cells/L" 3="10^3/uL" 4="10^6/uL" 5="10^9Cells/L" 6="K/uL" 7="M/uL" 8="g/dL" 9="mg/dL"
01. Principal	<b>lrh_mono_blood_val_v0/lrh_mono_blood_val_v2</b>	Monocytes # Blood - Lab Value - Visit 2 - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrh_neutro_blood_csig_v0/lrh_neutro_blood_csig_v2</b>	Neutrophils (ANC) # Blood - Clinically Significant - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_neutro_blood_done_v0/lrh_neutro_blood_done_v2</b>	Neutrophils (ANC) # Blood - Was Lab Specimen Collected? - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Misssing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>lrh_neutro_blood_range_v0/lrh_neutro_blood_range_v2</b>	Neutrophils (ANC) # Blood - Out Of Range - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_neutro_blood_units_v0/lrh_neutro_blood_units_v2</b>	Neutrophils (ANC) # Blood - Lab Test - Units - Visit 2 - [Hematology]		.F="No Record For This Visit" .N="N/A" 1="%" 2="10^12Cells/L" 3="10^3/uL" 4="10^6/uL" 5="10^9Cells/L" 6="K/uL" 7="M/uL" 8="g/dL" 9="mg/dL"
01. Principal	<b>lrh_neutro_blood_val_v0/lrh_neutro_blood_val_v2</b>	Neutrophils (ANC) # Blood - Lab Value - Visit 2 - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>lrh_plat_blood_csig_v0/lrh_plat_blood_csig_v2</b>	Platelets Blood - Clinically Significant - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_plat_blood_done_v0/lrh_plat_blood_done_v2</b>	Platelets Blood - Was Lab Specimen Collected? - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Misssing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>lrh_plat_blood_range_v0/lrh_plat_blood_range_v2</b>	Platelets Blood - Out Of Range - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_plat_blood_units_v0/lrh_plat_blood_units_v2</b>	Platelets Blood - Lab Test - Units - Visit 2 - [Hematology]		.F="No Record For This Visit" .N="N/A" 1="%" 2="10^12Cells/L" 3="10^3/uL" 4="10^6/uL" 5="10^9Cells/L" 6="K/uL" 7="M/uL" 8="g/dL" 9="mg/dL"
01. Principal	<b>lrh_plat_blood_val_v0/lrh_plat_blood_val_v2</b>	Platelets Blood - Lab Value - Visit 2 - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrh_rbc_blood_csig_v0/lrh_rbc_blood_csig_v2</b>	Red Blood Cells (RBC) # Blood - Clinically Significant - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_rbc_blood_done_v0/lrh_rbc_blood_done_v2</b>	Red Blood Cells (RBC) # Blood - Was Lab Specimen Collected? - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Misssing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>lrh_rbc_blood_range_v0/lrh_rbc_blood_range_v2</b>	Red Blood Cells (RBC) # Blood - Out Of Range - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_rbc_blood_units_v0/lrh_rbc_blood_units_v2</b>	Red Blood Cells (RBC) # Blood - Lab Test - Units - Visit 2 - [Hematology]		.F="No Record For This Visit" .N="N/A" 1="%" 2="10^12Cells/L" 3="10^3/uL" 4="10^6/uL" 5="10^9Cells/L" 6="K/uL" 7="M/uL" 8="g/dL" 9="mg/dL"

Class	Variable	Label	Description	Format Text
01. Principal	<b>lrh_rbc_blood_val_v0/lrh_rbc_blood_val_v2</b>	Red Blood Cells (RBC) # Blood - Lab Value - Visit 2 - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	<b>lrh_visit_num</b>	Visit Number - [Hematology]		.F="No Record For This Visit" 0="Baseline" 2="Post Intervention Evaluation"
01. Principal	<b>lrh_wbc_blood_clin_sig_v0/lrh_wbc_blood_clin_sig_v2</b>	White Blood Cells (WBC) # Blood - Clinically Significant - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_wbc_blood_done_v0/lrh_wbc_blood_done_v2</b>	White Blood Cells (WBC) # Blood - Was Lab Specimen Collected? - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Misssing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	<b>lrh_wbc_blood_out_of_range_v0/lrh_wbc_blood_out_of_range_v2</b>	White Blood Cells (WBC) # Blood - Out Of Range - Visit 2 - [Hematology]		.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	<b>lrh_wbc_blood_units_v0/lrh_wbc_blood_units_v2</b>	White Blood Cells (WBC) # Blood - Lab Test - Units - Visit 2 - [Hematology]		.F="No Record For This Visit" .N="N/A" 1="%" 2="10^12Cells/L" 3="10^3/uL" 4="10^6/uL" 5="10^9Cells/L" 6="K/uL" 7="M/uL" 8="g/dL" 9="mg/dL"
01. Principal	<b>lrh_wbc_blood_lab_val_v0/lrh_wbc_blood_lab_val_v2</b>	White Blood Cells (WBC) # Blood - Lab Value - Visit 2 - [Hematology]		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

## Section 31: Off Study

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



## Section 32: Step Information

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Class	Variable	Label	Description	Format Text
01. Principal	<b>stepinfo_event_desc1-2</b>	Event Description - Record 2 - [Step Information]		.N="N/A" 1="Pre-Registration" 2="Registration/Randomization"
01. Principal	<b>stepinfo_event_dt1-2</b>	Event Date - Record 2 - [Step Information]		SAS Date .N="N/A"
01. Principal	<b>stepinfo_event_tm1-2</b>	Event Time - Record 2 - [Step Information]		SAS Time .N="N/A"
01. Principal	<b>stepinfo_form_oid1-2</b>	Form OID - Record 2 - [Step Information]		Char
01. Principal	<b>stepinfo_reg_step_num1-2</b>	Registration Step - Record 2 - [Step Information]		Numeric .N="N/A"
01. Principal	<b>stepinfo_treat_arm1-2</b>	Treatment Arm - Record 2 - [Step Information]		.M="Missing" .N="N/A" 1="A"

## Section 33: QOL Comp

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Class	Variable	Label	Description	Format Text
01. Principal	<b>qol_cycle</b>	Visit Number - [QOL Comp]		Numeric .F="No Record For This Visit"
01. Principal	<b>qol_no_assesment_reason</b>	Reason Assesment Was Not Completed - [QOL Comp]		Numeric .F="No Record For This Visit" 1="Not administered: staff did not give/offer assessment to patient"

## Section 34: Was It Worth It? Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	<b>wiwi_cycle</b>	Visit Number - [Was It Worth It? Questionnaire]		Numeric .F="No Record For This Visit"
01. Principal	<b>wiwi_q01</b>	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" 3="Uncertain"
01. Principal	<b>wiwi_q02</b>	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" 3="Uncertain"
01. Principal	<b>wiwi_q03</b>	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" 3="Uncertain"
01. Principal	<b>wiwi_q04</b>	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 got worse" 2="It improved" 3="It stayed the same"
01. Principal	<b>wiwi_q05</b>	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	<b>wiwi_q06</b>	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	<b>wiwi_q07</b>	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"

## Section 35: Specimen Collection (Tissue)

Class	Variable	Label	Description	Format Text
01. Principal	<b>tisspc_com</b>	Comments - [Specimen Collection (Tissue)]		Char
01. Principal	<b>tisspc_livbiop_block_formalin</b>	Paraffin Blocks? - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tisspc_livbiop_block_RNAlater</b>	Paraffin Blocks? - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tisspc_livbiop_coltd_formalin</b>	Date Specimen Collected - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_coltd_RNAlater</b>	Date Specimen Collected - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_coltm_formalin</b>	Time Specimen Collected (Hh:Nn:Rr) - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_coltm_RNAlater</b>	Time Specimen Collected (Hh:Nn:Rr) - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_parafdt_formalin</b>	Date Of Paraffin Embedding - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_parafdt_RNAlater</b>	Date Of Paraffin Embedding - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tisspc_livbiop_pa raftm_formalin</b>	Time Of Sectioning (Hh:Nn:Rr) - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_pa raftm_RNAlater</b>	Time Of Sectioning (Hh:Nn:Rr) - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_se ctdt_formalin</b>	Date Of Sectioning (ddMMMyyyy) - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_se ctdt_RNAlater</b>	Date Of Sectioning (ddMMMyyyy) - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_se cttm_formalin</b>	Time Of Sectioning (Hh:Nn:Rr) - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_se cttm_RNAlater</b>	Time Of Sectioning (Hh:Nn:Rr) - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_sh ipdt_formalin</b>	Date Specimen Shipped - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_sh ipdt_RNAlater</b>	Date Specimen Shipped - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_sp cnum_formalin</b>	Number Of Specimens Collected - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livbiop_sp cnum_RNAlater</b>	Number Of Specimens Collected - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		Numeric .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tisspc_livbiop_sp crsn_formalin</b>	Not Collected Reason - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 1="Institution error" 2="Not available" 3="Sample not required" 4="Other"
01. Principal	<b>tisspc_livbiop_sp crsn_RNAlater</b>	Not Collected Reason - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 1="Institution error" 2="Not available" 3="Sample not required" 4="Other"
01. Principal	<b>tisspc_livbiop_sp crsp_formalin</b>	Not Collected Reason - Other (Specify) - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 1="Institution error" 2="Not available" 3="Sample not required" 4="Other"
01. Principal	<b>tisspc_livbiop_sp crsp_RNAlater</b>	Not Collected Reason - Other (Specify) - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 1="Institution error" 2="Not available" 3="Sample not required" 4="Other"
01. Principal	<b>tisspc_livbiop_su bm_formalin</b>	Was Specimen Collected? - Liver biopsy (2 Cores) - Formalin - Record 4 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tisspc_livbiop_su bm_RNAlater</b>	Was Specimen Collected? - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tisspc_livbiop_t mpt_formalin</b>	Time Point - Liver biopsy (2 Cores) Formalin - Record 4 - [Specimen Collection (Tissue)]		Char
01. Principal	<b>tisspc_livbiop_t mpt_RNAlater</b>	Time Point - Liver biopsy (2 Cores) - RNAlater - Record 3 - [Specimen Collection (Tissue)]		Char
01. Principal	<b>tisspc_livresct_bl ock_formalin</b>	Paraffin Blocks? - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tisspc_livresct_block_RNAlater</b>	Paraffin Blocks? - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tisspc_livresct_coldt_formalin</b>	Date Specimen Collected - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_coldt_RNAlater</b>	Date Specimen Collected - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_coltm_formalin</b>	Time Specimen Collected (Hh:Nn:Rr) - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_coltm_RNAlater</b>	Time Specimen Collected (Hh:Nn:Rr) - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_parafdt_formalin</b>	Date Of Paraffin Embedding - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_parafdt_RNAlater</b>	Date Of Paraffin Embedding - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_paraftm_formalin</b>	Time Of Sectioning (Hh:Nn:Rr) - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	<b>tisspc_livresct_p araftm_RNAlater</b>	Time Of Sectioning (Hh:Nn:Rr) - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_s ectdt_formalin</b>	Date Of Sectioning (ddMMMyyyy) - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_s ectdt_RNAlater</b>	Date Of Sectioning (ddMMMyyyy) - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_s ecttm_formalin</b>	Time Of Sectioning (Hh:Nn:Rr) - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_s ecttm_RNAlater</b>	Time Of Sectioning (Hh:Nn:Rr) - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		SAS Time .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_s hipdt_formalin</b>	Date Specimen Shipped - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_s hipdt_RNAlater</b>	Date Specimen Shipped - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		SAS Date .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_s pcnum_formalin</b>	Number Of Specimens Collected - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		Numeric .F="No Record For This Visit" .M="Missing"



Class	Variable	Label	Description	Format Text
01. Principal	<b>tisspc_livresct_s pcnum_RNAlater</b>	Number Of Specimens Collected - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>tisspc_livresct_s pcrsn_formalin</b>	Not Collected Reason - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 1="Institution error" 2="Not available" 3="Sample not required" 4="Other"
01. Principal	<b>tisspc_livresct_s pcrsn_RNAlater</b>	Not Collected Reason - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 1="Institution error" 2="Not available" 3="Sample not required" 4="Other"
01. Principal	<b>tisspc_livresct_s pcrsp_formalin</b>	Not Collected Reason - Other (Specify) - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 1="Institution error" 2="Not available" 3="Sample not required" 4="Other"
01. Principal	<b>tisspc_livresct_s pcrsp_RNAlater</b>	Not Collected Reason - Other (Specify) - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 1="Institution error" 2="Not available" 3="Sample not required" 4="Other"
01. Principal	<b>tisspc_livresct_s ubm_formalin</b>	Was Specimen Collected? - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tisspc_livresct_s ubm_RNAlater</b>	Was Specimen Collected? - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>tisspc_livresct_t mpt_formalin</b>	Time Point - Liver resection specimen (one 1-gram specimen) - Formalin - Record 2 - [Specimen Collection (Tissue)]		Char

Class	Variable	Label	Description	Format Text
01. Principal	<b>tisspc_livresct_t mpt_RNAlater</b>	Time Point - Liver resection specimen (one 1-gram specimen) - RNAlater - Record 1 - [Specimen Collection (Tissue)]		Char

## Section 36: Research Base (SAE Coordinator)

Class	Variable	Label	Description	Format Text
01. Principal	<b>nonaer_coord_ae_comments</b>	Comments - [Research Base (SAE Coordinator)]		Char
01. Principal	<b>nonaer_coord_ae_grade</b>	Grade - [Research Base (SAE Coordinator)]		.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	<b>nonaer_coord_ae_notify_dt</b>	Date Made Aware Of Events - [Research Base (SAE Coordinator)]		SAS Date .F="No Record For This Visit"
01. Principal	<b>nonaer_coord_aer_attach</b>	Attach Report Here - [Research Base (SAE Coordinator)]		Char
01. Principal	<b>nonaer_coord_aer_form</b>	Is This An Adverse Event Report Form? - [Research Base (SAE Coordinator)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>nonaer_coord_aer_med_attrib</b>	What Is The Attribution To The Study Medication? - [Research Base (SAE Coordinator)]		.F="No Record For This Visit" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probably" 5="Definite"
01. Principal	<b>nonaer_coord_aer_term</b>	Adverse Event Term (CTCAE V4.0) - [Research Base (SAE Coordinator)]		Numeric .F="No Record For This Visit"
01. Principal	<b>nonaer_coord_aer_type</b>	Report Format - [Research Base (SAE Coordinator)]		.F="No Record For This Visit" 1="MedWatch" 2="AdEERs" 3="Other"
01. Principal	<b>nonaer_coord_aer_type_sp</b>	Specify - [Research Base (SAE Coordinator)]		.F="No Record For This Visit" .M="Missing" 1="CPN SAE Form"
01. Principal	<b>nonaer_coord_cycle</b>	Visit Number - [Research Base (SAE Coordinator)]		Numeric .F="No Record For This Visit" .M="Missing"
01. Principal	<b>nonaer_coord_in_hospital</b>	Hospitalization - [Research Base (SAE Coordinator)]		.F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	<b>nonaer_coord_occur_dt</b>	Date Of First Occurrence Of Adverse Event - [Research Base (SAE Coordinator)]		SAS Date .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	<b>nonaer_coord_pg_dz</b>	Was Death Due To Progression? - [Research Base (SAE Coordinator)]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
01. Principal	<b>nonaer_coord_pt_dead</b>	Has Patient Died? - [Research Base (SAE Coordinator)]		.F="No Record For This Visit" 0="No" 1="Yes"