

# MAY2013-02-01 - Enhanced Person Data Dictionary

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## Document Summary

| Property          | Value  |
|-------------------|--|
| Document Title    | MAY2013-02-01 - Enhanced Person: Data Dictionary |
| Date Created      | 11/01/2024                                       |
| Sections          | 35   |
| Entries           | 625  |
| Document Filename | dictionary_enhanced_prsn.rtf                     |

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# MAY2013-02-01 - Enhanced Person: Data Dictionary

## Section 1: Identifiers

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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>Arm</b>                 | Treatment Arm -<br>[Checklist<br>(Registration)] |             | Char  |
| 01. Principal | <b>build_dt</b>            | Build Date                                       |             | SAS Date  |
| 01. Principal | <b>on_study_grp_factor</b> | Grouping Factor - [On<br>Study]                  |             | .R="Not Randomized"<br>1="Dose Escalation Cohort"<br>2="Expansion Cohort" |

## Section 3: Demographics

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| Class         | Variable                                   | Label                                   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>chklist_pre_age</b>                     | Age - [Checklist (Pre-Registration)]    |             | Numeric  |
| 01. Principal | <b>demo_country</b>                        | Country Of Residence - [Demographics]   |             | 1="US"<br>2="PR"   |
| 01. Principal | <b>demo_form_oid</b>                       | Form OID - [Demographics]               |             | Numeric  |
| 01. Principal | <b>demo_payment_method</b>                 | Method Of Payment - [Demographics]      |             | 1="Medicaid"<br>2="Private Insurance"<br>3="Self Pay (No Insurance)"<br>4="Other"<br>5="No Means Of Payment (No Insurance)"<br>9="Unknown" |
| 01. Principal | <b>ethnicity</b>                           | Ethnicity - [Demographics]              |             | 0="Not Hispanic Or Latino"<br>1="Hispanic Or Latino"   |
| 01. Principal | <b>gender</b>                              | Gender - [Demographics]                 |             | 1="Male"<br>2="Female"   |
| 01. Principal | <b>phyexam_height_v0/phyexam_height_v8</b> | Height (cm) - Visit # - [Physical Exam] |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"  |
| 01. Principal | <b>phyexam_weight_v0/phyexam_weight_v8</b> | Weight (kg) - Visit # - [Physical Exam] |             | Numeric<br>.F="No Record For This Visit"<br>.R="Not Randomized"  |
| 01. Principal | <b>race</b>                                | Race - [Demographics]                   |             | 1="White"<br>2="Black Or African American"<br>9="Unknown"  |

## Section 4: Screening

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| Class         | Variable                    | Label   | Description | Format Text  |
|---------------|-----------------------------|---|-------------|--|
| 01. Principal | <b>screen_comments</b>      | Comments - [Screening]                                  |             | Char   |
| 01. Principal | <b>screen_comp_dt</b>       | Screen Completion Date - [Screening]                    |             | SAS Date   |
| 01. Principal | <b>screen_fail_rsn</b>      | Which Screening Criteria Not Met? - [Screening]         |             | .N="N/A"<br>1="Did Not Meet Other Eligibility Criteria"<br>2="Investigator Decision"<br>3="Patient Decision" |
| 01. Principal | <b>screen_fail_rsn_spec</b> | Which Screening Criteria Not Met? Specify - [Screening] |             | Char   |
| 01. Principal | <b>screen_meet_crit</b>     | Does Participant Meet Screening Criteria? - [Screening] |             | 0="No"<br>1="Yes"  |

## Section 5: Checklist (Pre-Registration)

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| Class         | Variable                         | Label   | Description | Format Text                       |
|---------------|----------------------------------|---|-------------|-----------------------------------|
| 01. Principal | <b>chklist_enroll_dt</b>         | Enrollment Date -<br>[Checklist<br>(Pre-Registration)]  |             | SAS Date                          |
| 01. Principal | <b>chklist_pre_age_18</b>        | Age >=18 Years -<br>[Checklist<br>(Pre-Registration)]   |             | .M="Missing"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>chklist_pre_auth_bio_ca</b>   | Participant Has Given Permission To Collect And Store Blood For Future Use In Research To Learn About, Prevent, Treat Or Cure Cancer -<br>[Checklist<br>(Pre-Registration)] |             | 0="No"<br>1="Yes"                 |
| 01. Principal | <b>chklist_pre_auth_bio_oth</b>  | Participant Has Given Permission To Collect And Store Blood For Future Use In Research About Other Health Problems -<br>[Checklist<br>(Pre-Registration)]                   |             | 0="No"<br>1="Yes"                 |
| 01. Principal | <b>chklist_pre_auth_doc_con</b>  | Participant Has Given Permission To His/Her Doctor To Contact Them In The Future To Ask Them To Take Part In More Research -<br>[Checklist<br>(Pre-Registration)]           |             | 0="No"<br>1="Yes"                 |
| 01. Principal | <b>chklist_pre_auth_send_bio</b> | Participant Has Given Permission To Send Blood Sample(s) To Researchers At An Outside Institution -<br>[Checklist<br>(Pre-Registration)]                                    |             | 0="No"<br>1="Yes"                 |
| 01. Principal | <b>chklist_pre_auto_reg</b>      | All Participants Will Automatically Be Registered To The Correlative/Translational Components Of This Study   |             | 0="No"<br>1="Yes"                 |



| Class         | Variable                          | Label  | Description | Format Text                       |
|---------------|-----------------------------------|--|-------------|-----------------------------------|
| 01. Principal | <b>chklist_pre_autoimmune_dis</b> | Autoimmune Disorders, Transplant Recipients, Other Immunosuppression Including Any Concurrent Condition Requiring The Use Of Immunosuppressive/Immunomodulating Agents. Exception: Eye Drop-Containing And Infreq - [Checklist (Pre-Registration)] |             | .M="Missing"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>chklist_pre_avoid_alc</b>      | Willingness To Avoid Excessive Use Of Alcohol During The Study. Note: Excessive Use Is Defined As Drinking >=8 Alcoholic Drinks Per Week On Average - [Checklist (Pre-Registration)]   |             | .M="Missing"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>chklist_pre_bsl_screen</b>     | Baseline (Screening) Evaluations Must Be Completed Within The Guidelines Specified On The Schedule Of Events - [Checklist (Pre-Registration)]  |             | .M="Missing"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>chklist_pre_bsl_sym_reg</b>    | All Baseline Symptoms Must Be Documented And Graded - [Checklist (Pre-Registration)]   |             | .M="Missing"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>chklist_pre_cardiac_arryth</b> | History Of Cardiac Arrhythmia, Controlled Or Uncontrolled, Including Ventricular And Supraventricular Arrhythmia - [Checklist (Pre-Registration)]  |             | .M="Missing"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>chklist_pre_cardiac_pre_ex</b> | Current Diagnosis Or History Of Cardiac Pre-Excitation Syndromes (E.g., Wolff-Parkinson-White) - [Checklist (Pre-Registration)]  |             | .M="Missing"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>chklist_pre_case_det_id</b>    | Case Number - [Checklist (Pre-Registration)]   |             | Numeric                           |

| Class         | Variable                         | Label  | Description | Format Text                                   |
|---------------|----------------------------------|--|-------------|---|
| 01. Principal | <b>chklist_pre_chronic_hcv</b>   | Presence Of Chronic HCV Infection. Note: Chronic HCV Infection Is Defined By (1) Presence Of Plasma Or Serum HCV RNA In A Participant With HCV Antibody For >=180 Days, OR (2) Two Documented HCV RNA Positive Re - [Checklist (Pre-Registration)] |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_consent_dt</b>    | Date Informed Consent Signed - [Checklist (Pre-Registration)]  |             | SAS Date                                      |
| 01. Principal | <b>chklist_pre_ctype_arm</b>     | TAC/TAD Code - [Checklist (Pre-Registration)]  |             | 0="TAC-0"                                     |
| 01. Principal | <b>chklist_pre_eligible</b>      | Is The Participant Eligible For Inclusion On This Study? - [Checklist (Pre-Registration)]  |             | 0="No"<br>1="Yes"                             |
| 01. Principal | <b>chklist_pre_eres_num</b>      | ERES Number - [Checklist (Pre-Registration)]   |             | Char  |
| 01. Principal | <b>chklist_pre_fail_prev_hcv</b> | Failure Of Previous HCV Therapies - [Checklist (Pre-Registration)]   |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_fibrosis</b>      | Documented Evidence Of Fibrosis Or Cirrhosis (Metavir 2, 3, And 4) And Subjects With Significant Extrahepatic Manifestations Of Hepatitis C - [Checklist (Pre-Registration)]   |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_hbv</b>           | Ongoing HBV Infection - [Checklist (Pre-Registration)]   |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_health_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"<br>.N="N/A"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>chklist_pre_hipaa_dt</b>      | Date Of Authorization - [Checklist (Pre-Registration)]   |             | SAS Date<br>.M="Missing"                      |
| 01. Principal | <b>chklist_pre_hiv</b>           | HIV Infection - [Checklist (Pre-Registration)]   |             | .M="Missing"<br>0="No"<br>1="Yes"             |

| Class         | Variable                          | Label   | Description | Format Text                                   |
|---------------|-----------------------------------|---|-------------|---|
| 01. Principal | <b>chklist_pre_hiv_prev_trt</b>   | Any Previous Treatment For HCV <=6 Months Prior To Registration - [Checklist (Pre-Registration)]  |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_icf_signed</b>     | Consent Form Signed And Dated - [Checklist (Pre-Registration)]  |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_implanted_dev</b>  | Pacemaker Or Other Implanted Device - [Checklist (Pre-Registration)]  |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_inform_preg</b>    | Should A Female Partner Of A Male Study Participant Become Pregnant While The Male Is Participant Is On Study, The Male Participant Should Inform His Study Physician Immediately. - [Checklist (Pre-Registration)] |             | .M="Missing"<br>.N="N/A"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>chklist_pre_malignancy</b>     | Active Malignancy. Exception: Non-Melanoma Skin Cancer(s) For Which Diagnosis And Treatment Was Completed >=3 Years Prior To Pre-Registration - [Checklist (Pre-Registration)]                                      |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_metal_implants</b> | Metal Implants On Same Limb As Intended Administration Site - [Checklist (Pre-Registration)]  |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_modified_dt</b>    | Date Modified - [Checklist (Pre-Registration)]  |             | SAS Date                                      |
| 01. Principal | <b>chklist_pre_organ_trans</b>    | History Of Major Organ Transplantation With An Existing Functional Graft - [Checklist (Pre-Registration)]   |             | .M="Missing"<br>0="No"<br>1="Yes"             |

| Class         | Variable                           | Label   | Description | Format Text                                   |
|---------------|------------------------------------|---|-------------|---|
| 01. Principal | <b>chklist_pre_oth_liver_dis</b>   | Other Known Causes Of Significant Liver Disease Including Chronic Or Acute Hepatitis B, Acute Hepatitis A, Hemochromatosis, Or Homozygote Alpha-1 Antitrypsin Deficiency - [Checklist (Pre-Registration)] |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_oth_unc_ill</b>     | Other Uncontrolled Immune-Compromising Illness - [Checklist (Pre-Registration)]   |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_pre_reg</b>         | Has The Participant Been Pre-Registered Previously To This Study? - [Checklist (Pre-Registration)]  |             | 0="No"<br>1="Yes"                             |
| 01. Principal | <b>chklist_pre_preg_women</b>      | Pregnant Or Nursing Women - [Checklist (Pre-Registration)]  |             | .M="Missing"<br>.N="N/A"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>chklist_pre_prev_id</b>         | If Yes: Prior Participant CPN ID Number - [Checklist (Pre-Registration)]  |             | Char  |
| 01. Principal | <b>chklist_pre_seizure</b>         | Documentation Of History Of Seizure Within Previous 5 Years - [Checklist (Pre-Registration)]  |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_study_num</b>       | Study ID - [Checklist (Pre-Registration)]   |             | Numeric                                       |
| 01. Principal | <b>chklist_pre_tattoo_scar</b>     | Tattoos, Scars, Active Lesions, Or Rashes <=2 cm Of The Intended Site Of Treatment - [Checklist (Pre-Registration)]   |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_unc_cur_ill</b>     | Uncontrolled Intercurrent Illness Including - [Checklist (Pre-Registration)]  |             | .M="Missing"<br>0="No"<br>1="Yes"             |
| 01. Principal | <b>chklist_pre_unreas_inc_risk</b> | Any Condition That, In The Clinical Judgment Of The Investigator, Would Place A Participant At Unreasonably Increased Risk - [Checklist (Pre-Registration)]   |             | .M="Missing"<br>0="No"<br>1="Yes"             |

| Class         | Variable                         | Label  | Description | Format Text                       |
|---------------|----------------------------------|--|-------------|-----------------------------------|
| 01. Principal | <b>chklist_pre_willing_blood</b> | Willingness To Provide Blood Samples For Research Tests Specified In The Protocol - [Checklist (Pre-Registration)] |             | .M="Missing"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>chklist_pre_willing_icf</b>   | Ability To Understand And Willingness To Sign A Written Informed Consent Document - [Checklist (Pre-Registration)] |             | .M="Missing"<br>0="No"<br>1="Yes" |

## Section 6: Pregnancy Test Results

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| Class         | Variable   | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>preg_res_coll_dt_v0-1/preg_res_coll_dt_v3/preg_res_coll_dt_v6/preg_res_coll_dt_v8</b>         | Pregnancy Test Specimen Collection Date - Visit # - [Pregnancy Test]" |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"   |
| 01. Principal | <b>preg_res_comments_v0-1/preg_res_comments_v3/preg_res_comments_v6/preg_res_comments_v8</b>     | Comments - Visit # - [Pregnancy Test]"                                |             | Char   |
| 01. Principal | <b>preg_res_result_v0-1/preg_res_result_v3/preg_res_result_v6/preg_res_result_v8</b>             | Pregnancy Test Result - Visit # - [Pregnancy Test]"                   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Negative"<br>2="Not Obtained"<br>9="Not Applicable, Not Female Of Childbearing Potential" |
| 01. Principal | <b>preg_res_spec_type_v0-1/preg_res_spec_type_v3/preg_res_spec_type_v6/preg_res_spec_type_v8</b> | Pregnancy Test Specimen Type - Visit # - [Pregnancy Test]"            |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>1="Serum"<br>2="Urine"   |

## Section 7: Medical/Surgical History

| Class         | Variable                       | Label  | Description | Format Text   |
|---------------|--------------------------------|--|-------------|---|
| 01. Principal | <b>medsurg_bodysys1-10</b>     | Body System/Site - # - [Medical/Surgical History]                  |             | .N="N/A"<br>.R="Not Randomized"<br>1="Abdomen"<br>2="Cardiovascular"<br>3="Dermatologic"<br>4="Endocrine/Metabolic"<br>5="Gastrointestinal"<br>6="Genitourinary"<br>7="HEENT"<br>8="Hematopoietic/Lymph Node(s)"<br>9="Musculoskeletal"<br>10="Neurologic"<br>11="Respiratory"<br>12="Pelvis"<br>13="Psychologic"<br>14="Other" |
| 01. Principal | <b>medsurg_bodysys_oth1-10</b> | Other (Body) System/Site Text - # - [Medical/Surgical History]     |             | Char  |
| 01. Principal | <b>medsurg_comments1-10</b>    | Surgery Comments - # - [Medical/Surgical History]                  |             | Char  |
| 01. Principal | <b>medsurg_description1-10</b> | Comments - # - [Medical/Surgical History]                          |             | Char  |
| 01. Principal | <b>medsurg_dt1-10</b>          | Medical History Date - # - [Medical/Surgical History]              |             | SAS Date<br>.N="N/A"<br>.R="Not Randomized"   |
| 01. Principal | <b>medsurg_dx_day1-10</b>      | Date Of Diagnosis/Surgery (Day) - # - [Medical/Surgical History]   |             | Numeric<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"  |
| 01. Principal | <b>medsurg_dx_dt1-10</b>       | Date Of Diagnosis/Surgery - # - [Medical/Surgical History]         |             | SAS Date<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"   |
| 01. Principal | <b>medsurg_dx_month1-10</b>    | Date Of Diagnosis/Surgery (Month) - # - [Medical/Surgical History] |             | Numeric<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"  |
| 01. Principal | <b>medsurg_dx_year1-10</b>     | Date Of Diagnosis/Surgery (Year) - # - [Medical/Surgical History]  |             | Numeric<br>.N="N/A"<br>.R="Not Randomized"  |

| Class         | Variable           | Label   | Description | Format Text                    |
|---------------|--------------------|---|-------------|--------------------------------|
| 01. Principal | <b>medsurg_num</b> | Total Number Of Observations - [Medical/Surgical History] |             | Numeric<br>.R="Not Randomized" |



## Section 8: Baseline Symptoms

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| Class         | Variable                      | Label  | Description | Format Text  |
|---------------|-------------------------------|--|-------------|--|
| 01. Principal | <b>symptoms_comments1-7</b>   | Comments - # -<br>[Baseline Symptoms]                            |             | Char   |
| 01. Principal | <b>symptoms_eval_dt1-7</b>    | Evaluation Date - # -<br>[Baseline Symptoms]                     |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                 |
| 01. Principal | <b>symptoms_grade1-7</b>      | Grade - # - [Baseline Symptoms]                                  |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                  |
| 01. Principal | <b>symptoms_num_of</b>        | Total Number Of Observations -<br>[Baseline Symptoms]            |             | Numeric<br>.F="No Record For This Visit"<br>.R="Not Randomized"                              |
| 01. Principal | <b>symptoms_onset_dt1-7</b>   | Onset Date - # -<br>[Baseline Symptoms]                          |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | <b>symptoms_onset_year1-7</b> | Onset Date (Year) - # -<br>[Baseline Symptoms]                   |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                  |
| 01. Principal | <b>symptoms_verbatim1-7</b>   | Symptom Description (Verbatim Term) - # -<br>[Baseline Symptoms] |             | Char   |

## Section 9: Physical Exam

| Class         | Variable   | Label  | Description | Format Text  |
|---------------|--|--|-------------|--|
| 01. Principal | <b>phyexam_abdomen_spec_v0/phyexam_abdomen_spec_v8</b>       | Abdomen Status, Specify - Visit # - [Physical Exam]                      |             | Char   |
| 01. Principal | <b>phyexam_abdomen_v0/phyexam_abdomen_v8</b>                 | Abdomen Status - Visit # - [Physical Exam]                               |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Not Examined"<br>1="Normal"<br>2="Abnormal" |
| 01. Principal | <b>phyexam_allergy_spec_v0/phyexam_allergy_spec_v8</b>       | Does Participant Have Any Allergies? Specify - Visit # - [Physical Exam] |             | Char   |
| 01. Principal | <b>phyexam_allergy_v0/phyexam_allergy_v8</b>                 | Does Participant Have Any Allergies? - Visit # - [Physical Exam]         |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"               |
| 01. Principal | <b>phyexam_appearance_spec_v0/phyexam_appearance_spec_v8</b> | Appearance Status, Specify - Visit # - [Physical Exam]                   |             | Char   |
| 01. Principal | <b>phyexam_appearance_v0/phyexam_appearance_v8</b>           | Appearance Status - Visit # - [Physical Exam]                            |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Not Examined"<br>1="Normal"<br>2="Abnormal" |
| 01. Principal | <b>phyexam_cardio_spec_v0/phyexam_cardio_spec_v8</b>         | Cardiovascular Status, Specify - Visit # - [Physical Exam]               |             | Char   |
| 01. Principal | <b>phyexam_cardio_v0/phyexam_cardio_v8</b>                   | Cardiovascular Status - Visit # - [Physical Exam]                        |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Not Examined"<br>1="Normal"<br>2="Abnormal" |
| 01. Principal | <b>phyexam_cerv_lymph_spec_v0/phyexam_cerv_lymph_spec_v8</b> | Cervical Lymph Node Status, Specify - Visit # - [Physical Exam]          |             | Char   |
| 01. Principal | <b>phyexam_cerv_lymph_v0/phyexam_cerv_lymph_v8</b>           | Cervical Lymph Node Status - Visit # - [Physical Exam]                   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Not Examined"<br>1="Normal"<br>2="Abnormal" |
| 01. Principal | <b>phyexam_comments_v0/phyexam_comments_v8</b>               | Comments - Visit # - [Physical Exam]                                     |             | Char   |

| Class         | Variable   | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>phyexam_diastolic_v0/phyexam_diastolic_v8</b>               | Diastolic Blood Pressure (mmHg) - Visit # - [Physical Exam]     |             | Numeric<br>.F="No Record For This Visit"<br>.R="Not Randomized"  |
| 01. Principal | <b>phyexam_dt_v0/phyexam_dt_v8</b>                             | Physical Exam Date - Visit # - [Physical Exam]                  |             | SAS Date<br>.F="No Record For This Visit"<br>.R="Not Randomized"                                       |
| 01. Principal | <b>phyexam_ecog_ps_v0/phyexam_ecog_ps_v8</b>                   | ECOG Performance Score - Visit # - [Physical Exam]              |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                        |
| 01. Principal | <b>phyexam_heent_spec_v0/phyexam_heent_spec_v8</b>             | HEENT Status, Specify - Visit # - [Physical Exam]               |             | Char   |
| 01. Principal | <b>phyexam_heent_v0/phyexam_heent_v8</b>                       | HEENT Status - Visit # - [Physical Exam]                        |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Not Examined"<br>1="Normal"<br>2="Abnormal" |
| 01. Principal | <b>phyexam_ing_lymph_spec_v0/phyexam_ing_lymph_spec_v8</b>     | Inguinal Lymph Node Status, Specify - Visit # - [Physical Exam] |             | Char   |
| 01. Principal | <b>phyexam_ing_lymph_v0/phyexam_ing_lymph_v8</b>               | Inguinal Lymph Node Status - Visit # - [Physical Exam]          |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Not Examined"<br>1="Normal"<br>2="Abnormal" |
| 01. Principal | <b>phyexam_musculoskel_spec_v0/phyexam_musculoskel_spec_v8</b> | Musculoskeletal Status, Specify - Visit # - [Physical Exam]     |             | Char   |
| 01. Principal | <b>phyexam_musculoskel_v0/phyexam_musculoskel_v8</b>           | Musculoskeletal Status - Visit # - [Physical Exam]              |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Not Examined"<br>1="Normal"<br>2="Abnormal" |
| 01. Principal | <b>phyexam_pulse_v0/phyexam_pulse_v8</b>                       | Pulse - Visit # - [Physical Exam]                               |             | Numeric<br>.F="No Record For This Visit"<br>.R="Not Randomized"  |
| 01. Principal | <b>phyexam_respiratory_spec_v0/phyexam_respiratory_spec_v8</b> | Respiratory Status, Specify - Visit # - [Physical Exam]         |             | Char   |
| 01. Principal | <b>phyexam_respiratory_v0/phyexam_respiratory_v8</b>           | Respiratory Status - Visit # - [Physical Exam]                  |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Not Examined"<br>1="Normal"<br>2="Abnormal" |
| 01. Principal | <b>phyexam_skin_spec_v0/phyexam_skin_spec_v8</b>               | Skin Status, Specify - Visit # - [Physical Exam]                |             | Char   |

| Class         | Variable   | Label  | Description | Format Text  |
|---------------|--|--|-------------|--|
| 01. Principal | <b>phyexam_skin_v0/phyexam_skin_v8</b>                 | Skin Status - Visit # - [Physical Exam]                    |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Not Examined"<br>1="Normal"<br>2="Abnormal" |
| 01. Principal | <b>phyexam_systolic_v0/phyexam_systolic_v8</b>         | Systolic Blood Pressure (mmHg) - Visit # - [Physical Exam] |             | Numeric<br>.F="No Record For This Visit"<br>.R="Not Randomized"  |
| 01. Principal | <b>phyexam_temp_v0/phyexam_temp_v8</b>                 | Temperature (C) - Visit # - [Physical Exam]                |             | Numeric<br>.F="No Record For This Visit"<br>.R="Not Randomized"  |
| 01. Principal | <b>phyexam_thyroid_spec_v0/phyexam_thyroid_spec_v8</b> | Thyroid Status, Specify - Visit # - [Physical Exam]        |             | Char   |
| 01. Principal | <b>phyexam_thyroid_v0/phyexam_thyroid_v8</b>           | Thyroid Status - Visit # - [Physical Exam]                 |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Not Examined"<br>1="Normal"<br>2="Abnormal" |

## Section 10: Device

| Class         | Variable                             | Label   | Description | Format Text   |
|---------------|--------------------------------------|---|-------------|---|
| 01. Principal | <b>device_array_lot_num_v1/3/6/8</b> | CELLECTRA Array Lot Numbers - Visit # - [Device]                                  |             | Char  |
| 01. Principal | <b>device_attempt_v1/3/6/8</b>       | Total Number Of Attempts - Visit # - [Device]                                     |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                           |
| 01. Principal | <b>device_comments_v1/3/6/8</b>      | Comments - Visit # - [Device]   |             | Char  |
| 01. Principal | <b>device_data_sent_dt_v1/3/6/8</b>  | Date That The Data File Was Sent - Visit # - [Device]                             |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"          |
| 01. Principal | <b>device_down_sent_v1/3/6/8</b>     | Was The CELLECTRA Device Data Downloaded And Sent To Inovio? - Visit # - [Device] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>device_dt_v1/3/6/8</b>            | Electroporation Date - Visit # - [Device]   |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>device_handle_num_v1/3/6/8</b>    | CELLECTRA Applicator Serial Number - Visit # - [Device]                           |             | Char  |
| 01. Principal | <b>device_num_arrays_v1/3/6/8</b>    | Number Of Arrays Used - Visit # - [Device]  |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"           |
| 01. Principal | <b>device_oth_error_v1/3/6/8</b>     | Were Any Other Errors Displayed That Were Not Reported - Visit # - [Device]       |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | <b>device_serial_num_v1/3/6/8</b>    | CELLECTRA Electroporation Unit Serial Number - Visit # - [Device]                 |             | Char  |

## Section 11: Device Check

| Class         | Variable                              | Label   | Description | Format Text   |
|---------------|---------------------------------------|---|-------------|---|
| 01. Principal | <b>devchk_attempt_v1/3/6/8</b>        | Attempt Number - Visit # - [Device Check]                                       |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"   |
| 01. Principal | <b>devchk_com_v1/3/6/8</b>            | Comments - Visit # - [Device Check]   |             | Char  |
| 01. Principal | <b>devchk_disp_success_v1/3/6/8</b>   | Did The Display On The Device Read EP Successful? - Visit # - [Device Check]    |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                                   |
| 01. Principal | <b>devchk_dt_v1/3/6/8</b>             | Electroporation Date - Visit # - [Device Check]                                 |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"  |
| 01. Principal | <b>devchk_ep_reason_v1/3/6/8</b>      | If Yes, Provide Reason (Including Participant's BMI) - Visit # - [Device Check] |             | Char  |
| 01. Principal | <b>devchk_ep_used_v1/3/6/8</b>        | IM-5P, Was The EP Guide Used - Visit # - [Device Check]                         |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                                   |
| 01. Principal | <b>devchk_inject_success_v1/3/6/8</b> | Was The Injection Successful - Visit # - [Device Check]                         |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                                   |
| 01. Principal | <b>devchk_loc_spec_v1/3/6/8</b>       | Other Location, Specify - Visit # - [Device Check]                              |             | Char  |
| 01. Principal | <b>devchk_loc_v1/3/6/8</b>            | Location Of Treatment/EP - Visit # - [Device Check]                             |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Left Arm"<br>2="Right Arm"<br>3="Other, Specify" |
| 01. Principal | <b>devchk_time_v1/3/6/8</b>           | Electroporation Time - Visit # - [Device Check]                                 |             | SAS Time<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"  |

## Section 12: Lab Research Blood Chemistry

| Class         | Variable  | Label   | Description | Format Text  |
|---------------|---|---|-------------|--|
| 01. Principal | <b>lrc_albumin_clin_sig_v0-3/lrc_albumin_clin_sig_v6/lrc_albumin_clin_sig_v8</b>    | Albumin: Clinically Significant - Visit # - [Lab Research Blood Chemistry]                  |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_albumin_lab_done_v0-3/lrc_albumin_lab_done_v6/lrc_albumin_lab_done_v8</b>    | Albumin: Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry]              |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_albumin_oor_v0-3/lrc_albumin_oor_v6/lrc_albumin_oor_v8</b>                   | Albumin: Out Of Range - Visit # - [Lab Research Blood Chemistry]                            |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_albumin_result_v0-3/lrc_albumin_result_v6/lrc_albumin_result_v8</b>          | Albumin: Result - Visit # - [Lab Research Blood Chemistry]                                  |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrc_albumin_units_v0-3/lrc_albumin_units_v6/lrc_albumin_units_v8</b>             | Albumin: Units - Visit # - [Lab Research Blood Chemistry]                                   |             | Char   |
| 01. Principal | <b>lrc_alk_phos_clin_sig_v0-3/lrc_alk_phos_clin_sig_v6/lrc_alk_phos_clin_sig_v8</b> | Alkaline Phosphatase: Clinically Significant - Visit # - [Lab Research Blood Chemistry]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_alk_phos_lab_done_v0-3/lrc_alk_phos_lab_done_v6/lrc_alk_phos_lab_done_v8</b> | Alkaline Phosphatase: Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_alk_phos_oor_v0-3/lrc_alk_phos_oor_v6/lrc_alk_phos_oor_v8</b>                | Alkaline Phosphatase: Out Of Range - Visit # - [Lab Research Blood Chemistry]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_alk_phos_result_v0-3/lrc_alk_phos_result_v6/lrc_alk_phos_result_v8</b>       | Alkaline Phosphatase: Result - Visit # - [Lab Research Blood Chemistry]                     |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |

| Class         | Variable   | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>lrc_alk_phos_units_v0-3/lrc_alk_phos_units_v6/lrc_alk_phos_units_v8</b> | Alkaline Phosphatase: Units - Visit # - [Lab Research Blood Chemistry]  |             | Char   |
| 01. Principal | <b>lrc_alt_clin_sig_v0-3/lrc_alt_clin_sig_v6/lrc_alt_clin_sig_v8</b>       | Alanine Aminotransferase (ALT Or SGPT): Clinically Significant - Visit # - [Lab Research Blood Chemistry]           |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_alt_lab_done_v0-3/lrc_alt_lab_done_v6/lrc_alt_lab_done_v8</b>       | Alanine Aminotransferase (ALT Or SGPT): Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry]       |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_alt_oor_v0-3/lrc_alt_oor_v6/lrc_alt_oor_v8</b>                      | Alanine Aminotransferase (ALT Or SGPT): Out Of Range - Visit # - [Lab Research Blood Chemistry]                     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_alt_result_v0-3/lrc_alt_result_v6/lrc_alt_result_v8</b>             | Alanine Aminotransferase (ALT Or SGPT): Result - Visit # - [Lab Research Blood Chemistry]                           |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrc_alt_units_v0-3/lrc_alt_units_v6/lrc_alt_units_v8</b>                | Alanine Aminotransferase (ALT Or SGPT): Units - Visit # - [Lab Research Blood Chemistry]                            |             | Char   |
| 01. Principal | <b>lrc_aptt_clin_sig_v0-3/lrc_aptt_clin_sig_v6/lrc_aptt_clin_sig_v8</b>    | Activated Partial Thromboplastin Time (APTT): Clinically Significant - Visit # - [Lab Research Blood Chemistry]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_aptt_lab_done_v0-3/lrc_aptt_lab_done_v6/lrc_aptt_lab_done_v8</b>    | Activated Partial Thromboplastin Time (APTT): Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_aptt_oor_v0-3/lrc_aptt_oor_v6/lrc_aptt_oor_v8</b>                   | Activated Partial Thromboplastin Time (APTT): Out Of Range - Visit # - [Lab Research Blood Chemistry]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_aptt_result_v0-3/lrc_aptt_result_v6/lrc_aptt_result_v8</b>          | Activated Partial Thromboplastin Time (APTT): Result - Visit # - [Lab Research Blood Chemistry]                     |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |



| Class         | Variable  | Label   | Description | Format Text  |
|---------------|---|---|-------------|--|
| 01. Principal | <b>lrc_aptt_units_v0-3/lrc_aptt_units_v6/lrc_aptt_units_v8</b>                | Activated Partial Thromboplastin Time (APTT): Units - Visit # - [Lab Research Blood Chemistry]                  |             | Char   |
| 01. Principal | <b>lrc_ast_clin_sig_v0-3/lrc_ast_clin_sig_v6/lrc_ast_clin_sig_v8</b>          | Aspartate Aminotransferase (AST Or SGOT): Clinically Significant - Visit # - [Lab Research Blood Chemistry]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_ast_lab_done_v0-3/lrc_ast_lab_done_v6/lrc_ast_lab_done_v8</b>          | Aspartate Aminotransferase (AST Or SGOT): Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_ast_oor_v0-3/lrc_ast_oor_v6/lrc_ast_oor_v8</b>                         | Aspartate Aminotransferase (AST Or SGOT): Out Of Range - Visit # - [Lab Research Blood Chemistry]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_ast_result_v0-3/lrc_ast_result_v6/lrc_ast_result_v8</b>                | Aspartate Aminotransferase (AST Or SGOT): Result - Visit # - [Lab Research Blood Chemistry]                     |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrc_ast_units_v0-3/lrc_ast_units_v6/lrc_ast_units_v8</b>                   | Aspartate Aminotransferase (AST Or SGOT): Units - Visit # - [Lab Research Blood Chemistry]                      |             | Char   |
| 01. Principal | <b>lrc_bicarb_clin_sig_v0-3/lrc_bicarb_clin_sig_v6/lrc_bicarb_clin_sig_v8</b> | Bicarbonate: Clinically Significant - Visit # - [Lab Research Blood Chemistry]                                  |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_bicarb_lab_done_v0-3/lrc_bicarb_lab_done_v6/lrc_bicarb_lab_done_v8</b> | Bicarbonate: Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry]                              |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_bicarb_oor_v0-3/lrc_bicarb_oor_v6/lrc_bicarb_oor_v8</b>                | Bicarbonate: Out Of Range - Visit # - [Lab Research Blood Chemistry]  |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_bicarb_result_v0-3/lrc_bicarb_result_v6/lrc_bicarb_result_v8</b>       | Bicarbonate: Result - Visit # - [Lab Research Blood Chemistry]  |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |

| Class         | Variable   | Label  | Description | Format Text  |
|---------------|--|--|-------------|--|
| 01. Principal | <b>Irc_bicarb_units_v0-3/Irc_bicarb_units_v6/Irc_bicarb_units_v8</b>                   | Bicarbonate: Units - Visit # - [Lab Research Blood Chemistry]                                    |             | Char   |
| 01. Principal | <b>Irc_bilirubin_clin_sig_v0-3/Irc_bilirubin_clin_sig_v6/Irc_bilirubin_clin_sig_v8</b> | Bilirubin Total: Clinically Significant - Visit # - [Lab Research Blood Chemistry]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>Irc_bilirubin_lab_done_v0-3/Irc_bilirubin_lab_done_v6/Irc_bilirubin_lab_done_v8</b> | Bilirubin Total: Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry]           |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>Irc_bilirubin_oor_v0-3/Irc_bilirubin_oor_v6/Irc_bilirubin_oor_v8</b>                | Bilirubin Total: Out Of Range - Visit # - [Lab Research Blood Chemistry]                         |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>Irc_bilirubin_result_v0-3/Irc_bilirubin_result_v6/Irc_bilirubin_result_v8</b>       | Bilirubin Total: Result - Visit # - [Lab Research Blood Chemistry]                               |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>Irc_bilirubin_units_v0-3/Irc_bilirubin_units_v6/Irc_bilirubin_units_v8</b>          | Bilirubin Total: Units - Visit # - [Lab Research Blood Chemistry]                                |             | Char   |
| 01. Principal | <b>Irc_bun_clin_sig_v0-3/Irc_bun_clin_sig_v6/Irc_bun_clin_sig_v8</b>                   | Blood Urea Nitrogen (BUN): Clinically Significant - Visit # - [Lab Research Blood Chemistry]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>Irc_bun_lab_done_v0-3/Irc_bun_lab_done_v6/Irc_bun_lab_done_v8</b>                   | Blood Urea Nitrogen (BUN): Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>Irc_bun_oor_v0-3/Irc_bun_oor_v6/Irc_bun_oor_v8</b>                                  | Blood Urea Nitrogen (BUN): Out Of Range - Visit # - [Lab Research Blood Chemistry]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>Irc_bun_result_v0-3/Irc_bun_result_v6/Irc_bun_result_v8</b>                         | Blood Urea Nitrogen (BUN): Result - Visit # - [Lab Research Blood Chemistry]                     |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>Irc_bun_units_v0-3/Irc_bun_units_v6/Irc_bun_units_v8</b>                            | Blood Urea Nitrogen (BUN): Units - Visit # - [Lab Research Blood Chemistry]                      |             | Char   |

| Class         | Variable  | Label   | Description | Format Text  |
|---------------|---|---|-------------|--|
| 01. Principal | <b>lrc_calcium_clin_sig_v0-3/lrc_calcium_clin_sig_v6/lrc_calcium_clin_sig_v8</b>    | Calcium: Clinically Significant - Visit # - [Lab Research Blood Chemistry]      |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_calcium_lab_done_v0-3/lrc_calcium_lab_done_v6/lrc_calcium_lab_done_v8</b>    | Calcium: Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry]  |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_calcium_oor_v0-3/lrc_calcium_oor_v6/lrc_calcium_oor_v8</b>                   | Calcium: Out Of Range - Visit # - [Lab Research Blood Chemistry]                |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_calcium_result_v0-3/lrc_calcium_result_v6/lrc_calcium_result_v8</b>          | Calcium: Result - Visit # - [Lab Research Blood Chemistry]                      |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrc_calcium_units_v0-3/lrc_calcium_units_v6/lrc_calcium_units_v8</b>             | Calcium: Units - Visit # - [Lab Research Blood Chemistry]                       |             | Char   |
| 01. Principal | <b>lrc_chloride_clin_sig_v0-3/lrc_chloride_clin_sig_v6/lrc_chloride_clin_sig_v8</b> | Chloride: Clinically Significant - Visit # - [Lab Research Blood Chemistry]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_chloride_lab_done_v0-3/lrc_chloride_lab_done_v6/lrc_chloride_lab_done_v8</b> | Chloride: Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_chloride_oor_v0-3/lrc_chloride_oor_v6/lrc_chloride_oor_v8</b>                | Chloride: Out Of Range - Visit # - [Lab Research Blood Chemistry]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_chloride_result_v0-3/lrc_chloride_result_v6/lrc_chloride_result_v8</b>       | Chloride: Result - Visit # - [Lab Research Blood Chemistry]                     |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrc_chloride_units_v0-3/lrc_chloride_units_v6/lrc_chloride_units_v8</b>          | Chloride: Units - Visit # - [Lab Research Blood Chemistry]                      |             | Char   |
| 01. Principal | <b>lrc_comments_v0-3/lrc_comments_v6/lrc_comments_v8</b>                            | Comments - Visit # - [Lab Research Blood Chemistry]                             |             | Char   |

| Class         | Variable  | Label   | Description | Format Text  |
|---------------|---|---|-------------|--|
| 01. Principal | <b>lrc_cpk_clin_sig_v0-3/lrc_cpk_clin_sig_v6/lrc_cpk_clin_sig_v8</b>                      | Creatine Phosphokinase (CPK): Clinically Significant - Visit # - [Lab Research Blood Chemistry]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_cpk_lab_done_v0-3/lrc_cpk_lab_done_v6/lrc_cpk_lab_done_v8</b>                      | Creatine Phosphokinase (CPK): Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_cpk_oor_v0-3/lrc_cpk_oor_v6/lrc_cpk_oor_v8</b>                                     | Creatine Phosphokinase (CPK): Out Of Range - Visit # - [Lab Research Blood Chemistry]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_cpk_result_v0-3/lrc_cpk_result_v6/lrc_cpk_result_v8</b>                            | Creatine Phosphokinase (CPK): Result - Visit # - [Lab Research Blood Chemistry]                     |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrc_cpk_units_v0-3/lrc_cpk_units_v6/lrc_cpk_units_v8</b>                               | Creatine Phosphokinase (CPK): Units - Visit # - [Lab Research Blood Chemistry]                      |             | Char   |
| 01. Principal | <b>lrc_creatinine_clin_sig_v0-3/lrc_creatinine_clin_sig_v6/lrc_creatinine_clin_sig_v8</b> | Creatinine: Clinically Significant - Visit # - [Lab Research Blood Chemistry]                       |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_creatinine_lab_done_v0-3/lrc_creatinine_lab_done_v6/lrc_creatinine_lab_done_v8</b> | Creatinine: Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry]                   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_creatinine_oor_v0-3/lrc_creatinine_oor_v6/lrc_creatinine_oor_v8</b>                | Creatinine: Out Of Range - Visit # - [Lab Research Blood Chemistry]                                 |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_creatinine_result_v0-3/lrc_creatinine_result_v6/lrc_creatinine_result_v8</b>       | Creatinine: Result - Visit # - [Lab Research Blood Chemistry]                                       |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrc_creatinine_units_v0-3/lrc_creatinine_units_v6/lrc_creatinine_units_v8</b>          | Creatinine: Units - Visit # - [Lab Research Blood Chemistry]  |             | Char   |

| Class         | Variable   | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>lrc_fasting_v0-3/lrc_fasting_v6/lrc_fasting_v8</b>                            | Fasting - Visit # - [Lab Research Blood Chemistry]  |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_glucose_clin_sig_v0-3/lrc_glucose_clin_sig_v6/lrc_glucose_clin_sig_v8</b> | Glucose: Clinically Significant - Visit # - [Lab Research Blood Chemistry]                                      |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"     |
| 01. Principal | <b>lrc_glucose_lab_done_v0-3/lrc_glucose_lab_done_v6/lrc_glucose_lab_done_v8</b> | Glucose: Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry]                                  |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"                 |
| 01. Principal | <b>lrc_glucose_oor_v0-3/lrc_glucose_oor_v6/lrc_glucose_oor_v8</b>                | Glucose: Out Of Range - Visit # - [Lab Research Blood Chemistry]  |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"     |
| 01. Principal | <b>lrc_glucose_result_v0-3/lrc_glucose_result_v6/lrc_glucose_result_v8</b>       | Glucose: Result - Visit # - [Lab Research Blood Chemistry]  |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                              |
| 01. Principal | <b>lrc_glucose_units_v0-3/lrc_glucose_units_v6/lrc_glucose_units_v8</b>          | Glucose: Units - Visit # - [Lab Research Blood Chemistry]   |             | Char   |
| 01. Principal | <b>lrc_inr_clin_sig_v0-3/lrc_inr_clin_sig_v6/lrc_inr_clin_sig_v8</b>             | International Normalization Ration (INR): Clinically Significant - Visit # - [Lab Research Blood Chemistry]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"     |
| 01. Principal | <b>lrc_inr_lab_done_v0-3/lrc_inr_lab_done_v6/lrc_inr_lab_done_v8</b>             | International Normalization Ration (INR): Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"                 |
| 01. Principal | <b>lrc_inr_oor_v0-3/lrc_inr_oor_v6/lrc_inr_oor_v8</b>                            | International Normalization Ration (INR): Out Of Range - Visit # - [Lab Research Blood Chemistry]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"     |
| 01. Principal | <b>lrc_inr_result_v0-3/lrc_inr_result_v6/lrc_inr_result_v8</b>                   | International Normalization Ration (INR): Result - Visit # - [Lab Research Blood Chemistry]                     |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                              |

| Class         | Variable   | Label  | Description | Format Text  |
|---------------|--|--|-------------|--|
| 01. Principal | <b>lrc_inr_units_v0-3/lrc_inr_units_v6/lrc_inr_units_v8</b>                      | International Normalization Ration (INR): Units - Visit # - [Lab Research Blood Chemistry] |             | Char   |
| 01. Principal | <b>lrc_lab_dt_v0-3/lrc_lab_dt_v6/lrc_lab_dt_v8</b>                               | Sample Collection Date - Visit # - [Lab Research Blood Chemistry]                          |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                     |
| 01. Principal | <b>lrc_na_clin_sig_v0-3/lrc_na_clin_sig_v6/lrc_na_clin_sig_v8</b>                | Sodium: Clinically Significant - Visit # - [Lab Research Blood Chemistry]                  |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_na_lab_done_v0-3/lrc_na_lab_done_v6/lrc_na_lab_done_v8</b>                | Sodium: Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry]              |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_na_oor_v0-3/lrc_na_oor_v6/lrc_na_oor_v8</b>                               | Sodium: Out Of Range - Visit # - [Lab Research Blood Chemistry]                            |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_na_result_v0-3/lrc_na_result_v6/lrc_na_result_v8</b>                      | Sodium: Result - Visit # - [Lab Research Blood Chemistry]                                  |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrc_na_units_v0-3/lrc_na_units_v6/lrc_na_units_v8</b>                         | Sodium: Units - Visit # - [Lab Research Blood Chemistry]                                   |             | Char   |
| 01. Principal | <b>lrc_protein_clin_sig_v0-3/lrc_protein_clin_sig_v6/lrc_protein_clin_sig_v8</b> | Total Protein: Clinically Significant - Visit # - [Lab Research Blood Chemistry]           |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_protein_lab_done_v0-3/lrc_protein_lab_done_v6/lrc_protein_lab_done_v8</b> | Total Protein: Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry]       |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_protein_oor_v0-3/lrc_protein_oor_v6/lrc_protein_oor_v8</b>                | Total Protein: Out Of Range - Visit # - [Lab Research Blood Chemistry]                     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_protein_result_v0-3/lrc_protein_result_v6/lrc_protein_result_v8</b>       | Total Protein: Result - Visit # - [Lab Research Blood Chemistry]                           |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |

| Class         | Variable  | Label   | Description | Format Text  |
|---------------|---|---|-------------|--|
| 01. Principal | <b>lrc_protein_units_v0-3/lrc_protein_units_v6/lrc_protein_units_v8</b>             | Total Protein: Units - Visit # - [Lab Research Blood Chemistry]                                     |             | Char   |
| 01. Principal | <b>lrc_pt_bld_clin_sig_v0-3/lrc_pt_bld_clin_sig_v6/lrc_pt_bld_clin_sig_v8</b>       | Prothrombin Time (PT): Clinically Significant - Visit # - [Lab Research Blood Chemistry]            |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_pt_bld_lab_done_v0-3/lrc_pt_bld_lab_done_v6/lrc_pt_bld_lab_done_v8</b>       | Prothrombin Time (PT): Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry]        |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_pt_bld_oor_v0-3/lrc_pt_bld_oor_v6/lrc_pt_bld_oor_v8</b>                      | Prothrombin Time (PT): Out Of Range - Visit # - [Lab Research Blood Chemistry]                      |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_pt_bld_result_v0-3/lrc_pt_bld_result_v6/lrc_pt_bld_result_v8</b>             | Prothrombin Time (PT): Result - Visit # - [Lab Research Blood Chemistry]                            |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrc_pt_bld_units_v0-3/lrc_pt_bld_units_v6/lrc_pt_bld_units_v8</b>                | Prothrombin Time (PT): Units - Visit # - [Lab Research Blood Chemistry]                             |             | Char   |
| 01. Principal | <b>lrc_stim_hrm_clin_sig_v0-3/lrc_stim_hrm_clin_sig_v6/lrc_stim_hrm_clin_sig_v8</b> | Follicle Stimulating Hormone: Clinically Significant - Visit # - [Lab Research Blood Chemistry]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_stim_hrm_lab_done_v0-3/lrc_stim_hrm_lab_done_v6/lrc_stim_hrm_lab_done_v8</b> | Follicle Stimulating Hormone: Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrc_stim_hrm_oor_v0-3/lrc_stim_hrm_oor_v6/lrc_stim_hrm_oor_v8</b>                | Follicle Stimulating Hormone: Out Of Range - Visit # - [Lab Research Blood Chemistry]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrc_stim_hrm_result_v0-3/lrc_stim_hrm_result_v6/lrc_stim_hrm_result_v8</b>       | Follicle Stimulating Hormone: Result - Visit # - [Lab Research Blood Chemistry]                     |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrc_stim_hrm_units_v0-3/lrc_stim_hrm_units_v6/lrc_stim_hrm_units_v8</b>          | Follicle Stimulating Hormone: Units - Visit # - [Lab Research Blood Chemistry]                      |             | Char   |

## Section 13: Lab Research Blood Hematology

| Class         | Variable   | Label  | Description | Format Text  |
|---------------|--|--|-------------|--|
| 01. Principal | <b>lrh_anc_clin_sig_v0-3/lrh_anc_clin_sig_v6/lrh_anc_clin_sig_v8</b>                   | Neutrophils (ANC): Clinically Significant - Visit # - [Lab Research Blood Hematology]    |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_anc_lab_done_v0-3/lrh_anc_lab_done_v6/lrh_anc_lab_done_v8</b>                   | Neutrophils (ANC): Was Lab Specimen Collected - Visit # - [Lab Research Blood Chemistry] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrh_anc_oor_v0-3/lrh_anc_oor_v6/lrh_anc_oor_v8</b>                                  | Neutrophils (ANC): Out Of Range - Visit # - [Lab Research Blood Hematology]              |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_anc_result_v0-3/lrh_anc_result_v6/lrh_anc_result_v8</b>                         | Neutrophils (ANC): Results - Visit # - [Lab Research Blood Hematology]                   |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrh_anc_units_v0-3/lrh_anc_units_v6/lrh_anc_units_v8</b>                            | Neutrophils (ANC): Units - Visit # - [Lab Research Blood Hematology]                     |             | Char   |
| 01. Principal | <b>lrh_basophils_clin_sig_v0-3/lrh_basophils_clin_sig_v6/lrh_basophils_clin_sig_v8</b> | Basophils: Clinically Significant - Visit # - [Lab Research Blood Hematology]            |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_basophils_lab_done_v0-3/lrh_basophils_lab_done_v6/lrh_basophils_lab_done_v8</b> | Basophils: Was Lab Specimen Collected - Visit # - [Lab Research Blood Hematology]        |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrh_basophils_oor_v0-3/lrh_basophils_oor_v6/lrh_basophils_oor_v8</b>                | Basophils: Out Of Range - Visit # - [Lab Research Blood Hematology]                      |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |



| Class         | Variable   | Label  | Description | Format Text  |
|---------------|--|--|-------------|--|
| 01. Principal | <b>lrh_basophils_result_v0-3/lrh_basophils_result_v6/lrh_basophils_result_v8</b>             | Basophils: Results - Visit # - [Lab Research Blood Hematology]                       |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrh_basophils_units_v0-3/lrh_basophils_units_v6/lrh_basophils_units_v8</b>                | Basophils: Units - Visit # - [Lab Research Blood Hematology]                         |             | Char   |
| 01. Principal | <b>lrh_comments_v0-3/lrh_comments_v6/lrh_comments_v8</b>                                     | Comments - Visit # - [Lab Research Blood Hematology]                                 |             | Char   |
| 01. Principal | <b>lrh_eosinophils_clin_sig_v0-3/lrh_eosinophils_clin_sig_v6/lrh_eosinophils_clin_sig_v8</b> | Eosinophils: Clinically Significant - Visit # - [Lab Research Blood Hematology]      |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_eosinophils_lab_done_v0-3/lrh_eosinophils_lab_done_v6/lrh_eosinophils_lab_done_v8</b> | Eosinophils: Was Lab Specimen Collected - Visit # - [Lab Research Blood Hematology]  |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrh_eosinophils_oor_v0-3/lrh_eosinophils_oor_v6/lrh_eosinophils_oor_v8</b>                | Eosinophils: Out Of Range - Visit # - [Lab Research Blood Hematology]                |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_eosinophils_result_v0-3/lrh_eosinophils_result_v6/lrh_eosinophils_result_v8</b>       | Eosinophils: Results - Visit # - [Lab Research Blood Hematology]                     |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrh_eosinophils_units_v0-3/lrh_eosinophils_units_v6/lrh_eosinophils_units_v8</b>          | Eosinophils: Units - Visit # - [Lab Research Blood Hematology]                       |             | Char   |
| 01. Principal | <b>lrh_hematocrit_clin_sig_v0-3/lrh_hematocrit_clin_sig_v6/lrh_hematocrit_clin_sig_v8</b>    | Hematocrit %: Clinically Significant - Visit # - [Lab Research Blood Hematology]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"                 |
| 01. Principal | <b>lrh_hematocrit_lab_done_v0-3/lrh_hematocrit_lab_done_v6/lrh_hematocrit_lab_done_v8</b>    | Hematocrit %: Was Lab Specimen Collected - Visit # - [Lab Research Blood Hematology] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"                             |

| Class         | Variable   | Label  | Description | Format Text  |
|---------------|--|--|-------------|--|
| 01. Principal | <b>Irh_hematocrit_oor_v0-3/Irh_hematocrit_oor_v6/Irh_hematocrit_oor_v8</b>                   | Hematocrit %: Out Of Range - Visit # - [Lab Research Blood Hematology]             |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"                 |
| 01. Principal | <b>Irh_hematocrit_result_v0-3/Irh_hematocrit_result_v6/Irh_hematocrit_result_v8</b>          | Hematocrit %: Results - Visit # - [Lab Research Blood Hematology]                  |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"  |
| 01. Principal | <b>Irh_hematocrit_units_v0-3/Irh_hematocrit_units_v6/Irh_hematocrit_units_v8</b>             | Hematocrit %: Units - Visit # - [Lab Research Blood Hematology]                    |             | Char   |
| 01. Principal | <b>Irh_hemoglobin_clin_sig_v0-3/Irh_hemoglobin_clin_sig_v6/Irh_hemoglobin_clin_sig_v8</b>    | Hemoglobin: Clinically Significant - Visit # - [Lab Research Blood Hematology]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"                 |
| 01. Principal | <b>Irh_hemoglobin_lab_done_v0-3/Irh_hemoglobin_lab_done_v6/Irh_hemoglobin_lab_done_v8</b>    | Hemoglobin: Was Lab Specimen Collected - Visit # - [Lab Research Blood Hematology] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"                             |
| 01. Principal | <b>Irh_hemoglobin_oor_v0-3/Irh_hemoglobin_oor_v6/Irh_hemoglobin_oor_v8</b>                   | Hemoglobin: Out Of Range - Visit # - [Lab Research Blood Hematology]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"                 |
| 01. Principal | <b>Irh_hemoglobin_result_v0-3/Irh_hemoglobin_result_v6/Irh_hemoglobin_result_v8</b>          | Hemoglobin: Results - Visit # - [Lab Research Blood Hematology]                    |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"  |
| 01. Principal | <b>Irh_hemoglobin_units_v0-3/Irh_hemoglobin_units_v6/Irh_hemoglobin_units_v8</b>             | Hemoglobin: Units - Visit # - [Lab Research Blood Hematology]                      |             | Char   |
| 01. Principal | <b>Irh_lab_dt_v0-3/Irh_lab_dt_v6/Irh_lab_dt_v8</b>   | Sample Collection Date - Visit # - [Lab Research Blood Hematology]                 |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                                     |
| 01. Principal | <b>Irh_lymphocytes_clin_sig_v0-3/Irh_lymphocytes_clin_sig_v6/Irh_lymphocytes_clin_sig_v8</b> | Lymphocytes: Clinically Significant - Visit # - [Lab Research Blood Hematology]    |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |

| Class         | Variable   | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>lrh_lymphocytes_lab_done_v0-3/lrh_lymphocytes_lab_done_v6/lrh_lymphocytes_lab_done_v8</b> | Lymphocytes: Was Lab Specimen Collected - Visit # - [Lab Research Blood Hematology] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrh_lymphocytes_oor_v0-3/lrh_lymphocytes_oor_v6/lrh_lymphocytes_oor_v8</b>                | Lymphocytes: Out Of Range - Visit # - [Lab Research Blood Hematology]               |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_lymphocytes_result_v0-3/lrh_lymphocytes_result_v6/lrh_lymphocytes_result_v8</b>       | Lymphocytes: Results - Visit # - [Lab Research Blood Hematology]                    |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrh_lymphocytes_units_v0-3/lrh_lymphocytes_units_v6/lrh_lymphocytes_units_v8</b>          | Lymphocytes: Units - Visit # - [Lab Research Blood Hematology]                      |             | Char   |
| 01. Principal | <b>lrh_monocytes_clin_sig_v0-3/lrh_monocytes_clin_sig_v6/lrh_monocytes_clin_sig_v8</b>       | Monocytes: Clinically Significant - Visit # - [Lab Research Blood Hematology]       |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_monocytes_lab_done_v0-3/lrh_monocytes_lab_done_v6/lrh_monocytes_lab_done_v8</b>       | Monocytes: Was Lab Specimen Collected - Visit # - [Lab Research Blood Hematology]   |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrh_monocytes_oor_v0-3/lrh_monocytes_oor_v6/lrh_monocytes_oor_v8</b>                      | Monocytes: Out Of Range - Visit # - [Lab Research Blood Hematology]                 |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_monocytes_result_v0-3/lrh_monocytes_result_v6/lrh_monocytes_result_v8</b>             | Monocytes: Results - Visit # - [Lab Research Blood Hematology]                      |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrh_monocytes_units_v0-3/lrh_monocytes_units_v6/lrh_monocytes_units_v8</b>                | Monocytes: Units - Visit # - [Lab Research Blood Hematology]                        |             | Char   |

| Class         | Variable   | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>lrh_platelets_clin_sig_v0-3/lrh_platelets_clin_sig_v6/lrh_platelets_clin_sig_v8</b> | Platelets: Clinically Significant - Visit # - [Lab Research Blood Hematology]                 |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_platelets_lab_done_v0-3/lrh_platelets_lab_done_v6/lrh_platelets_lab_done_v8</b> | Platelets: Was Lab Specimen Collected - Visit # - [Lab Research Blood Hematology]             |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrh_platelets_oor_v0-3/lrh_platelets_oor_v6/lrh_platelets_oor_v8</b>                | Platelets: Out Of Range - Visit # - [Lab Research Blood Hematology]                           |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_platelets_result_v0-3/lrh_platelets_result_v6/lrh_platelets_result_v8</b>       | Platelets: Results - Visit # - [Lab Research Blood Hematology]                                |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrh_platelets_units_v0-3/lrh_platelets_units_v6/lrh_platelets_units_v8</b>          | Platelets: Units - Visit # - [Lab Research Blood Hematology]                                  |             | Char   |
| 01. Principal | <b>lrh_rbc_clin_sig_v0-3/lrh_rbc_clin_sig_v6/lrh_rbc_clin_sig_v8</b>                   | Red Blood Cells (RBC): Clinically Significant - Visit # - [Lab Research Blood Hematology]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_rbc_lab_done_v0-3/lrh_rbc_lab_done_v6/lrh_rbc_lab_done_v8</b>                   | Red Blood Cells (RBC): Was Lab Specimen Collected - Visit # - [Lab Research Blood Hematology] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrh_rbc_oor_v0-3/lrh_rbc_oor_v6/lrh_rbc_oor_v8</b>                                  | Red Blood Cells (RBC): Out Of Range - Visit # - [Lab Research Blood Hematology]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_rbc_result_v0-3/lrh_rbc_result_v6/lrh_rbc_result_v8</b>                         | Red Blood Cells (RBC): Results - Visit # - [Lab Research Blood Hematology]                    |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrh_rbc_units_v0-3/lrh_rbc_units_v6/lrh_rbc_units_v8</b>                            | Red Blood Cells (RBC): Units - Visit # - [Lab Research Blood Hematology]                      |             | Char   |

| Class         | Variable   | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>lrh_wbc_clin_sig_v0-3/lrh_wbc_clin_sig_v6/lrh_wbc_clin_sig_v8</b> | White Blood Cells (WBC): Clinically Significant - Visit # - [Lab Research Blood Hematology]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_wbc_lab_done_v0-3/lrh_wbc_lab_done_v6/lrh_wbc_lab_done_v8</b> | White Blood Cells (WBC): Was Lab Specimen Collected - Visit # - [Lab Research Blood Hematology] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrh_wbc_oor_v0-3/lrh_wbc_oor_v6/lrh_wbc_oor_v8</b>                | White Blood Cells (WBC): Out Of Range - Visit # - [Lab Research Blood Hematology]               |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrh_wbc_result_v0-3/lrh_wbc_result_v6/lrh_wbc_result_v8</b>       | White Blood Cells (WBC): Results - Visit # - [Lab Research Blood Hematology]                    |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrh_wbc_units_v0-3/lrh_wbc_units_v6/lrh_wbc_units_v8</b>          | White Blood Cells (WBC): Units - Visit # - [Lab Research Blood Hematology]                      |             | Char   |

## Section 14: Lab Research Blood HCV RNA

| Class         | Variable   | Label  | Description | Format Text  |
|---------------|--|--|-------------|--|
| 01. Principal | <b>lrhcv_clin_sig_v0-1/lrhcv_clin_sig_v3/lrhcv_clin_sig_v6/lrhcv_clin_sig_v8-9</b> | Hepatitis C: Clinically Significant - Visit # - [Lab Research HCV RNA] |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lrhcv_coll_dt_v0-1/lrhcv_coll_dt_v3/lrhcv_coll_dt_v6/lrhcv_coll_dt_v8-9</b>     | Hepatitis C: Sample Collection Date - Visit # - [Lab Research HCV RNA] |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                     |
| 01. Principal | <b>lrhcv_comments_v0-1/lrhcv_comments_v3/lrhcv_comments_v6/lrhcv_comments_v8-9</b> | Hepatitis C: Comments - Visit # - [Lab Research HCV RNA]               |             | Char   |
| 01. Principal | <b>lrhcv_lab_done_v0-1/lrhcv_lab_done_v3/lrhcv_lab_done_v6/lrhcv_lab_done_v8-9</b> | Hepatitis C: Lab Done - Visit # - [Lab Research HCV RNA]               |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"             |
| 01. Principal | <b>lrhcv_oor_v0-1/lrhcv_oor_v3/lrhcv_oor_v6/lrhcv_oor_v8-9</b>                     | Hepatitis C: Out Of Range - Visit # - [Lab Research HCV RNA]           |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |
| 01. Principal | <b>lrhcv_result_v0-1/lrhcv_result_v3/lrhcv_result_v6/lrhcv_result_v8-9</b>         | Hepatitis C: Result (IU/L) - Visit # - [Lab Research HCV RNA]          |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                          |

## Section 15: Lab Research Blood Other Tests

| Class         | Variable                                | Label   | Description | Format Text  |
|---------------|---|---|-------------|--|
| 01. Principal | <b>lroth_alpha_1_clin_sig_v2</b>        | Alpha-1 Fetoprotein: Clinically Significant - Visit 2 (Week 2) - [Lab Research Other Tests]               |             | .N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"                                      |
| 01. Principal | <b>lroth_alpha_1_coll_dt_v2</b>         | Alpha-1 Fetoprotein: Sample Collection Date - Visit 2 (Week 2) - [Lab Research Other Tests]               |             | SAS Date<br>.R="Not Randomized"  |
| 01. Principal | <b>lroth_alpha_1_lab_done_v2</b>        | Alpha-1 Fetoprotein: Was Lab Specimen Collected - Visit 2 (Week 2) - [Lab Research Other Tests]           |             | .R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"  |
| 01. Principal | <b>lroth_alpha_1_out_of_range_v2</b>    | Alpha-1 Fetoprotein: Out Of Range - Visit 2 (Week 2) - [Lab Research Other Tests]                         |             | .N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"                                      |
| 01. Principal | <b>lroth_alpha_1_results_v2</b>         | Alpha-1 Fetoprotein: Results - Visit 2 (Week 2) - [Lab Research Other Tests]                              |             | Numeric<br>.N="N/A"<br>.R="Not Randomized"   |
| 01. Principal | <b>lroth_alpha_1_units_v2</b>           | Alpha-1 Fetoprotein: Units - Visit 2 (Week 2) - [Lab Research Other Tests]                                |             | Char   |
| 01. Principal | <b>lroth_comments_v2</b>                | Comments - Visit 2 (Week 2) - [Lab Research Other Tests]  |             | Char   |
| 01. Principal | <b>lroth_hep_b_v2</b>                   | Hepatitis B Surface Antigen, Serum - Visit 2 (Week 2) - [Lab Research Other Tests]                        |             | .R="Not Randomized"<br>0="Negative"<br>9="Not Done"  |
| 01. Principal | <b>lroth_hep_c_genotype_clin_sig_v2</b> | Hepatitis C Virus Genotype (HCVG): Clinically Significant - Visit 2 (Week 2) - [Lab Research Other Tests] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>lroth_hep_c_genotype_coll_dt_v2</b>  | Hepatitis C Virus Genotype (HCVG): Sample Collection Date - Visit 2 (Week 2) - [Lab Research Other Tests] |             | SAS Date<br>.F="No Record For This Visit"<br>.R="Not Randomized"   |

| Class         | Variable                             | Label  | Description | Format Text   |
|---------------|--------------------------------------|--|-------------|---|
| 01. Principal | <b>Iroth_hep_c_gen_o_lab_done_v2</b> | Hepatitis C Virus Genotype (HCVG): Was Lab Specimen Collected - Visit 2 (Week 2) - [Lab Research Other Tests]  |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"      |
| 01. Principal | <b>Iroth_hep_c_gen_o_oor_v2</b>      | Hepatitis C Virus Genotype (HCVG): Out Of Range - Visit 2 (Week 2) - [Lab Research Other Tests]                |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"      |
| 01. Principal | <b>Iroth_hep_c_gen_o_result_v2</b>   | Hepatitis C Virus Genotype (HCVG): Results - Visit 2 (Week 2) - [Lab Research Other Tests]                     |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                               |
| 01. Principal | <b>Iroth_hep_c_gen_o_units_v2</b>    | Hepatitis C Virus Genotype (HCVG): Units - Visit 2 (Week 2) - [Lab Research Other Tests]                       |             | Char  |
| 01. Principal | <b>Iroth_hep_c_gen_otype_v2</b>      | Hepatitis C Virus Genotype (HCVG) - Visit 2 (Week 2) - [Lab Research Other Tests]                              |             | .M="Missing"<br>.R="Not Randomized"<br>0="Not Detected"<br>1="1"<br>2="1a"<br>3="1b"<br>4="2"<br>9="Not Done" |
| 01. Principal | <b>Iroth_hep_c_rna_clin_sig_v2</b>   | Hepatitis C Virus RNA Quantitative: Clinically Significant - Visit 2 (Week 2) - [Lab Research Other Tests]     |             | .N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"   |
| 01. Principal | <b>Iroth_hep_c_rna_coll_dt_v2</b>    | Hepatitis C Virus RNA Quantitative: Sample Collection Date - Visit 2 (Week 2) - [Lab Research Other Tests]     |             | SAS Date<br>.R="Not Randomized"   |
| 01. Principal | <b>Iroth_hep_c_rna_lab_done_v2</b>   | Hepatitis C Virus RNA Quantitative: Was Lab Specimen Collected - Visit 2 (Week 2) - [Lab Research Other Tests] |             | .R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"   |
| 01. Principal | <b>Iroth_hep_c_rna_oor_v2</b>        | Hepatitis C Virus RNA Quantitative: Out Of Range - Visit 2 (Week 2) - [Lab Research Other Tests]               |             | .N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"   |
| 01. Principal | <b>Iroth_hep_c_rna_result_v2</b>     | Hepatitis C Virus RNA Quantitative: Results - Visit 2 (Week 2) - [Lab Research Other Tests]                    |             | Numeric<br>.N="N/A"<br>.R="Not Randomized"  |



| Class         | Variable                        | Label   | Description | Format Text   |
|---------------|---------------------------------|---|-------------|---|
| 01. Principal | <b>Iroth_hep_c_rna_units_v2</b> | Hepatitis C Virus RNA Quantitative: Units - Visit 2 (Week 2) - [Lab Research Other Tests] |             | Char  |
| 01. Principal | <b>Iroth_hiv_v2</b>             | HIV Screen - Visit 2 (Week 2) - [Lab Research Other Tests]                                |             | .R="Not Randomized"<br>0="Negative"<br>9="Not Done" |

## Section 16: Concomitant Medications

| Class         | Variable                          | Label   | Description | Format Text  |
|---------------|-----------------------------------|---|-------------|--|
| 01. Principal | <b>conmed_comments1-21</b>        | Comments - # -<br>[Concomitant Medications]   |             | Char   |
| 01. Principal | <b>conmed_continuing1-21</b>      | Continuing - # -<br>[Concomitant Medications]   |             | .M="Missing"<br>.N="N/A"<br>0="No"<br>1="Yes"<br>2="Uncertain" |
| 01. Principal | <b>conmed_dose1-21</b>            | Dose - # - [Concomitant Medications]  |             | Numeric<br>.N="N/A"  |
| 01. Principal | <b>conmed_freq1-21</b>            | Frequency - # -<br>[Concomitant Medications]  |             | Char   |
| 01. Principal | <b>conmed_freq_spec1-21</b>       | Frequency (Specify) - # -<br>[Concomitant Medications]                                    |             | Char   |
| 01. Principal | <b>conmed_has1-21</b>             | Is The Participant Taking Any Concomitant Medications? - # -<br>[Concomitant Medications] |             | .N="N/A"<br>0="No"<br>1="Yes"<br>2="Uncertain"                 |
| 01. Principal | <b>conmed_indication1-21</b>      | Indication - # -<br>[Concomitant Medications]   |             | Char   |
| 01. Principal | <b>conmed_indication_spec1-21</b> | Indication (Specify) - # -<br>[Concomitant Medications]                                   |             | Char   |
| 01. Principal | <b>conmed_name1-21</b>            | Name - # -<br>[Concomitant Medications]   |             | Char   |
| 01. Principal | <b>conmed_num</b>                 | Total Number Of Observations -<br>[Concomitant Medications]                               |             | Numeric  |
| 01. Principal | <b>conmed_start_dt1-21</b>        | Start Date - # -<br>[Concomitant Medications]   |             | SAS Date<br>.M="Missing"<br>.N="N/A"                           |
| 01. Principal | <b>conmed_start_month1-21</b>     | Start Date (Month) - # -<br>[Concomitant Medications]                                     |             | Numeric<br>.M="Missing"<br>.N="N/A"                            |
| 01. Principal | <b>conmed_start_year1-21</b>      | Start Date (Year) - # -<br>[Concomitant Medications]                                      |             | Numeric<br>.M="Missing"<br>.N="N/A"                            |
| 01. Principal | <b>conmed_stop_dt1-21</b>         | Stop Date - # -<br>[Concomitant Medications]  |             | SAS Date<br>.M="Missing"<br>.N="N/A"                           |

| Class         | Variable                           | Label                                 | Description | Format Text |
|---------------|------------------------------------|---------------------------------------|-------------|-------------|
| 01. Principal | <b>conmed_units1-2</b><br><b>1</b> | Units - # - [Concomitant Medications] |             | Char        |

## Section 17: Checklist (Registration)

| Class         | Variable                          | Label   | Description | Format Text   |
|---------------|-----------------------------------|---|-------------|---|
| 01. Principal | <b>chklist_reg_afp_norm</b>       | Alpha Feto Protein (AFP) Levels Within Normal Institutional Limits Or Judged To Be Not Clinically Significant By The Investigator. - [Checklist (Registration)] |             | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"   |
| 01. Principal | <b>chklist_reg_antic_start_dt</b> | Anticipated Start Date Of First Treatment - [Checklist (Registration)]  |             | SAS Date<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>chklist_reg_cpn</b>            | Intervention Must Take Place At A CPN Member Institution Under The Supervision Of A CPN Physician - [Checklist (Registration)]                                  |             | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"   |
| 01. Principal | <b>chklist_reg_date_mod</b>       | Date Modified - [Checklist (Registration)]  |             | SAS Date<br>.R="Not Randomized"   |
| 01. Principal | <b>chklist_reg_dose_lvl</b>       | Dose Level - [Checklist (Registration)]   |             | .M="Missing"<br>.R="Not Randomized"<br>0="INO-8000"<br>1="INO-8000 + INO-9012 (0.3 mg)"<br>2="INO-8000 + INO-9012 (1 mg)"<br>3="INO-8000 + INO-9012 (3 mg)" |
| 01. Principal | <b>chklist_reg_ecog_stat</b>      | ECOG Performance Status 0 Or 1 - [Checklist (Registration)]   |             | .R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"   |
| 01. Principal | <b>chklist_reg_eligible</b>       | Is The Participant Eligible For Inclusion On This Study? - [Checklist (Registration)]   |             | .R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"   |
| 01. Principal | <b>chklist_reg_enroll_dt</b>      | Enrollment Date - [Checklist (Registration)]  |             | SAS Date<br>.R="Not Randomized"   |
| 01. Principal | <b>chklist_reg_group</b>          | Group - [Checklist (Registration)]  |             | .R="Not Randomized"<br>1="Dose Escalation Cohort"<br>2="Expansion Cohort"   |
| 01. Principal | <b>chklist_reg_hcv_geno_1</b>     | Screening HCV Genotype, Demonstrating Genotype 1 - [Checklist (Registration)]   |             | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"   |

| Class         | Variable                         | Label  | Description | Format Text   |
|---------------|----------------------------------|--|-------------|---|
| 01. Principal | <b>chklist_reg_hepc_lvl</b>      | HCV RNA Level At Baseline 1=Less Than 800,000 IU/mL<br>2=Greater Than Or Equal To 800,000 IU/mL - [Checklist (Registration)]   |             | .M="Missing"<br>.R="Not Randomized"<br>1="< 800,000 IU/mL"<br>2=">= 800,000 IU/mL"  |
| 01. Principal | <b>chklist_reg_hist_allergy</b>  | History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To INO-8000 And INO-9012 - [Checklist (Registration)]                  |             | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"   |
| 01. Principal | <b>chklist_reg_hrt_rhythm</b>    | 12-Lead ECG Showing Normal Heart Rhythm. If There Are Abnormalities, Then The Abnormalities Must Be Judged To Be Not Clinically Significant - [Checklist (Registration)] |             | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"   |
| 01. Principal | <b>chklist_reg_inter_reg</b>     | Intervention Cannot Begin Prior To Registration And Must Begin <=14 Days After Registration - [Checklist (Registration)]   |             | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"   |
| 01. Principal | <b>chklist_reg_lab_norm</b>      | Screening Laboratory Values Within Institutional Normal Range Or Judged To Be Not Clinically - [Checklist (Registration)]  |             | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"   |
| 01. Principal | <b>chklist_reg_oth_inv_agent</b> | Receiving Any Other Investigational Agents <=6 Months Prior To Registration - [Checklist (Registration)]   |             | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"   |
| 01. Principal | <b>chklist_reg_tac</b>           | TAC/TAD Code - [Checklist (Registration)]  |             | .R="Not Randomized"<br>1="TAC1 (INO-8000: 6 mg IM on Day 0 and at Weeks 4, 12 and 24)"<br>2="TAC2 (INO-8000: 6 mg IM + INO-9012: 0.3 mg IM on Day 0, and at Weeks 4, 12 and 24)"<br>3="TAC3 (INO-8000: 6 mg IM + INO-9012: 1 mg IM on Day 0, and at Weeks 4, 12 and 24)"<br>4="TAC4 (INO-8000: 6 mg IM + INO-9012: 3 mg IM on Day 0 and at Weeks 4, 12 and 24)" |
| 01. Principal | <b>chklist_var_hcv_rna_lvl</b>   | Serum Or Plasma HCV RNA Level >=10,000 IU/mL - [Checklist (Registration)]  |             | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"   |

## Section 18: Participant Status Baseline

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| Class         | Variable                           | Label  | Description | Format Text   |
|---------------|------------------------------------|--|-------------|---|
| 01. Principal | <b>event_bsl_ae_rep</b>            | Were Adverse Events Assessed During This Reporting Period? - [Participant Status]                |             | 0="No"<br>1="Yes, and reportable adverse events occurred"<br>2="Yes, but no reportable adverse events occurred" |
| 01. Principal | <b>event_bsl_contact_dt</b>        | Contact Date - [Participant Status]  |             | SAS Date<br>.M="Missing"  |
| 01. Principal | <b>event_bsl_part_cont</b>         | Will The Participant Continue To The Next Visit? - [Participant Status]                          |             | 0="No"<br>1="Yes"<br>2="Uncertain"  |
| 01. Principal | <b>event_bsl_part_vital_stat</b>   | Participant Vital Status - [Participant Status]  |             | Numeric<br>.M="Missing"   |
| 01. Principal | <b>event_bsl_phys_exam</b>         | Was The Overall Physical Exam Performed? - [Participant Status]                                  |             | 0="No"<br>1="Yes"<br>2="Uncertain"  |
| 01. Principal | <b>event_bsl_pre_int_sympt</b>     | Were There Any Pre-Intervention Symptoms? - [Participant Status]                                 |             | 0="No"<br>1="Yes"<br>2="Uncertain"  |
| 01. Principal | <b>event_bsl_relevant_med_hist</b> | Did The Participant Have Any Relevant Medical/Surgical History To Report? - [Participant Status] |             | 0="No"<br>1="Yes"<br>2="Uncertain"  |

## Section 19: Subject Enrollment

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| Class         | Variable                          | Label  | Description | Format Text  |
|---------------|-----------------------------------|--|-------------|--|
| 01. Principal | <b>subj_curr_site</b>             | Current Site CTEP ID -<br>[Subject Enrollment]   |             | Char   |
| 01. Principal | <b>subj_enroll_dt</b>             | Enrollment Date -<br>[Subject Enrollment]        |             | SAS Date   |
| 01. Principal | <b>subj_enroll_reg_membership</b> | Registering Membership - [Subject Enrollment]    |             | 1="Mayo Clinic"<br>2="Mayo Clinic In Florida"<br>3="Temple University Hospital"<br>4="University Of Puerto Rico" |
| 01. Principal | <b>subj_enroll_site</b>           | Enrolling Site CTEP ID -<br>[Subject Enrollment] |             | Char   |
| 01. Principal | <b>subj_enroll_source_app</b>     | Source Application -<br>[Subject Enrollment]     |             | 1="Remote Registration"  |
| 01. Principal | <b>subj_enroll_time</b>           | Enrollment Time -<br>[Subject Enrollment]        |             | SAS Time   |

## Section 21: Intervention Administration

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| Class         | Variable                       | Label  | Description | Format Text              |
|---------------|--------------------------------|--|-------------|--------------------------|
| 01. Principal | <b>intadmin_agent_end_dt</b>   | Date Agent Stopped -<br>[Intervention<br>Administration] |             | SAS Date<br>.M="Missing" |
| 01. Principal | <b>intadmin_agent_start_dt</b> | Date Agent Started -<br>[Intervention<br>Administration] |             | SAS Date<br>.M="Missing" |



## Section 22: Treatment Assignment

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| Class         | Variable                      | Label   | Description | Format Text   |
|---------------|-------------------------------|---|-------------|---|
| 01. Principal | <b>trt_assign_arm1-2</b>      | Treatment Arm - # -<br>[Treatment Assignment]                             |             | .N="N/A"<br>1="Dose Escalation"<br>2="INO-8000"<br>3="INO-8000 + INO-9012 (0.3 mg)"<br>4="INO-8000 + INO-9012 (1 mg)"<br>5="INO-8000 + INO-9012 (3 mg)" |
| 01. Principal | <b>trt_assign_dt1-2</b>       | Date Of Intervention/Treatment Assignment - # -<br>[Treatment Assignment] |             | SAS Date<br>.N="N/A"  |
| 01. Principal | <b>trt_assign_step_num1-2</b> | Registration Step - # -<br>[Treatment Assignment]                         |             | .N="N/A"<br>0="Pre-Registration"<br>1="Registration"  |
| 01. Principal | <b>trt_assign_time1-2</b>     | Event Time - # -<br>[Treatment Assignment]                                |             | SAS Time<br>.N="N/A"  |

## Section 23: Specimen Collection (Blood)

| Class         | Variable   | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>specbld_hcv_col_v0/1/3/6/8/9</b>              | Quantitative HCV RNA: Was Specimen Collected? - Visit # - [Specimen Collection (Blood)]       |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"  |
| 01. Principal | <b>specbld_hcv_comments_v0/1/3/6/8/9</b>         | Quantitative HCV RNA: Comments - Visit # - [Specimen Collection (Blood)]                      |             | Char   |
| 01. Principal | <b>specbld_hcv_container_v0/1/3/6/8/9</b>        | Quantitative HCV RNA: Container Or Additive - Visit # - [Specimen Collection (Blood)]         |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="ACD Tube Yellow Topped"<br>2="EDTA Lavender Topped"<br>3="Serum SST"  |
| 01. Principal | <b>specbld_hcv_not_col_rsn_spec_v0/1/3/6/8/9</b> | Quantitative HCV RNA: Not Collected Reason, Specify - Visit # - [Specimen Collection (Blood)] |             | Char   |
| 01. Principal | <b>specbld_hcv_not_col_rsn_v0/1/3/6/8/9</b>      | Quantitative HCV RNA: Not Collected Reason - Visit # - [Specimen Collection (Blood)]          |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sample Not Required"<br>2="Patient Unable To Submit Sample"<br>3="Patient Did Not Keep Appointment"<br>4="Intercurrent Illness"<br>5="Institution Error"<br>6="Other" |
| 01. Principal | <b>specbld_hcv_num_spec_col_v0/1/3/6/8/9</b>     | Quantitative HCV RNA: Number Of Specimens Collected - Visit # - [Specimen Collection (Blood)] |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"  |
| 01. Principal | <b>specbld_hcv_spec_col_dt_v0/1/3/6/8/9</b>      | Quantitative HCV RNA: Date Specimen Collected - Visit # - [Specimen Collection (Blood)]       |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>specbld_hcv_spec_ship_dt_v0/1/3/6/8/9</b>     | Quantitative HCV RNA: Date Specimen Shipped - Visit # - [Specimen Collection (Blood)]         |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |

| Class         | Variable   | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>specbld_hcv_stored_con_spec_v0/1/3/6/8/9</b>  | Quantitative HCV RNA: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored?, Specify - Visit # - [Specimen Collection (Blood)] |             | Char   |
| 01. Principal | <b>specbld_hcv_stored_con_v0/1/3/6/8/9</b>       | Quantitative HCV RNA: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? - Visit # - [Specimen Collection (Blood)]          |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sored Per Protocol"<br>2="Not Applicable"   |
| 01. Principal | <b>specbld_hla_col_v0/1/3/6/8/9</b>              | HLA Typing 6mL: Was Specimen Collected? - Visit # - [Specimen Collection (Blood)]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"  |
| 01. Principal | <b>specbld_hla_comments_v0/1/3/6/8/9</b>         | HLA Typing 6mL: Comments - Visit # - [Specimen Collection (Blood)]  |             | Char   |
| 01. Principal | <b>specbld_hla_container_v0/1/3/6/8/9</b>        | HLA Typing 6mL: Container Or Additive - Visit # - [Specimen Collection (Blood)]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="ACD Tube Yellow Topped"<br>2="EDTA Lavender Topped"<br>3="Serum SST"  |
| 01. Principal | <b>specbld_hla_not_col_rsn_spec_v0/1/3/6/8/9</b> | HLA Typing 6mL: Not Collected Reason, Specify - Visit # - [Specimen Collection (Blood)]   |             | Char   |
| 01. Principal | <b>specbld_hla_not_col_rsn_v0/1/3/6/8/9</b>      | HLA Typing 6mL: Not Collected Reason - Visit # - [Specimen Collection (Blood)]  |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sample Not Required"<br>2="Patient Unable To Submit Sample"<br>3="Patient Did Not Keep Appointment"<br>4="Intercurrent Illness"<br>5="Institution Error"<br>6="Other" |
| 01. Principal | <b>specbld_hla_num_spec_col_v0/1/3/6/8/9</b>     | HLA Typing 6mL: Number Of Specimens Collected - Visit # - [Specimen Collection (Blood)]   |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"  |
| 01. Principal | <b>specbld_hla_spec_col_dt_v0/1/3/6/8/9</b>      | HLA Typing 6mL: Date Specimen Collected - Visit # - [Specimen Collection (Blood)]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |

| Class         | Variable   | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>specbld_hla_spec_ship_dt_v0/1/3/6/8/9</b>     | HLA Typing 6mL: Date Specimen Shipped - Visit # - [Specimen Collection (Blood)]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>specbld_hla_stored_con_spec_v0/1/3/6/8/9</b>  | HLA Typing 6mL: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored?, Specify - Visit # - [Specimen Collection (Blood)] |             | Char   |
| 01. Principal | <b>specbld_hla_stored_con_v0/1/3/6/8/9</b>       | HLA Typing 6mL: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? - Visit # - [Specimen Collection (Blood)]          |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sored Per Protocol"<br>2="Not Applicable"   |
| 01. Principal | <b>specbld_ia1_col_v0/1/3/6/8/9</b>              | Immune Assays 10mL: Was Specimen Collected? - Visit # - [Specimen Collection (Blood)]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"  |
| 01. Principal | <b>specbld_ia1_comments_v0/1/3/6/8/9</b>         | Immune Assays 10mL: Comments - Visit # - [Specimen Collection (Blood)]  |             | Char   |
| 01. Principal | <b>specbld_ia1_container_v0/1/3/6/8/9</b>        | Immune Assays 10mL: Container Or Additive - Visit # - [Specimen Collection (Blood)]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="ACD Tube Yellow Topped"<br>2="EDTA Lavender Topped"<br>3="Serum SST"  |
| 01. Principal | <b>specbld_ia1_not_col_rsn_spec_v0/1/3/6/8/9</b> | Immune Assays 10mL: Not Collected Reason, Specify - Visit # - [Specimen Collection (Blood)]   |             | Char   |
| 01. Principal | <b>specbld_ia1_not_col_rsn_v0/1/3/6/8/9</b>      | Immune Assays 10mL: Not Collected Reason - Visit # - [Specimen Collection (Blood)]  |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sample Not Required"<br>2="Patient Unable To Submit Sample"<br>3="Patient Did Not Keep Appointment"<br>4="Intercurrent Illness"<br>5="Institution Error"<br>6="Other" |
| 01. Principal | <b>specbld_ia1_num_spec_col_v0/1/3/6/8/9</b>     | Immune Assays 10mL: Number Of Specimens Collected - Visit # - [Specimen Collection (Blood)]   |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"  |

| Class         | Variable  | Label   | Description | Format Text  |
|---------------|---|---|-------------|--|
| 01. Principal | <b>specbld_ia1_spec_col_dt_v0/1/3/6/8/9</b>       | Immune Assays 10mL: Date Specimen Collected - Visit # - [Specimen Collection (Blood)]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>specbld_ia1_spec_ship_dt_v0/1/3/6/8/9</b>      | Immune Assays 10mL: Date Specimen Shipped - Visit # - [Specimen Collection (Blood)]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>specbld_ia1_stored_con_spec_v0/1/3/6/8/9</b>   | Immune Assays 10mL: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored?, Specify - Visit # - [Specimen Collection (Blood)] |             | Char   |
| 01. Principal | <b>specbld_ia1_stored_con_v0/1/3/6/8/9</b>        | Immune Assays 10mL: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? - Visit # - [Specimen Collection (Blood)]          |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sored Per Protocol"<br>2="Not Applicable"   |
| 01. Principal | <b>specbld_ia34_col_v0/1/3/6/8/9</b>              | Immune Assays 34mL: Was Specimen Collected? - Visit # - [Specimen Collection (Blood)]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"  |
| 01. Principal | <b>specbld_ia34_comments_v0/1/3/6/8/9</b>         | Immune Assays 34mL: Comments - Visit # - [Specimen Collection (Blood)]  |             | Char   |
| 01. Principal | <b>specbld_ia34_container_v0/1/3/6/8/9</b>        | Immune Assays 34mL: Container Or Additive - Visit # - [Specimen Collection (Blood)]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="ACD Tube Yellow Topped"<br>2="EDTA Lavender Topped"<br>3="Serum SST"  |
| 01. Principal | <b>specbld_ia34_not_col_rsn_spec_v0/1/3/6/8/9</b> | Immune Assays 34mL: Not Collected Reason, Specify - Visit # - [Specimen Collection (Blood)]   |             | Char   |
| 01. Principal | <b>specbld_ia34_not_col_rsn_v0/1/3/6/8/9</b>      | Immune Assays 34mL: Not Collected Reason - Visit # - [Specimen Collection (Blood)]  |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sample Not Required"<br>2="Patient Unable To Submit Sample"<br>3="Patient Did Not Keep Appointment"<br>4="Intercurrent Illness"<br>5="Institution Error"<br>6="Other" |

| Class         | Variable  | Label   | Description | Format Text  |
|---------------|---|---|-------------|--|
| 01. Principal | <b>specbld_ia34_num_spec_col_v0/1/3/6/8/9</b>     | Immune Assays 34mL: Number Of Specimens Collected - Visit # - [Specimen Collection (Blood)]   |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"  |
| 01. Principal | <b>specbld_ia34_spec_col_dt_v0/1/3/6/8/9</b>      | Immune Assays 34mL: Date Specimen Collected - Visit # - [Specimen Collection (Blood)]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>specbld_ia34_spec_ship_dt_v0/1/3/6/8/9</b>     | Immune Assays 34mL: Date Specimen Shipped - Visit # - [Specimen Collection (Blood)]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>specbld_ia34_stored_con_spec_v0/1/3/6/8/9</b>  | Immune Assays 34mL: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored?, Specify - Visit # - [Specimen Collection (Blood)] |             | Char   |
| 01. Principal | <b>specbld_ia34_stored_con_v0/1/3/6/8/9</b>       | Immune Assays 34mL: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? - Visit # - [Specimen Collection (Blood)]          |             | .F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sored Per Protocol"<br>2="Not Applicable" |
| 01. Principal | <b>specbld_ifnl_col_v0/1/3/6/8/9</b>              | IFNL4 Genotyping 4mL: Was Specimen Collected? - Visit # - [Specimen Collection (Blood)]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"  |
| 01. Principal | <b>specbld_ifnl_comments_v0/1/3/6/8/9</b>         | IFNL4 Genotyping 4mL: Comments - Visit # - [Specimen Collection (Blood)]  |             | Char   |
| 01. Principal | <b>specbld_ifnl_container_v0/1/3/6/8/9</b>        | IFNL4 Genotyping 4mL: Container Or Additive - Visit # - [Specimen Collection (Blood)]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="ACD Tube Yellow Topped"<br>2="EDTA Lavender Topped"<br>3="Serum SST"  |
| 01. Principal | <b>specbld_ifnl_not_col_rsn_spec_v0/1/3/6/8/9</b> | IFNL4 Genotyping 4mL: Not Collected Reason, Specify - Visit # - [Specimen Collection (Blood)]   |             | Char   |

| Class         | Variable   | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>specbld_ifnl_not_col_rsn_v0/1/3/6/8/9</b>     | IFNL4 Genotyping 4mL: Not Collected Reason - Visit # - [Specimen Collection (Blood)]  |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sample Not Required"<br>2="Patient Unable To Submit Sample"<br>3="Patient Did Not Keep Appointment"<br>4="Intercurrent Illness"<br>5="Institution Error"<br>6="Other" |
| 01. Principal | <b>specbld_ifnl_num_spec_col_v0/1/3/6/8/9</b>    | IFNL4 Genotyping 4mL: Number Of Specimens Collected - Visit # - [Specimen Collection (Blood)]   |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"  |
| 01. Principal | <b>specbld_ifnl_spec_col_dt_v0/1/3/6/8/9</b>     | IFNL4 Genotyping 4mL: Date Specimen Collected - Visit # - [Specimen Collection (Blood)]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>specbld_ifnl_spec_ship_dt_v0/1/3/6/8/9</b>    | IFNL4 Genotyping 4mL: Date Specimen Shipped - Visit # - [Specimen Collection (Blood)]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>specbld_ifnl_stored_con_spec_v0/1/3/6/8/9</b> | IFNL4 Genotyping 4mL: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored?, Specify - Visit # - [Specimen Collection (Blood)] |             | Char   |
| 01. Principal | <b>specbld_ifnl_stored_con_v0/1/3/6/8/9</b>      | IFNL4 Genotyping 4mL: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? - Visit # - [Specimen Collection (Blood)]          |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sored Per Protocol"<br>2="Not Applicable"   |
| 01. Principal | <b>specbld_il28_col_v0/1/3/6/8/9</b>             | IL28 3mL Whole Blood: Was Specimen Collected? - Visit # - [Specimen Collection (Blood)]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"  |
| 01. Principal | <b>specbld_il28_comments_v0/1/3/6/8/9</b>        | IL28 3mL Whole Blood: Comments - Visit # - [Specimen Collection (Blood)]  |             | Char   |
| 01. Principal | <b>specbld_il28_container_v0/1/3/6/8/9</b>       | IL28 3mL Whole Blood: Container Or Additive - Visit # - [Specimen Collection (Blood)]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="ACD Tube Yellow Topped"<br>2="EDTA Lavender Topped"<br>3="Serum SST"  |

| Class         | Variable  | Label   | Description | Format Text  |
|---------------|---|---|-------------|--|
| 01. Principal | <b>specbld_il28_not_col_rsn_spec_v0/1/3/6/8/9</b> | IL28 3mL Whole Blood: Not Collected Reason, Specify - Visit # - [Specimen Collection (Blood)]   |             | Char   |
| 01. Principal | <b>specbld_il28_not_col_rsn_v0/1/3/6/8/9</b>      | IL28 3mL Whole Blood: Not Collected Reason - Visit # - [Specimen Collection (Blood)]  |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sample Not Required"<br>2="Patient Unable To Submit Sample"<br>3="Patient Did Not Keep Appointment"<br>4="Intercurrent Illness"<br>5="Institution Error"<br>6="Other" |
| 01. Principal | <b>specbld_il28_num_spec_col_v0/1/3/6/8/9</b>     | IL28 3mL Whole Blood: Number Of Specimens Collected - Visit # - [Specimen Collection (Blood)]   |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"  |
| 01. Principal | <b>specbld_il28_spec_col_dt_v0/1/3/6/8/9</b>      | IL28 3mL Whole Blood: Date Specimen Collected - Visit # - [Specimen Collection (Blood)]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>specbld_il28_spec_ship_dt_v0/1/3/6/8/9</b>     | IL28 3mL Whole Blood: Date Specimen Shipped - Visit # - [Specimen Collection (Blood)]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>specbld_il28_stored_con_spec_v0/1/3/6/8/9</b>  | IL28 3mL Whole Blood: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored?, Specify - Visit # - [Specimen Collection (Blood)] |             | Char   |
| 01. Principal | <b>specbld_il28_stored_con_v0/1/3/6/8/9</b>       | IL28 3mL Whole Blood: If Samples Were Not Shipped On The Day Of Collection, Under What Conditions Were The Specimens Stored? - Visit # - [Specimen Collection (Blood)]          |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="Sored Per Protocol"<br>2="Not Applicable"   |



## Section 24: On Study

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| Class         | Variable                      | Label                                  | Description | Format Text  |
|---------------|-------------------------------|--|-------------|--|
| 01. Principal | <b>on_study_cig_hist</b>      | Cigarette History - [On Study]         |             | .R="Not Randomized"<br>1="Current Smoker"<br>2="Never Smoked"<br>3="Quit, Former Smoker" |
| 01. Principal | <b>on_study_comments</b>      | Comments - [On Study]                  |             | Char   |
| 01. Principal | <b>on_study_dose_level</b>    | Dose Level - [On Study]                |             | Numeric<br>.R="Not Randomized"   |
| 01. Principal | <b>on_study_hcv_rna_level</b> | HCV RNA Level At Baseline - [On Study] |             | .M="Missing"<br>.R="Not Randomized"<br>0="< 800,000 IU/mL"<br>1=">= 800,000 IU/mL"       |

## Section 25: Step Information

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| Class         | Variable                       | Label                                      | Description | Format Text   |
|---------------|--------------------------------|--|-------------|---|
| 01. Principal | <b>step_info_event_dt1-2</b>   | Event Date - # - [Step Information]        |             | SAS Date<br>.N="N/A"  |
| 01. Principal | <b>step_info_event_time1-2</b> | Event Time - # - [Step Information]        |             | SAS Time<br>.N="N/A"  |
| 01. Principal | <b>step_info_step_num1-2</b>   | Registration Step - # - [Step Information] |             | .N="N/A"<br>0="Pre-Registration"<br>1="Registration"  |
| 01. Principal | <b>step_info_tx_arm1-2</b>     | Treatment Arm - # - [Step Information]     |             | .M="Missing"<br>.N="N/A"<br>1="Dose Escalation"<br>2="INO-8000"<br>3="INO-8000 + INO-9012 (0.3 mg)"<br>4="INO-8000 + INO-9012 (1 mg)"<br>5="INO-8000 + INO-9012 (3 mg)" |

## Section 26: Vaccine

| Class         | Variable                         | Label   | Description | Format Text  |
|---------------|----------------------------------|---|-------------|--|
| 01. Principal | <b>vacc_any_meds_spec_v1_1-7</b> | Medication List Names And Dosages - # - Visit # - [Vaccine]             |             | Char   |
| 01. Principal | <b>vacc_any_meds_spec_v3_1-7</b> | Medication List Names And Dosages - # - Visit # - [Vaccine]             |             | Char   |
| 01. Principal | <b>vacc_any_meds_spec_v6_1-7</b> | Medication List Names And Dosages - # - Visit # - [Vaccine]             |             | Char   |
| 01. Principal | <b>vacc_any_meds_spec_v8_1-7</b> | Medication List Names And Dosages - # - Visit # - [Vaccine]             |             | Char   |
| 01. Principal | <b>vacc_any_meds_v1_1-7</b>      | Did You Take Any Medications? - # - Visit # - [Vaccine]                 |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_any_meds_v3_1-7</b>      | Did You Take Any Medications? - # - Visit # - [Vaccine]                 |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_any_meds_v6_1-7</b>      | Did You Take Any Medications? - # - Visit # - [Vaccine]                 |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_any_meds_v8_1-7</b>      | Did You Take Any Medications? - # - Visit # - [Vaccine]                 |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_bruise_size_v1_1-7</b>   | If Bruising, Provide Maximum Measurement (cm) - # - Visit # - [Vaccine] |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"  |
| 01. Principal | <b>vacc_bruise_size_v3_1-7</b>   | If Bruising, Provide Maximum Measurement (cm) - # - Visit # - [Vaccine] |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"  |

| Class         | Variable  | Label  | Description | Format Text  |
|---------------|---|--|-------------|--|
| 01. Principal | <b>vacc_brui</b><br><b>size</b><br><b>_v6_1-7</b> | If Bruising, Provide<br>Maximum<br>Measurement (cm) - # -<br>Visit # - [Vaccine] |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"  |
| 01. Principal | <b>vacc_brui</b><br><b>size</b><br><b>_v8_1-7</b> | If Bruising, Provide<br>Maximum<br>Measurement (cm) - # -<br>Visit # - [Vaccine] |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"  |
| 01. Principal | <b>vacc_brui</b><br><b>v1_</b><br><b>1-7</b>      | Injection Site Symptom:<br>Bruising - # - Visit # -<br>[Vaccine]                 |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"        |
| 01. Principal | <b>vacc_brui</b><br><b>v3_</b><br><b>1-7</b>      | Injection Site Symptom:<br>Bruising - # - Visit # -<br>[Vaccine]                 |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"        |
| 01. Principal | <b>vacc_brui</b><br><b>v6_</b><br><b>1-7</b>      | Injection Site Symptom:<br>Bruising - # - Visit # -<br>[Vaccine]                 |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"        |
| 01. Principal | <b>vacc_brui</b><br><b>v8_</b><br><b>1-7</b>      | Injection Site Symptom:<br>Bruising - # - Visit # -<br>[Vaccine]                 |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"        |
| 01. Principal | <b>vacc_comments</b><br><b>_</b><br><b>v1_1-7</b> | Participant Comments -<br># - Visit # - [Vaccine]                                |             | Char   |
| 01. Principal | <b>vacc_comments</b><br><b>_</b><br><b>v3_1-7</b> | Participant Comments -<br># - Visit # - [Vaccine]                                |             | Char   |
| 01. Principal | <b>vacc_comments</b><br><b>_</b><br><b>v6_1-7</b> | Participant Comments -<br># - Visit # - [Vaccine]                                |             | Char   |
| 01. Principal | <b>vacc_comments</b><br><b>_</b><br><b>v8_1-7</b> | Participant Comments -<br># - Visit # - [Vaccine]                                |             | Char   |
| 01. Principal | <b>vacc_cra_comme</b><br><b>nts_v1_1-7</b>        | CRA Comments - # -<br>Visit # - [Vaccine]  |             | Char   |
| 01. Principal | <b>vacc_cra_comme</b><br><b>nts_v3_1-7</b>        | CRA Comments - # -<br>Visit # - [Vaccine]  |             | Char   |
| 01. Principal | <b>vacc_cra_comme</b><br><b>nts_v6_1-7</b>        | CRA Comments - # -<br>Visit # - [Vaccine]  |             | Char   |
| 01. Principal | <b>vacc_cra_comme</b><br><b>nts_v8_1-7</b>        | CRA Comments - # -<br>Visit # - [Vaccine]  |             | Char   |
| 01. Principal | <b>vacc_dt_v1_1-7</b>                             | Vaccine Date - # - Visit<br># - [Vaccine]  |             | SAS Date<br>.F="No Record For This Visit"<br>.R="Not Randomized"                 |
| 01. Principal | <b>vacc_dt_v3_1-7</b>                             | Vaccine Date - # - Visit<br># - [Vaccine]  |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | <b>vacc_dt_v6_1-7</b>                             | Vaccine Date - # - Visit<br># - [Vaccine]  |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized" |

| Class         | Variable                    | Label   | Description | Format Text  |
|---------------|-----------------------------|---|-------------|--|
| 01. Principal | <b>vacc_dt_v8_1-7</b>       | Vaccine Date - # - Visit # - [Vaccine]                    |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"   |
| 01. Principal | <b>vacc_headache_v1_1-7</b> | General Symptom: Headache - # - Visit # - [Vaccine]       |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe"                 |
| 01. Principal | <b>vacc_headache_v3_1-7</b> | General Symptom: Headache - # - Visit # - [Vaccine]       |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_headache_v6_1-7</b> | General Symptom: Headache - # - Visit # - [Vaccine]       |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_headache_v8_1-7</b> | General Symptom: Headache - # - Visit # - [Vaccine]       |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_itching_v1_1-7</b>  | Injection Site Symptom: Itching - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe"                 |
| 01. Principal | <b>vacc_itching_v3_1-7</b>  | Injection Site Symptom: Itching - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_itching_v6_1-7</b>  | Injection Site Symptom: Itching - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_itching_v8_1-7</b>  | Injection Site Symptom: Itching - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |

| Class         | Variable                      | Label   | Description | Format Text  |
|---------------|-------------------------------|---|-------------|--|
| 01. Principal | <b>vacc_joint_pain_v1_1-7</b> | General Symptom:<br>Joint Pain - # - Visit # -<br>[Vaccine]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe"                 |
| 01. Principal | <b>vacc_joint_pain_v3_1-7</b> | General Symptom:<br>Joint Pain - # - Visit # -<br>[Vaccine]   |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_joint_pain_v6_1-7</b> | General Symptom:<br>Joint Pain - # - Visit # -<br>[Vaccine]   |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_joint_pain_v8_1-7</b> | General Symptom:<br>Joint Pain - # - Visit # -<br>[Vaccine]   |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_musc_ache_v1_1-7</b>  | General Symptom:<br>Muscle Aches - # - Visit<br># - [Vaccine] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe"                 |
| 01. Principal | <b>vacc_musc_ache_v3_1-7</b>  | General Symptom:<br>Muscle Aches - # - Visit<br># - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_musc_ache_v6_1-7</b>  | General Symptom:<br>Muscle Aches - # - Visit<br># - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_musc_ache_v8_1-7</b>  | General Symptom:<br>Muscle Aches - # - Visit<br># - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |

| Class         | Variable                          | Label   | Description | Format Text  |
|---------------|-----------------------------------|---|-------------|--|
| 01. Principal | <b>vacc_nausea_v1_1-7</b>         | General Symptom:<br>Nausea Or Vomiting - #<br>- Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe"                 |
| 01. Principal | <b>vacc_nausea_v3_1-7</b>         | General Symptom:<br>Nausea Or Vomiting - #<br>- Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_nausea_v6_1-7</b>         | General Symptom:<br>Nausea Or Vomiting - #<br>- Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_nausea_v8_1-7</b>         | General Symptom:<br>Nausea Or Vomiting - #<br>- Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_oth_symp_1_grd_v1_1-7</b> | Other 1: Other<br>Symptom Category - #<br>- Visit # - [Vaccine]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe"     |
| 01. Principal | <b>vacc_oth_symp_1_grd_v3_1-7</b> | Other 1: Other<br>Symptom Category - #<br>- Visit # - [Vaccine]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe"     |
| 01. Principal | <b>vacc_oth_symp_1_grd_v6_1-7</b> | Other 1: Other<br>Symptom Category - #<br>- Visit # - [Vaccine]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe"     |
| 01. Principal | <b>vacc_oth_symp_1_grd_v8_1-7</b> | Other 1: Other<br>Symptom Category - #<br>- Visit # - [Vaccine]     |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe"     |

| Class         | Variable                           | Label   | Description | Format Text  |
|---------------|------------------------------------|---|-------------|--|
| 01. Principal | <b>vacc_oth_symp_1_spec_v1_1-7</b> | Other 1: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_1_spec_v3_1-7</b> | Other 1: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_1_spec_v6_1-7</b> | Other 1: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_1_spec_v8_1-7</b> | Other 1: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_1_v1_1-7</b>      | Other 1: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                              |
| 01. Principal | <b>vacc_oth_symp_1_v3_1-7</b>      | Other 1: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                              |
| 01. Principal | <b>vacc_oth_symp_1_v6_1-7</b>      | Other 1: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                              |
| 01. Principal | <b>vacc_oth_symp_1_v8_1-7</b>      | Other 1: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                              |
| 01. Principal | <b>vacc_oth_symp_2_grd_v1_1-7</b>  | Other 3: Other Symptom Category - # - Visit # - [Vaccine]                 |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_oth_symp_2_grd_v3_1-7</b>  | Other 3: Other Symptom Category - # - Visit # - [Vaccine]                 |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |



| Class         | Variable                           | Label   | Description | Format Text  |
|---------------|------------------------------------|---|-------------|--|
| 01. Principal | <b>vacc_oth_symp_2_grd_v6_1-7</b>  | Other 3: Other Symptom Category - # - Visit # - [Vaccine]                 |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_oth_symp_2_grd_v8_1-7</b>  | Other 3: Other Symptom Category - # - Visit # - [Vaccine]                 |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_oth_symp_2_spec_v1_1-7</b> | Other 3: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_2_spec_v3_1-7</b> | Other 3: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_2_spec_v6_1-7</b> | Other 3: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_2_spec_v8_1-7</b> | Other 3: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_2_v1_1-7</b>      | Other 3: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                              |
| 01. Principal | <b>vacc_oth_symp_2_v3_1-7</b>      | Other 3: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                              |
| 01. Principal | <b>vacc_oth_symp_2_v6_1-7</b>      | Other 3: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                              |
| 01. Principal | <b>vacc_oth_symp_2_v8_1-7</b>      | Other 3: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                              |

| Class         | Variable                           | Label   | Description | Format Text  |
|---------------|------------------------------------|---|-------------|--|
| 01. Principal | <b>vacc_oth_symp_3_grd_v1_1-7</b>  | Other 3: Other Symptom Category - #<br>- Visit # - [Vaccine]              |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_oth_symp_3_grd_v3_1-7</b>  | Other 3: Other Symptom Category - #<br>- Visit # - [Vaccine]              |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_oth_symp_3_grd_v6_1-7</b>  | Other 3: Other Symptom Category - #<br>- Visit # - [Vaccine]              |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_oth_symp_3_grd_v8_1-7</b>  | Other 3: Other Symptom Category - #<br>- Visit # - [Vaccine]              |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_oth_symp_3_spec_v1_1-7</b> | Other 3: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_3_spec_v3_1-7</b> | Other 3: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_3_spec_v6_1-7</b> | Other 3: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_3_spec_v8_1-7</b> | Other 3: Other Symptom Or Medical Event Specify - # - Visit # - [Vaccine] |             | Char   |
| 01. Principal | <b>vacc_oth_symp_3_v1_1-7</b>      | Other 3: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                              |
| 01. Principal | <b>vacc_oth_symp_3_v3_1-7</b>      | Other 3: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                              |

| Class         | Variable                        | Label   | Description | Format Text  |
|---------------|---------------------------------|---|-------------|--|
| 01. Principal | <b>vacc_oth_symp_3_v6_1-7</b>   | Other 3: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                                  |
| 01. Principal | <b>vacc_oth_symp_3_v8_1-7</b>   | Other 3: Did You Experience Any Other Symptoms? - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"                                  |
| 01. Principal | <b>vacc_pain_v1_1-7</b>         | Injection Site Symptom: Pain - # - Visit # - [Vaccine]                    |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe"                 |
| 01. Principal | <b>vacc_pain_v3_1-7</b>         | Injection Site Symptom: Pain - # - Visit # - [Vaccine]                    |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_pain_v6_1-7</b>         | Injection Site Symptom: Pain - # - Visit # - [Vaccine]                    |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_pain_v8_1-7</b>         | Injection Site Symptom: Pain - # - Visit # - [Vaccine]                    |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_redness_size_v1_1-7</b> | If Redness, Provide Maximum Measurement (cm) - # - Visit # - [Vaccine]    |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"  |
| 01. Principal | <b>vacc_redness_size_v3_1-7</b> | If Redness, Provide Maximum Measurement (cm) - # - Visit # - [Vaccine]    |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"  |
| 01. Principal | <b>vacc_redness_size_v6_1-7</b> | If Redness, Provide Maximum Measurement (cm) - # - Visit # - [Vaccine]    |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"  |
| 01. Principal | <b>vacc_redness_size_v8_1-7</b> | If Redness, Provide Maximum Measurement (cm) - # - Visit # - [Vaccine]    |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"  |

| Class         | Variable                      | Label   | Description | Format Text  |
|---------------|-------------------------------|---|-------------|--|
| 01. Principal | <b>vacc_redness_v1_1-7</b>    | Injection Site Symptom: Redness - # - Visit # - [Vaccine]               |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"              |
| 01. Principal | <b>vacc_redness_v3_1-7</b>    | Injection Site Symptom: Redness - # - Visit # - [Vaccine]               |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"              |
| 01. Principal | <b>vacc_redness_v6_1-7</b>    | Injection Site Symptom: Redness - # - Visit # - [Vaccine]               |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"              |
| 01. Principal | <b>vacc_redness_v8_1-7</b>    | Injection Site Symptom: Redness - # - Visit # - [Vaccine]               |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"              |
| 01. Principal | <b>vacc_swell_size_v1_1-7</b> | If Swelling, Provide Maximum Measurement (cm) - # - Visit # - [Vaccine] |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"        |
| 01. Principal | <b>vacc_swell_size_v3_1-7</b> | If Swelling, Provide Maximum Measurement (cm) - # - Visit # - [Vaccine] |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"        |
| 01. Principal | <b>vacc_swell_size_v6_1-7</b> | If Swelling, Provide Maximum Measurement (cm) - # - Visit # - [Vaccine] |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"        |
| 01. Principal | <b>vacc_swell_size_v8_1-7</b> | If Swelling, Provide Maximum Measurement (cm) - # - Visit # - [Vaccine] |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"        |
| 01. Principal | <b>vacc_swell_v1_1-7</b>      | Injection Site Symptom: Swelling - # - Visit # - [Vaccine]              |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"              |
| 01. Principal | <b>vacc_swell_v3_1-7</b>      | Injection Site Symptom: Swelling - # - Visit # - [Vaccine]              |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"              |
| 01. Principal | <b>vacc_swell_v6_1-7</b>      | Injection Site Symptom: Swelling - # - Visit # - [Vaccine]              |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"              |
| 01. Principal | <b>vacc_swell_v8_1-7</b>      | Injection Site Symptom: Swelling - # - Visit # - [Vaccine]              |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"              |
| 01. Principal | <b>vacc_temp_unit_v1_1-7</b>  | Vaccine Temperature Units - # - Visit # - [Vaccine]                     |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>1="C"<br>2="F" |

| Class         | Variable                     | Label   | Description | Format Text  |
|---------------|------------------------------|---|-------------|--|
| 01. Principal | <b>vacc_temp_unit_v3_1-7</b> | Vaccine Temperature Units - # - Visit # - [Vaccine]                       |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>1="C"<br>2="F"                     |
| 01. Principal | <b>vacc_temp_unit_v6_1-7</b> | Vaccine Temperature Units - # - Visit # - [Vaccine]                       |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>1="C"<br>2="F"                     |
| 01. Principal | <b>vacc_temp_unit_v8_1-7</b> | Vaccine Temperature Units - # - Visit # - [Vaccine]                       |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>1="C"<br>2="F"                     |
| 01. Principal | <b>vacc_temp_v1_1-7</b>      | Vaccine Temperature - # - Visit # - [Vaccine]                             |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                            |
| 01. Principal | <b>vacc_temp_v3_1-7</b>      | Vaccine Temperature - # - Visit # - [Vaccine]                             |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                            |
| 01. Principal | <b>vacc_temp_v6_1-7</b>      | Vaccine Temperature - # - Visit # - [Vaccine]                             |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                            |
| 01. Principal | <b>vacc_temp_v8_1-7</b>      | Vaccine Temperature - # - Visit # - [Vaccine]                             |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                            |
| 01. Principal | <b>vacc_time_v1_1-7</b>      | Vaccine Time Taken - # - Visit # - [Vaccine]                              |             | SAS Time<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                           |
| 01. Principal | <b>vacc_time_v3_1-7</b>      | Vaccine Time Taken - # - Visit # - [Vaccine]                              |             | SAS Time<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                           |
| 01. Principal | <b>vacc_time_v6_1-7</b>      | Vaccine Time Taken - # - Visit # - [Vaccine]                              |             | SAS Time<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                           |
| 01. Principal | <b>vacc_time_v8_1-7</b>      | Vaccine Time Taken - # - Visit # - [Vaccine]                              |             | SAS Time<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                           |
| 01. Principal | <b>vacc_tired_v1_1-7</b>     | General Symptom: Unusually Tired/Feeling Unwell - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |

| Class         | Variable                 | Label  | Description | Format Text  |
|---------------|--------------------------|--|-------------|--|
| 01. Principal | <b>vacc_tired_v3_1-7</b> | General Symptom:<br>Unusually Tired/Feeling Unwell - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_tired_v6_1-7</b> | General Symptom:<br>Unusually Tired/Feeling Unwell - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |
| 01. Principal | <b>vacc_tired_v8_1-7</b> | General Symptom:<br>Unusually Tired/Feeling Unwell - # - Visit # - [Vaccine] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="None"<br>1="Mild"<br>2="Moderate"<br>3="Severe" |

## Section 27: Participant Status Treatment

| Class         | Variable   | Label  | Description | Format Text   |
|---------------|--|--|-------------|---|
| 01. Principal | <b>event_tx_ae_rep_v1/event_tx_ae_rep_v3/event_tx_ae_rep_v6/event_tx_ae_rep_v8</b>                     | Were Adverse Events Assessed During This Reporting Period? - Visit # - [Participant Status Treatment]"               |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes, and reportable adverse events occurred"<br>2="Yes, but no reportable adverse events occurred" |
| 01. Principal | <b>event_tx_comments_v1/event_tx_comments_v3/event_tx_comments_v6/event_tx_comments_v8</b>             | Comments - Visit # - [Participant Status Treatment]"   |             | Char  |
| 01. Principal | <b>event_tx_contact_dt_v1/event_tx_contact_dt_v3/event_tx_contact_dt_v6/event_tx_contact_dt_v8</b>     | Contact Date - Visit # - [Participant Status Treatment]"   |             | SAS Date<br>.F="No Record For This Visit"<br>.R="Not Randomized"  |
| 01. Principal | <b>event_tx_fu_stat_v1/event_tx_fu_stat_v3/event_tx_fu_stat_v6/event_tx_fu_stat_v8</b>                 | Participant Vital Status - Visit # - [Participant Status Treatment]"   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="Alive"   |
| 01. Principal | <b>event_tx_part_cont_v1/event_tx_part_cont_v3/event_tx_part_cont_v6/event_tx_part_cont_v8</b>         | Will The Participant Continue To The Next Visit? - Visit # - [Participant Status Treatment]"                         |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"   |
| 01. Principal | <b>event_tx_post_int_fu_v1/event_tx_post_int_fu_v3/event_tx_post_int_fu_v6/event_tx_post_int_fu_v8</b> | Will The Participant Continue To The Post Intervention Follow-Up Period? - Visit # - [Participant Status Treatment]" |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"   |

## Section 28: Phone Follow-Up Contact

| Class         | Variable                          | Label  | Description | Format Text  |
|---------------|-----------------------------------|--|-------------|--|
| 01. Principal | <b>phone_ae_rep_v6-7</b>          | Were Any Adverse Events Reported? - Visit # - [Phone Follow-Up]                                  |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>phone_comments_v6-7</b>        | Comments - Visit # - [Phone Follow-Up]   |             | Char   |
| 01. Principal | <b>phone_fu_attempt_dt_v6-7</b>   | Date Follow-Up Phone Call Attempted - Visit # - [Phone Follow-Up]                                |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"         |
| 01. Principal | <b>phone_fu_attempt_v6-7</b>      | Was A Follow-Up Phone Call Attempted? - Visit # - [Phone Follow-Up]                              |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>phone_fu_completed_dt_v6-7</b> | Date Follow-Up Phone Call Completed - Visit # - [Phone Follow-Up]                                |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"         |
| 01. Principal | <b>phone_fu_completed_v6-7</b>    | Was A Follow-Up Phone Call Completed? - Visit # - [Phone Follow-Up]                              |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |
| 01. Principal | <b>phone_med_change_v6-7</b>      | Did The Participant Report Any Changes To Concomitant Medications? - Visit # - [Phone Follow-Up] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |



## Section 29: Off Study

| Class         | Variable                         | Label  | Description | Format Text  |
|---------------|----------------------------------|--|-------------|--|
| 01. Principal | <b>end_at_agent_end_dt</b>       | Agent End Date - [Off Study]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"  |
| 01. Principal | <b>end_at_comments</b>           | Comments - [Off Study]   |             | Char   |
| 01. Principal | <b>end_at_last_contact_dt</b>    | Date Of Last Contact - [Off Study]   |             | SAS Date<br>.F="No Record For This Visit"  |
| 01. Principal | <b>end_at_not_obt</b>            | Agent Not Obtained (Only If The Participant Did Not Start Study Agent) - [Off Study] |             | .F="No Record For This Visit"<br>0="No"<br>1="Yes"<br>2="Uncertain"  |
| 01. Principal | <b>end_at_off_fu_dt</b>          | Date Off Follow-Up - [Off Study]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"  |
| 01. Principal | <b>end_at_off_study_dt</b>       | Off Study Date - [Off Study]   |             | SAS Date<br>.F="No Record For This Visit"  |
| 01. Principal | <b>end_at_off_study_rsn</b>      | Off Study Reason - [Off Study]   |             | .F="No Record For This Visit"<br>1="Study Complete"<br>2="Lost To Follow-Up"<br>3="Ineligible"<br>4="Participant Withdrawal"<br>5="Other, Specify" |
| 01. Principal | <b>end_at_off_study_rsn_spec</b> | Off Study Reason, Specify - [Off Study]  |             | Char   |
| 01. Principal | <b>end_at_on_fu_dt</b>           | Date On Follow-Up - [Off Study]  |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"  |
| 01. Principal | <b>end_at_tx_end_dt_no</b>       | Not Obtained - [Off Study]   |             | .F="No Record For This Visit"<br>0="No"<br>1="Yes"<br>2="Uncertain"  |

## Section 30: Participant Status Contact Follow Up

| Class         | Variable                            | Label   | Description | Format Text   |
|---------------|-------------------------------------|---|-------------|---|
| 01. Principal | <b>event_cfu_ae_re<br/>p</b>        | Were Adverse Events Assessed During This Reporting Period? - [Participant Status Contact Follow Up]             |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes, and reportable adverse events occurred"<br>2="Yes, but no reportable adverse events occurred" |
| 01. Principal | <b>event_cfu_comm<br/>ents</b>      | Comments - [Participant Status Contact Follow Up]   |             | Char  |
| 01. Principal | <b>event_cfu_comp<br/>_dt</b>       | Date Completed - [Participant Status Contact Follow Up]   |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"  |
| 01. Principal | <b>event_cfu_conta<br/>ct_dt</b>    | Contact Date - [Participant Status Contact Follow Up]   |             | SAS Date<br>.F="No Record For This Visit"<br>.R="Not Randomized"  |
| 01. Principal | <b>event_cfu_last_f<br/>u_comp</b>  | Has The Participant Completed Their Last Follow-Up Visit? - [Participant Status Contact Follow Up]              |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"   |
| 01. Principal | <b>event_cfu_part_v<br/>it_stat</b> | Participant Vital Status - [Participant Status Contact Follow Up]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="Alive"   |
| 01. Principal | <b>event_cfu_wiwi_<br/>comp</b>     | Did The Participant Complete The Was It Worth It (WIWI) Questionnaire? - [Participant Status Contact Follow Up] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"   |

## Section 31: Was It Worth It Questionnaire

| Class         | Variable                 | Label  | Description | Format Text   |
|---------------|--------------------------|--|-------------|---|
| 01. Principal | <b>wiwi_comments</b>     | Comments - [WIWI Questionnaire]  |             | Char  |
| 01. Principal | <b>wiwi_do_again</b>     | If You Had To Do It Over, Would You Participate In This Research Study Again? - [WIWI Questionnaire]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"  |
| 01. Principal | <b>wiwi_experience</b>   | Overall, How Was Your Experience Of Participating In This Research Study? - [WIWI Questionnaire]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="Better Than I Expected"<br>2="The Same As I Expected"<br>3="Worse Than I Expected" |
| 01. Principal | <b>wiwi_improve_spec</b> | If There Was One Thing That Could Have Been Done To Improve Your Experience In This Research Study, What Would It Be? - [WIWI Questionnaire] |             | Char  |
| 01. Principal | <b>wiwi_qol_change</b>   | Overall, Did Your Quality Of Life Change By Participating In This Research Study? - [WIWI Questionnaire]                                     |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="It Improved"<br>2="It Stayed The Same"<br>3="It Got Worse"                         |
| 01. Principal | <b>wiwi_recommend</b>    | Would You Recommend Participating In This Research Study To Others? - [WIWI Questionnaire]   |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"  |
| 01. Principal | <b>wiwi_talk_concern</b> | Would You Like To Talk To Someone About Your Concerns? - [WIWI Questionnaire]  |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"  |
| 01. Principal | <b>wiwi_worthwhile</b>   | Was It Worthwhile For You To Participate In This Research Study? - [WIWI Questionnaire]  |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Uncertain"  |

## Section 32: Primary Endpoints

| Class         | Variable  | Label                                    | Description | Format Text   |
|---------------|---|--|-------------|---|
| 01. Principal | <b>prim_end_ns3_4a_v1/prim_end_ns3_4a_v4/prim_end_ns3_4a_v7/prim_end_ns3_4a_v9-10</b> | NS3.4A - Visit # -<br>[Primary Endpoint] |             | Numeric<br>.F="No Record For This Visit"<br>.R="Not Randomized" |
| 01. Principal | <b>prim_end_ns4b_v1/prim_end_ns4b_v4/prim_end_ns4b_v7/prim_end_ns4b_v9-10</b>         | NS4B - Visit # -<br>[Primary Endpoint]   |             | Numeric<br>.F="No Record For This Visit"<br>.R="Not Randomized" |
| 01. Principal | <b>prim_end_ns5a_v1/prim_end_ns5a_v4/prim_end_ns5a_v7/prim_end_ns5a_v9-10</b>         | NS5A - Visit # -<br>[Primary Endpoint]   |             | Numeric<br>.F="No Record For This Visit"<br>.R="Not Randomized" |

## Section 33: Translational Endpoint

| Class         | Variable                            | Label  | Description | Format Text  |
|---------------|-------------------------------------|--|-------------|--|
| 01. Principal | <b>sample_bap_col_dt_oth</b>        | BAP Sample Receipt Date - Visit Not Specified - [Translational Endpoint]     |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"   |
| 01. Principal | <b>sample_bap_col_dt_v1/4/7/10</b>  | BAP Sample Receipt Date - Visit # - [Translational Endpoint]                 |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                   |
| 01. Principal | <b>sample_bap_col_dt_v9_1-4</b>     | BAP Sample Receipt Date - Visit 9 (Week 26) - [Translational Endpoint]       |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                   |
| 01. Principal | <b>sample_hcv_rna_lvl_oth</b>       | HCV RNA Level (IU/mL) - Visit Not Specified - [Translational Endpoint]       |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                    |
| 01. Principal | <b>sample_hcv_rna_lvl_v1/4/7/10</b> | HCV RNA Level (IU/mL) - Visit # - [Translational Endpoint]                   |             | Numeric<br>.D="Undetected"<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | <b>sample_hcv_rna_lvl_v9_1-4</b>    | HCV RNA Level (IU/mL) - Visit 9 (Week 26) - [Translational Endpoint]         |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                    |
| 01. Principal | <b>sample_id_oth</b>                | Sample ID - Visit Not Specified - [Translational Endpoint]                   |             | Numeric<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"    |
| 01. Principal | <b>sample_id_v1/4/7/10</b>          | Sample ID - Visit # - [Translational Endpoint]                               |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                    |
| 01. Principal | <b>sample_id_v9_1-4</b>             | Sample ID - Visit 9 (Week 26) - [Translational Endpoint]                     |             | Numeric<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                    |
| 01. Principal | <b>sample_site_col_dt_oth</b>       | Site Sample Collection Date - Visit Not Specified - [Translational Endpoint] |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized"   |
| 01. Principal | <b>sample_site_col_dt_v1/4/7/10</b> | Site Sample Collection Date - Visit # - [Translational Endpoint]             |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                   |

| Class         | Variable                                       | Label  | Description | Format Text   |
|---------------|--|--|-------------|---|
| 01. Principal | <b>sample_site_col_dt_v9_1-4</b>               | Site Sample Collection Date - Visit 9 (Week 26) - [Translational Endpoint] |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                            |
| 01. Principal | <b>sample_test_name_oth</b>                    | Test Name - Visit Not Specified - [Translational Endpoint]                 |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="HCV RNA Detect/Quant, S (HCVQN)" |
| 01. Principal | <b>sample_test_name_v1/4/7/10</b>              | Test Name - Visit # - [Translational Endpoint]                             |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="HCV RNA Detect/Quant, S (HCVQN)" |
| 01. Principal | <b>sample_test_name_v9_1-4</b>                 | Test Name - Visit 9 (Week 26) - [Translational Endpoint]                   |             | .F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"<br>1="HCV RNA Detect/Quant, S (HCVQN)" |
| 01. Principal | <b>sample_test_order_dt_oth</b>                | Test Order Date - Visit Not Specified - [Translational Endpoint]           |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                            |
| 01. Principal | <b>sample_test_order_dt_v1/4/7/10</b>          | Test Order Date - Visit # - [Translational Endpoint]                       |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                            |
| 01. Principal | <b>sample_test_order_dt_v9_1-4</b>             | Test Order Date - Visit 9 (Week 26) - [Translational Endpoint]             |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                            |
| 01. Principal | <b>sample_verified_test_order_dt_oth</b>       | Verified Test Order Date - Visit Not Specified - [Translational Endpoint]  |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                            |
| 01. Principal | <b>sample_verified_test_order_dt_v1/4/7/10</b> | Verified Test Order Date - Visit # - [Translational Endpoint]              |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                            |
| 01. Principal | <b>sample_verified_test_order_dt_v9_1-4</b>    | Verified Test Order Date - Visit 9 (Week 26) - [Translational Endpoint]    |             | SAS Date<br>.F="No Record For This Visit"<br>.N="N/A"<br>.R="Not Randomized"                            |

## Section 34: Protocol Data

| Class         | Variable   | Label  | Description | Format Text   |
|---------------|--|--|-------------|---|
| 01. Principal | <b>protdata_agent_admin_v1/protdata_agent_admin_v3/protdata_agent_admin_v6/protdata_agent_admin_v8</b>                         | Was Agent Administered? - Visit # - [Protocol Data]                |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"          |
| 01. Principal | <b>protdata_agent_v1/protdata_agent_v3/protdata_agent_v6/protdata_agent_v8</b>   | Agent - Visit # - [Protocol Data]                                  |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="Study vaccine (INO-8000 +/- INO-9012)" |
| 01. Principal | <b>protdata_comments_v1/protdata_comments_v3/protdata_comments_v6/protdata_comments_v8</b>                                     | Comments - Visit # - [Protocol Data]                               |             | Char  |
| 01. Principal | <b>protdata_dose_dt_v1/protdata_dose_dt_v3/protdata_dose_dt_v6/protdata_dose_dt_v8</b>   | Dose Date - Visit # - [Protocol Data]                              |             | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                  |
| 01. Principal | <b>protdata_dose_time_v1/protdata_dose_time_v3/protdata_dose_time_v6/protdata_dose_time_v8</b>                                 | Dose Time - Visit # - [Protocol Data]                              |             | SAS Time<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"                  |
| 01. Principal | <b>protdata_eval_perf_v1/protdata_eval_perf_v3/protdata_eval_perf_v6/protdata_eval_perf_v8</b>                                 | Was Preinjection Evaluation Performed? - Visit # - [Protocol Data] |             | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"          |
| 01. Principal | <b>protdata_rsn_not_admin_v1/protdata_rsn_not_admin_v3/protdata_rsn_not_admin_v6/protdata_rsn_not_admin_v8</b>                 | Reason Agent Not Administered - Visit # - [Protocol Data]          |             | Char  |
| 01. Principal | <b>protdata_rx_delay_rsn_spec_v1/protdata_rx_delay_rsn_spec_v3/protdata_rx_delay_rsn_spec_v6/protdata_rx_delay_rsn_spec_v8</b> | Dose Delay Reason, Specify - Visit # - [Protocol Data]             |             | Char  |

| Class         | Variable   | Label  | Description | Format Text  |
|---------------|--|--|-------------|--|
| 01. Principal | <b>protdata_rx_delay_rsn_v1/protdata_rx_delay_rsn_v3/protdata_rx_delay_rsn_v6/protdata_rx_delay_rsn_v8</b> | Dose Delay Reason - Visit # - [Protocol Data]                  |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>and genetic disorders 4=""ear and labyrinth disorders 5 = "endocrine disorders 6 = "eye" and infestations 12="injury poisoning and procedural complications" circumstances 25=""surgical and medical procedures 26 = "vascular disorders" conditions 9=""hepatobiliary disorders 10 = "immune system disorders 11 = "infections" connective tissue disorders 16=""neoplasms benign malignant and unspecified (incl. cysts and polyps) 17=""nervous system disorders 18 = "pregnancy puerperium and disorders 7=""gastrointestinal disorders 8 = "general disorders and administration site" mediastinal disorders 23=""skin and subcutaneous tissue disorders 24 = "social perinatal conditions 19=""psychiatric disorders 20 = "renal and urinary disorders" 1=""blood and lymphatic system disorders 2 = "cardiac disorders 3 = "congenital familial" 13=""investigations 14 = "metabolism and nutrition disorders 15 = "musculoskeletal and"<br>21=""reproductive system and breast disorders 22 = "respiratory thoracic and" 99="other not per protocol" |
| 01. Principal | <b>protdata_rx_delay_v1/protdata_rx_delay_v3/protdata_rx_delay_v6/protdata_rx_delay_v8</b>                 | Was Protocol Intervention Delayed? - Visit # - [Protocol Data] |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown"   |
| 01. Principal | <b>protdata_site_v1/protdata_site_v3/protdata_site_v6/protdata_site_v8</b>                                 | Dose Site - Visit # - [Protocol Data]                          |             | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>1="Right Arm"<br>2="Left Arm"<br>3="Right Thigh"<br>4="Left Thigh"   |



## Section 35: Supporting Documents

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| Class         | Variable                           | Label  | Description | Format Text  |
|---------------|------------------------------------|--|-------------|--|
| 01. Principal | <b>supp_doc_asses<br/>s_dt1-7</b>  | Date Of Assessment -<br># - [Supporting<br>Documents]            |             | SAS Date<br>.N="N/A"   |
| 01. Principal | <b>supp_doc_num</b>                | Number Of Supporting<br>Documents -<br>[Supporting<br>Documents] |             | Numeric  |
| 01. Principal | <b>supp_doc_serial<br/>_num1-7</b> | Serial # Of Document -<br># - [Supporting<br>Documents]          |             | Numeric<br>.N="N/A"  |
| 01. Principal | <b>supp_doc_type1-<br/>7</b>       | Report Type - # -<br>[Supporting<br>Documents]                   |             | .N="N/A"<br>1="Clinic Note"<br>2="Pathology Report"<br>3="Other" |
| 01. Principal | <b>supp_doc_type_<br/>spec1-7</b>  | Report Type, Specify -<br># - [Supporting<br>Documents]          |             | Char   |

## Section 36: Adverse Events

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| Class         | Variable               | Label  | Description | Format Text |
|---------------|------------------------|--|-------------|-------------|
| 01. Principal | <b>ae_num_reported</b> | Number Of Adverse Events Reported - [Toxicity] |             | Numeric     |