# NWU2014-04-01 - Enhanced Person Data Dictionary

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| Document Title | NWU2014-04-01 - Enhanced Person: Data Dictionary |
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# NWU2014-04-01 - Enhanced Person: Data Dictionary
## Section 1: Identifiers

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **Participant_ID** | Participant ID | | Char |

# Section 2: Time Points

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | timepoint_follow up_end_dt | Time Point Follow Up End Date | Time Point Follow Up End Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | timepoint_follow up_notes | Time Point Follow Up Notes | Time Point Follow Up Notes | Char |
| 01. Principal | timepoint_follow up_start_dt | Time Point Follow Up Start Date | Time Point Follow Up Start Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | timepoint_month 13_end_dt | Time Point Month 1 - 3 End Date | Time Point Month 1 - 3 End Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | timepoint_month 13_notes | Time Point Month 1 - 3 Notes | Time Point Month 1 - 3 Notes | Char |
| 01. Principal | timepoint_month 13_start_dt | Time Point Month 1 - 3 Start Date | Time Point Month 1 - 3 Start Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | timepoint_month 46_end_dt | Time Point Month 4 - 6 End Date | Time Point Month 4 - 6 End Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | timepoint_month 46_notes | Time Point Month 4 - 6 Notes | Time Point Month 4 - 6 Notes | Char |
| 01. Principal | timepoint_month 46_start_dt | Time Point Month 4 - 6 Start Date | Time Point Month 4 - 6 Start Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | timepoint_screen 1_end_dt | Time Point Screen 1 End Date | Time Point Screen 1 End Date | SAS Date<br>.R="Not Randomized" |
| 01. Principal | timepoint_screen 1_notes | Time Point Screen 1 Notes | Time Point Screen 1 Notes | Char |
| 01. Principal | timepoint_screen 1_start_dt | Time Point Screen 1 Start Date | Time Point Screen 1 Start Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | timepoint_screen 2_end_dt | Time Point Screen 2 End Date | Time Point Screen 2 End Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | timepoint_screen 2_notes | Time Point Screen 2 Notes | Time Point Screen 2 Notes | Char |
| 01. Principal | timepoint_screen 2_start_dt | Time Point Screen 2 Start Date | Time Point Screen 2 Start Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | timepoint_visit1_ end_dt | Time Point Visit 1 End Date | Time Point Visit 1 End Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | timepoint_visit1_ notes | Time Point Visit 1 Notes | Time Point Visit 1 Notes | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **timepoint_visit1_start_dt** | Time Point Visit 1 Start Date | Time Point Visit 1 Start Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **timepoint_visit2_end_dt** | Time Point Visit 2 End Date | Time Point Visit 2 End Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **timepoint_visit2_notes** | Time Point Visit 2 Notes | Time Point Visit 2 Notes | Char |
| 01. Principal | **timepoint_visit2_start_dt** | Time Point Visit 2 Start Date | Time Point Visit 2 Start Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **timepoint_visit3_end_dt** | Time Point Visit 3 End Date | Time Point Visit 3 End Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **timepoint_visit3_notes** | Time Point Visit 3 Notes | Time Point Visit 3 Notes | Char |
| 01. Principal | **timepoint_visit3_start_dt** | Time Point Visit 3 Start Date | Time Point Visit 3 Start Date | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |

# Section 3: Pre-Enrollment

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **preenrl_country_code** | Participant Country Code | Participant Country Code | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="USA" |
| 01. Principal | **preenrl_ethnicity** | Participant Ethnicity | Participant Ethnicity | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Not Hispanic or Latino"<br>1="Hispanic or Latino" |
| 01. Principal | **preenrl_gender** | Participant Gender | Participant Gender | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="Female"<br>1="Male" |
| 01. Principal | **preenrl_method_pay** | Method Of Payment | Method Of Payment | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="Private Insurance"<br>2="Medicaid"<br>4="Military Sponsored (including CHAMPUS & TriCare)"<br>7="Medicare"<br>10="Managed Care/Medicare"<br>12="Military or Veterans Sponsored, NOS" |
| 01. Principal | **preenrl_other_spec** | Other, Specify | Other, Specify | Char |
| 01. Principal | **preenrl_race1** | Participant Race | Participant Race | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="Black or African American"<br>2="White" |
| 01. Principal | **preenrl_reg_institute** | Registering Institution | Registering Institution | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="CA016"<br>2="CA237"<br>3="PA015" |
| 01. Principal | **preenrl_screen1_dt** | Screen 1 Date | Screen 1 Date | SAS Date<br>.F="No Record For This Visit"<br>.R="Not Randomized" |
| 01. Principal | **preenrl_screen2_dt** | Screen 2 Date | Screen 2 Date | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **preenrl_screen_criteria** | Does This Participant Meet All Screening Criteria? | Does This Participant Meet All Screening Criteria? | .F="No Record For This Visit"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **preenrl_screen_failure** | If No, Specify Primary Reason For Screen Failure | If No, Specify Primary Reason For Screen Failure | .F="No Record For This Visit"<br>.N="Not Applicable"<br>.R="Not Randomized"<br>3="Did not meet eligibility criteria"<br>4="Other, specify" |
| 01. Principal | **preenrl_screen_id** | Screening Identification Number (SID) | Screening Identification Number (SID) | Char |

# Section 4: Enrollment

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **enrl_comments** | Comments | Comments | Char |
| 01. Principal | **enrl_rand_dt** | Participant Randomization Date | Participant Randomization Date | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **enrl_reg_dt** | Participant Registration Date | Participant Registration Date | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **enrl_start_dt** | Date Agent Started | Date Agent Started | SAS Date<br>.R="Not Randomized" |

# Section 5: Consent Form

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **icf_consent_biopspec1-2** | The Participant Agrees That His/Her Samples And Related Information May Be Kept In A NCI Biobank For Use In Future Health Research [1-2] | The Participant Agrees That His/Her Samples And Related Information May Be Kept In A NCI Biobank For Use In Future Health Research [1-2] | .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **icf_consent_dt1-2** | Date Of Consent   [1-2] | Date Of Consent   [1-2] | SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" |
| 01. Principal | **icf_consent_research1-2** | The Participant Agrees That His/Her Study Doctor, Or Their Representative, May Contact Him/Her Or His/Her Physician To See If He/She Wishes To Participate In Other Research In The Future [1-2] | The Participant Agrees That His/Her Study Doctor, Or Their Representative, May Contact Him/Her Or His/Her Physician To See If He/She Wishes To Participate In Other Research In The Future [1-2] | .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **icf_form_dt1-2** | Consent Form Version Date   [1-2] | Consent Form Version Date   [1-2] | SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" |
| 01. Principal | **icf_form_version1-2** | Consent Form Version [1-2] | Consent Form Version [1-2] | Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized" |

# Section 6: Eligibility

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **elig_comments** | Comments | Comments | Char |
| 01. Principal | **elig_inclusion** | Is The Participant Eligible For Inclusion On This Protocol? | Is The Participant Eligible For Inclusion On This Protocol? | .R="Not Randomized" 1="Yes" |
| 01. Principal | **elig_visit_dt_scr2** | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Date .R="Not Randomized" |

# Section 7: Concomitant Medication

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **conmed_comme nts1-48** | Comments For Concomitant Medications [1-48] | Comments For Concomitant Medications [1-48] | Char |
| 01. Principal | **conmed_continui ng1-48** | Continuing For Concomitant Medications [1-48] | Continuing For Concomitant Medications [1-48] | .M="Unknown"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **conmed_med_do se1-48** | Medication Dose For Concomitant Medications [1-48] | Medication Dose For Concomitant Medications [1-48] | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **conmed_med_do se_freq1-48** | Dose Frequency For Concomitant Medications [1-48] | Dose Frequency For Concomitant Medications [1-48] | Char |
| 01. Principal | **conmed_med_do se_freq_oth1-48** | Other Dose Frequency For Concomitant Medications [1-48] | Other Dose Frequency For Concomitant Medications [1-48] | Char |
| 01. Principal | **conmed_med_na me1-48** | Medication Name For Concomitant Medications [1-48] | Medication Name For Concomitant Medications [1-48] | Char |
| 01. Principal | **conmed_report_ dt1-48** | Medication Reported Date For Concomitant Medications [1-48] | Medication Reported Date For Concomitant Medications [1-48] | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **conmed_start_dt 1-48** | Start Date For Concomitant Medications [1-48] | Start Date For Concomitant Medications [1-48] | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **conmed_stop_dt 1-48** | Stop Date For Concomitant Medications [1-48] | Stop Date For Concomitant Medications [1-48] | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **conmed_units1-4 8** | Units For Concomitant Medications [1-48] | Units For Concomitant Medications [1-48] | Char |
| 01. Principal | **conmed_units_ot h1-48** | Other Units or Concomitant Medications [1-48] | Other Units or Concomitant Medications [1-48] | Char |

# Section 8: Baseline Questionnaire

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqbl_age** | Current Age | Current Age | Numeric<br>.R="Not Randomized" |
| 01. Principal | **stqbl_avg_weight_30/40/50/60/70** | What Was Your Approximate Average Weight When You Were: 70+ Years Old | What Was Your Approximate Average Weight When You Were: 70+ Years Old | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_cooperation** | The Participant's Cooperation Was: | The Participant's Cooperation Was: | .M="Missing"<br>.R="Not Randomized"<br>1="Excellent"<br>2="Very Good" |
| 01. Principal | **stqbl_country_birth** | If No: Which Country Were You Born In? | If No: Which Country Were You Born In? | Char |
| 01. Principal | **stqbl_diet_change** | Change Your Diet? | Change Your Diet? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **stqbl_education** | What Is The Highest Grade Or Level Of Schooling You Have Completed? Check One Box Only. | What Is The Highest Grade Or Level Of Schooling You Have Completed? Check One Box Only. | .R="Not Randomized"<br>4="High school graduate or GED"<br>6="Associate degree or some college"<br>7="Bachelor's degree"<br>8="Advanced degree (Master's degree or higher)" |
| 01. Principal | **stqbl_exercise_mild** | During The Past Year, Did You Do Mild Exercise? | During The Past Year, Did You Do Mild Exercise? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_exercise_moderate** | During The Past Year, Did You Do Moderate Exercise? | During The Past Year, Did You Do Moderate Exercise? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_exercise_muscle** | During The Past Year, Did You Do Exercises To Increase Muscle Strength And Endurance? | During The Past Year, Did You Do Exercises To Increase Muscle Strength And Endurance? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_exercise_strenuous** | During The Past Year, Did You Do Strenuous Exercise? | During The Past Year, Did You Do Strenuous Exercise? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_gender** | What Is Your Sex? | What Is Your Sex? | .R="Not Randomized"<br>1="Male"<br>2="Female" |
| 01. Principal | **stqbl_glucose_test** | Use A Home Glucose Test To Monitor Your Insulin Level? | Use A Home Glucose Test To Monitor Your Insulin Level? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **stqbl_golf_months** | How Many Months In The Past Year? | How Many Months In The Past Year? | .M="Missing"<br>.R="Not Randomized"<br>1="1-3"<br>2="4-6" |
| 01. Principal | **stqbl_has_healthcare** | Are You Covered By Health Insurance Or A Health Care Plan? | Are You Covered By Health Insurance Or A Health Care Plan? | .R="Not Randomized"<br>1="Yes" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_healthcare_medicaid** | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? Medicaid/Medi-Cal | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? Medicaid/Medi-Cal | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **stqbl_healthcare_medicare** | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? Medicare | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? Medicare | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_healthcare_military** | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? Military Health Care | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? Military Health Care | .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **stqbl_healthcare_private** | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? - Private Health Insurance | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? - Private Health Insurance | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_healthcare_self** | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? Self-Employed Health Plan | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? Self-Employed Health Plan | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_healthcare_unknown** | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? I Have Health Insurance, But I Don't Know What Type | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? I Have Health Insurance, But I Don't Know What Type | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **stqbl_healthplan_enroll** | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? Self-Employed Health Plan | What Type Of Health Insurance Or Health Care Plan Are You Enrolled In? Self-Employed Health Plan | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **stqbl_height_feet** | What Is Your Current Height? | What Is Your Current Height? | Numeric .R="Not Randomized" |
| 01. Principal | **stqbl_height_inch** | What Is Your Current Height? | What Is Your Current Height? | Numeric .R="Not Randomized" |
| 01. Principal | **stqbl_interview_another** | Did The Interview Include Another Person (Please Specify)? | Did The Interview Include Another Person (Please Specify)? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_interview_end_dt** | Date Interview Ended | Date Interview Ended | SAS Date .R="Not Randomized" |
| 01. Principal | **stqbl_interview_end_time** | Time Interview Ended | Time Interview Ended | SAS Time .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_interview_family** | Did The Interview Include Another Family Member? | Did The Interview Include Another Family Member? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_interview_part** | Did The Interview Include The Participant Only? | Did The Interview Include The Participant Only? | .R="Not Randomized" 0="No" 1="Yes" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_interview_spouse** | Did The Interview Include A Spouse Or Partner? | Did The Interview Include A Spouse Or Partner? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_interview_start_dt** | Date Interview Began | Date Interview Began | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **stqbl_interview_start_time** | Time Interview Began | Time Interview Began | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_jewish** | Do You Consider Yourself To Be Of Jewish Ancestry? | Do You Consider Yourself To Be Of Jewish Ancestry? | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_latino** | Do You Consider Yourself To Be Of Hispanic Or Latino Ancestry? | Do You Consider Yourself To Be Of Hispanic Or Latino Ancestry? | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_marital_stat** | What Is Your Current Marital Status? Check One Box Only. | What Is Your Current Marital Status? Check One Box Only. | .R="Not Randomized"<br>1="Single (never married)"<br>3="Married"<br>4="Divorced" |
| 01. Principal | **stqbl_mild_days** | How Many Days Per Week? | How Many Days Per Week? | .M="Missing"<br>.R="Not Randomized"<br>1="1-2" |
| 01. Principal | **stqbl_mild_hours** | How Many Hours Per Day? | How Many Hours Per Day? | .M="Missing"<br>.R="Not Randomized"<br>1="<1 hour"<br>2="1-2" |
| 01. Principal | **stqbl_moderate_days** | How Many Days Per Week? | How Many Days Per Week? | .M="Missing"<br>.R="Not Randomized"<br>1="1-2" |
| 01. Principal | **stqbl_moderate_minutes** | How Many Minutes Per Day? | How Many Minutes Per Day? | .M="Missing"<br>.R="Not Randomized"<br>1="10-25"<br>3="45-55" |
| 01. Principal | **stqbl_moderate_months** | How Many Months In The Past Year? | How Many Months In The Past Year? | .M="Missing"<br>.R="Not Randomized"<br>2="4-6" |
| 01. Principal | **stqbl_muscle_days** | How Many Days Per Week? | How Many Days Per Week? | .M="Missing"<br>.R="Not Randomized"<br>1="1-2"<br>2="3-4" |
| 01. Principal | **stqbl_muscle_minutes** | How Many Minutes Per Day? | How Many Minutes Per Day? | .M="Missing"<br>.R="Not Randomized"<br>1="10-25"<br>2="30-40"<br>3="45-55" |
| 01. Principal | **stqbl_muscle_months** | How Many Months In The Past Year? | How Many Months In The Past Year? | .M="Missing"<br>.R="Not Randomized"<br>1="1-3"<br>2="4-6"<br>3="7-9" |
| 01. Principal | **stqbl_other** | Other (Describe) | Other (Describe) | Char |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqbl_pace** | What Was Your Usual Pace? | What Was Your Usual Pace? | .R="Not Randomized"<br>1="Casual (each mile takes 30 minutes or more)"<br>2="Moderate (each mile takes 20-29 minutes)"<br>3="Fast (each mile takes 19 minutes or less)" |
| 01. Principal | **stqbl_person_specify** | Another Person, Specify: | Another Person, Specify: | Char |
| 01. Principal | **stqbl_q2_age** | Enter The Subject's Current Age From Question # 2 On The Previous Page. | Enter The Subject's Current Age From Question # 2 On The Previous Page. | Numeric<br>.R="Not Randomized" |
| 01. Principal | **stqbl_quality** | The Quality Of The Interview Is: | The Quality Of The Interview Is: | .M="Missing"<br>.R="Not Randomized"<br>1="Excellent"<br>2="Very Good" |
| 01. Principal | **stqbl_race_asian** | What Is Your Racial Background? Asian? | What Is Your Racial Background? Asian? | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_race_black** | What Is Your Racial Background? Black Or African American | What Is Your Racial Background? Black Or African American | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_race_hawaiian** | What Is Your Racial Background? Hawaiian Or Other Pacific Islander? | What Is Your Racial Background? Hawaiian Or Other Pacific Islander? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_race_native** | What Is Your Racial Background? Native American/American Indian? | What Is Your Racial Background? Native American/American Indian? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_race_other** | What Is Your Racial Background? Other (Please Describe)? | What Is Your Racial Background? Other (Please Describe)? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_race_white** | What Is Your Racial Background? White Or Caucasian | What Is Your Racial Background? White Or Caucasian | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_sedentary_hours** | How Many Hours Per Day? | How Many Hours Per Day? | .R="Not Randomized"<br>2="1-2"<br>4="4+ hours" |
| 01. Principal | **stqbl_sit_days** | During The Past Month, How Often Did You Participate In Sitting Activities? | During The Past Month, How Often Did You Participate In Sitting Activities? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_state_birth** | If Yes: Which State Were You Born In? | If Yes: Which State Were You Born In? | Char |
| 01. Principal | **stqbl_strenuous_days** | How Many Days Per Week? | How Many Days Per Week? | .M="Missing"<br>.R="Not Randomized"<br>1="1-2" |
| 01. Principal | **stqbl_strenuous_minutes** | How Many Minutes Per Day? | How Many Minutes Per Day? | .M="Missing"<br>.R="Not Randomized"<br>2="30-40"<br>3="45-55"<br>4="60+ minutes" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_strenuous_months** | How Many Months In The Past Year? | How Many Months In The Past Year? | .M="Missing"<br>.R="Not Randomized"<br>1="1-3"<br>2="4-6"<br>3="7-9" |
| 01. Principal | **stqbl_usa_born** | Were You Born In The U.S.? | Were You Born In The U.S.? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_visit_dt** | Visit Date | Visit Date | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **stqbl_walk** | During The Past Year, Did You Walk For Exercise? | During The Past Year, Did You Walk For Exercise? | .R="Not Randomized"<br>1="Yes" |
| 01. Principal | **stqbl_walk_days** | How Many Days Per Week? | How Many Days Per Week? | .R="Not Randomized"<br>1="1-2"<br>2="3-4"<br>4="7" |
| 01. Principal | **stqbl_walk_minutes** | How Many Minutes Per Day? | How Many Minutes Per Day? | .R="Not Randomized"<br>1="10-25"<br>2="30-40"<br>4="60+ minutes" |
| 01. Principal | **stqbl_walk_months** | How Many Months In The Past Year? | How Many Months In The Past Year? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_weight_3months** | If Yes, What Is Your Weight 3 Months Ago? | If Yes, What Is Your Weight 3 Months Ago? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_weight_6months** | If Yes, What Is Your Weight 6 Months Ago? | If Yes, What Is Your Weight 6 Months Ago? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_weight_lbs** | What Is Your Current Weight? | What Is Your Current Weight? | Numeric<br>.R="Not Randomized" |
| 01. Principal | **stqbl_weight_loss** | Have You Lost Weight In The Past 6 Months? | Have You Lost Weight In The Past 6 Months? | .R="Not Randomized"<br>0="No"<br>1="Yes" |

# Section 9: Baseline Questionnaire - Comorbidities

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_anemia** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Pernicious Anemia) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Pernicious Anemia) | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_anemia_age** | How Old Were You When A Doctor First Told You That You Had Pernicious Anemia? | How Old Were You When A Doctor First Told You That You Had Pernicious Anemia? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_barrett** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Barrett's Esophagus) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Barrett's Esophagus) | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_barrett_age** | How Old Were You When A Doctor First Told You That You Had Barrett's Esophagus? | How Old Were You When A Doctor First Told You That You Had Barrett's Esophagus? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_bowel** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Inflammatory Bowel) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Inflammatory Bowel) | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_bowel_age** | How Old Were You When A Doctor First Told You That You Had Inflammatory Bowel? | How Old Were You When A Doctor First Told You That You Had Inflammatory Bowel? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_cancer** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Cancer) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Cancer) | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_cancer_type** | If Had Cancer, Specify Type(s) | If Had Cancer, Specify Type(s) | Char |
| 01. Principal | **stqbl_celiac** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Celiac Disease) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Celiac Disease) | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_celiac_age** | How Old Were You When A Doctor First Told You That You Had Celiac Disease? | How Old Were You When A Doctor First Told You That You Had Celiac Disease? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqbl_cirrhosis** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Liver Cirrhosis) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Liver Cirrhosis) | .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_cirrhosis_age** | How Old Were You When A Doctor First Told You That You Had Liver Cirrhosis? | How Old Were You When A Doctor First Told You That You Had Liver Cirrhosis? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_colitis** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Ulcerative Colitis) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Ulcerative Colitis) | .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_colitis_age** | How Old Were You When A Doctor First Told You That You Had Ulcerative Colitis? | How Old Were You When A Doctor First Told You That You Had Ulcerative Colitis? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_diabetes** | Has A Doctor Or Health Care Provider Ever Told You That You Had Diabetes? | Has A Doctor Or Health Care Provider Ever Told You That You Had Diabetes? | .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **stqbl_diabetes_age** | How Old Were You When A Doctor First Told You That You Had Diabetes? | How Old Were You When A Doctor First Told You That You Had Diabetes? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_gallstone** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Gallstone) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Gallstone) | .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **stqbl_gallstone_age** | How Old Were You When A Doctor First Told You That You Had Gallstone? | How Old Were You When A Doctor First Told You That You Had Gallstone? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_heart_disease** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Heart Disease) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Heart Disease) | .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_heart_disease_age** | How Old Were You When A Doctor First Told You That You Had Heart Disease? | How Old Were You When A Doctor First Told You That You Had Heart Disease? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_hepatitis_b** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Hepatitis B) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Hepatitis B) | .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_hepatitis_b_age** | How Old Were You When A Doctor First Told You That You Had Hepatitis B? | How Old Were You When A Doctor First Told You That You Had Hepatitis B? | Numeric .M="Missing" .R="Not Randomized" |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_hepatitis_c** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Hepatitis C) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Hepatitis C) | .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_hepatitis_c_age** | How Old Were You When A Doctor First Told You That You Had Hepatitis C? | How Old Were You When A Doctor First Told You That You Had Hepatitis C? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_high_chol** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (High Cholesterol) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (High Cholesterol) | .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_high_chol_age** | How Old Were You When A Doctor First Told You That You Had High Cholesterol? | How Old Were You When A Doctor First Told You That You Had High Cholesterol? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_hypertension** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (High Blood Pressure) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (High Blood Pressure) | .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **stqbl_hypertension_age** | How Old Were You When A Doctor First Told You That You Had Hypertension? | How Old Were You When A Doctor First Told You That You Had Hypertension? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_panc** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Pancreatitis) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Pancreatitis) | .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_panc_age** | How Old Were You When A Doctor First Told You That You Had Pancreatitis? | How Old Were You When A Doctor First Told You That You Had Pancreatitis? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_panc_pseudo** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Pancreatic Pseudocyst) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Pancreatic Pseudocyst) | .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_panc_pseudo_age** | How Old Were You When A Doctor First Told You That You Had Pancreatitis Pseudocyst? | How Old Were You When A Doctor First Told You That You Had Pancreatitis Pseudocyst? | Numeric .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_small_ulcer** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Small Intestine Ulcer) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Small Intestine Ulcer) | .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_small_ulcer_age** | How Old Were You When A Doctor First Told You That You Had Small Intestine Ulcers? | How Old Were You When A Doctor First Told You That You Had Small Intestine Ulcers? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_stom_ulcer** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Stomach Ulcers) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Stomach Ulcers) | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **stqbl_stom_ulcer_age** | How Old Were You When A Doctor First Told You That You Had Stomach Ulcers? | How Old Were You When A Doctor First Told You That You Had Stomach Ulcers? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_stroke** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Stroke) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Stroke) | .R="Not Randomized" 0="No" |
| 01. Principal | **stqbl_stroke_age** | How Old Were You When A Doctor First Told You That You Had A Stroke? | How Old Were You When A Doctor First Told You That You Had A Stroke? | Numeric .M="Missing" .R="Not Randomized" |

# Section 10: Baseline Questionnaire - Alcohol/Smoking History

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqbl_alc_5drinks** | During The Past 6 Months About How Many Times Have You Had 5 Or More Drinks Of Alcohol In One Day? | During The Past 6 Months About How Many Times Have You Had 5 Or More Drinks Of Alcohol In One Day? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_alc_6months** | Did You Ever Drink Alcohol At Least Once A Week For 6 Months Or Longer? | Did You Ever Drink Alcohol At Least Once A Week For 6 Months Or Longer? | Numeric<br>.R="Not Randomized" |
| 01. Principal | **stqbl_alc_age** | How Old Were You When A Doctor First Told You That You Had Alcoholism? | How Old Were You When A Doctor First Told You That You Had Alcoholism? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_alc_per_week** | How Many Drinks Of Alcohol Do You Usually Have Per Week Now? | How Many Drinks Of Alcohol Do You Usually Have Per Week Now? | .M="Missing"<br>.R="Not Randomized"<br>1="< 1 drink per week"<br>2="1-6 drinks per week (less than 1 per day)"<br>3="7-13 drinks per week (1-2 per day)" |
| 01. Principal | **stqbl_alc_quit_time** | How Long Has It Been Since You Stopped Drinking Alcohol At Least Once A Week? | How Long Has It Been Since You Stopped Drinking Alcohol At Least Once A Week? | .M="Missing"<br>.R="Not Randomized"<br>2="Weeks"<br>3="Months"<br>4="Years" |
| 01. Principal | **stqbl_alc_start_age** | How Old Were You When You First Started Drinking Alcohol At Least Once A Week? | How Old Were You When You First Started Drinking Alcohol At Least Once A Week? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_alc_stopped** | How Long Has It Been Since You Stopped Drinking Alcohol At Least Once A Week? | How Long Has It Been Since You Stopped Drinking Alcohol At Least Once A Week? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_alc_weekly** | Do You Drink Alcohol At Least Once A Week Now? | Do You Drink Alcohol At Least Once A Week Now? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_alc_years** | About How Many Years Did You Drink Alcohol At Least Once A Week? | About How Many Years Did You Drink Alcohol At Least Once A Week? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_alcoholism** | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Alcoholism) | Has A Doctor Or Health Care Provider Ever Told You That You Had The Following Medical Condition? (Alcoholism) | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_cig_active** | Do You Smoke Cigarettes Now? | Do You Smoke Cigarettes Now? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_cig_last_age** | How Old Were You When You Last Smoked Cigarettes Daily? | How Old Were You When You Last Smoked Cigarettes Daily? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_cig_one_per_day** | Have You Ever Smoked At Least One Cigarette A Day For 6 Months Or Longer? | Have You Ever Smoked At Least One Cigarette A Day For 6 Months Or Longer? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_cig_per_day** | During The Time You Smoked, How Many Cigarettes Did You Usually Smoke Each Day? | During The Time You Smoked, How Many Cigarettes Did You Usually Smoke Each Day? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_cig_quit_1year** | Between [Age 1] And [Age 2, Or Now If Still Smoking] Did You Ever Quit Smoking For At Least 1 Year? | Between [Age 1] And [Age 2, Or Now If Still Smoking] Did You Ever Quit Smoking For At Least 1 Year? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_cig_quit_length** | How Long Has It Been Since You Quit Smoking Cigarettes? | How Long Has It Been Since You Quit Smoking Cigarettes? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_cig_quit_num** | At That Time (When You Quit Smoking) How Many Cigarettes Did You Usually Smoke Each Day? | At That Time (When You Quit Smoking) How Many Cigarettes Did You Usually Smoke Each Day? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_cig_quit_time** | How Long Has It Been Since You Quit Smoking Cigarettes? | How Long Has It Been Since You Quit Smoking Cigarettes? | .M="Missing"<br>.R="Not Randomized"<br>3="Months"<br>4="Years" |
| 01. Principal | **stqbl_cig_quit_years** | Between [Age 1] And [Age 2, Or Now If Still Smoking] Did You Ever Quit Smoking For At Least 1 Year? | Between [Age 1] And [Age 2, Or Now If Still Smoking] Did You Ever Quit Smoking For At Least 1 Year? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_cig_start_age** | How Old Were You When You First Started Smoking Cigarettes Daily? | How Old Were You When You First Started Smoking Cigarettes Daily? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_drink_18/30/45/60** | How Many Drinks Of Alcohol Did You Usually Have Per Week At Age 60? | How Many Drinks Of Alcohol Did You Usually Have Per Week At Age 60? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_inhale_last_age** | How Old Were You When You Last Took Your 1st Inhalable Powder? | How Old Were You When You Last Took Your 1st Inhalable Powder? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_inhale_months** | If Yes (Inhalable Powder) Ask: How Many Months? | If Yes (Inhalable Powder) Ask: How Many Months? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_inhale_powder_1st** | Was There A Period Of One Month Or More When You Did Not Take Your 1st Inhalable Powder? | Was There A Period Of One Month Or More When You Did Not Take Your 1st Inhalable Powder? | .M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_inhale_powder_name_1st** | What Was The Name Of Your 1st Inhalable Powder Medication? | What Was The Name Of Your 1st Inhalable Powder Medication? | Char |

# Section 11: Baseline Questionnaire - Surgical History - Surgical History

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqbl_appendix_surgery_age** | How Old Were You When You Had This Surgery? (Appendix) | How Old Were You When You Had This Surgery? (Appendix) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_breast_surgery_age** | How Old Were You When You Had This Surgery? (Breast) | How Old Were You When You Had This Surgery? (Breast) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_colon_surgery_age** | How Old Were You When You Had This Surgery? (Colon) | How Old Were You When You Had This Surgery? (Colon) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_gallblad_surgery_age** | How Old Were You When You Had This Surgery? (Gallbladder) | How Old Were You When You Had This Surgery? (Gallbladder) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_gallstone_surgery_age** | How Old Were You When You Had This Surgery? (Gallstone) | How Old Were You When You Had This Surgery? (Gallstone) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_ovary_surgery_age** | How Old Were You When You Had This Surgery? (Ovary) | How Old Were You When You Had This Surgery? (Ovary) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_stomach_surgery_age** | How Old Were You When You Had This Surgery? (Stomach) | How Old Were You When You Had This Surgery? (Stomach) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_surgery_appendix** | Have You Ever Had Surgery To Remove Your Appendix? | Have You Ever Had Surgery To Remove Your Appendix? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_surgery_breast** | Have You Ever Had Surgery To Remove Your Breast? | Have You Ever Had Surgery To Remove Your Breast? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_surgery_colon** | Have You Ever Had Surgery To Remove Your Colon? | Have You Ever Had Surgery To Remove Your Colon? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_surgery_gallbladder** | Have You Ever Had Surgery To Remove Your Gall Bladder? | Have You Ever Had Surgery To Remove Your Gall Bladder? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_surgery_gallstone** | Have You Ever Had Surgery To Remove Your Gall Stones? | Have You Ever Had Surgery To Remove Your Gall Stones? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_surgery_ovary** | Have You Ever Had Surgery To Remove Your Ovaries (Oophorectomy)? | Have You Ever Had Surgery To Remove Your Ovaries (Oophorectomy)? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_surgery_stomach** | Have You Ever Had Surgery To Remove Your Stomach? | Have You Ever Had Surgery To Remove Your Stomach? | .R="Not Randomized"<br>0="No" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_surgery_uterus** | Have You Ever Had Surgery To Remove Your Uterus (Hysterectomy)? | Have You Ever Had Surgery To Remove Your Uterus (Hysterectomy)? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_uterus_surgery_age** | How Old Were You When You Had This Surgery? (Uterus) | How Old Were You When You Had This Surgery? (Uterus) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

# Section 12: Baseline Questionnaire - Drug History

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | stqbl_anti_depress_last_age_1st | How Old Were You When You Last Took Your 1st Anti-Depressant Drug? | How Old Were You When You Last Took Your 1st Anti-Depressant Drug? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | stqbl_anti_depress_last_age_2nd | How Old Were You When You Last Took Your 2nd Anti-Depressant Drug? | How Old Were You When You Last Took Your 2nd Anti-Depressant Drug? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | stqbl_anti_depress_months | If Yes (Anti-Depressant Drug) Ask: How Many Months? | If Yes (Anti-Depressant Drug) Ask: How Many Months? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | stqbl_anti_depress_name_1st | What Was The Name Of Your 1st Anti-Depressant Medication? | What Was The Name Of Your 1st Anti-Depressant Medication? | Char |
| 01. Principal | stqbl_anti_depress_name_2nd | What Was The Name Of Your 2nd Anti-Depressant Medication? | What Was The Name Of Your 2nd Anti-Depressant Medication? | Char |
| 01. Principal | stqbl_anti_depress_period_1st | Was There A Period Of One Month Or More When You Did Not Take Your 1st Anti-Depressant Drug? | Was There A Period Of One Month Or More When You Did Not Take Your 1st Anti-Depressant Drug? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | stqbl_anti_depress_period_2nd | Was There A Period Of One Month Or More When You Did Not Take Your 2nd Anti-Depressant Drug? | Was There A Period Of One Month Or More When You Did Not Take Your 2nd Anti-Depressant Drug? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | stqbl_anti_depressant_1st | Have You Ever Taken 1st Anti-Depressant For One Year Or Longer? | Have You Ever Taken 1st Anti-Depressant For One Year Or Longer? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | stqbl_anti_depressant_2nd | Have You Ever Taken 2nd Anti-Depressant For One Year Or Longer? | Have You Ever Taken 2nd Anti-Depressant For One Year Or Longer? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | stqbl_anti_depressant_age_1st | How Old Were You When You First Took The 1st Anti-Depressant Drug? | How Old Were You When You First Took The 1st Anti-Depressant Drug? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | stqbl_antibiotic | Over The Past Year, Have You Taken An Antibiotic For Any Reason? | Over The Past Year, Have You Taken An Antibiotic For Any Reason? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | stqbl_antibiotic_course | Over The Past Year, How Many Courses Of Antibiotics Have You Taken? | Over The Past Year, How Many Courses Of Antibiotics Have You Taken? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqbl_antibiotic_month** | When Was The Last Time You Took Antibiotics? | When Was The Last Time You Took Antibiotics? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_antibiotic_year** | When Was The Last Time You Took Antibiotics? | When Was The Last Time You Took Antibiotics? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_antibiotics_name** | What Was The Name Of The Antibiotic(s) You Took? | What Was The Name Of The Antibiotic(s) You Took? | Char |
| 01. Principal | **stqbl_aspirin** | Have You Ever Taken Aspirin At Least 4 Days Per Week For 3 Months Or Longer? | Have You Ever Taken Aspirin At Least 4 Days Per Week For 3 Months Or Longer? | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_aspirin_4week** | Do You Take Aspirin At Least 4 Days Per Week Now? | Do You Take Aspirin At Least 4 Days Per Week Now? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_aspirin_4week_age** | How Old Were You When You Started Taking Aspirin At Least 4 Days Per Week? | How Old Were You When You Started Taking Aspirin At Least 4 Days Per Week? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_chronic** | To Treat Chronic Pain Or Headaches | To Treat Chronic Pain Or Headaches | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_existing** | To Treat An Existing Condition Such As Arthritis, Heart Disease, Or Stroke | To Treat An Existing Condition Such As Arthritis, Heart Disease, Or Stroke | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_extra_freq** | How Often Do/Did You Take Extra Strength Aspirin? | How Often Do/Did You Take Extra Strength Aspirin? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_extra_life_label** | Over A Lifetime, About How Long Did You Take Extra Strength Aspirin? (Label) | Over A Lifetime, About How Long Did You Take Extra Strength Aspirin? (Label) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_extra_life_type** | Over A Lifetime, About How Long Did You Take Extra Strength Aspirin? (Number) | Over A Lifetime, About How Long Did You Take Extra Strength Aspirin? (Number) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_extra_tablets** | How Many Extra Strength Dose Aspirin Tablets Did You Take At A Time? | How Many Extra Strength Dose Aspirin Tablets Did You Take At A Time? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_low_freq** | How Often Do/Did You Take Low-Dose Aspirin? | How Often Do/Did You Take Low-Dose Aspirin? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_low_life_label** | Over A Lifetime, About How Long Did You Take Low-Dose Aspirin? (Label) | Over A Lifetime, About How Long Did You Take Low-Dose Aspirin? (Label) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_low_life_type** | Over A Lifetime, About How Long Did You Take Low-Dose Aspirin? (Number) | Over A Lifetime, About How Long Did You Take Low-Dose Aspirin? (Number) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqbl_aspirin_low_tablets** | How Many Low-Dose Aspirin Tablets Did You Take At A Time? | How Many Low-Dose Aspirin Tablets Did You Take At A Time? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_other** | Other Reason (Describe) | Other Reason (Describe) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_other_char** | Other Reason (Describe) | Other Reason (Describe) | Char |
| 01. Principal | **stqbl_aspirin_other_dose** | Other Type Of Aspirin, Specify (Dose In Mg Per Tablet): | Other Type Of Aspirin, Specify (Dose In Mg Per Tablet): | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_other_freq** | How Often Do/Did You Take Other Aspirin? | How Often Do/Did You Take Other Aspirin? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_other_life_label** | Over A Lifetime, About How Long Did You Take Extra Strength Aspirin? (Label) | Over A Lifetime, About How Long Did You Take Extra Strength Aspirin? (Label) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_other_life_type** | Over A Lifetime, About How Long Did You Take Other Aspirin? (Number) | Over A Lifetime, About How Long Did You Take Other Aspirin? (Number) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_other_name** | Other Type Of Aspirin, Specify (Name): | Other Type Of Aspirin, Specify (Name): | Char |
| 01. Principal | **stqbl_aspirin_other_tablets** | How Many Other Aspirin Tablets Did You Take At A Time? | How Many Other Aspirin Tablets Did You Take At A Time? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_prevent** | To Prevent Heart Attacks, Stroke, Or Cancer | To Prevent Heart Attacks, Stroke, Or Cancer | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_reg_freq** | How Often Do/Did You Take Regular Strength Aspirin? | How Often Do/Did You Take Regular Strength Aspirin? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_reg_life_label** | Over A Lifetime, About How Long Did You Take Regular Strength Aspirin? (Label) | Over A Lifetime, About How Long Did You Take Regular Strength Aspirin? (Label) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_reg_life_type** | Over A Lifetime, About How Long Did You Take Regular Strength Aspirin? (Number) | Over A Lifetime, About How Long Did You Take Regular Strength Aspirin? (Number) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_aspirin_reg_tablets** | How Many Regular Strength Dose Aspirin Tablets Did You Take At A Time? | How Many Regular Strength Dose Aspirin Tablets Did You Take At A Time? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_hypertension_drug_1st** | Have You Ever Taken 1st Prescription Drug For Hypertension For One Year Or Longer? | Have You Ever Taken 1st Prescription Drug For Hypertension For One Year Or Longer? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_hypertension_drug_2nd** | Have You Ever Taken 2nd Prescription Drug For Hypertension For One Year Or Longer? | Have You Ever Taken 2nd Prescription Drug For Hypertension For One Year Or Longer? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_hypertension_last_age_1st** | How Old Were You When You Last Took Your 1st Hypertension Drug? | How Old Were You When You Last Took Your 1st Hypertension Drug? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_hypertension_last_age_2nd** | How Old Were You When You Last Took Your 2nd Hypertension Drug? | How Old Were You When You Last Took Your 2nd Hypertension Drug? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_hypertension_months_1st** | If Yes (1st Hypertension Drug) Ask: How Many Months? | If Yes (1st Hypertension Drug) Ask: How Many Months? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_hypertension_months_2nd** | If Yes (2nd Hypertension Drug) Ask: How Many Months? | If Yes (2nd Hypertension Drug) Ask: How Many Months? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_hypertension_name_1st** | What Was The Name Of Your 1st Hypertension Medication? | What Was The Name Of Your 1st Hypertension Medication? | Char |
| 01. Principal | **stqbl_hypertension_name_2nd** | What Was The Name Of Your 2nd Hypertension Medication? | What Was The Name Of Your 2nd Hypertension Medication? | Char |
| 01. Principal | **stqbl_hypertension_period_1st** | Was There A Period Of One Month Or More When You Did Not Take Your 1st Hypertension Drug? | Was There A Period Of One Month Or More When You Did Not Take Your 1st Hypertension Drug? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_hypertension_period_2nd** | Was There A Period Of One Month Or More When You Did Not Take Your 2nd Hypertension Drug? | Was There A Period Of One Month Or More When You Did Not Take Your 2nd Hypertension Drug? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_hyptertension_drug_age_1st** | How Old Were You When You First Took The 1st Hypertension Drug? | How Old Were You When You First Took The 1st Hypertension Drug? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_hyptertension_drug_age_2nd** | How Old Were You When You First Took The 2nd Hypertension Drug? | How Old Were You When You First Took The 2nd Hypertension Drug? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_insulin_inject** | Take Insulin By Injection? | Take Insulin By Injection? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **stqbl_insulin_inject_1st** | Have You Ever Taken 1st Insulin Injection For Diabetes For One Year Or Longer? | Have You Ever Taken 1st Insulin Injection For Diabetes For One Year Or Longer? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_insulin_inject_2nd** | Have You Ever Taken 2nd Insulin Injection For Diabetes For One Year Or Longer? | Have You Ever Taken 2nd Insulin Injection For Diabetes For One Year Or Longer? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_insulin_inject_age_1st** | How Old Were You When You First Took The 1st Insulin Injection? | How Old Were You When You First Took The 1st Insulin Injection? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_insulin_inject_age_2nd** | How Old Were You When You First Took The 2nd Insulin Injection? | How Old Were You When You First Took The 2nd Insulin Injection? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_insulin_last_age_1st** | How Old Were You When You Last Took Your 1st Insulin Injection? | How Old Were You When You Last Took Your 1st Insulin Injection? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_insulin_last_age_2nd** | How Old Were You When You Last Took Your 2nd Insulin Injection? | How Old Were You When You Last Took Your 2nd Insulin Injection? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_insulin_months_1st** | If Yes (1st Insulin Injection) Ask: How Many Months? | If Yes (1st Insulin Injection) Ask: How Many Months? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_insulin_months_2nd** | If Yes (2nd Insulin Injection) Ask: How Many Months? | If Yes (2nd Insulin Injection) Ask: How Many Months? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_insulin_name_1st** | What Was The Name Of Your 1st Insulin Injection Medication? | What Was The Name Of Your 1st Insulin Injection Medication? | Char |
| 01. Principal | **stqbl_insulin_name_2nd** | What Was The Name Of Your 2nd Insulin Injection Medication? | What Was The Name Of Your 2nd Insulin Injection Medication? | Char |
| 01. Principal | **stqbl_insulin_other_last_age_1st** | How Old Were You When You Last Took Your 1st Other Injection? | How Old Were You When You Last Took Your 1st Other Injection? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_insulin_other_last_age_2nd** | How Old Were You When You Last Took Your 2nd Other Injection? | How Old Were You When You Last Took Your 2nd Other Injection? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_insulin_other_name_1st** | What Was The Name Of Your 1st Other Injection Medication? | What Was The Name Of Your 1st Other Injection Medication? | Char |
| 01. Principal | **stqbl_insulin_other_name_2nd** | What Was The Name Of Your 2nd Other Injection Medication? | What Was The Name Of Your 2nd Other Injection Medication? | Char |
| 01. Principal | **stqbl_insulin_other_period_1st** | Was There A Period Of One Month Or More When You Did Not Take Your 1st Other Injection? | Was There A Period Of One Month Or More When You Did Not Take Your 1st Other Injection? | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqbl_insulin_other_period_2nd** | Was There A Period Of One Month Or More When You Did Not Take Your 2nd Other Injection? | Was There A Period Of One Month Or More When You Did Not Take Your 2nd Other Injection? | Numeric .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqbl_insulin_period_1st** | Was There A Period Of One Month Or More When You Did Not Take Your 1st Insulin Injection? | Was There A Period Of One Month Or More When You Did Not Take Your 1st Insulin Injection? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_insulin_period_2nd** | Was There A Period Of One Month Or More When You Did Not Take Your 2nd Insulin Injection? | Was There A Period Of One Month Or More When You Did Not Take Your 2nd Insulin Injection? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_mouth_med** | Take Medication By Mouth? | Take Medication By Mouth? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **stqbl_oral_1st** | Have You Ever Taken 1st Oral Agent For Diabetes For One Year Or Longer? | Have You Ever Taken 1st Oral Agent For Diabetes For One Year Or Longer? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_oral_2nd** | Have You Ever Taken 2nd Oral Agent For Diabetes For One Year Or Longer? | Have You Ever Taken 2nd Oral Agent For Diabetes For One Year Or Longer? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_oral_age_1st** | How Old Were You When You First Took The 1st Oral Agent? | How Old Were You When You First Took The 1st Oral Agent? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_oral_age_2nd** | How Old Were You When You First Took The 2nd Oral Agent? | How Old Were You When You First Took The 2nd Oral Agent? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_oral_last_age_1st** | How Old Were You When You Last Took Your 1st Oral Agent? | How Old Were You When You Last Took Your 1st Oral Agent? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_oral_last_age_2nd** | How Old Were You When You Last Took Your 2nd Oral Agent? | How Old Were You When You Last Took Your 2nd Oral Agent? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_oral_months_1st** | If Yes (1st Oral Agent) Ask: How Many Months? | If Yes (1st Oral Agent) Ask: How Many Months? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_oral_months_2nd** | If Yes (2nd Oral Agent) Ask: How Many Months? | If Yes (2nd Oral Agent) Ask: How Many Months? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_oral_name_1st** | What Was The Name Of Your 1st Oral Agent Medication? | What Was The Name Of Your 1st Oral Agent Medication? | Char |
| 01. Principal | **stqbl_oral_name_2nd** | What Was The Name Of Your 2nd Oral Agent Medication? | What Was The Name Of Your 2nd Oral Agent Medication? | Char |
| 01. Principal | **stqbl_oral_period_1st** | Was There A Period Of One Month Or More When You Did Not Take Your 1st Oral Agent? | Was There A Period Of One Month Or More When You Did Not Take Your 1st Oral Agent? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqbl_oral_period_2nd** | Was There A Period Of One Month Or More When You Did Not Take Your 2nd Oral Agent? | Was There A Period Of One Month Or More When You Did Not Take Your 2nd Oral Agent? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_other_healthplan** | Other Health Insurance Plan (Describe) | Other Health Insurance Plan (Describe) | Char |
| 01. Principal | **stqbl_other_inject_1st** | Have You Ever Taken 1st Other Injection For Diabetes For One Year Or Longer? | Have You Ever Taken 1st Other Injection For Diabetes For One Year Or Longer? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_other_inject_2nd** | Have You Ever Taken 2nd Other Injection For Diabetes For One Year Or Longer? | Have You Ever Taken 2nd Other Injection For Diabetes For One Year Or Longer? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **stqbl_other_inject_age_1st** | How Old Were You When You First Took The 1st Other Injection? | How Old Were You When You First Took The 1st Other Injection? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_other_inject_age_2nd** | How Old Were You When You First Took The 2nd Other Injection? | How Old Were You When You First Took The 2nd Other Injection? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_other_inject_months_1st** | If Yes (1st Other Injection) Ask: How Many Months? | If Yes (1st Other Injection) Ask: How Many Months? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_other_inject_months_2nd** | If Yes (2nd Other Injection) Ask: How Many Months? | If Yes (2nd Other Injection) Ask: How Many Months? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqbl_probiatic_name** | What Was The Name Of The Antibiotic(s) You Took? | What Was The Name Of The Antibiotic(s) You Took? | Char |
| 01. Principal | **stqbl_probiotic** | Have You Ever Used Over-The-Counter Probiotic Supplements? | Have You Ever Used Over-The-Counter Probiotic Supplements? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqbl_probiotic_age** | How Old Were You The Last Time You Took Probiotics? | How Old Were You The Last Time You Took Probiotics? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

# Section 13: Unblinding

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **unblind_agent_dose** | Agent Dose | Agent Dose | Numeric<br>.R="Not Randomized" |
| 01. Principal | **unblind_agent_name** | Agent Name | Agent Name | .R="Not Randomized"<br>0="Placebo"<br>1="Simvastatin" |
| 01. Principal | **unblind_consortium_code** | Registration Consortium Code | Registration Consortium Code | Char |
| 01. Principal | **unblind_institution_code** | Registering Institution Code | Registering Institution Code | Char |
| 01. Principal | **unblind_institution_name** | Registering Institution Name | Registering Institution Name | Char |
| 01. Principal | **unblind_protocol_number** | DCP Protocol Number | DCP Protocol Number | Char |
| 01. Principal | **unblind_rand_num** | Randomization Number | Randomization Number | Numeric<br>.R="Not Randomized" |
| 01. Principal | **unblind_treatment_code** | Treatment Assignment Code | Treatment Assignment Code | .R="Not Randomized"<br>2="TAC1" |

# Section 14: Baseline Symptoms

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **blsymp_comments1-8** | Comments | Comments | Char |
| 01. Principal | **blsymp_onset_dt1-8** | Onset Date | Onset Date | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **blsymp_severity1-8** | Severity | Severity | .F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized"<br>1="Mild Adverse Event"<br>2="Moderate Adverse Event" |
| 01. Principal | **blsymp_symptom_desc1-8** | Symptom Description | Symptom Description | Char |
| 01. Principal | **blsymp_visit_dt1-8** | Visit Date | Visit Date | SAS Date<br>.F="No Record For This Visit"<br>.M="Missing"<br>.R="Not Randomized" |

# Section 15: Treatment Assignment Codes (TAC) and Treatment Assignment Descriptions (TAD)

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | tactad_comment_scr1 | Treatment Assignment Code (TAC) Comments At Screen 1 | Treatment Assignment Code (TAC) Comments At Screen 1 | Char |
| 01. Principal | tactad_comment_scr2 | Treatment Assignment Code (TAC) Comments At Screen 2 | Treatment Assignment Code (TAC) Comments At Screen 2 | Char |
| 01. Principal | tactad_comment_v1 | Treatment Assignment Code (TAC) Comments At Visit 1 | Treatment Assignment Code (TAC) Comments At Visit 1 | Char |
| 01. Principal | tactad_start_dt_scr1 | Treatment Assignment Code (TAC) Start Date At Screen 1 | Treatment Assignment Code (TAC) Start Date At Screen 1 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | tactad_start_dt_scr2 | Treatment Assignment Code (TAC) Start Date At Screen 2 | Treatment Assignment Code (TAC) Start Date At Screen 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | tactad_start_dt_v1 | Treatment Assignment Code (TAC) Start Date At Visit 1 | Treatment Assignment Code (TAC) Start Date At Visit 1 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | tactad_treatment_code_scr1 | Treatment Assignment Code (TAC) At Screen 1 | Treatment Assignment Code (TAC) At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | tactad_treatment_code_scr2 | Treatment Assignment Code (TAC) At Screen 2 | Treatment Assignment Code (TAC) At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | tactad_treatment_code_v1 | Treatment Assignment Code (TAC) At Visit 1 | Treatment Assignment Code (TAC) At Visit 1 | .M="Missing" .R="Not Randomized" 2="TAC1" |

# Section 16: Physical Exam

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **physex_abdomen_comment_scr2** | Abdomen: Comments At Screen 2 | Abdomen: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_abdomen_comment_v1** | Abdomen: Comments At Visit 1 | Abdomen: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_abdomen_comment_v2** | Abdomen: Comments At Visit 2 | Abdomen: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_abdomen_comment_v3** | Abdomen: Comments At Visit 3 | Abdomen: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_abdomen_scr2** | Abdomen At Screen 2 | Abdomen At Screen 2 | .M="Missing" .R="Not Randomized" 0="Normal" 1="Abnormal" |
| 01. Principal | **physex_abdomen_v1** | Abdomen At Visit 1 | Abdomen At Visit 1 | .M="Missing" .R="Not Randomized" 1="Abnormal" |
| 01. Principal | **physex_abdomen_v2** | Abdomen At Visit 2 | Abdomen At Visit 2 | .M="Missing" .R="Not Randomized" 0="Normal" 1="Abnormal" |
| 01. Principal | **physex_abdomen_v3** | Abdomen At Visit 3 | Abdomen At Visit 3 | .M="Missing" .R="Not Randomized" 0="Normal" 1="Abnormal" |
| 01. Principal | **physex_appear_comment_scr2** | Appearance: Comments At Screen 2 | Appearance: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_appear_comment_v1** | Appearance: Comments At Visit 1 | Appearance: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_appear_comment_v2** | Appearance: Comments At Visit 2 | Appearance: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_appear_comment_v3** | Appearance: Comments At Visit 3 | Appearance: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_breast_comment_scr2** | Breasts: Comments At Screen 2 | Breasts: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_breast_comment_v1** | Breasts: Comments At Visit 1 | Breasts: Comments At Visit 1 (Required If Abnormal) | Char |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **physex_breast_comment_v2** | Breasts: Comments At Visit 2 | Breasts: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_breast_comment_v3** | Breasts: Comments At Visit 3 | Breasts: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_chest_comment_scr2** | Chest: Comments At Screen 2 | Chest: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_chest_comment_v1** | Chest: Comments At Visit 1 | Chest: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_chest_comment_v2** | Chest: Comments At Visit 2 | Chest: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_chest_comment_v3** | Chest: Comments At Visit 3 | Chest: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_comment_scr2** | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | **physex_comment_v1** | Comments At Visit 1 | Comments At Visit 1 | Char |
| 01. Principal | **physex_comment_v2** | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | **physex_comment_v3** | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | **physex_genit_comment_scr2** | Genitalia: Comments At Screen 2 | Genitalia: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_genit_comment_v1** | Genitalia: Comments At Visit 1 | Genitalia: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_genit_comment_v2** | Genitalia: Comments At Visit 2 | Genitalia: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_genit_comment_v3** | Genitalia: Comments At Visit 3 | Genitalia: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_heart_comment_scr2** | Heart: Comments At Screen 2 | Heart: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_heart_comment_v1** | Heart: Comments At Visit 1 | Heart: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_heart_comment_v2** | Heart: Comments At Visit 2 | Heart: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_heart_comment_v3** | Heart: Comments At Visit 3 | Heart: Comments At Visit 3 (Required If Abnormal) | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **physex_heent_co mment_scr2** | H/E/E/N/T: Comments At Screen 2 | H/E/E/N/T: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_heent_co mment_v1** | H/E/E/N/T: Comments At Visit 1 | H/E/E/N/T: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_heent_co mment_v2** | H/E/E/N/T: Comments At Visit 2 | H/E/E/N/T: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_heent_co mment_v3** | H/E/E/N/T: Comments At Visit 3 | H/E/E/N/T: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_lungs_co mment_scr2** | Lungs: Comments At Screen 2 | Lungs: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_lungs_co mment_v1** | Lungs: Comments At Visit 1 | Lungs: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_lungs_co mment_v2** | Lungs: Comments At Visit 2 | Lungs: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_lungs_co mment_v3** | Lungs: Comments At Visit 3 | Lungs: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_lymph_c omment_scr2** | Lymph Nodes: Comments At Screen 2 | Lymph Nodes: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_lymph_c omment_v1** | Lymph Nodes: Comments At Visit 1 | Lymph Nodes: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_lymph_c omment_v2** | Lymph Nodes: Comments At Visit 2 | Lymph Nodes: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_lymph_c omment_v3** | Lymph Nodes: Comments At Visit 3 | Lymph Nodes: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_musc_co mment_scr2** | Musculoskeletal: Comments At Screen 2 | Musculoskeletal: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_musc_co mment_v1** | Musculoskeletal: Comments At Visit 1 | Musculoskeletal: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_musc_co mment_v2** | Musculoskeletal: Comments At Visit 2 | Musculoskeletal: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_musc_co mment_v3** | Musculoskeletal: Comments At Visit 3 | Musculoskeletal: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_neur_co mment_scr2** | Neurological: Comments At Screen 2 | Neurological: Comments At Screen 2 (Required If Abnormal) | Char |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **physex_neur_comment_v1** | Neurological: Comments At Visit 1 | Neurological: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_neur_comment_v2** | Neurological: Comments At Visit 2 | Neurological: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_neur_comment_v3** | Neurological: Comments At Visit 3 | Neurological: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_oth_abn_scr2** | Were Any Other Systems/Sites Abnormal At Screen 2? If Yes, Complete The Abnormal Systems Below | Were Any Other Systems/Sites Abnormal At Screen 2? If Yes, Complete The Abnormal Systems Below | .M="Missing" .R="Not Randomized" 0="Normal" |
| 01. Principal | **physex_oth_abn_v1** | Were Any Other Systems/Sites Abnormal At Visit 1? If Yes, Complete The Abnormal Systems Below | Were Any Other Systems/Sites Abnormal At Visit 1? If Yes, Complete The Abnormal Systems Below | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **physex_oth_abn_v2** | Were Any Other Systems/Sites Abnormal At Visit 2? If Yes, Complete The Abnormal Systems Below | Were Any Other Systems/Sites Abnormal At Visit 2? If Yes, Complete The Abnormal Systems Below | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **physex_oth_abn_v3** | Were Any Other Systems/Sites Abnormal At Visit 3? If Yes, Complete The Abnormal Systems Below | Were Any Other Systems/Sites Abnormal At Visit 3? If Yes, Complete The Abnormal Systems Below | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **physex_other_comment_scr2** | Other Body System/Site: Comments At Screen 2 | Other Body System/Site: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_other_comment_v1** | Other Body System/Site: Comments At Visit 1 | Other Body System/Site: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_other_comment_v2** | Other Body System/Site: Comments At Visit 2 | Other Body System/Site: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_other_comment_v3** | Other Body System/Site: Comments At Visit 3 | Other Body System/Site: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_other_scr2** | Specify Other Body System/Site At Screen 2 | Specify Other Body System/Site At Screen 2 | Char |
| 01. Principal | **physex_other_v1** | Specify Other Body System/Site At Visit 1 | Specify Other Body System/Site At Visit 1 | Char |
| 01. Principal | **physex_other_v2** | Specify Other Body System/Site At Visit 2 | Specify Other Body System/Site At Visit 2 | Char |
| 01. Principal | **physex_other_v3** | Specify Other Body System/Site At Visit 3 | Specify Other Body System/Site At Visit 3 | Char |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **physex_pelvis_comment_scr2** | Pelvis: Comments At Screen 2 | Pelvis: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_pelvis_comment_v1** | Pelvis: Comments At Visit 1 | Pelvis: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_pelvis_comment_v2** | Pelvis: Comments At Visit 2 | Pelvis: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_pelvis_comment_v3** | Pelvis: Comments At Visit 3 | Pelvis: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_pros_comment_scr2** | Prostate: Comments At Screen 2 | Prostate: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_pros_comment_v1** | Prostate: Comments At Visit 1 | Prostate: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_pros_comment_v2** | Prostate: Comments At Visit 2 | Prostate: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_pros_comment_v3** | Prostate: Comments At Visit 3 | Prostate: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_rectal_comment_scr2** | Rectal: Comments At Screen 2 | Rectal: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_rectal_comment_v1** | Rectal: Comments At Visit 1 | Rectal: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_rectal_comment_v2** | Rectal: Comments At Visit 2 | Rectal: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_rectal_comment_v3** | Rectal: Comments At Visit 3 | Rectal: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_skin_comment_scr2** | Skin: Comments At Screen 2 | Skin: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_skin_comment_v1** | Skin: Comments At Visit 1 | Skin: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_skin_comment_v2** | Skin: Comments At Visit 2 | Skin: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_skin_comment_v3** | Skin: Comments At Visit 3 | Skin: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_thyr_comment_scr2** | Thyroid: Comments At Screen 2 | Thyroid: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_thyr_comment_v1** | Thyroid: Comments At Visit 1 | Thyroid: Comments At Visit 1 (Required If Abnormal) | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **physex_thyr_comment_v2** | Thyroid: Comments At Visit 2 | Thyroid: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_thyr_comment_v3** | Thyroid: Comments At Visit 3 | Thyroid: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_vasc_comment_scr2** | Vascular: Comments At Screen 2 | Vascular: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_vasc_comment_v1** | Vascular: Comments At Visit 1 | Vascular: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **physex_vasc_comment_v2** | Vascular: Comments At Visit 2 | Vascular: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **physex_vasc_comment_v3** | Vascular: Comments At Visit 3 | Vascular: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **physex_visit_dt_scr2** | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **physex_visit_dt_v1** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **physex_visit_dt_v2** | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **physex_visit_dt_v3** | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date .M="Missing" .R="Not Randomized" |

# Section 17: Vital Signs

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | vitsig_bp_diastolic_scr2 | Blood Pressure Diastolic At Screen 2 | Blood Pressure Diastolic At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | vitsig_bp_diastolic_unk | Blood Pressure Diastolic (Visit Not Known) | Blood Pressure Diastolic (Visit Not Known) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | vitsig_bp_diastolic_v1 | Blood Pressure Diastolic At Visit 1 | Blood Pressure Diastolic At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | vitsig_bp_diastolic_v2 | Blood Pressure Diastolic At Visit 2 | Blood Pressure Diastolic At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | vitsig_bp_diastolic_v3 | Blood Pressure Diastolic At Visit 3 | Blood Pressure Diastolic At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | vitsig_bp_systolic_scr2 | Blood Pressure Systolic At Screen 2 | Blood Pressure Systolic At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | vitsig_bp_systolic_unk | Blood Pressure Systolic (Visit Not Known) | Blood Pressure Systolic (Visit Not Known) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | vitsig_bp_systolic_v1 | Blood Pressure Systolic At Visit 1 | Blood Pressure Systolic At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | vitsig_bp_systolic_v2 | Blood Pressure Systolic At Visit 2 | Blood Pressure Systolic At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | vitsig_bp_systolic_v3 | Blood Pressure Systolic At Visit 3 | Blood Pressure Systolic At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | vitsig_comment_scr2 | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | vitsig_comment_unk | Comments (Visit Not Known) | Comments (Visit Not Known) | Char |
| 01. Principal | vitsig_comment_v1 | Comments At Visit 1 | Comments At Visit 1 | Char |
| 01. Principal | vitsig_comment_v2 | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | vitsig_comment_v3 | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | vitsig_performance_stat_scr2 | Performance Status At Screen 2 | Performance Status At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | vitsig_performance_stat_unk | Performance Status (Visit Not Known) | Performance Status (Visit Not Known) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **vitsig_performance_stat_v1** | Performance Status At Visit 1 | Performance Status At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_performance_stat_v2** | Performance Status At Visit 2 | Performance Status At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_performance_stat_v3** | Performance Status At Visit 3 | Performance Status At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_pulse_scr2** | Pulse At Screen 2 | Pulse At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_pulse_unk** | Pulse (Visit Not Known) | Pulse (Visit Not Known) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_pulse_v1** | Pulse At Visit 1 | Pulse At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_pulse_v2** | Pulse At Visit 2 | Pulse At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_pulse_v3** | Pulse At Visit 3 | Pulse At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_respiration_scr2** | Respiration At Screen 2 | Respiration At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_respiration_unk** | Respiration (Visit Not Known) | Respiration (Visit Not Known) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_respiration_v1** | Respiration At Visit 1 | Respiration At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_respiration_v2** | Respiration At Visit 2 | Respiration At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_respiration_v3** | Respiration At Visit 3 | Respiration At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_temperature_scr2** | Temperature At Screen 2 | Temperature At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_temperature_unk** | Temperature (Visit Not Known) | Temperature (Visit Not Known) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_temperature_v1** | Temperature At Visit 1 | Temperature At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_temperature_v2** | Temperature At Visit 2 | Temperature At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **vitsig_temperature_v3** | Temperature At Visit 3 | Temperature At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_visit_dt_scr2** | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_visit_dt_unk** | Visit Date (Visit Not Known) | Visit Date (Visit Not Known) | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_visit_dt_v1** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_visit_dt_v2** | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_visit_dt_v3** | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_weight_scr2** | Weight At Screen 2 | Weight At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_weight_unk** | Weight (Visit Not Known) | Weight (Visit Not Known) | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_weight_v1** | Weight At Visit 1 | Weight At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_weight_v2** | Weight At Visit 2 | Weight At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **vitsig_weight_v3** | Weight At Visit 3 | Weight At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

# Section 18: Pregnancy Test

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **pregt_comment_scr2** | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | **pregt_comment_v2** | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | **pregt_comment_v3** | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | **pregt_test_result_scr2** | Pregnancy Test Results At Screen 2 | Pregnancy Test Results At Screen 2 | .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 2="Negative" 3="Not applicable, not female of child-bearing potential" |
| 01. Principal | **pregt_test_result_v2** | Pregnancy Test Results At Visit 2 | Pregnancy Test Results At Visit 2 | .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 2="Negative" 3="Not applicable, not female of child-bearing potential" |
| 01. Principal | **pregt_test_result_v3** | Pregnancy Test Results At Visit 3 | Pregnancy Test Results At Visit 3 | .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 2="Negative" 3="Not applicable, not female of child-bearing potential" |
| 01. Principal | **pregt_visit_dt_scr2** | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" |
| 01. Principal | **pregt_visit_dt_v2** | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" |
| 01. Principal | **pregt_visit_dt_v3** | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" |

# Section 19: Quality Of Life Questionnaire

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **qlq_abdominal_scr2** | Have You Had Abdominal Discomfort At Screen 2? | Have You Had Abdominal Discomfort At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_abdominal_v1** | Have You Had Abdominal Discomfort At Visit 1? | Have You Had Abdominal Discomfort At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_abdominal_v2** | Have You Had Abdominal Discomfort At Visit 2? | Have You Had Abdominal Discomfort At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_abdominal_v3** | Have You Had Abdominal Discomfort At Visit 3? | Have You Had Abdominal Discomfort At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_alc_difficult_scr2** | Have You Found It Difficult To Avoid Drinking Alcohol At Screen 2? | Have You Found It Difficult To Avoid Drinking Alcohol At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>2="A Little" |
| 01. Principal | **qlq_alc_difficult_v1** | Have You Found It Difficult To Avoid Drinking Alcohol At Visit 1? | Have You Found It Difficult To Avoid Drinking Alcohol At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>0="Not Applicable"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_alc_difficult_v2** | Have You Found It Difficult To Avoid Drinking Alcohol At Visit 2? | Have You Found It Difficult To Avoid Drinking Alcohol At Visit 2? | .R="Not Randomized"<br>0="Not Applicable"<br>1="Not at All" |
| 01. Principal | **qlq_alc_difficult_v3** | Have You Found It Difficult To Avoid Drinking Alcohol At Visit 3? | Have You Found It Difficult To Avoid Drinking Alcohol At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>0="Not Applicable"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_alc_guilty_scr2** | Have You Felt Guilty Or Embarrassed About Drinking Alcohol At Screen 2? | Have You Felt Guilty Or Embarrassed About Drinking Alcohol At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_alc_guilty_v1** | Have You Felt Guilty Or Embarrassed About Drinking Alcohol At Visit 1? | Have You Felt Guilty Or Embarrassed About Drinking Alcohol At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>0="Not Applicable"<br>1="Not at All" |
| 01. Principal | **qlq_alc_guilty_v2** | Have You Felt Guilty Or Embarrassed About Drinking Alcohol At Visit 2? | Have You Felt Guilty Or Embarrassed About Drinking Alcohol At Visit 2? | .R="Not Randomized"<br>0="Not Applicable"<br>1="Not at All" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_alc_guilty_v3** | Have You Felt Guilty Or Embarrassed About Drinking Alcohol At Visit 3? | Have You Felt Guilty Or Embarrassed About Drinking Alcohol At Visit 3? | .N="N/A" .R="Not Randomized" 0="Not Applicable" 1="Not at All" |
| 01. Principal | **qlq_appetite_scr2** | Have You Lacked Appetite At Screen 2? | Have You Lacked Appetite At Screen 2? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_appetite_v1** | Have You Lacked Appetite At Visit 1? | Have You Lacked Appetite At Visit 1? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" 3="Quite a Bit" 4="Very Much" |
| 01. Principal | **qlq_appetite_v2** | Have You Lacked Appetite At Visit 2? | Have You Lacked Appetite At Visit 2? | .R="Not Randomized" 1="Not at All" 2="A Little" 3="Quite a Bit" |
| 01. Principal | **qlq_appetite_v3** | Have You Lacked Appetite At Visit 3? | Have You Lacked Appetite At Visit 3? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" |
| 01. Principal | **qlq_attraction_scr2** | Have You Felt Physically Less Attractive As A Result Of Your Disease And Treatment At Screen 2? | Have You Felt Physically Less Attractive As A Result Of Your Disease And Treatment At Screen 2? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_attraction_v1** | Have You Felt Physically Less Attractive As A Result Of Your Disease And Treatment At Visit 1? | Have You Felt Physically Less Attractive As A Result Of Your Disease And Treatment At Visit 1? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" 3="Quite a Bit" |
| 01. Principal | **qlq_attraction_v2** | Have You Felt Physically Less Attractive As A Result Of Your Disease And Treatment At Visit 2? | Have You Felt Physically Less Attractive As A Result Of Your Disease And Treatment At Visit 2? | .R="Not Randomized" 1="Not at All" 2="A Little" |
| 01. Principal | **qlq_attraction_v3** | Have You Felt Physically Less Attractive As A Result Of Your Disease And Treatment At Visit 3? | Have You Felt Physically Less Attractive As A Result Of Your Disease And Treatment At Visit 3? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" 3="Quite a Bit" |
| 01. Principal | **qlq_back_pain_scr2** | Have You Had Back Pain At Screen 2? | Have You Had Back Pain At Screen 2? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_back_pain_v1** | Have You Had Back Pain At Visit 1? | Have You Had Back Pain At Visit 1? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" 3="Quite a Bit" |
| 01. Principal | **qlq_back_pain_v2** | Have You Had Back Pain At Visit 2? | Have You Had Back Pain At Visit 2? | .R="Not Randomized" 1="Not at All" 2="A Little" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | qlq_back_pain_v3 | Have You Had Back Pain At Visit 3? | Have You Had Back Pain At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | qlq_bed_scr2 | Do You Need To Stay In Bed Or A Chair During The Day At Screen 2? | Do You Need To Stay In Bed Or A Chair During The Day At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | qlq_bed_v1 | Do You Need To Stay In Bed Or A Chair During The Day At Visit 1? | Do You Need To Stay In Bed Or A Chair During The Day At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | qlq_bed_v2 | Do You Need To Stay In Bed Or A Chair During The Day At Visit 2? | Do You Need To Stay In Bed Or A Chair During The Day At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | qlq_bed_v3 | Do You Need To Stay In Bed Or A Chair During The Day At Visit 3? | Do You Need To Stay In Bed Or A Chair During The Day At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | qlq_bloat_scr2 | Did You Have A Bloated Feeling In Your Abdomen At Screen 2? | Did You Have A Bloated Feeling In Your Abdomen At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | qlq_bloat_v1 | Did You Have A Bloated Feeling In Your Abdomen At Visit 1? | Did You Have A Bloated Feeling In Your Abdomen At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | qlq_bloat_v2 | Did You Have A Bloated Feeling In Your Abdomen At Visit 2? | Did You Have A Bloated Feeling In Your Abdomen At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | qlq_bloat_v3 | Did You Have A Bloated Feeling In Your Abdomen At Visit 3? | Did You Have A Bloated Feeling In Your Abdomen At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | qlq_body_scr2 | Have You Been Dissatisfied With Your Body At Screen 2? | Have You Been Dissatisfied With Your Body At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | qlq_body_v1 | Have You Been Dissatisfied With Your Body At Visit 1? | Have You Been Dissatisfied With Your Body At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | qlq_body_v2 | Have You Been Dissatisfied With Your Body At Visit 2? | Have You Been Dissatisfied With Your Body At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | qlq_body_v3 | Have You Been Dissatisfied With Your Body At Visit 3? | Have You Been Dissatisfied With Your Body At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_bowel_move_scr2** | Did You Feel The Urge To Move Your Bowels Quickly At Screen 2? | Did You Feel The Urge To Move Your Bowels Quickly At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_bowel_move_v1** | Did You Feel The Urge To Move Your Bowels Quickly At Visit 1? | Did You Feel The Urge To Move Your Bowels Quickly At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>3="Quite a Bit" |
| 01. Principal | **qlq_bowel_move_v2** | Did You Feel The Urge To Move Your Bowels Quickly At Visit 2? | Did You Feel The Urge To Move Your Bowels Quickly At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_bowel_move_v3** | Did You Feel The Urge To Move Your Bowels Quickly At Visit 3? | Did You Feel The Urge To Move Your Bowels Quickly At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_bowel_scr2** | Did You Have Frequent Bowel Movements At Screen 2? | Did You Have Frequent Bowel Movements At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_bowel_v1** | Did You Have Frequent Bowel Movements At Visit 1? | Did You Have Frequent Bowel Movements At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_bowel_v2** | Did You Have Frequent Bowel Movements At Visit 2? | Did You Have Frequent Bowel Movements At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_bowel_v3** | Did You Have Frequent Bowel Movements At Visit 3? | Did You Have Frequent Bowel Movements At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_breath_scr2** | Were You Short Of Breath At Screen 2? | Were You Short Of Breath At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_breath_v1** | Were You Short Of Breath At Visit 1? | Were You Short Of Breath At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_breath_v2** | Were You Short Of Breath At Visit 2? | Were You Short Of Breath At Visit 2? | .R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_breath_v3** | Were You Short Of Breath At Visit 3? | Were You Short Of Breath At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_comment_scr2** | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | **qlq_comment_v1** | Comments At Visit 1 | Comments At Visit 1 | Char |
| 01. Principal | **qlq_comment_v2** | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | **qlq_comment_v3** | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | **qlq_comments_scr2** | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | **qlq_comments_v1** | Comments At Visit 1 | Comments At Visit 1 | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_comments_v2** | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | **qlq_comments_v3** | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | **qlq_concentrate_scr2** | Have You Had Difficulty In Concentrating On Things At Screen 2? | Have You Had Difficulty In Concentrating On Things At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_concentrate_v1** | Have You Had Difficulty In Concentrating On Things At Visit 1? | Have You Had Difficulty In Concentrating On Things At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_concentrate_v2** | Have You Had Difficulty In Concentrating On Things At Visit 2? | Have You Had Difficulty In Concentrating On Things At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_concentrate_v3** | Have You Had Difficulty In Concentrating On Things At Visit 3? | Have You Had Difficulty In Concentrating On Things At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_constipate_scr2** | Have You Been Constipated At Screen 2? | Have You Been Constipated At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_constipate_v1** | Have You Been Constipated At Visit 1? | Have You Been Constipated At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_constipate_v2** | Have You Been Constipated At Visit 2? | Have You Been Constipated At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_constipate_v3** | Have You Been Constipated At Visit 3? | Have You Been Constipated At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_depress_scr2** | Did You Feel Depressed At Screen 2? | Did You Feel Depressed At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_depress_v1** | Did You Feel Depressed At Visit 1? | Did You Feel Depressed At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_depress_v2** | Did You Feel Depressed At Visit 2? | Did You Feel Depressed At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>3="Quite a Bit" |
| 01. Principal | **qlq_depress_v3** | Did You Feel Depressed At Visit 3? | Did You Feel Depressed At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_diarrhea_scr2** | Have You Had Diarrhea At Screen 2? | Have You Had Diarrhea At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |

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| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **qlq_diarrhea_v1** | Have You Had Diarrhea At Visit 1? | Have You Had Diarrhea At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_diarrhea_v2** | Have You Had Diarrhea At Visit 2? | Have You Had Diarrhea At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>3="Quite a Bit" |
| 01. Principal | **qlq_diarrhea_v3** | Have You Had Diarrhea At Visit 3? | Have You Had Diarrhea At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>3="Quite a Bit" |
| 01. Principal | **qlq_dry_mouth_scr2** | Did You Have A Dry Mouth At Screen 2? | Did You Have A Dry Mouth At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_dry_mouth_v1** | Did You Have A Dry Mouth At Visit 1? | Did You Have A Dry Mouth At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_dry_mouth_v2** | Did You Have A Dry Mouth At Visit 2? | Did You Have A Dry Mouth At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_dry_mouth_v3** | Did You Have A Dry Mouth At Visit 3? | Did You Have A Dry Mouth At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_family_scr2** | Has Your Physical Condition Or Medical Treatment Interfered With Your Family Life At Screen 2? | Has Your Physical Condition Or Medical Treatment Interfered With Your Family Life At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_family_v1** | Has Your Physical Condition Or Medical Treatment Interfered With Your Family Life At Visit 1? | Has Your Physical Condition Or Medical Treatment Interfered With Your Family Life At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_family_v2** | Has Your Physical Condition Or Medical Treatment Interfered With Your Family Life At Visit 2? | Has Your Physical Condition Or Medical Treatment Interfered With Your Family Life At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_family_v3** | Has Your Physical Condition Or Medical Treatment Interfered With Your Family Life At Visit 3? | Has Your Physical Condition Or Medical Treatment Interfered With Your Family Life At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_financial_scr2** | Has Your Physical Condition Or Medical Treatment Caused You Financial Difficulties At Screen 2? | Has Your Physical Condition Or Medical Treatment Caused You Financial Difficulties At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **qlq_financial_v1** | Has Your Physical Condition Or Medical Treatment Caused You Financial Difficulties At Visit 1? | Has Your Physical Condition Or Medical Treatment Caused You Financial Difficulties At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_financial_v2** | Has Your Physical Condition Or Medical Treatment Caused You Financial Difficulties At Visit 2? | Has Your Physical Condition Or Medical Treatment Caused You Financial Difficulties At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_financial_v3** | Has Your Physical Condition Or Medical Treatment Caused You Financial Difficulties At Visit 3? | Has Your Physical Condition Or Medical Treatment Caused You Financial Difficulties At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_food_amount _scr2** | Were You Restricted In The Amounts Of Food You Can Eat As A Result Of Your Disease Or Treatment At Screen 2? | Were You Restricted In The Amounts Of Food You Can Eat As A Result Of Your Disease Or Treatment At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_food_amount _v1** | Were You Restricted In The Amounts Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 1? | Were You Restricted In The Amounts Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_food_amount _v2** | Were You Restricted In The Amounts Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 2? | Were You Restricted In The Amounts Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_food_amount _v3** | Were You Restricted In The Amounts Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 3? | Were You Restricted In The Amounts Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_food_taste_s cr2** | Did Food And Drink Taste Different From Usual At Screen 2? | Did Food And Drink Taste Different From Usual At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_food_taste_v 1** | Did Food And Drink Taste Different From Usual At Visit 1? | Did Food And Drink Taste Different From Usual At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_food_taste_v 2** | Did Food And Drink Taste Different From Usual At Visit 2? | Did Food And Drink Taste Different From Usual At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_food_taste_v 3** | Did Food And Drink Taste Different From Usual At Visit 3? | Did Food And Drink Taste Different From Usual At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_food_type_scr2** | Were You Restricted In The Types Of Food You Can Eat As A Result Of Your Disease Or Treatment At Screen 2? | Were You Restricted In The Types Of Food You Can Eat As A Result Of Your Disease Or Treatment At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>2="A Little" |
| 01. Principal | **qlq_food_type_v1** | Were You Restricted In The Types Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 1? | Were You Restricted In The Types Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_food_type_v2** | Were You Restricted In The Types Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 2? | Were You Restricted In The Types Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_food_type_v3** | Were You Restricted In The Types Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 3? | Were You Restricted In The Types Of Food You Can Eat As A Result Of Your Disease Or Treatment At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_future_health_scr2** | Were You Worried About Your Health In The Future At Screen 2? | Were You Worried About Your Health In The Future At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>2="A Little" |
| 01. Principal | **qlq_future_health_v1** | Were You Worried About Your Health In The Future At Visit 1? | Were You Worried About Your Health In The Future At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_future_health_v2** | Were You Worried About Your Health In The Future At Visit 2? | Were You Worried About Your Health In The Future At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_future_health_v3** | Were You Worried About Your Health In The Future At Visit 3? | Were You Worried About Your Health In The Future At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_gas_scr2** | Were You Bothered By Gas At Screen 2 (Flatulence)? | Were You Bothered By Gas At Screen 2 (Flatulence)? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_gas_v1** | Were You Bothered By Gas At Visit 1 (Flatulence)? | Were You Bothered By Gas At Visit 1 (Flatulence)? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_gas_v2** | Were You Bothered By Gas At Visit 2 (Flatulence)? | Were You Bothered By Gas At Visit 2 (Flatulence)? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_gas_v3** | Were You Bothered By Gas At Visit 3 (Flatulence)? | Were You Bothered By Gas At Visit 3 (Flatulence)? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_health_scr2** | How Would You Rate Your Overall Health During The Past Week At Screen 2? | Scale from 1 = "Very Poor" to 7 = "Excellent" | .N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **qlq_health_support_scr2** | Have You Received Adequate Support From Your Health Care Professionals At Screen 2? | Have You Received Adequate Support From Your Health Care Professionals At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>4="Very Much" |
| 01. Principal | **qlq_health_support_v1** | Have You Received Adequate Support From Your Health Care Professionals At Visit 1? | Have You Received Adequate Support From Your Health Care Professionals At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_health_support_v2** | Have You Received Adequate Support From Your Health Care Professionals At Visit 2? | Have You Received Adequate Support From Your Health Care Professionals At Visit 2? | .R="Not Randomized"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_health_support_v3** | Have You Received Adequate Support From Your Health Care Professionals At Visit 3? | Have You Received Adequate Support From Your Health Care Professionals At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_health_v1** | How Would You Rate Your Overall Health During The Past Week At Visit 2? | How Would You Rate Your Overall Health During The Past Week At Visit 2? | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **qlq_health_v2** | How Would You Rate Your Overall Health During The Past Week At Visit 2? | How Would You Rate Your Overall Health During The Past Week At Visit 2? | Numeric<br>.R="Not Randomized" |
| 01. Principal | **qlq_health_v3** | How Would You Rate Your Overall Health During The Past Week At Visit 3? | How Would You Rate Your Overall Health During The Past Week At Visit 3? | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **qlq_help_scr2** | Do You Need Help With Eating, Dressing, Washing At Screen 2? | Do You Need Help With Eating, Dressing, Washing At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_help_v1** | Do You Need Help With Eating, Dressing, Washing At Visit 1? | Do You Need Help With Eating, Dressing, Washing At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_help_v2** | Do You Need Help With Eating, Dressing, Washing At Visit 2? | Do You Need Help With Eating, Dressing, Washing At Visit 2? | .R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_help_v3** | Do You Need Help With Eating, Dressing, Washing At Visit 3? | Do You Need Help With Eating, Dressing, Washing At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_indigestion_scr2** | Have You Had Indigestion At Screen 2? | Have You Had Indigestion At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>2="A Little" |
| 01. Principal | **qlq_indigestion_v1** | Have You Had Indigestion At Visit 1? | Have You Had Indigestion At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>3="Quite a Bit" |
| 01. Principal | **qlq_indigestion_v2** | Have You Had Indigestion At Visit 2? | Have You Had Indigestion At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_indigestion_v3** | Have You Had Indigestion At Visit 3? | Have You Had Indigestion At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_irritable_scr2** | Did You Feel Irritable At Screen 2? | Did You Feel Irritable At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_irritable_v1** | Did You Feel Irritable At Visit 1? | Did You Feel Irritable At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_irritable_v2** | Did You Feel Irritable At Visit 2? | Did You Feel Irritable At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_irritable_v3** | Did You Feel Irritable At Visit 3? | Did You Feel Irritable At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_itch_scr2** | Have You Had Itching At Screen 2? | Have You Had Itching At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_itch_v1** | Have You Had Itching At Visit 1? | Have You Had Itching At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_itch_v2** | Have You Had Itching At Visit 2? | Have You Had Itching At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_itch_v3** | Have You Had Itching At Visit 3? | Have You Had Itching At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_limit_leisure_scr2** | Were you Limited in Pursuing Your Hobbies Or Other Leisure Time Activities At Screen 2? | Were you Limited in Pursuing Your Hobbies Or Other Leisure Time Activities At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_limit_leisure _v1** | Were you Limited in Pursuing Your Hobbies Or Other Leisure Time Activities At Visit 1? | Were you Limited in Pursuing Your Hobbies Or Other Leisure Time Activities At Visit 1? | .N="N/A" .R="Not Randomized" 1="Not at All" 3="Quite a Bit" 4="Very Much" |
| 01. Principal | **qlq_limit_leisure _v2** | Were you Limited in Pursuing Your Hobbies Or Other Leisure Time Activities At Visit 2? | Were you Limited in Pursuing Your Hobbies Or Other Leisure Time Activities At Visit 2? | .R="Not Randomized" 1="Not at All" 2="A Little" |
| 01. Principal | **qlq_limit_leisure _v3** | Were you Limited in Pursuing Your Hobbies Or Other Leisure Time Activities At Visit 3? | Were you Limited in Pursuing Your Hobbies Or Other Leisure Time Activities At Visit 3? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" |
| 01. Principal | **qlq_limit_plan_sc r2** | Were You Limited In Planning Activities In Advance At Screen 2? | Were You Limited In Planning Activities In Advance At Screen 2? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_limit_plan_v1** | Were You Limited In Planning Activities In Advance At Visit 1? | Were You Limited In Planning Activities In Advance At Visit 1? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" 3="Quite a Bit" 4="Very Much" |
| 01. Principal | **qlq_limit_plan_v2** | Were You Limited In Planning Activities In Advance At Visit 2? | Were You Limited In Planning Activities In Advance At Visit 2? | .R="Not Randomized" 1="Not at All" 2="A Little" 4="Very Much" |
| 01. Principal | **qlq_limit_plan_v3** | Were You Limited In Planning Activities In Advance At Visit 3? | Were You Limited In Planning Activities In Advance At Visit 3? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" |
| 01. Principal | **qlq_limit_work_s cr2** | Were You Limited In Doing Either Your Work Or Other Daily Activities At Screen 2? | Were You Limited In Doing Either Your Work Or Other Daily Activities At Screen 2? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_limit_work_v 1** | Were You Limited In Doing Either Your Work Or Other Daily Activities At Visit 1? | Were You Limited In Doing Either Your Work Or Other Daily Activities At Visit 1? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" 3="Quite a Bit" 4="Very Much" |
| 01. Principal | **qlq_limit_work_v 2** | Were You Limited In Doing Either Your Work Or Other Daily Activities At Visit 2? | Were You Limited In Doing Either Your Work Or Other Daily Activities At Visit 2? | .R="Not Randomized" 1="Not at All" 2="A Little" |
| 01. Principal | **qlq_limit_work_v 3** | Were You Limited In Doing Either Your Work Or Other Daily Activities At Visit 3? | Were You Limited In Doing Either Your Work Or Other Daily Activities At Visit 3? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" 3="Quite a Bit" |
| 01. Principal | **qlq_long_walk_s cr2** | Do You Have Any Trouble Taking A Long Walk At Screen 2? | Do You Have Any Trouble Taking A Long Walk At Screen 2? | .N="N/A" .R="Not Randomized" 1="Not at All" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_long_walk_v1** | Do You Have Any Trouble Taking A Long Walk At Visit 1? | Do You Have Any Trouble Taking A Long Walk At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_long_walk_v2** | Do You Have Any Trouble Taking A Long Walk At Visit 2? | Do You Have Any Trouble Taking A Long Walk At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_long_walk_v3** | Do You Have Any Trouble Taking A Long Walk At Visit 3? | Do You Have Any Trouble Taking A Long Walk At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_nausea_scr2** | Have You Felt Nauseated At Screen 2? | Have You Felt Nauseated At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_nausea_v1** | Have You Felt Nauseated At Visit 1? | Have You Felt Nauseated At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_nausea_v2** | Have You Felt Nauseated At Visit 2? | Have You Felt Nauseated At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_nausea_v3** | Have You Felt Nauseated At Visit 3? | Have You Felt Nauseated At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_night_pain_scr2** | Did You Have Pain During The Night At Screen 2? | Did You Have Pain During The Night At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_night_pain_v1** | Did You Have Pain During The Night At Visit 1? | Did You Have Pain During The Night At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_night_pain_v2** | Did You Have Pain During The Night At Visit 2? | Did You Have Pain During The Night At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_night_pain_v3** | Did You Have Pain During The Night At Visit 3? | Did You Have Pain During The Night At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_pain_interfere_scr2** | Did Pain Interfere With Your Daily Activities At Screen 2? | Did Pain Interfere With Your Daily Activities At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_pain_interfere_v1** | Did Pain Interfere With Your Daily Activities At Visit 1? | Did Pain Interfere With Your Daily Activities At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_pain_interfere_v2** | Did Pain Interfere With Your Daily Activities At Visit 2? | Did Pain Interfere With Your Daily Activities At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_pain_interfere_v3** | Did Pain Interfere With Your Daily Activities At Visit 3? | Did Pain Interfere With Your Daily Activities At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_pain_scr2** | Have You Had Pain At Screen 2? | Have You Had Pain At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_pain_v1** | Have You Had Pain At Visit 1? | Have You Had Pain At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_pain_v2** | Have You Had Pain At Visit 2? | Have You Had Pain At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_pain_v3** | Have You Had Pain At Visit 3? | Have You Had Pain At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_quality_scr2** | How Would You Rate Your Overall Quality Of Life During The Past Week At Screen 2? | How Would You Rate Your Overall Quality Of Life During The Past Week At Screen 2? | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **qlq_quality_v1** | How Would You Rate Your Overall Quality Of Life During The Past Week At Visit 1? | How Would You Rate Your Overall Quality Of Life During The Past Week At Visit 1? | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **qlq_quality_v2** | How Would You Rate Your Overall Quality Of Life During The Past Week At Visit 2? | How Would You Rate Your Overall Quality Of Life During The Past Week At Visit 2? | Numeric<br>.R="Not Randomized" |
| 01. Principal | **qlq_quality_v3** | How Would You Rate Your Overall Quality Of Life During The Past Week At Visit 3? | How Would You Rate Your Overall Quality Of Life During The Past Week At Visit 3? | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **qlq_remember_scr2** | Have You Had Difficulty Remembering Things At Screen 2? | Have You Had Difficulty Remembering Things At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_remember_v1** | Have You Had Difficulty Remembering Things At Visit 1? | Have You Had Difficulty Remembering Things At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_remember_v2** | Have You Had Difficulty Remembering Things At Visit 2? | Have You Had Difficulty Remembering Things At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_remember_v3** | Have You Had Difficulty Remembering Things At Visit 3? | Have You Had Difficulty Remembering Things At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_rest_scr2** | Did You Need To Rest At Screen 2? | Did You Need To Rest At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_rest_v1** | Did You Need To Rest At Visit 1? | Did You Need To Rest At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_rest_v2** | Did You Need To Rest At Visit 2? | Did You Need To Rest At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_rest_v3** | Did You Need To Rest At Visit 3? | Did You Need To Rest At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_sex_enjoyment_scr2** | Have You Felt Less Sexual Enjoyment At Screen 2? | Have You Felt Less Sexual Enjoyment At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_sex_enjoyment_v1** | Have You Felt Less Sexual Enjoyment At Visit 1? | Have You Felt Less Sexual Enjoyment At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_sex_enjoyment_v2** | Have You Felt Less Sexual Enjoyment At Visit 2? | Have You Felt Less Sexual Enjoyment At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_sex_enjoyment_v3** | Have You Felt Less Sexual Enjoyment At Visit 3? | Have You Felt Less Sexual Enjoyment At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_sex_interest_scr2** | Have You Felt Less Interest In Sex At Screen 2? | Have You Felt Less Interest In Sex At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_sex_interest_v1** | Have You Felt Less Interest In Sex At Visit 1? | Have You Felt Less Interest In Sex At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_sex_interest_v2** | Have You Felt Less Interest In Sex At Visit 2? | Have You Felt Less Interest In Sex At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>4="Very Much" |
| 01. Principal | **qlq_sex_interest_v3** | Have You Felt Less Interest In Sex At Visit 3? | Have You Felt Less Interest In Sex At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **qlq_short_walk_s cr2** | Do You Have Any Trouble Taking A Short Walk Outside Of The House At Screen 2? | Do You Have Any Trouble Taking A Short Walk Outside Of The House At Screen 2? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_short_walk_v 1** | Do You Have Any Trouble Taking A Short Walk Outside Of The House At Visit 1? | Do You Have Any Trouble Taking A Short Walk Outside Of The House At Visit 1? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_short_walk_v 2** | Do You Have Any Trouble Taking A Short Walk Outside Of The House At Visit 2? | Do You Have Any Trouble Taking A Short Walk Outside Of The House At Visit 2? | .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_short_walk_v 3** | Do You Have Any Trouble Taking A Short Walk Outside Of The House At Visit 3? | Do You Have Any Trouble Taking A Short Walk Outside Of The House At Visit 3? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_side_effect_s cr2** | To What Extent Have You Been Troubled With Side Effects From Your Treatment At Screen 2? | To What Extent Have You Been Troubled With Side Effects From Your Treatment At Screen 2? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_side_effect_v 1** | To What Extent Have You Been Troubled With Side Effects From Your Treatment At Visit 1? | To What Extent Have You Been Troubled With Side Effects From Your Treatment At Visit 1? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" 3="Quite a Bit" |
| 01. Principal | **qlq_side_effect_v 2** | To What Extent Have You Been Troubled With Side Effects From Your Treatment At Visit 2? | To What Extent Have You Been Troubled With Side Effects From Your Treatment At Visit 2? | .R="Not Randomized" 1="Not at All" 2="A Little" |
| 01. Principal | **qlq_side_effect_v 3** | To What Extent Have You Been Troubled With Side Effects From Your Treatment At Visit 3? | To What Extent Have You Been Troubled With Side Effects From Your Treatment At Visit 3? | .N="N/A" .R="Not Randomized" 1="Not at All" 2="A Little" 3="Quite a Bit" |
| 01. Principal | **qlq_skin_yellow_ scr2** | To What Extent Was Your Skin Yellow At Screen 2? | To What Extent Was Your Skin Yellow At Screen 2? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_skin_yellow_ v1** | To What Extent Was Your Skin Yellow At Visit 1? | To What Extent Was Your Skin Yellow At Visit 1? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_skin_yellow_ v2** | To What Extent Was Your Skin Yellow At Visit 2? | To What Extent Was Your Skin Yellow At Visit 2? | .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_skin_yellow_ v3** | To What Extent Was Your Skin Yellow At Visit 3? | To What Extent Was Your Skin Yellow At Visit 3? | .N="N/A" .R="Not Randomized" 1="Not at All" |
| 01. Principal | **qlq_sleep_scr2** | Have You Had Trouble Sleeping At Screen 2? | Have You Had Trouble Sleeping At Screen 2? | .N="N/A" .R="Not Randomized" 1="Not at All" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **qlq_sleep_v1** | Have You Had Trouble Sleeping At Visit 1? | Have You Had Trouble Sleeping At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_sleep_v2** | Have You Had Trouble Sleeping At Visit 2? | Have You Had Trouble Sleeping At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_sleep_v3** | Have You Had Trouble Sleeping At Visit 3? | Have You Had Trouble Sleeping At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_social_scr2** | Has Your Physical Condition Or Medical Treatment Interfered With Your Social Activities At Screen 2? | Has Your Physical Condition Or Medical Treatment Interfered With Your Social Activities At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_social_v1** | Has Your Physical Condition Or Medical Treatment Interfered With Your Social Activities At Visit 1? | Has Your Physical Condition Or Medical Treatment Interfered With Your Social Activities At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>4="Very Much" |
| 01. Principal | **qlq_social_v2** | Has Your Physical Condition Or Medical Treatment Interfered With Your Social Activities At Visit 2? | Has Your Physical Condition Or Medical Treatment Interfered With Your Social Activities At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_social_v3** | Has Your Physical Condition Or Medical Treatment Interfered With Your Social Activities At Visit 3? | Has Your Physical Condition Or Medical Treatment Interfered With Your Social Activities At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_strenuous_scr2** | Do You Have Any Trouble Doing Strenuous Activities At Screen 2? | Do You Have Any Trouble Doing Strenuous Activities At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_strenuous_v1** | Do You Have Any Trouble Doing Strenuous Activities At Visit 1? | Do You Have Any Trouble Doing Strenuous Activities At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_strenuous_v2** | Do You Have Any Trouble Doing Strenuous Activities At Visit 2? | Do You Have Any Trouble Doing Strenuous Activities At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_strenuous_v3** | Do You Have Any Trouble Doing Strenuous Activities At Visit 3? | Do You Have Any Trouble Doing Strenuous Activities At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_tense_scr2** | Did You Feel Tense At Screen 2? | Did You Feel Tense At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_tense_v1** | Did You Feel Tense At Visit 1? | Did You Feel Tense At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_tense_v2** | Did You Feel Tense At Visit 2? | Did You Feel Tense At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_tense_v3** | Did You Feel Tense At Visit 3? | Did You Feel Tense At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_tired_scr2** | Were You Tired At Screen 2? | Were You Tired At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_tired_v1** | Were You Tired At Visit 1? | Were You Tired At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_tired_v2** | Were You Tired At Visit 2? | Were You Tired At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_tired_v3** | Were You Tired At Visit 3? | Were You Tired At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_treatment_info_scr2** | Has The Information Given About Your Physical Condition And Treatment Been Adequate At Screen 2? | Has The Information Given About Your Physical Condition And Treatment Been Adequate At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>3="Quite a Bit" |
| 01. Principal | **qlq_treatment_info_v1** | Has The Information Given About Your Physical Condition And Treatment Been Adequate At Visit 1? | Has The Information Given About Your Physical Condition And Treatment Been Adequate At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_treatment_info_v2** | Has The Information Given About Your Physical Condition And Treatment Been Adequate At Visit 2? | Has The Information Given About Your Physical Condition And Treatment Been Adequate At Visit 2? | .R="Not Randomized"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_treatment_info_v3** | Has The Information Given About Your Physical Condition And Treatment Been Adequate At Visit 3? | Has The Information Given About Your Physical Condition And Treatment Been Adequate At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_uncomfortable_scr2** | Did You Find It Uncomfortable In Certain Positions At Screen 2? | Did You Find It Uncomfortable In Certain Positions At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **qlq_uncomfortable_v1** | Did You Find It Uncomfortable In Certain Positions At Visit 1? | Did You Find It Uncomfortable In Certain Positions At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit"<br>4="Very Much" |
| 01. Principal | **qlq_uncomfortable_v2** | Did You Find It Uncomfortable In Certain Positions At Visit 2? | Did You Find It Uncomfortable In Certain Positions At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_uncomfortable_v3** | Did You Find It Uncomfortable In Certain Positions At Visit 3? | Did You Find It Uncomfortable In Certain Positions At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_visit_dt_scr2** | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Date<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **qlq_visit_dt_v1** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Date<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **qlq_visit_dt_v2** | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **qlq_visit_dt_v3** | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **qlq_vomit_scr2** | Have You Vomited At Screen 2? | Have You Vomited At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_vomit_v1** | Have You Vomited At Visit 1? | Have You Vomited At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_vomit_v2** | Have You Vomited At Visit 2? | Have You Vomited At Visit 2? | .R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_vomit_v3** | Have You Vomited At Visit 3? | Have You Vomited At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_weak_scr2** | Have You Felt Weak At Screen 2? | Have You Felt Weak At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_weak_v1** | Have You Felt Weak At Visit 1? | Have You Felt Weak At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_weak_v2** | Have You Felt Weak At Visit 2? | Have You Felt Weak At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_weak_v3** | Have You Felt Weak At Visit 3? | Have You Felt Weak At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **qlq_weight_low_scr2** | Have You Worried About Your Weight Being Too Low At Screen 2? | Have You Worried About Your Weight Being Too Low At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_weight_low_v1** | Have You Worried About Your Weight Being Too Low At Visit 1? | Have You Worried About Your Weight Being Too Low At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>4="Very Much" |
| 01. Principal | **qlq_weight_low_v2** | Have You Worried About Your Weight Being Too Low At Visit 2? | Have You Worried About Your Weight Being Too Low At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_weight_low_v3** | Have You Worried About Your Weight Being Too Low At Visit 3? | Have You Worried About Your Weight Being Too Low At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |
| 01. Principal | **qlq_worry_scr2** | Did You Worry At Screen 2? | Did You Worry At Screen 2? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All" |
| 01. Principal | **qlq_worry_v1** | Did You Worry At Visit 1? | Did You Worry At Visit 1? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_worry_v2** | Did You Worry At Visit 2? | Did You Worry At Visit 2? | .R="Not Randomized"<br>1="Not at All"<br>2="A Little"<br>3="Quite a Bit" |
| 01. Principal | **qlq_worry_v3** | Did You Worry At Visit 3? | Did You Worry At Visit 3? | .N="N/A"<br>.R="Not Randomized"<br>1="Not at All"<br>2="A Little" |

# Section 20: Follow-Up Questionnaire

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqfu_comments** | Comments | Comments | Char |
| 01. Principal | **stqfu_cooperation** | The Participant's Cooperation Was | The Participant's Cooperation Was | .R="Not Randomized"<br>1="Excellent"<br>2="Very Good" |
| 01. Principal | **stqfu_family_interview** | Did The Interview Include Another Family Member? | Did The Interview Include Another Family Member? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqfu_height_ft** | What Is Your Current Height? | What Is Your Current Height? | Numeric<br>.R="Not Randomized" |
| 01. Principal | **stqfu_height_in** | What Is Your Current Height? | What Is Your Current Height? | Numeric<br>.R="Not Randomized" |
| 01. Principal | **stqfu_interview_end_dt** | Date Interview Ended | Date Interview Ended | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **stqfu_interview_end_time** | Time Interview Ended | Time Interview Ended | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_interview_start_dt** | Date Interview Began | Date Interview Began | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **stqfu_interview_start_time** | Time Interview Began | Time Interview Began | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_marital_stat** | What Is Your Current Marital Status? | What Is Your Current Marital Status? | .R="Not Randomized"<br>1="Single (never married)"<br>3="Married"<br>4="Divorced" |
| 01. Principal | **stqfu_mild_days** | How Many Days Per Week Did You Do Mild Exercises? | How Many Days Per Week Did You Do Mild Exercises? | .M="Missing"<br>.R="Not Randomized"<br>1="1-2"<br>2="3-4" |
| 01. Principal | **stqfu_mild_exercise** | Since Your First Study Visit, Did You Do Mild Exercise? | Since Your First Study Visit, Did You Do Mild Exercise? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqfu_mild_hours** | How Many Hours Per Week Did You Do Mild Exercise? | How Many Hours Per Week Did You Do Mild Exercise? | .M="Missing"<br>.R="Not Randomized"<br>1="<1 hour"<br>2="1-2" |
| 01. Principal | **stqfu_mod_days** | How Many Days Per Week Did You Do Moderate Exercise? | How Many Days Per Week Did You Do Moderate Exercise? | .M="Missing"<br>.R="Not Randomized"<br>1="1-2" |
| 01. Principal | **stqfu_mod_exercise** | Since Your First Study Visit, Did You Do Moderate Exercise? | Since Your First Study Visit, Did You Do Moderate Exercise? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqfu_mod_minutes** | How Many Minutes Per Day Did You Do Moderate Exercise? | How Many Minutes Per Day Did You Do Moderate Exercise? | .M="Missing"<br>.R="Not Randomized"<br>1="10-25"<br>2="30-40"<br>3="45-55" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqfu_muscle_days** | How Many Days Per Week Did You Do Muscle Exercise? | How Many Days Per Week Did You Do Muscle Exercise? | .M="Missing"<br>.R="Not Randomized"<br>1="1-2"<br>2="3-4" |
| 01. Principal | **stqfu_muscle_exercise** | Since Your First Study Visit, Did You Do Exercises To Increase Muscle Strength And Endurance? | Since Your First Study Visit, Did You Do Exercises To Increase Muscle Strength And Endurance? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqfu_muscle_minutes** | How Many Minutes Per Day Did You Do Muscle Exercise? | How Many Minutes Per Day Did You Do Muscle Exercise? | .M="Missing"<br>.R="Not Randomized"<br>3="45-55" |
| 01. Principal | **stqfu_other_interview** | Did The Interview Include Another Person | Did The Interview Include Another Person | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqfu_other_interview_spec** | Did The Interview Include Another Person | Did The Interview Include Another Person | Char |
| 01. Principal | **stqfu_part_interview** | Did The Interview Include The Participant Only? | Did The Interview Include The Participant Only? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqfu_quality_interview** | The Quality Of The Interview Is | The Quality Of The Interview Is | .R="Not Randomized"<br>1="Excellent"<br>2="Generally reliable" |
| 01. Principal | **stqfu_sit_days** | Since Your First Study Visit, How Often Did You Participate In Sitting Activities? | Since Your First Study Visit, How Often Did You Participate In Sitting Activities? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_sit_hours** | How Many Hours Per Day Did You Do Sitting Exercise? | How Many Hours Per Day Did You Do Sitting Exercise? | .R="Not Randomized"<br>1="<1 hour"<br>2="1-2"<br>4="4+ hours" |
| 01. Principal | **stqfu_spouse_interview** | Did The Interview Include A Spouse Or Partner? | Did The Interview Include A Spouse Or Partner? | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqfu_stren_days** | How Many Days Per Week Did You Do Strenuous Exercise | How Many Days Per Week Did You Do Strenuous Exercise | .M="Missing"<br>.R="Not Randomized"<br>1="1-2"<br>2="3-4" |
| 01. Principal | **stqfu_stren_exercise** | Since Your First Study Visit, Did You Do Strenuous Exercise? | Since Your First Study Visit, Did You Do Strenuous Exercise? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqfu_stren_minutes** | How Many Minutes Per Day Did You Do Strenuous Exercise | How Many Minutes Per Day Did You Do Strenuous Exercise | .M="Missing"<br>.R="Not Randomized"<br>2="30-40"<br>3="45-55"<br>4="60+ minutes" |
| 01. Principal | **stqfu_visit_dt** | Visit Date | Visit Date | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **stqfu_walk_days** | How Many Days Per Week Did You Do Walk Exercises? | How Many Days Per Week Did You Do Walk Exercises? | .R="Not Randomized"<br>2="3-4"<br>3="5-6" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqfu_walk_exercise** | Since Your First Research Visit For This Study On (Date Of Last Study Visit) Did You Walk For Exercise? | Since Your First Research Visit For This Study On (Date Of Last Study Visit) Did You Walk For Exercise? | .R="Not Randomized"<br>1="Yes" |
| 01. Principal | **stqfu_walk_minutes** | How Many Minutes Per Week Did You Do Walk Exercise? | How Many Minutes Per Week Did You Do Walk Exercise? | .R="Not Randomized"<br>1="10-25"<br>2="30-40" |
| 01. Principal | **stqfu_walk_pace** | What Was Your Usual Walking Pace? | What Was Your Usual Walking Pace? | .M="Missing"<br>.R="Not Randomized"<br>1="Casual (each mile takes 30 minutes or more)"<br>2="Moderate (each mile takes 20-29 minutes)" |
| 01. Principal | **stqfu_weight_lbs** | What Is Your Current Weight? | What Is Your Current Weight? | Numeric<br>.R="Not Randomized" |

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# Section 21: Follow-Up Questionnaire - Comorbidities

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqfu_anemia_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Pernicious Anemia That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Pernicious Anemia That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_anemia_dt** | When Did A Doctor Tell You That You Had Pernicious Anemia | When Did A Doctor Tell You That You Had Pernicious Anemia | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_barretts_dt** | When Did A Doctor Tell You That You Had Barrett's Esophagus | When Did A Doctor Tell You That You Had Barrett's Esophagus | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_bowel_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Inflammatory Bowel Disease That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Inflammatory Bowel Disease That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_bowel_dt** | When Did A Doctor Tell You That You Had Inflammatory Bowel Disease | When Did A Doctor Tell You That You Had Inflammatory Bowel Disease | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_cancer_dt** | When Did A Doctor Tell You That You Had Cancer | When Did A Doctor Tell You That You Had Cancer | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_cancer_type** | Cancer (Type) | Cancer (Type) | Char |
| 01. Principal | **stqfu_celiac_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Celiac Disease That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Celiac Disease That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_celiac_dt** | When Did A Doctor Tell You That You Had Celiac Disease | When Did A Doctor Tell You That You Had Celiac Disease | SAS Date .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqfu_cirrhosis_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Liver Cirrhosis That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Liver Cirrhosis That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_cirrhosis_dt** | When Did A Doctor Tell You That You Had Liver Cirrhosis | When Did A Doctor Tell You That You Had Liver Cirrhosis | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_colitis_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Ulcerative Colitis That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Ulcerative Colitis That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_colitis_dt** | When Did A Doctor Tell You That You Had Ulcerative Colitis | When Did A Doctor Tell You That You Had Ulcerative Colitis | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_diabetes_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Diabetes That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Diabetes That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_diabetes_dt** | When Did A Doctor Tell You That You Had Diabetes | When Did A Doctor Tell You That You Had Diabetes | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_gallstone_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Gallstones That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Gallstones That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_gallstone_dt** | When Did A Doctor Tell You That You Had Gallstones | When Did A Doctor Tell You That You Had Gallstones | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_heart_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Heart Disease That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Heart Disease That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqfu_heart_dt** | When Did A Doctor Tell You That You Had Heart Disease | When Did A Doctor Tell You That You Had Heart Disease | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_hepatitis_b _current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Hepatitis B That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Hepatitis B That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_hepatitis_b _dt** | When Did A Doctor Tell You That You Had Hepatitis B | When Did A Doctor Tell You That You Had Hepatitis B | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_hepatitis_c _current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Hepatitis C That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Hepatitis C That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_hepatitis_c _dt** | When Did A Doctor Tell You That You Had Hepatitis C | When Did A Doctor Tell You That You Had Hepatitis C | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_high_chol_ current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed High Cholesterol That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed High Cholesterol That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_high_chol_ dt** | When Did A Doctor Tell You That You Had High Cholesterol | When Did A Doctor Tell You That You Had High Cholesterol | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_hypertensi on_1st** | Since Your First Research Visit For This Study Have You Taken A Drug To Control Hypertension (1st)? | Since Your First Research Visit For This Study Have You Taken A Drug To Control Hypertension (1st)? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_hypertensi on_2nd** | Since Your First Research Visit For This Study Have You Taken A Drug To Control Hypertension (2nd)? | Since Your First Research Visit For This Study Have You Taken A Drug To Control Hypertension (2nd)? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_hypertensi on_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Hypertension That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Hypertension That You Had Not Reported Previously? | .R="Not Randomized" 0="No" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqfu_hypertension_dt** | When Did A Doctor Tell You That You Had Hypertension | When Did A Doctor Tell You That You Had Hypertension | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_hypertension_dt_1st** | When Did You Last Take Your 1st Hypertension Drug | When Did You Last Take Your 1st Hypertension Drug | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_hypertension_dt_2nd** | When Did You Last Take Your 2nd Hypertension Drug | When Did You Last Take Your 2nd Hypertension Drug | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_panc_pseudo_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Pancreatic Pseudocyst That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Pancreatic Pseudocyst That You Had Not Reported Previously? | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqfu_panc_pseudo_dt** | When Did A Doctor Tell You That You Had A Pancreatic Pseudocyst | When Did A Doctor Tell You That You Had A Pancreatic Pseudocyst | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_small_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Ulcer In Your Small Intestine That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Ulcer In Your Small Intestine That You Had Not Reported Previously? | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqfu_small_ulcer_dt** | When Did A Doctor Tell You That You Had Ulcers In Your Small Intestine | When Did A Doctor Tell You That You Had Ulcers In Your Small Intestine | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_stomach_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Stomach Ulcers That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Stomach Ulcers That You Had Not Reported Previously? | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqfu_stomach_ulcer_dt** | When Did A Doctor Tell You That You Had Stomach Ulcers | When Did A Doctor Tell You That You Had Stomach Ulcers | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_stroke_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Stroke That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Stroke That You Had Not Reported Previously? | .R="Not Randomized"<br>0="No" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqfu_stroke_dt** | When Did A Doctor Tell You That You Had A Stroke | When Did A Doctor Tell You That You Had A Stroke | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |

# Section 22: Follow-Up Questionnaire - Alcohol/Smoking History

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqfu_alc_current** | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Alcoholism That You Had Not Reported Previously? | Since Your First Research Visit For This Study Has A Doctor Or Healthcare Provider Told That You Have Developed Alcoholism That You Had Not Reported Previously? | .R="Not Randomized"<br>0="No" |
| 01. Principal | **stqfu_alc_ever** | Since Your First Research Visit For This Study, Have You Had A Drink Of Alcohol? | Since Your First Research Visit For This Study, Have You Had A Drink Of Alcohol? | .R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **stqfu_alc_per_week** | How Many Drinks Of Alcohol Do You Usually Have Per Week? | How Many Drinks Of Alcohol Do You Usually Have Per Week? | .M="Missing"<br>.R="Not Randomized"<br>1="< 1 drink per week" |
| 01. Principal | **stqfu_alcoholism_dt** | When Did A Doctor Tell You That You Had Alcoholism | When Did A Doctor Tell You That You Had Alcoholism | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_cigs_per_day** | How Many Cigarettes Do You Usually Smoke Each Day? | How Many Cigarettes Do You Usually Smoke Each Day? | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_last_alc_dt** | When Did You Last Have A Drink Of Alcohol? | When Did You Last Have A Drink Of Alcohol? | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_last_smk_dt** | When Did You Last Smoke A Cigarette? | When Did You Last Smoke A Cigarette? | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **stqfu_smk** | Since Your First Research Visit For This Study, Have You Smoked Cigarettes? | Since Your First Research Visit For This Study, Have You Smoked Cigarettes? | .R="Not Randomized"<br>0="No"<br>1="Yes" |

# Section 23: Follow-Up Questionnaire - Surgical History

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | stqfu_appendix_surgery | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Appendix? | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Appendix? | .R="Not Randomized" 0="No" |
| 01. Principal | stqfu_appendix_surgery_dt | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Appendix | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Appendix | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | stqfu_breast_surgery | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Breast? | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Breast? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | stqfu_breast_surgery_dt | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Breast | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Breast | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | stqfu_colon_surgery | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Colon? | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Colon? | .R="Not Randomized" 0="No" |
| 01. Principal | stqfu_colon_surgery_dt | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Colon | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Colon | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | stqfu_gallblad_surgery | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Gall Bladder? | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Gall Bladder? | .R="Not Randomized" 0="No" |
| 01. Principal | stqfu_gallblad_surgery_dt | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Gallbladder | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Gallbladder | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | stqfu_gallstone_surgery | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Gall Stones? | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Gall Stones? | .R="Not Randomized" 0="No" |
| 01. Principal | stqfu_gallstone_surgery_dt | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Gallstones | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Gallstones | SAS Date .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqfu_ovaries_su rgery_dt** | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Ovaries | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Ovaries | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_ovary_surg ery** | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Ovaries? | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Ovaries? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_stomach_s urgery** | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Stomach? | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Stomach? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_stomach_s urgery_dt** | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Stomach | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Stomach | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_uterus_sur gery** | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Uterus? | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Uterus? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_uterus_sur gery_dt** | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Uterus | Since Your First Research Visit For This Study Have You Had Surgery To Remove Your Uterus | SAS Date .M="Missing" .R="Not Randomized" |

# Section 24: Follow-Up Questionnaire - Drug History

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqfu_anti_depress_1st** | Since Your First Research Visit For This Study Have You Taken An Anti-Depressant (1st)? | Since Your First Research Visit For This Study Have You Taken An Anti-Depressant (1st)? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_anti_depress_2nd** | Since Your First Research Visit For This Study Have You Taken An Anti-Depressant (2nd)? | Since Your First Research Visit For This Study Have You Taken An Anti-Depressant (2nd)? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_anti_depress_dt_1st** | When Did You Last Take Your 1st Anti-Depressant Drug | When Did You Last Take Your 1st Anti-Depressant Drug | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_anti_depress_dt_2nd** | When Did You Last Take Your 2nd Anti-Depressant Drug | When Did You Last Take Your 2nd Anti-Depressant Drug | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_anti_depress_name_1st** | What Was The Name Of The 1st Anti-Depressant Drug? | What Was The Name Of The 1st Anti-Depressant Drug? | Char |
| 01. Principal | **stqfu_anti_depress_name_2nd** | What Was The Name Of The 2nd Anti-Depressant Drug? | What Was The Name Of The 2nd Anti-Depressant Drug? | Char |
| 01. Principal | **stqfu_antibiotic_dt_1st** | When Did You Last Take Your 1st Antibiotic | When Did You Last Take Your 1st Antibiotic | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_antibiotic_dt_2nd** | When Did You Last Take Your 2nd Antibiotic | When Did You Last Take Your 2nd Antibiotic | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_antibiotic_name_1st** | What Was The Name Of The 1st Antibiotic? | What Was The Name Of The 1st Antibiotic? | Char |
| 01. Principal | **stqfu_antibiotic_name_2nd** | What Was The Name Of The 2nd Antibiotic? | What Was The Name Of The 2nd Antibiotic? | Char |
| 01. Principal | **stqfu_extra_aspirin_dt_1st** | When Did You Last Take Extra Dose Aspirin | When Did You Last Take Extra Dose Aspirin | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_extra_dose_aspirin** | Since Your First Research Visit For This Study Have You Taken Extra Dose Aspirin At Least 4 Days A Week? | Since Your First Research Visit For This Study Have You Taken Extra Dose Aspirin At Least 4 Days A Week? | .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **stqfu_extra_dose_aspirin_freq** | How Often Do You Take Extra Dose Aspirin | How Often Do You Take Extra Dose Aspirin | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_extra_dose_aspirin_num** | How Many Extra Dose Tablets Did You Take At A Time | How Many Extra Dose Tablets Did You Take At A Time | Numeric .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **stqfu_hypertension_name_1st** | What Was The Name Of The 1st Hypertension Drug? | What Was The Name Of The 1st Hypertension Drug? | Char |
| 01. Principal | **stqfu_hypertension_name_2nd** | What Was The Name Of The 2nd Hypertension Drug? | What Was The Name Of The 2nd Hypertension Drug? | Char |
| 01. Principal | **stqfu_inhale_powder_dt_1st** | When Did You Last Take Your Inhalable Powder | When Did You Last Take Your Inhalable Powder | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_inhale_powder_name** | What Was The Name Of The Inhalable Powder? | What Was The Name Of The Inhalable Powder? | Char |
| 01. Principal | **stqfu_insulin_dt_1st** | When Did You Last Take Your 1st Insulin Agent | When Did You Last Take Your 1st Insulin Agent | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_insulin_dt_2nd** | When Did You Last Take Your 2nd Insulin Agent | When Did You Last Take Your 2nd Insulin Agent | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_insulin_name_1st** | What Was The Name Of The 1st Insulin Injection Agent? | What Was The Name Of The 1st Insulin Injection Agent? | Char |
| 01. Principal | **stqfu_insulin_name_2nd** | What Was The Name Of The 2nd Insulin Injection Agent? | What Was The Name Of The 2nd Insulin Injection Agent? | Char |
| 01. Principal | **stqfu_low_aspirin_dt_1st** | When Did You Last Take Low Dose Aspirin | When Did You Last Take Low Dose Aspirin | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_low_dose_aspirin** | Since Your First Research Visit For This Study Have You Taken Low Dose Aspirin At Least 4 Days A Week? | Since Your First Research Visit For This Study Have You Taken Low Dose Aspirin At Least 4 Days A Week? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_low_dose_aspirin_freq** | How Often Do You Take Low Dose Aspirin | How Often Do You Take Low Dose Aspirin | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_low_dose_aspirin_num** | How Many Low Dose Tablets Did You Take At A Time | How Many Low Dose Tablets Did You Take At A Time | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_oral_agent_dt_1st** | When Did You Last Take Your 1st Oral Agent | When Did You Last Take Your 1st Oral Agent | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_oral_agent_dt_2nd** | When Did You Last Take Your 2nd Oral Agent | When Did You Last Take Your 2nd Oral Agent | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_oral_agent_name_1st** | What Was The Name Of The 1st Oral Agent? | What Was The Name Of The 1st Oral Agent? | Char |
| 01. Principal | **stqfu_oral_agent_name_2nd** | What Was The Name Of The 2nd Oral Agent? | What Was The Name Of The 2nd Oral Agent? | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **stqfu_other_aspirin** | Since Your First Research Visit For This Study Have You Taken Other Dose Aspirin At Least 4 Days A Week? | Since Your First Research Visit For This Study Have You Taken Other Dose Aspirin At Least 4 Days A Week? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_other_aspirin_dt_2nd** | When Did You Last Take Other Dose Aspirin | When Did You Last Take Other Dose Aspirin | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_other_aspirin_mg** | Other Type Of Aspirin, Specify | Other Type Of Aspirin, Specify | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_other_aspirin_name** | Other Type Of Aspirin, Specify | Other Type Of Aspirin, Specify | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_other_aspirin_num** | How Many Extra Dose Tablets Did You Take At A Time | How Many Extra Dose Tablets Did You Take At A Time | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_other_dose_aspirin_freq** | How Often Do You Take Other Dose Aspirin | How Often Do You Take Other Dose Aspirin | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_other_dt_1st** | When Did You Last Take Your 1st Other Injection For Diabetes | When Did You Last Take Your 1st Other Injection For Diabetes | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_other_dt_2nd** | When Did You Last Take Your 2nd Other Injection For Diabetes | When Did You Last Take Your 2nd Other Injection For Diabetes | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_other_inject** | Since Your First Research Visit For This Study Have You Taken An Injectable For Diabetes (Other)? | Since Your First Research Visit For This Study Have You Taken An Injectable For Diabetes (Other)? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_other_name_1st** | What Was The Name Of The 1st Other Injection Agent? | What Was The Name Of The 1st Other Injection Agent? | Char |
| 01. Principal | **stqfu_other_name_2nd** | What Was The Name Of The 2nd Other Injection Agent? | What Was The Name Of The 2nd Other Injection Agent? | Char |
| 01. Principal | **stqfu_reg_aspirin_dt** | When Did You Last Take Regular Dose Aspirin | When Did You Last Take Regular Dose Aspirin | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_reg_dose_aspirin** | Since Your First Research Visit For This Study Have You Taken Regular Dose Aspirin At Least 4 Days A Week? | Since Your First Research Visit For This Study Have You Taken Regular Dose Aspirin At Least 4 Days A Week? | .R="Not Randomized" 0="No" |
| 01. Principal | **stqfu_reg_dose_aspirin_freq** | How Often Do You Take Regular Dose Aspirin | How Often Do You Take Regular Dose Aspirin | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **stqfu_reg_dose_aspirin_num** | How Many Regular Dose Tablets Did You Take At A Time | How Many Regular Dose Tablets Did You Take At A Time | Numeric .M="Missing" .R="Not Randomized" |

# Section 25: Medical History

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **medhx_any_abnormal_scr1** | Were Any Systems/Sites Abnormal At Screen 1? | Were Any Systems/Sites Abnormal At Screen 1? If Yes, Complete The Abnormal | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **medhx_any_abnormal_scr2** | Were Any Systems/Sites Abnormal At Screen 2? | Were Any Systems/Sites Abnormal At Screen 2? If Yes, Complete The Abnormal | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **medhx_any_abnormal_v1** | Were Any Systems/Sites Abnormal At Visit 1? | Were Any Systems/Sites Abnormal At Visit 1? If Yes, Complete The Abnormal | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **medhx_any_abnormal_v2** | Were Any Systems/Sites Abnormal At Visit 2? | Were Any Systems/Sites Abnormal At Visit 2? If Yes, Complete The Abnormal | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **medhx_any_abnormal_v3** | Were Any Systems/Sites Abnormal At Visit 3? | Were Any Systems/Sites Abnormal At Visit 3? If Yes, Complete The Abnormal | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **medhx_breast_comments_scr1** | Breasts: Comments At Screen 1 | Breasts: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_breast_comments_scr2** | Breasts: Comments At Screen 2 | Breasts: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_breast_comments_v1** | Breasts: Comments At Visit 1 | Breasts: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_breast_comments_v2** | Breasts: Comments At Visit 2 | Breasts: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_breast_comments_v3** | Breasts: Comments At Visit 3 | Breasts: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_cardio_comments_scr1** | Cardiovascular: Comments At Screen 1 | Cardiovascular: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_cardio_comments_scr2** | Cardiovascular: Comments At Screen 2 | Cardiovascular: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_cardio_comments_v1** | Cardiovascular: Comments At Visit 1 | Cardiovascular: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_cardio_comments_v2** | Cardiovascular: Comments At Visit 2 | Cardiovascular: Comments At Visit 2 (Required If Abnormal) | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **medhx_cardio_comments_v3** | Cardiovascular: Comments At Visit 3 | Cardiovascular: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_comments_scr1** | Comments At Screen 1 | Comments At Screen 1 | Char |
| 01. Principal | **medhx_comments_scr2** | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | **medhx_comments_v1** | Comments At Visit 1 | Comments At Visit 1 | Char |
| 01. Principal | **medhx_comments_v2** | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | **medhx_comments_v3** | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | **medhx_derm_comments_scr1** | Dermatologic: Comments At Screen 1 | Dermatologic: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_derm_comments_scr2** | Dermatologic: Comments At Screen 2 | Dermatologic: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_derm_comments_v1** | Dermatologic: Comments At Visit 1 | Dermatologic: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_derm_comments_v2** | Dermatologic: Comments At Visit 2 | Dermatologic: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_derm_comments_v3** | Dermatologic: Comments At Visit 3 | Dermatologic: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_endo_comments_scr1** | Endocrine/Metabolic: Comments At Screen 1 | Endocrine/Metabolic: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_endo_comments_scr2** | Endocrine/Metabolic: Comments At Screen 2 | Endocrine/Metabolic: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_endo_comments_v1** | Endocrine/Metabolic: Comments At Visit 1 | Endocrine/Metabolic: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_endo_comments_v2** | Endocrine/Metabolic: Comments At Visit 2 | Endocrine/Metabolic: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_endo_comments_v3** | Endocrine/Metabolic: Comments At Visit 3 | Endocrine/Metabolic: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_gast_comments_scr1** | Gastrointestinal: Comments At Screen 1 | Gastrointestinal: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_gast_comments_scr2** | Gastrointestinal: Comments At Screen 2 | Gastrointestinal: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_gast_comments_v1** | Gastrointestinal: Comments At Visit 1 | Gastrointestinal: Comments At Visit 1 (Required If Abnormal) | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **medhx_gast_comments_v2** | Gastrointestinal: Comments At Visit 2 | Gastrointestinal: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_gast_comments_v3** | Gastrointestinal: Comments At Visit 3 | Gastrointestinal: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_geni_comments_scr1** | Genitourinary: Comments At Screen 1 | Genitourinary: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_geni_comments_scr2** | Genitourinary: Comments At Screen 2 | Genitourinary: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_geni_comments_v1** | Genitourinary: Comments At Visit 1 | Genitourinary: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_geni_comments_v2** | Genitourinary: Comments At Visit 2 | Genitourinary: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_geni_comments_v3** | Genitourinary: Comments At Visit 3 | Genitourinary: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_heent_comments_scr1** | H/E/E/N/T: Comments At Screen 1 | H/E/E/N/T: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_heent_comments_scr2** | H/E/E/N/T: Comments At Screen 2 | H/E/E/N/T: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_heent_comments_v1** | H/E/E/N/T: Comments At Visit 1 | H/E/E/N/T: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_heent_comments_v2** | H/E/E/N/T: Comments At Visit 2 | H/E/E/N/T: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_heent_comments_v3** | H/E/E/N/T: Comments At Visit 3 | H/E/E/N/T: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_hema_comments_scr1** | Hematopoietic/Lymph: Comments At Screen 1 | Hematopoietic/Lymph: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_hema_comments_scr2** | Hematopoietic/Lymph: Comments At Screen 2 | Hematopoietic/Lymph: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_hema_comments_v1** | Hematopoietic/Lymph: Comments At Visit 1 | Hematopoietic/Lymph: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_hema_comments_v2** | Hematopoietic/Lymph: Comments At Visit 2 | Hematopoietic/Lymph: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_hema_comments_v3** | Hematopoietic/Lymph: Comments At Visit 3 | Hematopoietic/Lymph: Comments At Visit 3 (Required If Abnormal) | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **medhx_musc_comments_scr1** | Musculoskeletal: Comments At Screen 1 | Musculoskeletal: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_musc_comments_scr2** | Musculoskeletal: Comments At Screen 2 | Musculoskeletal: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_musc_comments_v1** | Musculoskeletal: Comments At Visit 1 | Musculoskeletal: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_musc_comments_v2** | Musculoskeletal: Comments At Visit 2 | Musculoskeletal: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_musc_comments_v3** | Musculoskeletal: Comments At Visit 3 | Musculoskeletal: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_neck_comments_scr1** | Neck: Comments At Screen 1 | Neck: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_neck_comments_scr2** | Neck: Comments At Screen 2 | Neck: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_neck_comments_v1** | Neck: Comments At Visit 1 | Neck: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_neck_comments_v2** | Neck: Comments At Visit 2 | Neck: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_neck_comments_v3** | Neck: Comments At Visit 3 | Neck: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_neur_comments_scr1** | Neurologic: Comments At Screen 1 | Neurologic: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_neur_comments_scr2** | Neurologic: Comments At Screen 2 | Neurologic: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_neur_comments_v1** | Neurologic: Comments At Visit 1 | Neurologic: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_neur_comments_v2** | Neurologic: Comments At Visit 2 | Neurologic: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_neur_comments_v3** | Neurologic: Comments At Visit 3 | Neurologic: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_other_comments_scr1** | Other Body System/Site: Comments At Screen 1 | Other Body System/Site: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_other_comments_scr2** | Other Body System/Site: Comments At Screen 2 | Other Body System/Site: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_other_comments_v1** | Other Body System/Site: Comments At Visit 1 | Other Body System/Site: Comments At Visit 1 (Required If Abnormal) | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **medhx_other_co mments_v2** | Other Body System/Site: Comments At Visit 2 | Other Body System/Site: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_other_co mments_v3** | Other Body System/Site: Comments At Visit 3 | Other Body System/Site: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_other_scr 1** | Specify Other Body System/Site At Screen 1 | Specify Other Body System/Site At Screen 1 | Char |
| 01. Principal | **medhx_other_scr 2** | Specify Other Body System/Site At Screen 2 | Specify Other Body System/Site At Screen 2 | Char |
| 01. Principal | **medhx_other_v1** | Specify Other Body System/Site At Visit 1 | Specify Other Body System/Site At Visit 1 | Char |
| 01. Principal | **medhx_other_v2** | Specify Other Body System/Site At Visit 2 | Specify Other Body System/Site At Visit 2 | Char |
| 01. Principal | **medhx_other_v3** | Specify Other Body System/Site At Visit 3 | Specify Other Body System/Site At Visit 3 | Char |
| 01. Principal | **medhx_resp_co mments_scr1** | Respiratory: Comments At Screen 1 | Respiratory: Comments At Screen 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_resp_co mments_scr2** | Respiratory: Comments At Screen 2 | Respiratory: Comments At Screen 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_resp_co mments_v1** | Respiratory: Comments At Visit 1 | Respiratory: Comments At Visit 1 (Required If Abnormal) | Char |
| 01. Principal | **medhx_resp_co mments_v2** | Respiratory: Comments At Visit 2 | Respiratory: Comments At Visit 2 (Required If Abnormal) | Char |
| 01. Principal | **medhx_resp_co mments_v3** | Respiratory: Comments At Visit 3 | Respiratory: Comments At Visit 3 (Required If Abnormal) | Char |
| 01. Principal | **medhx_visit_dt_s cr1** | Visit Date At Screen 1 | Visit Date At Screen 1 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **medhx_visit_dt_s cr2** | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **medhx_visit_dt_v 1** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **medhx_visit_dt_v 2** | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **medhx_visit_dt_v 3** | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date .M="Missing" .R="Not Randomized" |

# Section 26: Blood Chemistry Creatine Phosphokinase

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_cpk_comments** | Comments At Visit 1 | Comments At Visit 1 | Char |
| 01. Principal | **bldchem_cpk_comments_2** | Comments At Visit 1 (2nd) | Comments At Visit 1 (2nd) | Char |
| 01. Principal | **bldchem_cpk_oor** | CPK Out Of Range At Visit 1? | CPK Out Of Range At Visit 1? | .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_cpk_oor_2** | CPK Out Of Range At Visit 1? | CPK Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_cpk_oor_sig** | CPK If Out Of Range, Is It Clinically Significant At Visit 1? | CPK If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_cpk_oor_sig_2** | CPK If Out Of Range, Is It Clinically Significant At Visit 1? (2nd) | CPK If Out Of Range, Is It Clinically Significant At Visit 1? (2nd) | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_cpk_result** | CPK Result At Visit 1 [u/L] | CPK Result At Visit 1 [u/L] | Numeric .R="Not Randomized" |
| 01. Principal | **bldchem_cpk_result_2** | CPK Result At Visit 1 (2nd) | CPK Result At Visit 1 (2nd) | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_cpk_visit_dt** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Date .R="Not Randomized" |
| 01. Principal | **bldchem_cpk_visit_dt_2** | Visit Date At Visit 1 (2nd) | Visit Date At Visit 1 (2nd) | SAS Date .M="Missing" .R="Not Randomized" |

# Section 27: Blood Chemistry Hemoglobin A1c

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_hba1c_ comments_v1** | Comments At Visit 1 | Comments At Visit 1 | Char |
| 01. Principal | **bldchem_hba1c_ comments_v3** | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | **bldchem_hba1c_ oor_sig_v1** | If Out Of Range, Is It Clinically Significant At Visit 1? | If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_hba1c_ oor_sig_v3** | If Out Of Range, Is It Clinically Significant At Visit 3? | If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_hba1c_ oor_v1** | If Out Of Range At Visit 1? | If Out Of Range At Visit 1? | .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_hba1c_ oor_v3** | If Out Of Range At Visit 3? | If Out Of Range At Visit 3? | .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_hba1c_ result_v1** | Results At Visit 1 [%] | Results At Visit 1 [%] | Numeric .R="Not Randomized" |
| 01. Principal | **bldchem_hba1c_ result_v3** | Results At Visit 3 [%] | Results At Visit 3 [%] | Numeric .R="Not Randomized" |
| 01. Principal | **bldchem_hba1c_ visit_dt_v1** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Date .R="Not Randomized" |
| 01. Principal | **bldchem_hba1c_ visit_dt_v3** | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date .R="Not Randomized" |

# Section 28: Blood Chemistry Lipids

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **bldchem_chol_oor_scr2** | Cholesterol Out Of Range At Screen 2? | Cholesterol Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_chol_oor_sig_scr2** | Cholesterol If Out Of Range, Is It Clinically Significant At Screen 2? | Cholesterol If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_chol_oor_sig_v1** | Cholesterol If Out Of Range, Is It Clinically Significant At Visit 1? | Cholesterol If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_chol_oor_sig_v2** | Cholesterol If Out Of Range, Is It Clinically Significant At Visit 2? | Cholesterol If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_chol_oor_sig_v3** | Cholesterol If Out Of Range, Is It Clinically Significant At Visit 3? | Cholesterol If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chol_oor_v1** | Cholesterol Out Of Range At Visit 1? | Cholesterol Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_chol_oor_v2** | Cholesterol Out Of Range At Visit 2? | Cholesterol Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_chol_oor_v3** | Cholesterol Out Of Range At Visit 3? | Cholesterol Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_chol_result_scr2** | Cholesterol Result In mg/dL At Screen 2 | Cholesterol Result In mg/dL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chol_result_v1** | Cholesterol Result In mg/dL At Visit 1 | Cholesterol Result In mg/dL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chol_result_v2** | Cholesterol Result In mg/dL At Visit 2 | Cholesterol Result In mg/dL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chol_result_v3** | Cholesterol Result In mg/dL At Visit 3 | Cholesterol Result In mg/dL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_comments_scr2** | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | **bldchem_comments_v1** | Comments At Visit 1 | Comments At Visit 1 | Char |
| 01. Principal | **bldchem_comments_v2** | Comments At Visit 2 | Comments At Visit 2 | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_comments_v3** | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | **bldchem_hdl_oor_scr2** | HDL Out Of Range At Screen 2? | HDL Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_hdl_oor_sig_scr2** | HDL If Out Of Range, Is It Clinically Significant At Screen 2? | HDL If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_hdl_oor_sig_v1** | HDL If Out Of Range, Is It Clinically Significant At Visit 1? | HDL If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **bldchem_hdl_oor_sig_v2** | HDL If Out Of Range, Is It Clinically Significant At Visit 2? | HDL If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_hdl_oor_sig_v3** | HDL If Out Of Range, Is It Clinically Significant At Visit 3? | HDL If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_hdl_oor_v1** | HDL Out Of Range At Visit 1? | HDL Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_hdl_oor_v2** | HDL Out Of Range At Visit 2? | HDL Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_hdl_oor_v3** | HDL Out Of Range At Visit 3? | HDL Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_hdl_result_scr2** | HDL Result In mg/dL At Screen 2 | HDL Result In mg/dL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_hdl_result_v1** | HDL Result In mg/dL At Visit 1 | HDL Result In mg/dL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_hdl_result_v2** | HDL Result In mg/dL At Visit 2 | HDL Result In mg/dL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_hdl_result_v3** | HDL Result In mg/dL At Visit 3 | HDL Result In mg/dL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_ldl_oor_scr2** | LDL Out Of Range At Screen 2? | LDL Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_ldl_oor_sig_scr2** | LDL If Out Of Range, Is It Clinically Significant At Screen 2? | LDL If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_ldl_oor_sig_v1** | LDL If Out Of Range, Is It Clinically Significant At Visit 1? | LDL If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **bldchem_ldl_oor _sig_v2** | LDL If Out Of Range, Is It Clinically Significant At Visit 2? | LDL If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_ldl_oor _sig_v3** | LDL If Out Of Range, Is It Clinically Significant At Visit 3? | LDL If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_ldl_oor _v1** | LDL Out Of Range At Visit 1? | LDL Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_ldl_oor _v2** | LDL Out Of Range At Visit 2? | LDL Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_ldl_oor _v3** | LDL Out Of Range At Visit 3? | LDL Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_ldl_res ult_scr2** | IDL Result In mg/dL At Screen 2 | IDL Result In mg/dL At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_ldl_res ult_v1** | IDL Result In mg/dL At Visit 1 | IDL Result In mg/dL At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_ldl_res ult_v2** | IDL Result In mg/dL At Visit 2 | IDL Result In mg/dL At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_ldl_res ult_v3** | IDL Result In mg/dL At Visit 3 | IDL Result In mg/dL At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_lipid_vi sit_dt_scr2** | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_lipid_vi sit_dt_v1** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_lipid_vi sit_dt_v2** | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date .R="Not Randomized" |
| 01. Principal | **bldchem_lipid_vi sit_dt_v3** | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_trig_oo r_scr2** | Triglycerides Out Of Range At Screen 2? | Triglycerides Out Of Range At Screen 2? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_trig_oo r_sig_scr2** | Triglycerides If Out Of Range, Is It Clinically Significant At Screen 2? | Triglycerides If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_trig_oo r_sig_v1** | Triglycerides If Out Of Range, Is It Clinically Significant At Visit 1? | Triglycerides If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" 0="No" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_trig_oor_sig_v2** | Triglycerides If Out Of Range, Is It Clinically Significant At Visit 2? | Triglycerides If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_trig_oor_sig_v3** | Triglycerides If Out Of Range, Is It Clinically Significant At Visit 3? | Triglycerides If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_trig_oor_v1** | Triglycerides Out Of Range At Visit 1? | Triglycerides Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_trig_oor_v2** | Triglycerides Out Of Range At Visit 2? | Triglycerides Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_trig_oor_v3** | Triglycerides Out Of Range At Visit 3? | Triglycerides Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_trig_result_scr2** | Triglycerides Result In mg/dL At Screen 2 | Triglycerides Result In mg/dL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_trig_result_v1** | Triglycerides Result In mg/dL At Visit 1 | Triglycerides Result In mg/dL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_trig_result_v2** | Triglycerides Result In mg/dL At Visit 2 | Triglycerides Result In mg/dL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_trig_result_v3** | Triglycerides Result In mg/dL At Visit 3 | Triglycerides Result In mg/dL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

# Section 29: Endoscopic Ultrasound

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | eus_comments_scr2 | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | eus_comments_v2 | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | eus_comments_v3 | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | eus_score_scr2 | EUS Score At Screen 2 | EUS Score At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | eus_score_v2 | EUS Score At Visit 2 | EUS Score At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | eus_score_v3 | EUS Score At Visit 3 | EUS Score At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | eus_visit_dt_scr2 | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | eus_visit_dt_v2 | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | eus_visit_dt_v3 | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |

# Section 30: Hematology

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **hema_anc_oor_scr1** | Absolute Neutrophil Count (ANC) Out Of Range At Screen 1 | Absolute Neutrophil Count (ANC) Out Of Range At Screen 1 | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_anc_oor_scr2** | Absolute Neutrophil Count (ANC) Out Of Range At Screen 2 | Absolute Neutrophil Count (ANC) Out Of Range At Screen 2 | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **hema_anc_oor_sig_scr1** | Absolute Neutrophil Count (ANC) If Out Of Range, Is It Clinically Significant At Screen 1? | Absolute Neutrophil Count (ANC) If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_anc_oor_sig_scr2** | Absolute Neutrophil Count (ANC) If Out Of Range, Is It Clinically Significant At Screen 2? | Absolute Neutrophil Count (ANC) If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_anc_oor_sig_v1** | Absolute Neutrophil Count (ANC) If Out Of Range, Is It Clinically Significant At Visit 1? | Absolute Neutrophil Count (ANC) If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **hema_anc_oor_sig_v2** | Absolute Neutrophil Count (ANC) If Out Of Range, Is It Clinically Significant At Visit 2? | Absolute Neutrophil Count (ANC) If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_anc_oor_sig_v3** | Absolute Neutrophil Count (ANC) If Out Of Range, Is It Clinically Significant At Visit 3? | Absolute Neutrophil Count (ANC) If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_anc_oor_v1** | Absolute Neutrophil Count (ANC) Out Of Range At Visit 1 | Absolute Neutrophil Count (ANC) Out Of Range At Visit 1 | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **hema_anc_oor_v2** | Absolute Neutrophil Count (ANC) Out Of Range At Visit 2 | Absolute Neutrophil Count (ANC) Out Of Range At Visit 2 | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_anc_oor_v3** | Absolute Neutrophil Count (ANC) Out Of Range At Visit 3 | Absolute Neutrophil Count (ANC) Out Of Range At Visit 3 | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_anc_result_scr1** | Absolute Neutrophil Count (ANC) Result In K/uL At Screen 1 | Absolute Neutrophil Count (ANC) Result In K/uL At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_anc_result_scr2** | Absolute Neutrophil Count (ANC) Result In K/uL At Screen 2 | Absolute Neutrophil Count (ANC) Result In K/uL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_anc_result_v1** | Absolute Neutrophil Count (ANC) Result In K/uL At Visit 1 | Absolute Neutrophil Count (ANC) Result In K/uL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **hema_anc_result _v2** | Absolute Neutrophil Count (ANC) Result In K/uL At Visit 2 | Absolute Neutrophil Count (ANC) Result In K/uL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_anc_result _v3** | Absolute Neutrophil Count (ANC) Result In K/uL At Visit 3 | Absolute Neutrophil Count (ANC) Result In K/uL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_comments _scr1** | Comments At Screen 1 | Comments At Screen 1 | Char |
| 01. Principal | **hema_comments _scr2** | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | **hema_comments _v1** | Comments At Visit 1 | Comments At Visit 1 | Char |
| 01. Principal | **hema_comments _v2** | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | **hema_comments _v3** | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | **hema_hemoglobi n_oor_scr1** | Hemoglobin Out Of Range At Screen 1? | Hemoglobin Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **hema_hemoglobi n_oor_scr2** | Hemoglobin Out Of Range At Screen 2? | Hemoglobin Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **hema_hemoglobi n_oor_sig_scr1** | Hemoglobin If Out Of Range, Is It Clinically Significant At Screen 1? | Hemoglobin If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_hemoglobi n_oor_sig_scr2** | Hemoglobin If Out Of Range, Is It Clinically Significant At Screen 2? | Hemoglobin If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_hemoglobi n_oor_sig_v1** | Hemoglobin If Out Of Range, Is It Clinically Significant At Visit 1? | Hemoglobin If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **hema_hemoglobi n_oor_sig_v2** | Hemoglobin If Out Of Range, Is It Clinically Significant At Visit 2? | Hemoglobin If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_hemoglobi n_oor_sig_v3** | Hemoglobin If Out Of Range, Is It Clinically Significant At Visit 3? | Hemoglobin If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_hemoglobi n_oor_v1** | Hemoglobin Out Of Range At Visit 1? | Hemoglobin Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **hema_hemoglobi n_oor_v2** | Hemoglobin Out Of Range At Visit 2? | Hemoglobin Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **hema_hemoglobi n_oor_v3** | Hemoglobin Out Of Range At Visit 3? | Hemoglobin Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **hema_hemoglobin_result_scr1** | Hemoglobin Result In g/dL At Screen 1 | Hemoglobin Result In g/dL At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_hemoglobin_result_scr2** | Hemoglobin Result In g/dL At Screen 2 | Hemoglobin Result In g/dL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_hemoglobin_result_v1** | Hemoglobin Result In g/dL At Visit 1 | Hemoglobin Result In g/dL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_hemoglobin_result_v2** | Hemoglobin Result In g/dL At Visit 2 | Hemoglobin Result In g/dL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_hemoglobin_result_v3** | Hemoglobin Result In g/dL At Visit 3 | Hemoglobin Result In g/dL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_other1_oor_scr1** | Other Test 1 Out Of Range At Screen 1? | Other Test 1 Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **hema_other1_oor_scr2** | Other Test 1 Out Of Range At Screen 2? | Other Test 1 Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **hema_other1_oor_sig_scr1** | Other Test 1 If Out Of Range, Is It Clinically Significant At Screen 1? | Other Test 1 If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_other1_oor_sig_scr2** | Other Test 1 If Out Of Range, Is It Clinically Significant At Screen 2? | Other Test 1 If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_other1_oor_sig_v1** | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 1? | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **hema_other1_oor_sig_v2** | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 2? | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_other1_oor_sig_v3** | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 3? | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_other1_oor_v1** | Other Test 1 Out Of Range At Visit 1? | Other Test 1 Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **hema_other1_oor_v2** | Other Test 1 Out Of Range At Visit 2? | Other Test 1 Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **hema_other1_oor_v3** | Other Test 1 Out Of Range At Visit 3? | Other Test 1 Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **hema_other1_result_scr1** | Other Test 1 Result In g/dL At Screen 1 | Other Test 1 Result In g/dL At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

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| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **hema_other1_result_scr2** | Other Test 1 Result In g/dL At Screen 2 | Other Test 1 Result In g/dL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_other1_result_v1** | Other Test 1 Result In g/dL At Visit 1 | Other Test 1 Result In g/dL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_other1_result_v2** | Other Test 1 Result In g/dL At Visit 2 | Other Test 1 Result In g/dL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_other1_result_v3** | Other Test 1 Result In g/dL At Visit 3 | Other Test 1 Result In g/dL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_other1_test_scr1** | Other Test 1 Specify At Screen 1 | Other Test 1 Specify At Screen 1 | Char |
| 01. Principal | **hema_other1_test_scr2** | Other Test 1 Specify At Screen 2 | Other Test 1 Specify At Screen 2 | Char |
| 01. Principal | **hema_other1_test_v1** | Other Test 1 Specify At Visit 1 | Other Test 1 Specify At Visit 1 | Char |
| 01. Principal | **hema_other1_test_v2** | Other Test 1 Specify At Visit 2 | Other Test 1 Specify At Visit 2 | Char |
| 01. Principal | **hema_other1_test_v3** | Other Test 1 Specify At Visit 3 | Other Test 1 Specify At Visit 3 | Char |
| 01. Principal | **hema_other1_units_scr1** | Other Test 1 Units At Screen 1 | Other Test 1 Units At Screen 1 | Char |
| 01. Principal | **hema_other1_units_scr2** | Other Test 1 Units At Screen 2 | Other Test 1 Units At Screen 2 | Char |
| 01. Principal | **hema_other1_units_v1** | Other Test 1 Units At Visit 1 | Other Test 1 Units At Visit 1 | Char |
| 01. Principal | **hema_other1_units_v2** | Other Test 1 Units At Visit 2 | Other Test 1 Units At Visit 2 | Char |
| 01. Principal | **hema_other1_units_v3** | Other Test 1 Units At Visit 3 | Other Test 1 Units At Visit 3 | Char |
| 01. Principal | **hema_other2_oor_scr1** | Other Test 2 Out Of Range At Screen 1? | Other Test 2 Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **hema_other2_oor_scr2** | Other Test 2 Out Of Range At Screen 2? | Other Test 2 Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **hema_other2_oor_sig_scr1** | Other Test 2 If Out Of Range, Is It Clinically Significant At Screen 1? | Other Test 2 If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_other2_oor_sig_scr2** | Other Test 2 If Out Of Range, Is It Clinically Significant At Screen 2? | Other Test 2 If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_other2_oor_sig_v1** | Other Test 2 If Out Of Range, Is It Clinically Significant At Visit 1? | Other Test 2 If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **hema_other2_oor_sig_v2** | Other Test 2 If Out Of Range, Is It Clinically Significant At Visit 2? | Other Test 2 If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **hema_other2_oor_sig_v3** | Other Test 2 If Out Of Range, Is It Clinically Significant At Visit 3? | Other Test 2 If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **hema_other2_oor_v1** | Other Test 2 Out Of Range At Visit 1? | Other Test 2 Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **hema_other2_oor_v2** | Other Test 2 Out Of Range At Visit 2? | Other Test 2 Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **hema_other2_oor_v3** | Other Test 2 Out Of Range At Visit 3? | Other Test 2 Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **hema_other2_result_scr1** | Other Test 2 Result In g/dL At Screen 1 | Other Test 2 Result In g/dL At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other2_result_scr2** | Other Test 2 Result In g/dL At Screen 2 | Other Test 2 Result In g/dL At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other2_result_v1** | Other Test 2 Result In g/dL At Visit 1 | Other Test 2 Result In g/dL At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other2_result_v2** | Other Test 2 Result In g/dL At Visit 2 | Other Test 2 Result In g/dL At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other2_result_v3** | Other Test 2 Result In g/dL At Visit 3 | Other Test 2 Result In g/dL At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other2_test_scr1** | Other Test 2 Specify At Screen 1 | Other Test 2 Specify At Screen 1 | Char |
| 01. Principal | **hema_other2_test_scr2** | Other Test 2 Specify At Screen 2 | Other Test 2 Specify At Screen 2 | Char |
| 01. Principal | **hema_other2_test_v1** | Other Test 2 Specify At Visit 1 | Other Test 2 Specify At Visit 1 | Char |
| 01. Principal | **hema_other2_test_v2** | Other Test 2 Specify At Visit 2 | Other Test 2 Specify At Visit 2 | Char |
| 01. Principal | **hema_other2_test_v3** | Other Test 2 Specify At Visit 3 | Other Test 2 Specify At Visit 3 | Char |
| 01. Principal | **hema_other2_units_scr1** | Other Test 2 Units At Screen 1 | Other Test 2 Units At Screen 1 | Char |
| 01. Principal | **hema_other2_units_scr2** | Other Test 2 Units At Screen 2 | Other Test 2 Units At Screen 2 | Char |
| 01. Principal | **hema_other2_units_v1** | Other Test 2 Units At Visit 1 | Other Test 2 Units At Visit 1 | Char |
| 01. Principal | **hema_other2_units_v2** | Other Test 2 Units At Visit 2 | Other Test 2 Units At Visit 2 | Char |
| 01. Principal | **hema_other2_units_v3** | Other Test 2 Units At Visit 3 | Other Test 2 Units At Visit 3 | Char |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **hema_other3_oor _scr1** | Other Test 3 Out Of Range At Screen 1? | Other Test 3 Out Of Range At Screen 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other3_oor _scr2** | Other Test 3 Out Of Range At Screen 2? | Other Test 3 Out Of Range At Screen 2? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **hema_other3_oor _sig_scr1** | Other Test 3 If Out Of Range, Is It Clinically Significant At Screen 1? | Other Test 3 If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other3_oor _sig_scr2** | Other Test 3 If Out Of Range, Is It Clinically Significant At Screen 2? | Other Test 3 If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **hema_other3_oor _sig_v1** | Other Test 3 If Out Of Range, Is It Clinically Significant At Visit 1? | Other Test 3 If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **hema_other3_oor _sig_v2** | Other Test 3 If Out Of Range, Is It Clinically Significant At Visit 2? | Other Test 3 If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other3_oor _sig_v3** | Other Test 3 If Out Of Range, Is It Clinically Significant At Visit 3? | Other Test 3 If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **hema_other3_oor _v1** | Other Test 3 Out Of Range At Visit 1? | Other Test 3 Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **hema_other3_oor _v2** | Other Test 3 Out Of Range At Visit 2? | Other Test 3 Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other3_oor _v3** | Other Test 3 Out Of Range At Visit 3? | Other Test 3 Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **hema_other3_res ult_scr1** | Other Test 3Result In g/dL At Screen 1 | Other Test 3Result In g/dL At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other3_res ult_scr2** | Other Test 3Result In g/dL At Screen 2 | Other Test 3Result In g/dL At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other3_res ult_v1** | Other Test 3Result In g/dL At Visit 1 | Other Test 3Result In g/dL At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other3_res ult_v2** | Other Test 3Result In g/dL At Visit 2 | Other Test 3Result In g/dL At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other3_res ult_v3** | Other Test 3Result In g/dL At Visit 3 | Other Test 3Result In g/dL At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_other3_tes t_scr1** | Other Test 3 Specify At Screen 1 | Other Test 3 Specify At Screen 1 | Char |
| 01. Principal | **hema_other3_tes t_scr2** | Other Test 3 Specify At Screen 2 | Other Test 3 Specify At Screen 2 | Char |
| 01. Principal | **hema_other3_tes t_v1** | Other Test 3 Specify At Visit 1 | Other Test 3 Specify At Visit 1 | Char |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **hema_other3_test_v2** | Other Test 3 Specify At Visit 2 | Other Test 3 Specify At Visit 2 | Char |
| 01. Principal | **hema_other3_test_v3** | Other Test 3 Specify At Visit 3 | Other Test 3 Specify At Visit 3 | Char |
| 01. Principal | **hema_other3_units_scr1** | Other Test 3 Units At Screen 1 | Other Test 3 Units At Screen 1 | Char |
| 01. Principal | **hema_other3_units_scr2** | Other Test 3 Units At Screen 2 | Other Test 3 Units At Screen 2 | Char |
| 01. Principal | **hema_other3_units_v1** | Other Test 3 Units At Visit 1 | Other Test 3 Units At Visit 1 | Char |
| 01. Principal | **hema_other3_units_v2** | Other Test 3 Units At Visit 2 | Other Test 3 Units At Visit 2 | Char |
| 01. Principal | **hema_other3_units_v3** | Other Test 3 Units At Visit 3 | Other Test 3 Units At Visit 3 | Char |
| 01. Principal | **hema_platelet_oor_scr1** | Platelets Out Of Range At Screen 1? | Platelets Out Of Range At Screen 1? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **hema_platelet_oor_scr2** | Platelets Out Of Range At Screen 2? | Platelets Out Of Range At Screen 2? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **hema_platelet_oor_sig_scr1** | Platelets If Out Of Range, Is It Clinically Significant At Screen 1? | Platelets If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **hema_platelet_oor_sig_scr2** | Platelets If Out Of Range, Is It Clinically Significant At Screen 2? | Platelets If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **hema_platelet_oor_sig_v1** | Platelets If Out Of Range, Is It Clinically Significant At Visit 1? | Platelets If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **hema_platelet_oor_sig_v2** | Platelets If Out Of Range, Is It Clinically Significant At Visit 2? | Platelets If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_platelet_oor_sig_v3** | Platelets If Out Of Range, Is It Clinically Significant At Visit 3? | Platelets If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **hema_platelet_oor_v1** | Platelets Out Of Range At Visit 1? | Platelets Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **hema_platelet_oor_v2** | Platelets Out Of Range At Visit 2? | Platelets Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **hema_platelet_oor_v3** | Platelets Out Of Range At Visit 3? | Platelets Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **hema_platelet_result_scr1** | Platelets Result In g/dL At Screen 1 | Platelets Result In g/dL At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **hema_platelet_result_scr2** | Platelets Result In g/dL At Screen 2 | Platelets Result In g/dL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_platelet_result_v1** | Platelets Result In g/dL At Visit 1 | Platelets Result In g/dL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_platelet_result_v2** | Platelets Result In g/dL At Visit 2 | Platelets Result In g/dL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_platelet_result_v3** | Platelets Result In g/dL At Visit 3 | Platelets Result In g/dL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_visit_dt_scr1** | Visit Date At Screen 1 | Visit Date At Screen 1 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_visit_dt_scr2** | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_visit_dt_v1** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_visit_dt_v2** | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_visit_dt_v3** | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_wbc_oor_scr1** | WBC Out Of Range At Screen 1? | WBC Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_wbc_oor_scr2** | WBC Out Of Range At Screen 2? | WBC Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **hema_wbc_oor_sig_scr1** | WBC If Out Of Range, Is It Clinically Significant At Screen 1? | WBC If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_wbc_oor_sig_scr2** | WBC If Out Of Range, Is It Clinically Significant At Screen 2? | WBC If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_wbc_oor_sig_v1** | WBC If Out Of Range, Is It Clinically Significant At Visit 1? | WBC If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **hema_wbc_oor_sig_v2** | WBC If Out Of Range, Is It Clinically Significant At Visit 2? | WBC If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_wbc_oor_sig_v3** | WBC If Out Of Range, Is It Clinically Significant At Visit 3? | WBC If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **hema_wbc_oor_v1** | WBC Out Of Range At Visit 1? | WBC Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **hema_wbc_oor_v2** | WBC Out Of Range At Visit 2? | WBC Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_wbc_oor_v3** | WBC Out Of Range At Visit 3? | WBC Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **hema_wbc_result_scr1** | WBC Result In #/uL At Screen 1 | WBC Result In #/uL At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_wbc_result_scr2** | WBC Result In #/uL At Screen 2 | WBC Result In #/uL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_wbc_result_v1** | WBC Result In #/uL At Visit 1 | WBC Result In #/uL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_wbc_result_v2** | WBC Result In #/uL At Visit 2 | WBC Result In #/uL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **hema_wbc_result_v3** | WBC Result In #/uL At Visit 3 | WBC Result In #/uL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

# Section 31: Multiplex Fluorescent Immunoassay

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **mfi_bca1_scr1** | BCA1/CXCL13 At Screen 1 | BCA1/CXCL13 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_bca1_v1** | BCA1/CXCL13 At Visit 1 | BCA1/CXCL13 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_bca1_v2** | BCA1/CXCL13 At Visit 2 | BCA1/CXCL13 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_ckine_scr1** | 6CKINE/CCL21/EXODUS2 At Screen 1 | 6CKINE/CCL21/EXODUS2 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ckine_v1** | 6CKINE/CCL21/EXODUS2 At Visit 1 | 6CKINE/CCL21/EXODUS2 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ckine_v2** | 6CKINE/CCL21/EXODUS2 At Visit 2 | 6CKINE/CCL21/EXODUS2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_ctack_scr1** | CTACK/CCL27 At Screen 1 | CTACK/CCL27 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ctack_v1** | CTACK/CCL27 At Visit 1 | CTACK/CCL27 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ctack_v2** | CTACK/CCL27 At Visit 2 | CTACK/CCL27 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_egf_scr1** | EGF At Screen 1 | EGF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_egf_v1** | EGF At Visit 1 | EGF At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_egf_v2** | EGF At Visit 2 | EGF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_ena78_scr1** | ENA78/CXCL5 At Screen 1 | ENA78/CXCL5 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ena78_v1** | ENA78/CXCL5 At Visit 1 | ENA78/CXCL5 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ena78_v2** | ENA78/CXCL5 At Visit 2 | ENA78/CXCL5 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_eotaxin2_scr1** | EOTAXIN2/CCL24/MPIF2 At Screen 1 | EOTAXIN2/CCL24/MPIF2 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_eotaxin2_v1** | EOTAXIN2/CCL24/MPIF2 At Visit 1 | EOTAXIN2/CCL24/MPIF2 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_eotaxin2_v2** | EOTAXIN2/CCL24/MPIF2 At Visit 2 | EOTAXIN2/CCL24/MPIF2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_eotaxin3_scr1** | EOTAXIN3/CCL26 At Screen 1 | EOTAXIN3/CCL26 At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **mfi_eotaxin3_v1** | EOTAXIN3/CCL26 At Visit 1 | EOTAXIN3/CCL26 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_eotaxin3_v2** | EOTAXIN3/CCL26 At Visit 2 | EOTAXIN3/CCL26 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_eotaxin_scr1** | EOTAXIN/CCL11 At Screen 1 | EOTAXIN/CCL11 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_eotaxin_v1** | EOTAXIN/CCL11 At Visit 1 | EOTAXIN/CCL11 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_eotaxin_v2** | EOTAXIN/CCL11 At Visit 2 | EOTAXIN/CCL11 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_fasl_scr1** | FASL At Screen 1 | FASL At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_fasl_v1** | FASL At Visit 1 | FASL At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_fasl_v2** | FASL At Visit 2 | FASL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_fgf2_scr1** | FGF2/FGFB At Screen 1 | FGF2/FGFB At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_fgf2_v1** | FGF2/FGFB At Visit 1 | FGF2/FGFB At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_fgf2_v2** | FGF2/FGFB At Visit 2 | FGF2/FGFB At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_flt3l_scr1** | FLT3L At Screen 1 | FLT3L At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_flt3l_v1** | FLT3L At Visit 1 | FLT3L At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_flt3l_v2** | FLT3L At Visit 2 | FLT3L At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_fractalkine_scr1** | FRACTALKINE/CX3CL1 At Screen 1 | FRACTALKINE/CX3CL1 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_fractalkine_v1** | FRACTALKINE/CX3CL1 At Visit 1 | FRACTALKINE/CX3CL1 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_fractalkine_v2** | FRACTALKINE/CX3CL1 At Visit 2 | FRACTALKINE/CX3CL1 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_gcsf_scr1** | GCSF At Screen 1 | GCSF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_gcsf_v1** | GCSF At Visit 1 | GCSF At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_gcsf_v2** | GCSF At Visit 2 | GCSF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_gmcsf_scr1** | GMCSF At Screen 1 | GMCSF At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **mfi_gmcsf_v1** | GMCSF At Visit 1 | GMCSF At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_gmcsf_v2** | GMCSF At Visit 2 | GMCSF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_groa_scr1** | GROA At Screen 1 | GROA At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_groa_v1** | GROA At Visit 1 | GROA At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_groa_v2** | GROA At Visit 2 | GROA At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_hgf_scr1** | HGF At Screen 1 | HGF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_hgf_v1** | HGF At Visit 1 | HGF At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_hgf_v2** | HGF At Visit 2 | HGF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_i309_scr1** | I309/CCL1 At Screen 1 | I309/CCL1 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_i309_v1** | I309/CCL1 At Visit 1 | I309/CCL1 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_i309_v2** | I309/CCL1 At Visit 2 | I309/CCL1 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_ifna2_scr1** | IFNA2 At Screen 1 | IFNA2 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ifna2_v1** | IFNA2 At Visit 1 | IFNA2 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ifna2_v2** | IFNA2 At Visit 2 | IFNA2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_ifng_scr1** | IFNG At Screen 1 | IFNG At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ifng_v1** | IFNG At Visit 1 | IFNG At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ifng_v2** | IFNG At Visit 2 | IFNG At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il10_scr1** | IL10 At Screen 1 | IL10 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il10_v1** | IL10 At Visit 1 | IL10 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il10_v2** | IL10 At Visit 2 | IL10 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il12p40_scr1** | IL12P40 At Screen 1 | IL12P40 At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **mfi_il12p40_v1** | IL12P40 At Visit 1 | IL12P40 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il12p40_v2** | IL12P40 At Visit 2 | IL12P40 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il12p70_scr1** | IL12P70 At Screen 1 | IL12P70 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il12p70_v1** | IL12P70 At Visit 1 | IL12P70 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il12p70_v2** | IL12P70 At Visit 2 | IL12P70 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il13_scr1** | IL13 At Screen 1 | IL13 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il13_v1** | IL13 At Visit 1 | IL13 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il13_v2** | IL13 At Visit 2 | IL13 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il15_scr1** | IL15 At Screen 1 | IL15 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il15_v1** | IL15 At Visit 1 | IL15 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il15_v2** | IL15 At Visit 2 | IL15 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il16_scr1** | IL16 At Screen 1 | IL16 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il16_v1** | IL16 At Visit 1 | IL16 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il16_v2** | IL16 At Visit 2 | IL16 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il17a_scr1** | IL17A/CTLA8 At Screen 1 | IL17A/CTLA8 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il17a_v1** | IL17A/CTLA8 At Visit 1 | IL17A/CTLA8 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il17a_v2** | IL17A/CTLA8 At Visit 2 | IL17A/CTLA8 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il17e_scr1** | IL17E/IL-25 At Screen 1 | IL17E/IL-25 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il17e_v1** | IL17E/IL-25 At Visit 1 | IL17E/IL-25 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il17e_v2** | IL17E/IL-25 At Visit 2 | IL17E/IL-25 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il17f_scr1** | IL17F At Screen 1 | IL17F At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **mfi_il17f_v1** | IL17F At Visit 1 | IL17F At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il17f_v2** | IL17F At Visit 2 | IL17F At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il18_scr1** | IL18 At Screen 1 | IL18 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il18_v1** | IL18 At Visit 1 | IL18 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il18_v2** | IL18 At Visit 2 | IL18 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il1a_scr1** | IL1A At Screen 1 | IL1A At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il1a_v1** | IL1A At Visit 1 | IL1A At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il1a_v2** | IL1A At Visit 2 | IL1A At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il1b_scr1** | IL1B At Screen 1 | IL1B At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il1b_v1** | IL1B At Visit 1 | IL1B At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il1b_v2** | IL1B At Visit 2 | IL1B At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il1ra_scr1** | IL1RA At Screen 1 | IL1RA At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il1ra_v1** | IL1RA At Visit 1 | IL1RA At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il1ra_v2** | IL1RA At Visit 2 | IL1RA At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il20_scr1** | IL20 At Screen 1 | IL20 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il20_v1** | IL20 At Visit 1 | IL20 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il20_v2** | IL20 At Visit 2 | IL20 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il21_scr1** | IL21 At Screen 1 | IL21 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il21_v1** | IL21 At Visit 1 | IL21 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il21_v2** | IL21 At Visit 2 | IL21 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il22_scr1** | IL22 At Screen 1 | IL22 At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **mfi_il22_v1** | IL22 At Visit 1 | IL22 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il22_v2** | IL22 At Visit 2 | IL22 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il23_scr1** | IL23 At Screen 1 | IL23 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il23_v1** | IL23 At Visit 1 | IL23 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il23_v2** | IL23 At Visit 2 | IL23 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il27_scr1** | IL27 At Screen 1 | IL27 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il27_v1** | IL27 At Visit 1 | IL27 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il27_v2** | IL27 At Visit 2 | IL27 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il28a_scr1** | IL28A/IFNL2 At Screen 1 | IL28A/IFNL2 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il28a_v1** | IL28A/IFNL2 At Visit 1 | IL28A/IFNL2 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il28a_v2** | IL28A/IFNL2 At Visit 2 | IL28A/IFNL2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il2_scr1** | IL2 At Screen 1 | IL2 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il2_v1** | IL2 At Visit 1 | IL2 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il2_v2** | IL2 At Visit 2 | IL2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il33_scr1** | IL33/NFHEV(MATURE) At Screen 1 | IL33/NFHEV(MATURE) At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il33_v1** | IL33/NFHEV(MATURE) At Visit 1 | IL33/NFHEV(MATURE) At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il33_v2** | IL33/NFHEV(MATURE) At Visit 2 | IL33/NFHEV(MATURE) At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il3_scr1** | IL3 At Screen 1 | IL3 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il3_v1** | IL3 At Visit 1 | IL3 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il3_v2** | IL3 At Visit 2 | IL3 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il4_scr1** | IL4 At Screen 1 | IL4 At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **mfi_il4_v1** | IL4 At Visit 1 | IL4 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il4_v2** | IL4 At Visit 2 | IL4 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il5_scr1** | IL5 At Screen 1 | IL5 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il5_v1** | IL5 At Visit 1 | IL5 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il5_v2** | IL5 At Visit 2 | IL5 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il6_scr1** | IL6 At Screen 1 | IL6 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il6_v1** | IL6 At Visit 1 | IL6 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il6_v2** | IL6 At Visit 2 | IL6 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il7_scr1** | IL7 At Screen 1 | IL7 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il7_v1** | IL7 At Visit 1 | IL7 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il7_v2** | IL7 At Visit 2 | IL7 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il8_scr1** | IL8/CXCL8 At Screen 1 | IL8/CXCL8 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il8_v1** | IL8/CXCL8 At Visit 1 | IL8/CXCL8 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il8_v2** | IL8/CXCL8 At Visit 2 | IL8/CXCL8 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_il9_scr1** | IL9 At Screen 1 | IL9 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il9_v1** | IL9 At Visit 1 | IL9 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_il9_v2** | IL9 At Visit 2 | IL9 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_ip10_scr1** | IP10/CXCL10 At Screen 1 | IP10/CXCL10 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ip10_v1** | IP10/CXCL10 At Visit 1 | IP10/CXCL10 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_ip10_v2** | IP10/CXCL10 At Visit 2 | IP10/CXCL10 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_leptin_scr1** | LEPTIN At Screen 1 | LEPTIN At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **mfi_leptin_v1** | LEPTIN At Visit 1 | LEPTIN At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_leptin_v2** | LEPTIN At Visit 2 | LEPTIN At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_lif_scr1** | LIF At Screen 1 | LIF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_lif_v1** | LIF At Visit 1 | LIF At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_lif_v2** | LIF At Visit 2 | LIF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp1_scr1** | MCP1/CCL2 At Screen 1 | MCP1/CCL2 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp1_v1** | MCP1/CCL2 At Visit 1 | MCP1/CCL2 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp1_v2** | MCP1/CCL2 At Visit 2 | MCP1/CCL2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp2_scr1** | MCP2/CCL8 At Screen 1 | MCP2/CCL8 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp2_v1** | MCP2/CCL8 At Visit 1 | MCP2/CCL8 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp2_v2** | MCP2/CCL8 At Visit 2 | MCP2/CCL8 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp3_scr1** | MCP3/CCL7 At Screen 1 | MCP3/CCL7 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp3_v1** | MCP3/CCL7 At Visit 1 | MCP3/CCL7 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp3_v2** | MCP3/CCL7 At Visit 2 | MCP3/CCL7 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp4_scr1** | MCP4/CCL13 At Screen 1 | MCP4/CCL13 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp4_v1** | MCP4/CCL13 At Visit 1 | MCP4/CCL13 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcp4_v2** | MCP4/CCL13 At Visit 2 | MCP4/CCL13 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcsf_scr1** | MCSF At Screen 1 | MCSF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcsf_v1** | MCSF At Visit 1 | MCSF At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mcsf_v2** | MCSF At Visit 2 | MCSF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_mdc_scr1** | MDC/CCL22 At Screen 1 | MDC/CCL22 At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **mfi_mdc_v1** | MDC/CCL22 At Visit 1 | MDC/CCL22 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mdc_v2** | MDC/CCL22 At Visit 2 | MDC/CCL22 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_mif_scr1** | MIF At Screen 1 | MIF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mif_v1** | MIF At Visit 1 | MIF At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mif_v2** | MIF At Visit 2 | MIF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_mig_scr1** | MIG/CXCL9 At Screen 1 | MIG/CXCL9 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mig_v1** | MIG/CXCL9 At Visit 1 | MIG/CXCL9 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mig_v2** | MIG/CXCL9 At Visit 2 | MIG/CXCL9 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_mip1a_scr1** | MIP1A/CCL3 At Screen 1 | MIP1A/CCL3 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mip1a_v1** | MIP1A/CCL3 At Visit 1 | MIP1A/CCL3 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mip1a_v2** | MIP1A/CCL3 At Visit 2 | MIP1A/CCL3 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_mip1b_scr1** | MIP1B/CCL4 At Screen 1 | MIP1B/CCL4 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mip1b_v1** | MIP1B/CCL4 At Visit 1 | MIP1B/CCL4 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mip1b_v2** | MIP1B/CCL4 At Visit 2 | MIP1B/CCL4 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_mip1d_scr1** | MIP1D/MIP5/CCL15 At Screen 1 | MIP1D/MIP5/CCL15 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mip1d_v1** | MIP1D/MIP5/CCL15 At Visit 1 | MIP1D/MIP5/CCL15 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_mip1d_v2** | MIP1D/MIP5/CCL15 At Visit 2 | MIP1D/MIP5/CCL15 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_pai1_scr1** | PAI1/SERPINE At Screen 1 | PAI1/SERPINE At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_pai1_v1** | PAI1/SERPINE At Visit 1 | PAI1/SERPINE At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_pai1_v2** | PAI1/SERPINE At Visit 2 | PAI1/SERPINE At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_pdgfaa_scr1** | PDGFAA At Screen 1 | PDGFAA At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **mfi_pdgfaa_v1** | PDGFAA At Visit 1 | PDGFAA At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_pdgfaa_v2** | PDGFAA At Visit 2 | PDGFAA At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_pdgfab_scr1** | PDGFAB/BB At Screen 1 | PDGFAB/BB At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_pdgfab_v1** | PDGFAB/BB At Visit 1 | PDGFAB/BB At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_pdgfab_v2** | PDGFAB/BB At Visit 2 | PDGFAB/BB At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_rantes_scr1** | RANTES/CCL5 At Screen 1 | RANTES/CCL5 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_rantes_v1** | RANTES/CCL5 At Visit 1 | RANTES/CCL5 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_rantes_v2** | RANTES/CCL5 At Visit 2 | RANTES/CCL5 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_resistin_scr1** | RESISTIN At Screen 1 | RESISTIN At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_resistin_v1** | RESISTIN At Visit 1 | RESISTIN At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_resistin_v2** | RESISTIN At Visit 2 | RESISTIN At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_scd40l_scr1** | SCD40L At Screen 1 | SCD40L At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_scd40l_v1** | SCD40L At Visit 1 | SCD40L At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_scd40l_v2** | SCD40L At Visit 2 | SCD40L At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_scf_scr1** | SCF At Screen 1 | SCF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_scf_v1** | SCF At Visit 1 | SCF At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_scf_v2** | SCF At Visit 2 | SCF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_sdf1a_scr1** | SDF1A+B/CXCL12 At Screen 1 | SDF1A+B/CXCL12 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_sdf1a_v1** | SDF1A+B/CXCL12 At Visit 1 | SDF1A+B/CXCL12 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_sdf1a_v2** | SDF1A+B/CXCL12 At Visit 2 | SDF1A+B/CXCL12 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_sfas_scr1** | SFAS/TNFRSF6 At Screen 1 | SFAS/TNFRSF6 At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **mfi_sfas_v1** | SFAS/TNFRSF6 At Visit 1 | SFAS/TNFRSF6 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_sfas_v2** | SFAS/TNFRSF6 At Visit 2 | SFAS/TNFRSF6 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_sicam1_scr1** | SICAM1 At Screen 1 | SICAM1 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_sicam1_v1** | SICAM1 At Visit 1 | SICAM1 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_sicam1_v2** | SICAM1 At Visit 2 | SICAM1 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_svcam1_scr1** | SVCAM1 At Screen 1 | SVCAM1 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_svcam1_v1** | SVCAM1 At Visit 1 | SVCAM1 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_svcam1_v2** | SVCAM1 At Visit 2 | SVCAM1 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_tarc_scr1** | TARC/CCL17 At Screen 1 | TARC/CCL17 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_tarc_v1** | TARC/CCL17 At Visit 1 | TARC/CCL17 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_tarc_v2** | TARC/CCL17 At Visit 2 | TARC/CCL17 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_tgfa_scr1** | TGFA At Screen 1 | TGFA At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_tgfa_v1** | TGFA At Visit 1 | TGFA At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_tgfa_v2** | TGFA At Visit 2 | TGFA At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_tnfa_scr1** | TNFA At Screen 1 | TNFA At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_tnfa_v1** | TNFA At Visit 1 | TNFA At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_tnfa_v2** | TNFA At Visit 2 | TNFA At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_tnfb_scr1** | TNFB/LYMPHOTOXINA(LTA) At Screen 1 | TNFB/LYMPHOTOXINA (LTA) At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_tnfb_v1** | TNFB/LYMPHOTOXINA(LTA) At Visit 1 | TNFB/LYMPHOTOXINA (LTA) At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_tnfb_v2** | TNFB/LYMPHOTOXINA(LTA) At Visit 2 | TNFB/LYMPHOTOXINA (LTA) At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_tpo_scr1** | TPO At Screen 1 | TPO At Screen 1 | Numeric<br>.R="Not Randomized" |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **mfi_tpo_v1** | TPO At Visit 1 | TPO At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_tpo_v2** | TPO At Visit 2 | TPO At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_trail_scr1** | TRAIL/TNFSF10 At Screen 1 | TRAIL/TNFSF10 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_trail_v1** | TRAIL/TNFSF10 At Visit 1 | TRAIL/TNFSF10 At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_trail_v2** | TRAIL/TNFSF10 At Visit 2 | TRAIL/TNFSF10 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_tslp_scr1** | TSLP At Screen 1 | TSLP At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_tslp_v1** | TSLP At Visit 1 | TSLP At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_tslp_v2** | TSLP At Visit 2 | TSLP At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **mfi_vegf_scr1** | VEGF At Screen 1 | VEGF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_vegf_v1** | VEGF At Visit 1 | VEGF At Visit 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **mfi_vegf_v2** | VEGF At Visit 2 | VEGF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

# Section 32: Pancreatic Fluid And Serum Levels

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **pgml_bca1_scr1** | BCA1/CXCL13 At Screen 1 | BCA1/CXCL13 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_bca1_v1** | BCA1/CXCL13 At Visit 1 | BCA1/CXCL13 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_bca1_v2** | BCA1/CXCL13 At Visit 2 | BCA1/CXCL13 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ckine_scr1** | 6CKINE/CCL21/EXODUS2 At Screen 1 | 6CKINE/CCL21/EXODUS2 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_ckine_v1** | 6CKINE/CCL21/EXODUS2 At Visit 1 | 6CKINE/CCL21/EXODUS2 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ckine_v2** | 6CKINE/CCL21/EXODUS2 At Visit 2 | 6CKINE/CCL21/EXODUS2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ctack_scr1** | CTACK/CCL27 At Screen 1 | CTACK/CCL27 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_ctack_v1** | CTACK/CCL27 At Visit 1 | CTACK/CCL27 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ctack_v2** | CTACK/CCL27 At Visit 2 | CTACK/CCL27 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_egf_scr1** | EGF At Screen 1 | EGF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_egf_v1** | EGF At Visit 1 | EGF At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_egf_v2** | EGF At Visit 2 | EGF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ena78_scr1** | ENA78/CXCL5 At Screen 1 | ENA78/CXCL5 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_ena78_v1** | ENA78/CXCL5 At Visit 1 | ENA78/CXCL5 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ena78_v2** | ENA78/CXCL5 At Visit 2 | ENA78/CXCL5 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_eotaxin2_scr1** | EOTAXIN2/CCL24/MPIF2 At Screen 1 | EOTAXIN2/CCL24/MPIF2 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_eotaxin2_v1** | EOTAXIN2/CCL24/MPIF2 At Visit 1 | EOTAXIN2/CCL24/MPIF2 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **pgml_eotaxin2_v2** | EOTAXIN2/CCL24/MPIF2 At Visit 2 | EOTAXIN2/CCL24/MPIF2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_eotaxin3_scr1** | EOTAXIN3/CCL26 At Screen 1 | EOTAXIN3/CCL26 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_eotaxin3_v1** | EOTAXIN3/CCL26 At Visit 1 | EOTAXIN3/CCL26 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_eotaxin3_v2** | EOTAXIN3/CCL26 At Visit 2 | EOTAXIN3/CCL26 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_eotaxin_scr1** | EOTAXIN/CCL11 At Screen 1 | EOTAXIN/CCL11 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_eotaxin_v1** | EOTAXIN/CCL11 At Visit 1 | EOTAXIN/CCL11 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_eotaxin_v2** | EOTAXIN/CCL11 At Visit 2 | EOTAXIN/CCL11 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_fasl_scr1** | FASL At Screen 1 | FASL At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_fasl_v1** | FASL At Visit 1 | FASL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_fasl_v2** | FASL At Visit 2 | FASL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_fgf2_scr1** | FGF2/FGFB At Screen 1 | FGF2/FGFB At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_fgf2_v1** | FGF2/FGFB At Visit 1 | FGF2/FGFB At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_fgf2_v2** | FGF2/FGFB At Visit 2 | FGF2/FGFB At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_flt3l_scr1** | FLT3L At Screen 1 | FLT3L At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_flt3l_v1** | FLT3L At Visit 1 | FLT3L At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_flt3l_v2** | FLT3L At Visit 2 | FLT3L At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_fractalkine_scr1** | FRACTALKINE/CX3CL1 At Screen 1 | FRACTALKINE/CX3CL1 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_fractalkine_v1** | FRACTALKINE/CX3CL1 At Visit 1 | FRACTALKINE/CX3CL1 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_fractalkine_v2** | FRACTALKINE/CX3CL1 At Visit 2 | FRACTALKINE/CX3CL1 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **pgml_gcsf_scr1** | GCSF At Screen 1 | GCSF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_gcsf_v1** | GCSF At Visit 1 | GCSF At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_gcsf_v2** | GCSF At Visit 2 | GCSF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_gmcsf_scr 1** | GMCSF At Screen 1 | GMCSF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_gmcsf_v1** | GMCSF At Visit 1 | GMCSF At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_gmcsf_v2** | GMCSF At Visit 2 | GMCSF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_groa_scr1** | GROA At Screen 1 | GROA At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_groa_v1** | GROA At Visit 1 | GROA At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_groa_v2** | GROA At Visit 2 | GROA At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_hgf_scr1** | HGF At Screen 1 | HGF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_hgf_v1** | HGF At Visit 1 | HGF At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_hgf_v2** | HGF At Visit 2 | HGF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_i309_scr1** | I309/CCL1 At Screen 1 | I309/CCL1 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_i309_v1** | I309/CCL1 At Visit 1 | I309/CCL1 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_i309_v2** | I309/CCL1 At Visit 2 | I309/CCL1 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ifna2_scr1** | IFNA2 At Screen 1 | IFNA2 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_ifna2_v1** | IFNA2 At Visit 1 | IFNA2 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ifna2_v2** | IFNA2 At Visit 2 | IFNA2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ifng_scr1** | IFNG At Screen 1 | IFNG At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **pgml_ifng_v1** | IFNG At Visit 1 | IFNG At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ifng_v2** | IFNG At Visit 2 | IFNG At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il10_scr1** | IL10 At Screen 1 | IL10 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il10_v1** | IL10 At Visit 1 | IL10 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il10_v2** | IL10 At Visit 2 | IL10 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il12p40_scr1** | IL12P40 At Screen 1 | IL12P40 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il12p40_v1** | IL12P40 At Visit 1 | IL12P40 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il12p40_v2** | IL12P40 At Visit 2 | IL12P40 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il12p70_scr1** | IL12P70 At Screen 1 | IL12P70 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il12p70_v1** | IL12P70 At Visit 1 | IL12P70 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il12p70_v2** | IL12P70 At Visit 2 | IL12P70 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il13_scr1** | IL13 At Screen 1 | IL13 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il13_v1** | IL13 At Visit 1 | IL13 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il13_v2** | IL13 At Visit 2 | IL13 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il15_scr1** | IL15 At Screen 1 | IL15 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il15_v1** | IL15 At Visit 1 | IL15 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il15_v2** | IL15 At Visit 2 | IL15 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il16_scr1** | IL16 At Screen 1 | IL16 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il16_v1** | IL16 At Visit 1 | IL16 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

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| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **pgml_il16_v2** | IL16 At Visit 2 | IL16 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il17a_scr1** | IL17A/CTLA8 At Screen 1 | IL17A/CTLA8 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il17a_v1** | IL17A/CTLA8 At Visit 1 | IL17A/CTLA8 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il17a_v2** | IL17A/CTLA8 At Visit 2 | IL17A/CTLA8 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il17e_scr1** | IL17E/IL-25 At Screen 1 | IL17E/IL-25 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il17e_v1** | IL17E/IL-25 At Visit 1 | IL17E/IL-25 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il17e_v2** | IL17E/IL-25 At Visit 2 | IL17E/IL-25 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il17f_scr1** | IL17F At Screen 1 | IL17F At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il17f_v1** | IL17F At Visit 1 | IL17F At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il17f_v2** | IL17F At Visit 2 | IL17F At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il18_scr1** | IL18 At Screen 1 | IL18 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il18_v1** | IL18 At Visit 1 | IL18 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il18_v2** | IL18 At Visit 2 | IL18 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il1a_scr1** | IL1A At Screen 1 | IL1A At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il1a_v1** | IL1A At Visit 1 | IL1A At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il1a_v2** | IL1A At Visit 2 | IL1A At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il1b_scr1** | IL1B At Screen 1 | IL1B At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il1b_v1** | IL1B At Visit 1 | IL1B At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il1b_v2** | IL1B At Visit 2 | IL1B At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **pgml_il1ra_scr1** | IL1RA At Screen 1 | IL1RA At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il1ra_v1** | IL1RA At Visit 1 | IL1RA At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il1ra_v2** | IL1RA At Visit 2 | IL1RA At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il20_scr1** | IL20 At Screen 1 | IL20 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il20_v1** | IL20 At Visit 1 | IL20 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il20_v2** | IL20 At Visit 2 | IL20 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il21_scr1** | IL21 At Screen 1 | IL21 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il21_v1** | IL21 At Visit 1 | IL21 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il21_v2** | IL21 At Visit 2 | IL21 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il22_scr1** | IL22 At Screen 1 | IL22 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il22_v1** | IL22 At Visit 1 | IL22 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il22_v2** | IL22 At Visit 2 | IL22 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il23_scr1** | IL23 At Screen 1 | IL23 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il23_v1** | IL23 At Visit 1 | IL23 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il23_v2** | IL23 At Visit 2 | IL23 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il27_scr1** | IL27 At Screen 1 | IL27 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il27_v1** | IL27 At Visit 1 | IL27 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il27_v2** | IL27 At Visit 2 | IL27 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il28a_scr1** | IL28A/IFNL2 At Screen 1 | IL28A/IFNL2 At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **pgml_il28a_v1** | IL28A/IFNL2 At Visit 1 | IL28A/IFNL2 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il28a_v2** | IL28A/IFNL2 At Visit 2 | IL28A/IFNL2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il2_scr1** | IL2 At Screen 1 | IL2 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il2_v1** | IL2 At Visit 1 | IL2 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il2_v2** | IL2 At Visit 2 | IL2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il33_scr1** | IL33/NFHEV(MATURE) At Screen 1 | IL33/NFHEV(MATURE) At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il33_v1** | IL33/NFHEV(MATURE) At Visit 1 | IL33/NFHEV(MATURE) At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il33_v2** | IL33/NFHEV(MATURE) At Visit 2 | IL33/NFHEV(MATURE) At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il3_scr1** | IL3 At Screen 1 | IL3 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il3_v1** | IL3 At Visit 1 | IL3 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il3_v2** | IL3 At Visit 2 | IL3 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il4_scr1** | IL4 At Screen 1 | IL4 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il4_v1** | IL4 At Visit 1 | IL4 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il4_v2** | IL4 At Visit 2 | IL4 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il5_scr1** | IL5 At Screen 1 | IL5 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il5_v1** | IL5 At Visit 1 | IL5 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il5_v2** | IL5 At Visit 2 | IL5 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il6_scr1** | IL6 At Screen 1 | IL6 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il6_v1** | IL6 At Visit 1 | IL6 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **pgml_il6_v2** | IL6 At Visit 2 | IL6 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il7_scr1** | IL7 At Screen 1 | IL7 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il7_v1** | IL7 At Visit 1 | IL7 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il7_v2** | IL7 At Visit 2 | IL7 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il8_scr1** | IL8/CXCL8 At Screen 1 | IL8/CXCL8 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il8_v1** | IL8/CXCL8 At Visit 1 | IL8/CXCL8 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il8_v2** | IL8/CXCL8 At Visit 2 | IL8/CXCL8 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il9_scr1** | IL9 At Screen 1 | IL9 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_il9_v1** | IL9 At Visit 1 | IL9 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_il9_v2** | IL9 At Visit 2 | IL9 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ip10_scr1** | IP10/CXCL10 At Screen 1 | IP10/CXCL10 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_ip10_v1** | IP10/CXCL10 At Visit 1 | IP10/CXCL10 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_ip10_v2** | IP10/CXCL10 At Visit 2 | IP10/CXCL10 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_leptin_scr1** | LEPTIN At Screen 1 | LEPTIN At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_leptin_v1** | LEPTIN At Visit 1 | LEPTIN At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_leptin_v2** | LEPTIN At Visit 2 | LEPTIN At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_lif_scr1** | LIF At Screen 1 | LIF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_lif_v1** | LIF At Visit 1 | LIF At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_lif_v2** | LIF At Visit 2 | LIF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **pgml_mcp1_scr1** | MCP1/CCL2 At Screen 1 | MCP1/CCL2 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcp1_v1** | MCP1/CCL2 At Visit 1 | MCP1/CCL2 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcp1_v2** | MCP1/CCL2 At Visit 2 | MCP1/CCL2 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcp2_scr1** | MCP2/CCL8 At Screen 1 | MCP2/CCL8 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcp2_v1** | MCP2/CCL8 At Visit 1 | MCP2/CCL8 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcp2_v2** | MCP2/CCL8 At Visit 2 | MCP2/CCL8 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcp3_scr1** | MCP3/CCL7 At Screen 1 | MCP3/CCL7 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcp3_v1** | MCP3/CCL7 At Visit 1 | MCP3/CCL7 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcp3_v2** | MCP3/CCL7 At Visit 2 | MCP3/CCL7 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcp4_scr1** | MCP4/CCL13 At Screen 1 | MCP4/CCL13 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcp4_v1** | MCP4/CCL13 At Visit 1 | MCP4/CCL13 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcp4_v2** | MCP4/CCL13 At Visit 2 | MCP4/CCL13 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcsf_scr1** | MCSF At Screen 1 | MCSF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcsf_v1** | MCSF At Visit 1 | MCSF At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mcsf_v2** | MCSF At Visit 2 | MCSF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mdc_scr1** | MDC/CCL22 At Screen 1 | MDC/CCL22 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_mdc_v1** | MDC/CCL22 At Visit 1 | MDC/CCL22 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mdc_v2** | MDC/CCL22 At Visit 2 | MDC/CCL22 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mif_scr1** | MIF At Screen 1 | MIF At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **pgml_mif_v1** | MIF At Visit 1 | MIF At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mif_v2** | MIF At Visit 2 | MIF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mig_scr1** | MIG/CXCL9 At Screen 1 | MIG/CXCL9 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_mig_v1** | MIG/CXCL9 At Visit 1 | MIG/CXCL9 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mig_v2** | MIG/CXCL9 At Visit 2 | MIG/CXCL9 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mip1a_scr1** | MIP1A/CCL3 At Screen 1 | MIP1A/CCL3 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_mip1a_v1** | MIP1A/CCL3 At Visit 1 | MIP1A/CCL3 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mip1a_v2** | MIP1A/CCL3 At Visit 2 | MIP1A/CCL3 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mip1b_scr1** | MIP1B/CCL4 At Screen 1 | MIP1B/CCL4 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_mip1b_v1** | MIP1B/CCL4 At Visit 1 | MIP1B/CCL4 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mip1b_v2** | MIP1B/CCL4 At Visit 2 | MIP1B/CCL4 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mip1d_scr1** | MIP1D/MIP5/CCL15 At Screen 1 | MIP1D/MIP5/CCL15 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_mip1d_v1** | MIP1D/MIP5/CCL15 At Visit 1 | MIP1D/MIP5/CCL15 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_mip1d_v2** | MIP1D/MIP5/CCL15 At Visit 2 | MIP1D/MIP5/CCL15 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_pai1_scr1** | PAI1/SERPINE At Screen 1 | PAI1/SERPINE At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_pai1_v1** | PAI1/SERPINE At Visit 1 | PAI1/SERPINE At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_pai1_v2** | PAI1/SERPINE At Visit 2 | PAI1/SERPINE At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_pdgfaa_scr1** | PDGFAA At Screen 1 | PDGFAA At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_pdgfaa_v1** | PDGFAA At Visit 1 | PDGFAA At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **pgml_pdgfaa_v2** | PDGFAA At Visit 2 | PDGFAA At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_pdgfab_scr 1** | PDGFAB/BB At Screen 1 | PDGFAB/BB At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_pdgfab_v1** | PDGFAB/BB At Visit 1 | PDGFAB/BB At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_pdgfab_v2** | PDGFAB/BB At Visit 2 | PDGFAB/BB At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_rantes_scr 1** | RANTES/CCL5 At Screen 1 | RANTES/CCL5 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_rantes_v1** | RANTES/CCL5 At Visit 1 | RANTES/CCL5 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_rantes_v2** | RANTES/CCL5 At Visit 2 | RANTES/CCL5 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_resistin_sc r1** | RESISTIN At Screen 1 | RESISTIN At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_resistin_v1** | RESISTIN At Visit 1 | RESISTIN At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_resistin_v2** | RESISTIN At Visit 2 | RESISTIN At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_scd40l_scr 1** | SCD40L At Screen 1 | SCD40L At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_scd40l_v1** | SCD40L At Visit 1 | SCD40L At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_scd40l_v2** | SCD40L At Visit 2 | SCD40L At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_scf_scr1** | SCF At Screen 1 | SCF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_scf_v1** | SCF At Visit 1 | SCF At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_scf_v2** | SCF At Visit 2 | SCF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_sdf1a_scr1** | SDF1A+B/CXCL12 At Screen 1 | SDF1A+B/CXCL12 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_sdf1a_v1** | SDF1A+B/CXCL12 At Visit 1 | SDF1A+B/CXCL12 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_sdf1a_v2** | SDF1A+B/CXCL12 At Visit 2 | SDF1A+B/CXCL12 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **pgml_sfas_scr1** | SFAS/TNFRSF6 At Screen 1 | SFAS/TNFRSF6 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_sfas_v1** | SFAS/TNFRSF6 At Visit 1 | SFAS/TNFRSF6 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_sfas_v2** | SFAS/TNFRSF6 At Visit 2 | SFAS/TNFRSF6 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_sicam1_scr1** | SICAM1 At Screen 1 | SICAM1 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_sicam1_v1** | SICAM1 At Visit 1 | SICAM1 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_sicam1_v2** | SICAM1 At Visit 2 | SICAM1 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_svcam1_scr1** | SVCAM1 At Screen 1 | SVCAM1 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_svcam1_v1** | SVCAM1 At Visit 1 | SVCAM1 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_svcam1_v2** | SVCAM1 At Visit 2 | SVCAM1 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tarc_scr1** | TARC/CCL17 At Screen 1 | TARC/CCL17 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_tarc_v1** | TARC/CCL17 At Visit 1 | TARC/CCL17 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tarc_v2** | TARC/CCL17 At Visit 2 | TARC/CCL17 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tgfa_scr1** | TGFA At Screen 1 | TGFA At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_tgfa_v1** | TGFA At Visit 1 | TGFA At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tgfa_v2** | TGFA At Visit 2 | TGFA At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tnfa_scr1** | TNFA At Screen 1 | TNFA At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_tnfa_v1** | TNFA At Visit 1 | TNFA At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tnfa_v2** | TNFA At Visit 2 | TNFA At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tnfb_scr1** | TNFB/LYMPHOTOXINA(LTA) At Screen 1 | TNFB/LYMPHOTOXINA (LTA) At Screen 1 | Numeric<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **pgml_tnfb_v1** | TNFB/LYMPHOTOXINA(LTA) At Visit 1 | TNFB/LYMPHOTOXINA(LTA) At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tnfb_v2** | TNFB/LYMPHOTOXINA(LTA) At Visit 2 | TNFB/LYMPHOTOXINA(LTA) At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tpo_scr1** | TPO At Screen 1 | TPO At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_tpo_v1** | TPO At Visit 1 | TPO At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tpo_v2** | TPO At Visit 2 | TPO At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_trail_scr1** | TRAIL/TNFSF10 At Screen 1 | TRAIL/TNFSF10 At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_trail_v1** | TRAIL/TNFSF10 At Visit 1 | TRAIL/TNFSF10 At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_trail_v2** | TRAIL/TNFSF10 At Visit 2 | TRAIL/TNFSF10 At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tslp_scr1** | TSLP At Screen 1 | TSLP At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_tslp_v1** | TSLP At Visit 1 | TSLP At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_tslp_v2** | TSLP At Visit 2 | TSLP At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_vegf_scr1** | VEGF At Screen 1 | VEGF At Screen 1 | Numeric<br>.R="Not Randomized" |
| 01. Principal | **pgml_vegf_v1** | VEGF At Visit 1 | VEGF At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **pgml_vegf_v2** | VEGF At Visit 2 | VEGF At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

# Section 33: Pancreatic Fluid Collection

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **panccoll_collect_amt_fup_t1-5** | Amount Of Specimen Collected (mL) At Follow Up | Amount Of Specimen Collected (mL) At Follow Up | Numeric<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_collect_amt_scr1_t1-5** | Amount Of Specimen Collected (mL) At Screen 1 | Amount Of Specimen Collected (mL) At Screen 1 | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_collect_amt_scr2_t1-5** | Amount Of Specimen Collected (mL) At Screen 2 | Amount Of Specimen Collected (mL) At Screen 2 | Numeric<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_collect_amt_v2_t1-5** | Amount Of Specimen Collected (mL) At Visit 2 | Amount Of Specimen Collected (mL) At Visit 2 | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_collect_amt_v3_t1-5** | Amount Of Specimen Collected (mL) At Visit 3 | Amount Of Specimen Collected (mL) At Visit 3 | Numeric<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_comment_fup_t1-5** | Comments At Follow Up | Comments At Follow Up | Char |
| 01. Principal | **panccoll_comment_scr1_t1-5** | Comments At Screen 1 | Comments At Screen 1 | Char |
| 01. Principal | **panccoll_comment_scr2_t1-5** | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | **panccoll_comment_v2_t1-5** | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | **panccoll_comment_v3_t1-5** | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | **panccoll_daughter_id_fup_t1-5** | Daughter Specimen IDs Associated With Parent Specimen At Follow Up | Daughter Specimen IDs Associated With Parent Specimen At Follow Up | Char |
| 01. Principal | **panccoll_daughter_id_scr1_t1-5** | Daughter Specimen IDs Associated With Parent Specimen At Screen 1 | Daughter Specimen IDs Associated With Parent Specimen At Screen 1 | Char |
| 01. Principal | **panccoll_daughter_id_scr2_t1-5** | Daughter Specimen IDs Associated With Parent Specimen At Screen 2 | Daughter Specimen IDs Associated With Parent Specimen At Screen 2 | Char |
| 01. Principal | **panccoll_daughter_id_v2_t1-5** | Daughter Specimen IDs Associated With Parent Specimen At Visit 2 | Daughter Specimen IDs Associated With Parent Specimen At Visit 2 | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **panccoll_daughter_id_v3_t1-5** | Daughter Specimen IDs Associated With Parent Specimen At Visit 3 | Daughter Specimen IDs Associated With Parent Specimen At Visit 3 | Char |
| 01. Principal | **panccoll_daughter_num_fup_t1-5** | Number Of Daughter Specimen Associated With Parent Specimen At Follow Up | Number Of Daughter Specimen Associated With Parent Specimen At Follow Up | Numeric<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_daughter_num_scr1_t1-5** | Number Of Daughter Specimen Associated With Parent Specimen At Screen 1 | Number Of Daughter Specimen Associated With Parent Specimen At Screen 1 | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_daughter_num_scr2_t1-5** | Number Of Daughter Specimen Associated With Parent Specimen At Screen 2 | Number Of Daughter Specimen Associated With Parent Specimen At Screen 2 | Numeric<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_daughter_num_v2_t1-5** | Number Of Daughter Specimen Associated With Parent Specimen At Visit 2 | Number Of Daughter Specimen Associated With Parent Specimen At Visit 2 | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_daughter_num_v3_t1-5** | Number Of Daughter Specimen Associated With Parent Specimen At Visit 3 | Number Of Daughter Specimen Associated With Parent Specimen At Visit 3 | Numeric<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_parent_id_fup_t1-5** | Parent Specimen ID At Follow Up | Parent Specimen ID At Follow Up | Char |
| 01. Principal | **panccoll_parent_id_scr1_t1-5** | Parent Specimen ID At Screen 1 | Parent Specimen ID At Screen 1 | Char |
| 01. Principal | **panccoll_parent_id_scr2_t1-5** | Parent Specimen ID At Screen 2 | Parent Specimen ID At Screen 2 | Char |
| 01. Principal | **panccoll_parent_id_v2_t1-5** | Parent Specimen ID At Visit 2 | Parent Specimen ID At Visit 2 | Char |
| 01. Principal | **panccoll_parent_id_v3_t1-5** | Parent Specimen ID At Visit 3 | Parent Specimen ID At Visit 3 | Char |
| 01. Principal | **panccoll_parent_type_fup_t1-5** | Parent Specimen ID | Parent Specimen ID | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_parent_type_scr1_t1-5** | Parent Specimen ID | Parent Specimen ID | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_parent_type_scr2_t1-5** | Parent Specimen ID | Parent Specimen ID | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_parent_type_v2_t1-5** | Parent Specimen ID | Parent Specimen ID | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_parent_type_v3_t1-5** | Parent Specimen ID | Parent Specimen ID | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_spec_dt_fup_t1-5** | Specimen Collection Date At Follow Up | Specimen Collection Date At Follow Up | SAS Date<br>.N="N/A"<br>.R="Not Randomized" |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **panccoll_spec_dt _scr1_t1-5** | Specimen Collection Date At Screen 1 | Specimen Collection Date At Screen 1 | SAS Date .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_spec_dt _scr2_t1-5** | Specimen Collection Date At Screen 2 | Specimen Collection Date At Screen 2 | SAS Date .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_spec_dt _v2_t1-5** | Specimen Collection Date At Visit 2 | Specimen Collection Date At Visit 2 | SAS Date .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_spec_dt _v3_t1-5** | Specimen Collection Date At Visit 3 | Specimen Collection Date At Visit 3 | SAS Date .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_spec_ti me_fup_t1-5** | Time Specimen Collected At Follow Up | Time Specimen Collected At Follow Up | SAS Time .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_spec_ti me_scr1_t1-5** | Time Specimen Collected At Screen 1 | Time Specimen Collected At Screen 1 | SAS Time .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_spec_ti me_scr2_t1-5** | Time Specimen Collected At Screen 2 | Time Specimen Collected At Screen 2 | SAS Time .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_spec_ti me_v2_t1-5** | Time Specimen Collected At Visit 2 | Time Specimen Collected At Visit 2 | SAS Time .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_spec_ti me_v3_t1-5** | Time Specimen Collected At Visit 3 | Time Specimen Collected At Visit 3 | SAS Time .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_storage _temp_fup_t1-5** | Storage Temperature (C) At Follow Up | Storage Temperature (C) At Follow Up | Numeric .M="Missing" .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_storage _temp_scr1_t1-5** | Storage Temperature (C) At Screen 1 | Storage Temperature (C) At Screen 1 | Numeric .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_storage _temp_scr2_t1-5** | Storage Temperature (C) At Screen 2 | Storage Temperature (C) At Screen 2 | Numeric .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_storage _temp_v2_t1-5** | Storage Temperature (C) At Visit 2 | Storage Temperature (C) At Visit 2 | Numeric .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_storage _temp_v3_t1-5** | Storage Temperature (C) At Visit 3 | Storage Temperature (C) At Visit 3 | Numeric .M="Missing" .N="N/A" .R="Not Randomized" |
| 01. Principal | **panccoll_visit_dt _scr1** | Visit Date At Screen 1 | Visit Date At Screen 1 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **panccoll_visit_dt _scr2** | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **panccoll_visit_dt _v1** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Date .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **panccoll_visit_dt _v2** | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **panccoll_visit_dt _v3** | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |

# Section 34: Bicarbonate

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **bicarbonate_level_scr1_t1-5** | 5th Bicarbonate Level At Screen 1 | 5th Bicarbonate Level At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bicarbonate_level_v1_t1-5** | 5th Bicarbonate Level At Visit 1 | 5th Bicarbonate Level At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bicarbonate_level_v2_t1-5** | 5th Bicarbonate Level At Visit 2 | 5th Bicarbonate Level At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bicarbonate_visit_dt_scr1** | Visit Date At Screen 1 | Visit Date At Screen 1 | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **bicarbonate_visit_dt_v1** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **bicarbonate_visit_dt_v2** | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **bicarbonate_vol_coll_scr1_t1-5** | 5th Volume Collected At Screen 1 | 5th Volume Collected At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bicarbonate_vol_coll_v1_t1-5** | 5th Volume Collected At Visit 1 | 5th Volume Collected At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bicarbonate_vol_coll_v2_t1-5** | 5th Volume Collected At Visit 2 | 5th Volume Collected At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

# Section 35: Blood Chemistry Comprehensive Metabolic Panel

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | bldchem_albumin_oor_scr1 | Albumin Out Of Range At Screen 1? | Albumin Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | bldchem_albumin_oor_scr2 | Albumin Out Of Range At Screen 2? | Albumin Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | bldchem_albumin_oor_v1 | Albumin Out Of Range At Visit 1? | Albumin Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | bldchem_albumin_oor_v2 | Albumin Out Of Range At Visit 2? | Albumin Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | bldchem_albumin_oor_v3 | Albumin Out Of Range At Visit 3? | Albumin Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | bldchem_albumin_result_scr1 | Albumin Result In g/dL At Screen 1 | Albumin Result In g/dL At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | bldchem_albumin_result_scr2 | Albumin Result In g/dL At Screen 2 | Albumin Result In g/dL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | bldchem_albumin_result_v1 | Albumin Result In g/dL At Visit 1 | Albumin Result In g/dL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | bldchem_albumin_result_v2 | Albumin Result In g/dL At Visit 2 | Albumin Result In g/dL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | bldchem_albumin_result_v3 | Albumin Result In g/dL At Visit 3 | Albumin Result In g/dL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | bldchem_alkalin_oor_scr1 | Alkaline If Out Of Range At Screen 1 | Alkaline If Out Of Range At Screen 1 | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | bldchem_alkalin_oor_scr2 | Alkaline If Out Of Range At Screen 2 | Alkaline If Out Of Range At Screen 2 | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | bldchem_alkalin_oor_sig_scr1 | Alkaline If Out Of Range, Is It Clinically Significant At Screen 1? | Alkaline If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | bldchem_alkalin_oor_sig_scr2 | Alkaline If Out Of Range, Is It Clinically Significant At Screen 2? | Alkaline If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | bldchem_alkalin_oor_sig_v1 | Alkaline If Out Of Range, Is It Clinically Significant At Visit 1? | Alkaline If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **bldchem_alkalin_oor_sig_v2** | Alkaline If Out Of Range, Is It Clinically Significant At Visit 2? | Alkaline If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_alkalin_oor_sig_v3** | Alkaline If Out Of Range, Is It Clinically Significant At Visit 3? | Alkaline If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_alkalin_oor_v1** | Alkaline If Out Of Range At Visit 1 | Alkaline If Out Of Range At Visit 1 | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_alkalin_oor_v2** | Alkaline If Out Of Range At Visit 2 | Alkaline If Out Of Range At Visit 2 | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **bldchem_alkalin_oor_v3** | Alkaline If Out Of Range At Visit 3 | Alkaline If Out Of Range At Visit 3 | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **bldchem_alkalin_result_scr1** | Alkaline Result In g/dL At Screen 1 | Alkaline Result In g/dL At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_alkalin_result_scr2** | Alkaline Result In g/dL At Screen 2 | Alkaline Result In g/dL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_alkalin_result_v1** | Alkaline Result In g/dL At Visit 1 | Alkaline Result In g/dL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_alkalin_result_v2** | Alkaline Result In g/dL At Visit 2 | Alkaline Result In g/dL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_alkalin_result_v3** | Alkaline Result In g/dL At Visit 3 | Alkaline Result In g/dL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_bili_oor_scr1** | Bilirubin, Total Out Of Range At Screen 1? | Bilirubin, Total Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_bili_oor_scr2** | Bilirubin, Total Out Of Range At Screen 2? | Bilirubin, Total Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_bili_oor_sig_scr1** | Bilirubin, Total If Out Of Range, Is It Clinically Significant At Screen 1? | Bilirubin, Total If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_bili_oor_sig_scr2** | Bilirubin, Total If Out Of Range, Is It Clinically Significant At Screen 2? | Bilirubin, Total If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_bili_oor_sig_v1** | Bilirubin, Total If Out Of Range, Is It Clinically Significant At Visit 1? | Bilirubin, Total If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **bldchem_bili_oor_sig_v2** | Bilirubin, Total If Out Of Range, Is It Clinically Significant At Visit 2? | Bilirubin, Total If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **bldchem_bili_oor _sig_v3** | Bilirubin, Total If Out Of Range, Is It Clinically Significant At Visit 3? | Bilirubin, Total If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_bili_oor _v1** | Bilirubin, Total Out Of Range At Visit 1? | Bilirubin, Total Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_bili_oor _v2** | Bilirubin, Total Out Of Range At Visit 2? | Bilirubin, Total Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_bili_oor _v3** | Bilirubin, Total Out Of Range At Visit 3? | Bilirubin, Total Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_bili_res ult_scr1** | Bilirubin, Total Result In mg/dL At Screen 1 | Bilirubin, Total Result In mg/dL At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bili_res ult_scr2** | Bilirubin, Total Result In mg/dL At Screen 2 | Bilirubin, Total Result In mg/dL At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bili_res ult_v1** | Bilirubin, Total Result In mg/dL At Visit 1 | Bilirubin, Total Result In mg/dL At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bili_res ult_v2** | Bilirubin, Total Result In mg/dL At Visit 2 | Bilirubin, Total Result In mg/dL At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bili_res ult_v3** | Bilirubin, Total Result In mg/dL At Visit 3 | Bilirubin, Total Result In mg/dL At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_oo r_scr1** | Bun Out Of Range At Screen 1? | Bun Out Of Range At Screen 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_oo r_scr2** | Bun Out Of Range At Screen 2? | Bun Out Of Range At Screen 2? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_bun_oo r_sig_scr1** | Bun If Out Of Range, Is It Clinically Significant At Screen 1? | Bun If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_oo r_sig_scr2** | Bun If Out Of Range, Is It Clinically Significant At Screen 2? | Bun If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_bun_oo r_sig_v1** | Bun If Out Of Range, Is It Clinically Significant At Visit 1? | Bun If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_oo r_sig_v2** | Bun If Out Of Range, Is It Clinically Significant At Visit 2? | Bun If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_oo r_sig_v3** | Bun If Out Of Range, Is It Clinically Significant At Visit 3? | Bun If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_oo r_v1** | Bun Out Of Range At Visit 1? | Bun Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_bun_oor_v2** | Bun Out Of Range At Visit 2? | Bun Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_oor_v3** | Bun Out Of Range At Visit 3? | Bun Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_result_scr1** | Bun Result In mg/dL At Screen 1 | Bun Result In mg/dL At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_result_scr2** | Bun Result In mg/dL At Screen 2 | Bun Result In mg/dL At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_result_v1** | Bun Result In mg/dL At Visit 1 | Bun Result In mg/dL At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_result_v2** | Bun Result In mg/dL At Visit 2 | Bun Result In mg/dL At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_bun_result_v3** | Bun Result In mg/dL At Visit 3 | Bun Result In mg/dL At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_calcium_oor_scr1** | Calcium Out Of Range At Screen 1? | Calcium Out Of Range At Screen 1? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_calcium_oor_scr2** | Calcium Out Of Range At Screen 2? | Calcium Out Of Range At Screen 2? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_calcium_oor_sig_scr1** | Calcium If Out Of Range, Is It Clinically Significant At Screen 1? | Calcium If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_calcium_oor_sig_scr2** | Calcium If Out Of Range, Is It Clinically Significant At Screen 2? | Calcium If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_calcium_oor_sig_v1** | Calcium If Out Of Range, Is It Clinically Significant At Visit 1? | Calcium If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_calcium_oor_sig_v2** | Calcium If Out Of Range, Is It Clinically Significant At Visit 2? | Calcium If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_calcium_oor_sig_v3** | Calcium If Out Of Range, Is It Clinically Significant At Visit 3? | Calcium If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_calcium_oor_v1** | Calcium Out Of Range At Visit 1? | Calcium Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_calcium_oor_v2** | Calcium Out Of Range At Visit 2? | Calcium Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_calcium_oor_v3** | Calcium Out Of Range At Visit 3? | Calcium Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_calcium_result_scr1** | Calcium Result In mg/dL At Screen 1 | Calcium Result In mg/dL At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_calcium _result_scr2** | Calcium Result In mg/dL At Screen 2 | Calcium Result In mg/dL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_calcium _result_v1** | Calcium Result In mg/dL At Visit 1 | Calcium Result In mg/dL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_calcium _result_v2** | Calcium Result In mg/dL At Visit 2 | Calcium Result In mg/dL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_calcium _result_v3** | Calcium Result In mg/dL At Visit 3 | Calcium Result In mg/dL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _oor_scr1** | Carbon Out Of Range At Screen 1? | Carbon Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _oor_scr2** | Carbon Out Of Range At Screen 2? | Carbon Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _oor_sig_scr1** | Carbon If Out Of Range, Is It Clinically Significant At Screen 1? | Carbon If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _oor_sig_scr2** | Carbon If Out Of Range, Is It Clinically Significant At Screen 2? | Carbon If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _oor_sig_v1** | Carbon If Out Of Range, Is It Clinically Significant At Visit 1? | Carbon If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _oor_sig_v2** | Carbon If Out Of Range, Is It Clinically Significant At Visit 2? | Carbon If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _oor_sig_v3** | Carbon If Out Of Range, Is It Clinically Significant At Visit 3? | Carbon If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _oor_v1** | Carbon Out Of Range At Visit 1? | Carbon Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _oor_v2** | Carbon Out Of Range At Visit 2? | Carbon Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _oor_v3** | Carbon Out Of Range At Visit 3? | Carbon Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _result_scr1** | Carbon Result In mEq/L At Screen 1 | Carbon Result In mEq/L At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _result_scr2** | Carbon Result In mEq/L At Screen 2 | Carbon Result In mEq/L At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _result_v1** | Carbon Result In mEq/L At Visit 1 | Carbon Result In mEq/L At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_carbon _result_v2** | Carbon Result In mEq/L At Visit 2 | Carbon Result In mEq/L At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_carbon _result_v3** | Carbon Result In mEq/L At Visit 3 | Carbon Result In mEq/L At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _oor_scr1** | Chloride Out Of Range At Screen 1? | Chloride Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _oor_scr2** | Chloride Out Of Range At Screen 2? | Chloride Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _oor_sig_scr1** | Chloride If Out Of Range, Is It Clinically Significant At Screen 1? | Chloride If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _oor_sig_scr2** | Chloride If Out Of Range, Is It Clinically Significant At Screen 2? | Chloride If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _oor_sig_v1** | Chloride If Out Of Range, Is It Clinically Significant At Visit 1? | Chloride If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **bldchem_chlorid _oor_sig_v2** | Chloride If Out Of Range, Is It Clinically Significant At Visit 2? | Chloride If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _oor_sig_v3** | Chloride If Out Of Range, Is It Clinically Significant At Visit 3? | Chloride If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _oor_v1** | Chloride Out Of Range At Visit 1? | Chloride Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **bldchem_chlorid _oor_v2** | Chloride Out Of Range At Visit 2? | Chloride Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _oor_v3** | Chloride Out Of Range At Visit 3? | Chloride Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _result_scr1** | Chloride Result In mEq/L At Screen 1 | Chloride Result In mEq/L At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _result_scr2** | Chloride Result In mEq/L At Screen 2 | Chloride Result In mEq/L At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _result_v1** | Chloride Result In mEq/L At Visit 1 | Chloride Result In mEq/L At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _result_v2** | Chloride Result In mEq/L At Visit 2 | Chloride Result In mEq/L At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_chlorid _result_v3** | Chloride Result In mEq/L At Visit 3 | Chloride Result In mEq/L At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_cmp_vi sit_dt_scr1** | Visit Date At Screen 1 | Visit Date At Screen 1 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_cmp_vi sit_dt_scr2** | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **bldchem_cmp_visit_dt_v1** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_cmp_visit_dt_v2** | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_cmp_visit_dt_v3** | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_comments_scr1** | Comments At Screen 1 | Comments At Screen 1 | Char |
| 01. Principal | **bldchem_comments_scr2** | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | **bldchem_comments_v1** | Comments At Visit 1 | Comments At Visit 1 | Char |
| 01. Principal | **bldchem_comments_v2** | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | **bldchem_comments_v3** | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | **bldchem_creatin_oor_scr1** | Creatinine Out Of Range At Screen 1? | Creatinine Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_creatin_oor_scr2** | Creatinine Out Of Range At Screen 2? | Creatinine Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_creatin_oor_sig_scr1** | Creatinine If Out Of Range, Is It Clinically Significant At Screen 1? | Creatinine If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_creatin_oor_sig_scr2** | Creatinine If Out Of Range, Is It Clinically Significant At Screen 2? | Creatinine If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_creatin_oor_sig_v1** | Creatinine If Out Of Range, Is It Clinically Significant At Visit 1? | Creatinine If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **bldchem_creatin_oor_sig_v2** | Creatinine If Out Of Range, Is It Clinically Significant At Visit 2? | Creatinine If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_creatin_oor_sig_v3** | Creatinine If Out Of Range, Is It Clinically Significant At Visit 3? | Creatinine If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_creatin_oor_v1** | Creatinine Out Of Range At Visit 1? | Creatinine Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_creatin_oor_v2** | Creatinine Out Of Range At Visit 2? | Creatinine Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **bldchem_creatin_oor_v3** | Creatinine Out Of Range At Visit 3? | Creatinine Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_creatin_result_scr1** | Creatinine Result In mg/dL At Screen 1 | Creatinine Result In mg/dL At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_creatin_result_scr2** | Creatinine Result In mg/dL At Screen 2 | Creatinine Result In mg/dL At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_creatin_result_v1** | Creatinine Result In mg/dL At Visit 1 | Creatinine Result In mg/dL At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_creatin_result_v2** | Creatinine Result In mg/dL At Visit 2 | Creatinine Result In mg/dL At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_creatin_result_v3** | Creatinine Result In mg/dL At Visit 3 | Creatinine Result In mg/dL At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_glucose_oor_scr1** | Glucose, Serum Out Of Range At Screen 1? | Glucose, Serum Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_glucose_oor_scr2** | Glucose, Serum Out Of Range At Screen 2? | Glucose, Serum Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_glucose_oor_sig_scr1** | Glucose, Serum If Out Of Range, Is It Clinically Significant At Screen 1? | Glucose, Serum If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_glucose_oor_sig_scr2** | Glucose, Serum If Out Of Range, Is It Clinically Significant At Screen 2? | Glucose, Serum If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_glucose_oor_sig_v1** | Glucose, Serum If Out Of Range, Is It Clinically Significant At Visit 1? | Glucose, Serum If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **bldchem_glucose_oor_sig_v2** | Glucose, Serum If Out Of Range, Is It Clinically Significant At Visit 2? | Glucose, Serum If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_glucose_oor_sig_v3** | Glucose, Serum If Out Of Range, Is It Clinically Significant At Visit 3? | Glucose, Serum If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_glucose_oor_v1** | Glucose, Serum Out Of Range At Visit 1? | Glucose, Serum Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **bldchem_glucose_oor_v2** | Glucose, Serum Out Of Range At Visit 2? | Glucose, Serum Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_glucose_oor_v3** | Glucose, Serum Out Of Range At Visit 3? | Glucose, Serum Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_glucose_result_scr1** | Glucose, Serum Result In mg/dL At Screen 1 | Glucose, Serum Result In mg/dL At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_glucose_result_scr2** | Glucose, Serum Result In mg/dL At Screen 2 | Glucose, Serum Result In mg/dL At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_glucose_result_v1** | Glucose, Serum Result In mg/dL At Visit 1 | Glucose, Serum Result In mg/dL At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_glucose_result_v2** | Glucose, Serum Result In mg/dL At Visit 2 | Glucose, Serum Result In mg/dL At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_glucose_result_v3** | Glucose, Serum Result In mg/dL At Visit 3 | Glucose, Serum Result In mg/dL At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_other1_oor_scr1** | Other Test 1 Out Of Range At Screen 1? | Other Test 1 Out Of Range At Screen 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_other1_oor_scr2** | Other Test 1 Out Of Range At Screen 2? | Other Test 1 Out Of Range At Screen 2? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_other1_oor_sig_scr1** | Other Test 1 If Out Of Range, Is It Clinically Significant At Screen 1? | Other Test 1 If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_other1_oor_sig_scr2** | Other Test 1 If Out Of Range, Is It Clinically Significant At Screen 2? | Other Test 1 If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_other1_oor_sig_v1** | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 1? | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_other1_oor_sig_v2** | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 2? | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_other1_oor_sig_v3** | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 3? | Other Test 1 If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_other1_oor_v1** | Other Test 1 Out Of Range At Visit 1? | Other Test 1 Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_other1_oor_v2** | Other Test 1 Out Of Range At Visit 2? | Other Test 1 Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_other1_oor_v3** | Other Test 1 Out Of Range At Visit 3? | Other Test 1 Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_other1_result_scr1** | Other Test 1 Result At Screen 1 | Other Test 1 Result At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **bldchem_other1_result_scr2** | Other Test 1 Result At Screen 2 | Other Test 1 Result At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_other1_result_v1** | Other Test 1 Result At Visit 1 | Other Test 1 Result At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_other1_result_v2** | Other Test 1 Result At Visit 2 | Other Test 1 Result At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_other1_result_v3** | Other Test 1 Result At Visit 3 | Other Test 1 Result At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_other1_type_scr1** | Other Test 1 Type At Screen 1 | Other Test 1 Type At Screen 1 | Char |
| 01. Principal | **bldchem_other1_type_scr2** | Other Test 1 Type At Screen 2 | Other Test 1 Type At Screen 2 | Char |
| 01. Principal | **bldchem_other1_type_v1** | Other Test 1 Type At Visit 1 | Other Test 1 Type At Visit 1 | Char |
| 01. Principal | **bldchem_other1_type_v2** | Other Test 1 Type At Visit 2 | Other Test 1 Type At Visit 2 | Char |
| 01. Principal | **bldchem_other1_type_v3** | Other Test 1 Type At Visit 3 | Other Test 1 Type At Visit 3 | Char |
| 01. Principal | **bldchem_other1_units_scr1** | Other Test 1 Units At Screen 1 | Other Test 1 Units At Screen 1 | Char |
| 01. Principal | **bldchem_other1_units_scr2** | Other Test 1 Units At Screen 2 | Other Test 1 Units At Screen 2 | Char |
| 01. Principal | **bldchem_other1_units_v1** | Other Test 1 Units At Visit 1 | Other Test 1 Units At Visit 1 | Char |
| 01. Principal | **bldchem_other1_units_v2** | Other Test 1 Units At Visit 2 | Other Test 1 Units At Visit 2 | Char |
| 01. Principal | **bldchem_other1_units_v3** | Other Test 1 Units At Visit 3 | Other Test 1 Units At Visit 3 | Char |
| 01. Principal | **bldchem_otherany_oor_scr1** | Any Other Blood Chemistry Tests Out Of Range At Screen 1? | Any Other Blood Chemistry Tests Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_otherany_oor_scr2** | Any Other Blood Chemistry Tests Out Of Range At Screen 2? | Any Other Blood Chemistry Tests Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_otherany_oor_v1** | Any Other Blood Chemistry Tests Out Of Range At Visit 1? | Any Other Blood Chemistry Tests Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_otherany_oor_v2** | Any Other Blood Chemistry Tests Out Of Range At Visit 2? | Any Other Blood Chemistry Tests Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_otherany_oor_v3** | Any Other Blood Chemistry Tests Out Of Range At Visit 3? | Any Other Blood Chemistry Tests Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_potass _oor_scr1** | Potassium Out Of Range At Screen 1? | Potassium Out Of Range At Screen 1? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_potass _oor_scr2** | Potassium Out Of Range At Screen 2? | Potassium Out Of Range At Screen 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _oor_sig_scr1** | Potassium If Out Of Range, Is It Clinically Significant At Screen 1? | Potassium If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_potass _oor_sig_scr2** | Potassium If Out Of Range, Is It Clinically Significant At Screen 2? | Potassium If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _oor_sig_v1** | Potassium If Out Of Range, Is It Clinically Significant At Visit 1? | Potassium If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _oor_sig_v2** | Potassium If Out Of Range, Is It Clinically Significant At Visit 2? | Potassium If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _oor_sig_v3** | Potassium If Out Of Range, Is It Clinically Significant At Visit 3? | Potassium If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _oor_v1** | Potassium Out Of Range At Visit 1? | Potassium Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _oor_v2** | Potassium Out Of Range At Visit 2? | Potassium Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _oor_v3** | Potassium Out Of Range At Visit 3? | Potassium Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _result_scr1** | Potassium Result In mEq/L At Screen 1 | Potassium Result In mEq/L At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _result_scr2** | Potassium Result In mEq/L At Screen 2 | Potassium Result In mEq/L At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _result_v1** | Potassium Result In mEq/L At Visit 1 | Potassium Result In mEq/L At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _result_v2** | Potassium Result In mEq/L At Visit 2 | Potassium Result In mEq/L At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_potass _result_v3** | Potassium Result In mEq/L At Visit 3 | Potassium Result In mEq/L At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _oor_scr1** | Protein Out Of Range At Screen 1? | Protein Out Of Range At Screen 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _oor_scr2** | Protein Out Of Range At Screen 2? | Protein Out Of Range At Screen 2? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_protein _oor_sig_scr1** | Protein If Out Of Range, Is It Clinically Significant At Screen 1? | Protein If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **bldchem_protein _oor_sig_scr2** | Protein If Out Of Range, Is It Clinically Significant At Screen 2? | Protein If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _oor_sig_v1** | Protein If Out Of Range, Is It Clinically Significant At Visit 1? | Protein If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _oor_sig_v2** | Protein If Out Of Range, Is It Clinically Significant At Visit 2? | Protein If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _oor_sig_v3** | Protein If Out Of Range, Is It Clinically Significant At Visit 3? | Protein If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _oor_v1** | Protein Out Of Range At Visit 1? | Protein Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _oor_v2** | Protein Out Of Range At Visit 2? | Protein Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _oor_v3** | Protein Out Of Range At Visit 3? | Protein Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _result_scr1** | Protein Result In g/dL At Screen 1 | Protein Result In g/dL At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _result_scr2** | Protein Result In g/dL At Screen 2 | Protein Result In g/dL At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _result_v1** | Protein Result In g/dL At Visit 1 | Protein Result In g/dL At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _result_v2** | Protein Result In g/dL At Visit 2 | Protein Result In g/dL At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_protein _result_v3** | Protein Result In g/dL At Visit 3 | Protein Result In g/dL At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sgotast _oor_scr1** | Sgot/Ast Out Of Range At Screen 1? | Sgot/Ast Out Of Range At Screen 1? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_sgotast _oor_scr2** | Sgot/Ast Out Of Range At Screen 2? | Sgot/Ast Out Of Range At Screen 2? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_sgotast _oor_sig_scr1** | Sgot/Ast If Out Of Range, Is It Clinically Significant At Screen 1? | Sgot/Ast If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_sgotast _oor_sig_scr2** | Sgot/Ast If Out Of Range, Is It Clinically Significant At Screen 2? | Sgot/Ast If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_sgotast _oor_sig_v1** | Sgot/Ast If Out Of Range, Is It Clinically Significant At Visit 1? | Sgot/Ast If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" 0="No" |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_sgotast_oor_sig_v2** | Sgot/Ast If Out Of Range, Is It Clinically Significant At Visit 2? | Sgot/Ast If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_sgotast_oor_sig_v3** | Sgot/Ast If Out Of Range, Is It Clinically Significant At Visit 3? | Sgot/Ast If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_sgotast_oor_v1** | Sgot/Ast Out Of Range At Visit 1? | Sgot/Ast Out Of Range At Visit 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_sgotast_oor_v2** | Sgot/Ast Out Of Range At Visit 2? | Sgot/Ast Out Of Range At Visit 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_sgotast_oor_v3** | Sgot/Ast Out Of Range At Visit 3? | Sgot/Ast Out Of Range At Visit 3? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_sgotast_result_scr1** | Sgot/Ast Result In U/L At Screen 1 | Sgot/Ast Result In U/L At Screen 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_sgotast_result_scr2** | Sgot/Ast Result In U/L At Screen 2 | Sgot/Ast Result In U/L At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_sgotast_result_v1** | Sgot/Ast Result In U/L At Visit 1 | Sgot/Ast Result In U/L At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_sgotast_result_v2** | Sgot/Ast Result In U/L At Visit 2 | Sgot/Ast Result In U/L At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_sgotast_result_v3** | Sgot/Ast Result In U/L At Visit 3 | Sgot/Ast Result In U/L At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **bldchem_sgptalt_oor_scr1** | Sgpt/Alt Out Of Range At Screen 1? | Sgpt/Alt Out Of Range At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_sgptalt_oor_scr2** | Sgpt/Alt Out Of Range At Screen 2? | Sgpt/Alt Out Of Range At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_sgptalt_oor_sig_scr1** | Sgpt/Alt If Out Of Range, Is It Clinically Significant At Screen 1? | Sgpt/Alt If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing"<br>.R="Not Randomized"<br>0="No" |
| 01. Principal | **bldchem_sgptalt_oor_sig_scr2** | Sgpt/Alt If Out Of Range, Is It Clinically Significant At Screen 2? | Sgpt/Alt If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **bldchem_sgptalt_oor_sig_v1** | Sgpt/Alt If Out Of Range, Is It Clinically Significant At Visit 1? | Sgpt/Alt If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_sgptalt _oor_sig_v2** | Sgpt/Alt If Out Of Range, Is It Clinically Significant At Visit 2? | Sgpt/Alt If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_sgptalt _oor_sig_v3** | Sgpt/Alt If Out Of Range, Is It Clinically Significant At Visit 3? | Sgpt/Alt If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_sgptalt _oor_v1** | Sgpt/Alt Out Of Range At Visit 1? | Sgpt/Alt Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_sgptalt _oor_v2** | Sgpt/Alt Out Of Range At Visit 2? | Sgpt/Alt Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_sgptalt _oor_v3** | Sgpt/Alt Out Of Range At Visit 3? | Sgpt/Alt Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" 0="No" 1="Yes" |
| 01. Principal | **bldchem_sgptalt _result_scr1** | Sgpt/Alt Result In U/L At Screen 1 | Sgpt/Alt Result In U/L At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sgptalt _result_scr2** | Sgpt/Alt Result In U/L At Screen 2 | Sgpt/Alt Result In U/L At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sgptalt _result_v1** | Sgpt/Alt Result In U/L At Visit 1 | Sgpt/Alt Result In U/L At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sgptalt _result_v2** | Sgpt/Alt Result In U/L At Visit 2 | Sgpt/Alt Result In U/L At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sgptalt _result_v3** | Sgpt/Alt Result In U/L At Visit 3 | Sgpt/Alt Result In U/L At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sodium _oor_scr1** | Sodium Out Of Range At Screen 1? | Sodium Out Of Range At Screen 1? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_sodium _oor_scr2** | Sodium Out Of Range At Screen 2? | Sodium Out Of Range At Screen 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sodium _oor_sig_scr1** | Sodium If Out Of Range, Is It Clinically Significant At Screen 1? | Sodium If Out Of Range, Is It Clinically Significant At Screen 1? | .M="Missing" .R="Not Randomized" 0="No" |
| 01. Principal | **bldchem_sodium _oor_sig_scr2** | Sodium If Out Of Range, Is It Clinically Significant At Screen 2? | Sodium If Out Of Range, Is It Clinically Significant At Screen 2? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sodium _oor_sig_v1** | Sodium If Out Of Range, Is It Clinically Significant At Visit 1? | Sodium If Out Of Range, Is It Clinically Significant At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sodium _oor_sig_v2** | Sodium If Out Of Range, Is It Clinically Significant At Visit 2? | Sodium If Out Of Range, Is It Clinically Significant At Visit 2? | .M="Missing" .R="Not Randomized" 0="No" |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **bldchem_sodium _oor_sig_v3** | Sodium If Out Of Range, Is It Clinically Significant At Visit 3? | Sodium If Out Of Range, Is It Clinically Significant At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sodium _oor_v1** | Sodium Out Of Range At Visit 1? | Sodium Out Of Range At Visit 1? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sodium _oor_v2** | Sodium Out Of Range At Visit 2? | Sodium Out Of Range At Visit 2? | .M="Missing" .R="Not Randomized" 1="Yes" |
| 01. Principal | **bldchem_sodium _oor_v3** | Sodium Out Of Range At Visit 3? | Sodium Out Of Range At Visit 3? | .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sodium _result_scr1** | Sodium Result In mEq/L At Screen 1 | Sodium Result In mEq/L At Screen 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sodium _result_scr2** | Sodium Result In mEq/L At Screen 2 | Sodium Result In mEq/L At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sodium _result_v1** | Sodium Result In mEq/L At Visit 1 | Sodium Result In mEq/L At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sodium _result_v2** | Sodium Result In mEq/L At Visit 2 | Sodium Result In mEq/L At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **bldchem_sodium _result_v3** | Sodium Result In mEq/L At Visit 3 | Sodium Result In mEq/L At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |

# Section 36: Research Specimen Collection

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **spec_col_comment_scr2** | Comments At Screen 2 | Comments At Screen 2 | Char |
| 01. Principal | **spec_col_comment_v1** | Comments At Visit 1 | Comments At Visit 1 | Char |
| 01. Principal | **spec_col_comment_v2** | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | **spec_col_comment_v3** | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | **spec_col_dau1_id_scr2** | Parent Specimen 1 - Daughter Specimen IDs Associated With Parent At Screen 2 | Parent Specimen 1 - Daughter Specimen IDs Associated With Parent At Screen 2 | Char |
| 01. Principal | **spec_col_dau1_id_v1** | Parent Specimen 1 - Daughter Specimen IDs Associated With Parent At Visit 1 | Parent Specimen 1 - Daughter Specimen IDs Associated With Parent At Visit 1 | Char |
| 01. Principal | **spec_col_dau1_id_v2** | Parent Specimen 1 - Daughter Specimen IDs Associated With Parent At Visit 2 | Parent Specimen 1 - Daughter Specimen IDs Associated With Parent At Visit 2 | Char |
| 01. Principal | **spec_col_dau1_id_v3** | Parent Specimen 1 - Daughter Specimen IDs Associated With Parent At Visit 3 | Parent Specimen 1 - Daughter Specimen IDs Associated With Parent At Visit 3 | Char |
| 01. Principal | **spec_col_dau1_num_scr2** | Parent Specimen 1 - Number Of Daughter Specimen Associated With Parent At Screen 2 | Parent Specimen 1 - Number Of Daughter Specimen Associated With Parent At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_dau1_num_v1** | Parent Specimen 1 - Number Of Daughter Specimen Associated With Parent At Visit 1 | Parent Specimen 1 - Number Of Daughter Specimen Associated With Parent At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_dau1_num_v2** | Parent Specimen 1 - Number Of Daughter Specimen Associated With Parent At Visit 2 | Parent Specimen 1 - Number Of Daughter Specimen Associated With Parent At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_dau1_num_v3** | Parent Specimen 1 - Number Of Daughter Specimen Associated With Parent At Visit 3 | Parent Specimen 1 - Number Of Daughter Specimen Associated With Parent At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_dau2_id_scr2** | Parent Specimen 2 - Daughter Specimen IDs Associated With Parent At Screen 2 | Parent Specimen 2 - Daughter Specimen IDs Associated With Parent At Screen 2 | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **spec_col_dau2_id_v1** | Parent Specimen 2 - Daughter Specimen IDs Associated With Parent At Visit 1 | Parent Specimen 2 - Daughter Specimen IDs Associated With Parent At Visit 1 | Char |
| 01. Principal | **spec_col_dau2_id_v2** | Parent Specimen 2 - Daughter Specimen IDs Associated With Parent At Visit 2 | Parent Specimen 2 - Daughter Specimen IDs Associated With Parent At Visit 2 | Char |
| 01. Principal | **spec_col_dau2_id_v3** | Parent Specimen 2 - Daughter Specimen IDs Associated With Parent At Visit 3 | Parent Specimen 2 - Daughter Specimen IDs Associated With Parent At Visit 3 | Char |
| 01. Principal | **spec_col_dau2_num_scr2** | Parent Specimen 2 - Number Of Daughter Specimen Associated With Parent At Screen 2 | Parent Specimen 2 - Number Of Daughter Specimen Associated With Parent At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_dau2_num_v1** | Parent Specimen 2 - Number Of Daughter Specimen Associated With Parent At Visit 1 | Parent Specimen 2 - Number Of Daughter Specimen Associated With Parent At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_dau2_num_v2** | Parent Specimen 2 - Number Of Daughter Specimen Associated With Parent At Visit 2 | Parent Specimen 2 - Number Of Daughter Specimen Associated With Parent At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_dau2_num_v3** | Parent Specimen 2 - Number Of Daughter Specimen Associated With Parent At Visit 3 | Parent Specimen 2 - Number Of Daughter Specimen Associated With Parent At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_dau3_id_scr2** | Parent Specimen 3 - Daughter Specimen IDs Associated With Parent At Screen 2 | Parent Specimen 3 - Daughter Specimen IDs Associated With Parent At Screen 2 | Char |
| 01. Principal | **spec_col_dau3_id_v1** | Parent Specimen 3 - Daughter Specimen IDs Associated With Parent At Visit 1 | Parent Specimen 3 - Daughter Specimen IDs Associated With Parent At Visit 1 | Char |
| 01. Principal | **spec_col_dau3_id_v2** | Parent Specimen 3 - Daughter Specimen IDs Associated With Parent At Visit 2 | Parent Specimen 3 - Daughter Specimen IDs Associated With Parent At Visit 2 | Char |
| 01. Principal | **spec_col_dau3_id_v3** | Parent Specimen 3 - Daughter Specimen IDs Associated With Parent At Visit 3 | Parent Specimen 3 - Daughter Specimen IDs Associated With Parent At Visit 3 | Char |
| 01. Principal | **spec_col_dau3_num_scr2** | Parent Specimen 3 - Number Of Daughter Specimen Associated With Parent At Screen 2 | Parent Specimen 3 - Number Of Daughter Specimen Associated With Parent At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_dau3_num_v1** | Parent Specimen 3 - Number Of Daughter Specimen Associated With Parent At Visit 1 | Parent Specimen 3 - Number Of Daughter Specimen Associated With Parent At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **spec_col_dau3_num_v2** | Parent Specimen 3 - Number Of Daughter Specimen Associated With Parent At Visit 2 | Parent Specimen 3 - Number Of Daughter Specimen Associated With Parent At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_dau3_num_v3** | Parent Specimen 3 - Number Of Daughter Specimen Associated With Parent At Visit 3 | Parent Specimen 3 - Number Of Daughter Specimen Associated With Parent At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_dau4_id_scr2** | Parent Specimen 4 - Daughter Specimen IDs Associated With Parent At Screen 2 | Parent Specimen 4 - Daughter Specimen IDs Associated With Parent At Screen 2 | Char |
| 01. Principal | **spec_col_dau4_id_v1** | Parent Specimen 4 - Daughter Specimen IDs Associated With Parent At Visit 1 | Parent Specimen 4 - Daughter Specimen IDs Associated With Parent At Visit 1 | Char |
| 01. Principal | **spec_col_dau4_id_v2** | Parent Specimen 4 - Daughter Specimen IDs Associated With Parent At Visit 2 | Parent Specimen 4 - Daughter Specimen IDs Associated With Parent At Visit 2 | Char |
| 01. Principal | **spec_col_dau4_id_v3** | Parent Specimen 4 - Daughter Specimen IDs Associated With Parent At Visit 3 | Parent Specimen 4 - Daughter Specimen IDs Associated With Parent At Visit 3 | Char |
| 01. Principal | **spec_col_dau4_num_scr2** | Parent Specimen 4 - Number Of Daughter Specimen Associated With Parent At Screen 2 | Parent Specimen 4 - Number Of Daughter Specimen Associated With Parent At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_dau4_num_v1** | Parent Specimen 4 - Number Of Daughter Specimen Associated With Parent At Visit 1 | Parent Specimen 4 - Number Of Daughter Specimen Associated With Parent At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_dau4_num_v2** | Parent Specimen 4 - Number Of Daughter Specimen Associated With Parent At Visit 2 | Parent Specimen 4 - Number Of Daughter Specimen Associated With Parent At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_dau4_num_v3** | Parent Specimen 4 - Number Of Daughter Specimen Associated With Parent At Visit 3 | Parent Specimen 4 - Number Of Daughter Specimen Associated With Parent At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par1_amt_scr2** | Parent Specimen 1 - Amount Of Specimen Collected (mL) At Screen 2 | Parent Specimen 1 - Amount Of Specimen Collected (mL) At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par1_amt_v1** | Parent Specimen 1 - Amount Of Specimen Collected (mL) At Visit 1 | Parent Specimen 1 - Amount Of Specimen Collected (mL) At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par1_amt_v2** | Parent Specimen 1 - Amount Of Specimen Collected (mL) At Visit 2 | Parent Specimen 1 - Amount Of Specimen Collected (mL) At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **spec_col_par1_amt_v3** | Parent Specimen 1 - Amount Of Specimen Collected (mL) At Visit 3 | Parent Specimen 1 - Amount Of Specimen Collected (mL) At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_id_scr2** | Parent Specimen 1 - Parent Specimen ID At Screen 2 | Parent Specimen 1 - Parent Specimen ID At Screen 2 | Char |
| 01. Principal | **spec_col_par1_id_v1** | Parent Specimen 1 - Parent Specimen ID At Visit 1 | Parent Specimen 1 - Parent Specimen ID At Visit 1 | Char |
| 01. Principal | **spec_col_par1_id_v2** | Parent Specimen 1 - Parent Specimen ID At Visit 2 | Parent Specimen 1 - Parent Specimen ID At Visit 2 | Char |
| 01. Principal | **spec_col_par1_id_v3** | Parent Specimen 1 - Parent Specimen ID At Visit 3 | Parent Specimen 1 - Parent Specimen ID At Visit 3 | Char |
| 01. Principal | **spec_col_par1_spec_dt_scr2** | Parent Specimen 1 - Specimen Collection Date At Screen 2 | Parent Specimen 1 - Specimen Collection Date At Screen 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_spec_dt_v1** | Parent Specimen 1 - Specimen Collection Date At Visit 1 | Parent Specimen 1 - Specimen Collection Date At Visit 1 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_spec_dt_v2** | Parent Specimen 1 - Specimen Collection Date At Visit 2 | Parent Specimen 1 - Specimen Collection Date At Visit 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_spec_dt_v3** | Parent Specimen 1 - Specimen Collection Date At Visit 3 | Parent Specimen 1 - Specimen Collection Date At Visit 3 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_spec_temp_scr2** | Parent Specimen 1 - Storage Temperature (C) At Screen 2 | Parent Specimen 1 - Storage Temperature (C) At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_spec_temp_v1** | Parent Specimen 1 - Storage Temperature (C) At Visit 1 | Parent Specimen 1 - Storage Temperature (C) At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_spec_temp_v2** | Parent Specimen 1 - Storage Temperature (C) At Visit 2 | Parent Specimen 1 - Storage Temperature (C) At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_spec_temp_v3** | Parent Specimen 1 - Storage Temperature (C) At Visit 3 | Parent Specimen 1 - Storage Temperature (C) At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_spec_time_scr2** | Parent Specimen 1 - Time Specimen Collected At Screen 2 | Parent Specimen 1 - Time Specimen Collected At Screen 2 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_spec_time_v1** | Parent Specimen 1 - Time Specimen Collected At Visit 1 | Parent Specimen 1 - Time Specimen Collected At Visit 1 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_spec_time_v2** | Parent Specimen 1 - Time Specimen Collected At Visit 2 | Parent Specimen 1 - Time Specimen Collected At Visit 2 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par1_spec_time_v3** | Parent Specimen 1 - Time Specimen Collected At Visit 3 | Parent Specimen 1 - Time Specimen Collected At Visit 3 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **spec_col_par1_spectype_scr2** | Parent Specimen 1 - Specimen Collection Type At Screen 2 | Parent Specimen 1 - Specimen Collection Type At Screen 2 | .M="Missing" <br> .R="Not Randomized" <br> 1="Blood" |
| 01. Principal | **spec_col_par1_spectype_v1** | Parent Specimen 1 - Specimen Collection Type At Visit 1 | Parent Specimen 1 - Specimen Collection Type At Visit 1 | .M="Missing" <br> .R="Not Randomized" <br> 1="Blood" <br> 3="Feces" |
| 01. Principal | **spec_col_par1_spectype_v2** | Parent Specimen 1 - Specimen Collection Type At Visit 2 | Parent Specimen 1 - Specimen Collection Type At Visit 2 | .M="Missing" <br> .R="Not Randomized" <br> 1="Blood" <br> 2="Feced" <br> 3="Feces" |
| 01. Principal | **spec_col_par1_spectype_v3** | Parent Specimen 1 - Specimen Collection Type At Visit 3 | Parent Specimen 1 - Specimen Collection Type At Visit 3 | .M="Missing" <br> .R="Not Randomized" <br> 1="Blood" <br> 3="Feces" |
| 01. Principal | **spec_col_par1_vactype_scr2** | Parent Specimen 1 - Parent Specimen Vacutainer Type At Screen 2 | Parent Specimen 1 - Parent Specimen Vacutainer Type At Screen 2 | .M="Missing" <br> .R="Not Randomized" <br> 1="Red" |
| 01. Principal | **spec_col_par1_vactype_v1** | Parent Specimen 1 - Parent Specimen Vacutainer Type At Visit 1 | Parent Specimen 1 - Parent Specimen Vacutainer Type At Visit 1 | .M="Missing" <br> .R="Not Randomized" <br> 1="Red" |
| 01. Principal | **spec_col_par1_vactype_v2** | Parent Specimen 1 - Parent Specimen Vacutainer Type At Visit 2 | Parent Specimen 1 - Parent Specimen Vacutainer Type At Visit 2 | .M="Missing" <br> .R="Not Randomized" <br> 1="Red" |
| 01. Principal | **spec_col_par1_vactype_v3** | Parent Specimen 1 - Parent Specimen Vacutainer Type At Visit 3 | Parent Specimen 1 - Parent Specimen Vacutainer Type At Visit 3 | .M="Missing" <br> .R="Not Randomized" <br> 1="Red" |
| 01. Principal | **spec_col_par2_amt_scr2** | Parent Specimen 2 - Amount Of Specimen Collected (mL) At Screen 2 | Parent Specimen 2 - Amount Of Specimen Collected (mL) At Screen 2 | Numeric <br> .M="Missing" <br> .R="Not Randomized" |
| 01. Principal | **spec_col_par2_amt_v1** | Parent Specimen 2 - Amount Of Specimen Collected (mL) At Visit 1 | Parent Specimen 2 - Amount Of Specimen Collected (mL) At Visit 1 | Numeric <br> .M="Missing" <br> .R="Not Randomized" |
| 01. Principal | **spec_col_par2_amt_v2** | Parent Specimen 2 - Amount Of Specimen Collected (mL) At Visit 2 | Parent Specimen 2 - Amount Of Specimen Collected (mL) At Visit 2 | Numeric <br> .M="Missing" <br> .R="Not Randomized" |
| 01. Principal | **spec_col_par2_amt_v3** | Parent Specimen 2 - Amount Of Specimen Collected (mL) At Visit 3 | Parent Specimen 2 - Amount Of Specimen Collected (mL) At Visit 3 | Numeric <br> .M="Missing" <br> .R="Not Randomized" |
| 01. Principal | **spec_col_par2_id_scr2** | Parent Specimen 2 - Parent Specimen ID At Screen 2 | Parent Specimen 2 - Parent Specimen ID At Screen 2 | Char |
| 01. Principal | **spec_col_par2_id_v1** | Parent Specimen 2 - Parent Specimen ID At Visit 1 | Parent Specimen 2 - Parent Specimen ID At Visit 1 | Char |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **spec_col_par2_id_v2** | Parent Specimen 2 - Parent Specimen ID At Visit 2 | Parent Specimen 2 - Parent Specimen ID At Visit 2 | Char |
| 01. Principal | **spec_col_par2_id_v3** | Parent Specimen 2 - Parent Specimen ID At Visit 3 | Parent Specimen 2 - Parent Specimen ID At Visit 3 | Char |
| 01. Principal | **spec_col_par2_spec_dt_scr2** | Parent Specimen 2 - Specimen Collection Date At Screen 2 | Parent Specimen 2 - Specimen Collection Date At Screen 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spec_dt_v1** | Parent Specimen 2 - Specimen Collection Date At Visit 1 | Parent Specimen 2 - Specimen Collection Date At Visit 1 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spec_dt_v2** | Parent Specimen 2 - Specimen Collection Date At Visit 2 | Parent Specimen 2 - Specimen Collection Date At Visit 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spec_dt_v3** | Parent Specimen 2 - Specimen Collection Date At Visit 3 | Parent Specimen 2 - Specimen Collection Date At Visit 3 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spec_temp_scr2** | Parent Specimen 2 - Storage Temperature At Screen 2 | Parent Specimen 2 - Storage Temperature At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spec_temp_v1** | Parent Specimen 2 - Storage Temperature At Visit 1 | Parent Specimen 2 - Storage Temperature At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spec_temp_v2** | Parent Specimen 2 - Storage Temperature At Visit 2 | Parent Specimen 2 - Storage Temperature At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spec_temp_v3** | Parent Specimen 2 - Storage Temperature At Visit 3 | Parent Specimen 2 - Storage Temperature At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spec_time_scr2** | Parent Specimen 2 - Time Specimen Collected At Screen 2 | Parent Specimen 2 - Time Specimen Collected At Screen 2 | SAS Time .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spec_time_v1** | Parent Specimen 2 - Time Specimen Collected At Visit 1 | Parent Specimen 2 - Time Specimen Collected At Visit 1 | SAS Time .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spec_time_v2** | Parent Specimen 2 - Time Specimen Collected At Visit 2 | Parent Specimen 2 - Time Specimen Collected At Visit 2 | SAS Time .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spec_time_v3** | Parent Specimen 2 - Time Specimen Collected At Visit 3 | Parent Specimen 2 - Time Specimen Collected At Visit 3 | SAS Time .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par2_spectype_scr2** | Parent Specimen 2 - Specimen Collection Type At Screen 2 | Parent Specimen 2 - Specimen Collection Type At Screen 2 | .M="Missing" .R="Not Randomized" 1="Blood" |
| 01. Principal | **spec_col_par2_spectype_v1** | Parent Specimen 2 - Specimen Collection Type At Visit 1 | Parent Specimen 2 - Specimen Collection Type At Visit 1 | .M="Missing" .R="Not Randomized" 1="Blood" |
| 01. Principal | **spec_col_par2_spectype_v2** | Parent Specimen 2 - Specimen Collection Type At Visit 2 | Parent Specimen 2 - Specimen Collection Type At Visit 2 | .M="Missing" .R="Not Randomized" 1="Blood" |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **spec_col_par2_spectype_v3** | Parent Specimen 2 - Specimen Collection Type At Visit 3 | Parent Specimen 2 - Specimen Collection Type At Visit 3 | .M="Missing"<br>.R="Not Randomized"<br>1="Blood"<br>3="Feces" |
| 01. Principal | **spec_col_par2_vactype_scr2** | Parent Specimen 2 - Parent Specimen Vacutainer Type At Screen 2 | Parent Specimen 2 - Parent Specimen Vacutainer Type At Screen 2 | .M="Missing"<br>.R="Not Randomized"<br>2="Lavender" |
| 01. Principal | **spec_col_par2_vactype_v1** | Parent Specimen 2 - Parent Specimen Vacutainer Type At Visit 1 | Parent Specimen 2 - Parent Specimen Vacutainer Type At Visit 1 | .M="Missing"<br>.R="Not Randomized"<br>1="Red" |
| 01. Principal | **spec_col_par2_vactype_v2** | Parent Specimen 2 - Parent Specimen Vacutainer Type At Visit 2 | Parent Specimen 2 - Parent Specimen Vacutainer Type At Visit 2 | .M="Missing"<br>.R="Not Randomized"<br>1="Red" |
| 01. Principal | **spec_col_par2_vactype_v3** | Parent Specimen 2 - Parent Specimen Vacutainer Type At Visit 3 | Parent Specimen 2 - Parent Specimen Vacutainer Type At Visit 3 | .M="Missing"<br>.R="Not Randomized"<br>1="Red"<br>2="Lavender" |
| 01. Principal | **spec_col_par3_amt_scr2** | Parent Specimen 3 - Amount Of Specimen Collected (mL) At Screen 2 | Parent Specimen 3 - Amount Of Specimen Collected (mL) At Screen 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par3_amt_v1** | Parent Specimen 3 - Amount Of Specimen Collected (mL) At Visit 1 | Parent Specimen 3 - Amount Of Specimen Collected (mL) At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par3_amt_v2** | Parent Specimen 3 - Amount Of Specimen Collected (mL) At Visit 2 | Parent Specimen 3 - Amount Of Specimen Collected (mL) At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par3_amt_v3** | Parent Specimen 3 - Amount Of Specimen Collected (mL) At Visit 3 | Parent Specimen 3 - Amount Of Specimen Collected (mL) At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par3_id_scr2** | Parent Specimen 3 - Parent Specimen ID At Screen 2 | Parent Specimen 3 - Parent Specimen ID At Screen 2 | Char |
| 01. Principal | **spec_col_par3_id_v1** | Parent Specimen 3 - Parent Specimen ID At Visit 1 | Parent Specimen 3 - Parent Specimen ID At Visit 1 | Char |
| 01. Principal | **spec_col_par3_id_v2** | Parent Specimen 3 - Parent Specimen ID At Visit 2 | Parent Specimen 3 - Parent Specimen ID At Visit 2 | Char |
| 01. Principal | **spec_col_par3_id_v3** | Parent Specimen 3 - Parent Specimen ID At Visit 3 | Parent Specimen 3 - Parent Specimen ID At Visit 3 | Char |
| 01. Principal | **spec_col_par3_spec_dt_scr2** | Parent Specimen 3 - Specimen Collection Date At Screen 2 | Parent Specimen 3 - Specimen Collection Date At Screen 2 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par3_spec_dt_v1** | Parent Specimen 3 - Specimen Collection Date At Visit 1 | Parent Specimen 3 - Specimen Collection Date At Visit 1 | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |

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| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **spec_col_par3_spec_dt_v2** | Parent Specimen 3 - Specimen Collection Date At Visit 2 | Parent Specimen 3 - Specimen Collection Date At Visit 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par3_spec_dt_v3** | Parent Specimen 3 - Specimen Collection Date At Visit 3 | Parent Specimen 3 - Specimen Collection Date At Visit 3 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par3_spec_temp_scr2** | Parent Specimen 3 - Storage Temperature At Screen 2 | Parent Specimen 3 - Storage Temperature At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par3_spec_temp_v1** | Parent Specimen 3 - Storage Temperature At Visit 1 | Parent Specimen 3 - Storage Temperature At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par3_spec_temp_v2** | Parent Specimen 3 - Storage Temperature At Visit 2 | Parent Specimen 3 - Storage Temperature At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par3_spec_temp_v3** | Parent Specimen 3 - Storage Temperature At Visit 3 | Parent Specimen 3 - Storage Temperature At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par3_spec_time_scr2** | Parent Specimen 3 - Time Specimen Collected At Screen 2 | Parent Specimen 3 - Time Specimen Collected At Screen 2 | SAS Time .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par3_spec_time_v1** | Parent Specimen 3 - Time Specimen Collected At Visit 1 | Parent Specimen 3 - Time Specimen Collected At Visit 1 | SAS Time .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par3_spec_time_v2** | Parent Specimen 3 - Time Specimen Collected At Visit 2 | Parent Specimen 3 - Time Specimen Collected At Visit 2 | SAS Time .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par3_spec_time_v3** | Parent Specimen 3 - Time Specimen Collected At Visit 3 | Parent Specimen 3 - Time Specimen Collected At Visit 3 | SAS Time .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par3_spectype_scr2** | Parent Specimen 3 - Specimen Collection Type At Screen 2 | Parent Specimen 3 - Specimen Collection Type At Screen 2 | .M="Missing" .R="Not Randomized" 3="Feces" |
| 01. Principal | **spec_col_par3_spectype_v1** | Parent Specimen 3 - Specimen Collection Type At Visit 1 | Parent Specimen 3 - Specimen Collection Type At Visit 1 | .M="Missing" .R="Not Randomized" 1="Blood" |
| 01. Principal | **spec_col_par3_spectype_v2** | Parent Specimen 3 - Specimen Collection Type At Visit 2 | Parent Specimen 3 - Specimen Collection Type At Visit 2 | .M="Missing" .R="Not Randomized" 1="Blood" |
| 01. Principal | **spec_col_par3_spectype_v3** | Parent Specimen 3 - Specimen Collection Type At Visit 3 | Parent Specimen 3 - Specimen Collection Type At Visit 3 | .M="Missing" .R="Not Randomized" 1="Blood" 3="Feces" |
| 01. Principal | **spec_col_par3_vactype_scr2** | Parent Specimen 3 - Parent Specimen Vacutainer Type At Screen 2 | Parent Specimen 3 - Parent Specimen Vacutainer Type At Screen 2 | .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par3_vactype_v1** | Parent Specimen 3 - Parent Specimen Vacutainer Type At Visit 1 | Parent Specimen 3 - Parent Specimen Vacutainer Type At Visit 1 | .M="Missing" .R="Not Randomized" 2="Lavender" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **spec_col_par3_vactype_v2** | Parent Specimen 3 - Parent Specimen Vacutainer Type At Visit 2 | Parent Specimen 3 - Parent Specimen Vacutainer Type At Visit 2 | .M="Missing" .R="Not Randomized" 2="Lavender" |
| 01. Principal | **spec_col_par3_vactype_v3** | Parent Specimen 3 - Parent Specimen Vacutainer Type At Visit 3 | Parent Specimen 3 - Parent Specimen Vacutainer Type At Visit 3 | .M="Missing" .R="Not Randomized" 2="Lavender" |
| 01. Principal | **spec_col_par4_amt_scr2** | Parent Specimen 4 - Amount Of Specimen Collected (mL) At Screen 2 | Parent Specimen 4 - Amount Of Specimen Collected (mL) At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par4_amt_v1** | Parent Specimen 4 - Amount Of Specimen Collected (mL) At Visit 1 | Parent Specimen 4 - Amount Of Specimen Collected (mL) At Visit 1 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par4_amt_v2** | Parent Specimen 4 - Amount Of Specimen Collected (mL) At Visit 2 | Parent Specimen 4 - Amount Of Specimen Collected (mL) At Visit 2 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par4_amt_v3** | Parent Specimen 4 - Amount Of Specimen Collected (mL) At Visit 3 | Parent Specimen 4 - Amount Of Specimen Collected (mL) At Visit 3 | Numeric .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par4_id_scr2** | Parent Specimen 4 - Parent Specimen ID At Screen 2 | Parent Specimen 4 - Parent Specimen ID At Screen 2 | Char |
| 01. Principal | **spec_col_par4_id_v1** | Parent Specimen 4 - Parent Specimen ID At Visit 1 | Parent Specimen 4 - Parent Specimen ID At Visit 1 | Char |
| 01. Principal | **spec_col_par4_id_v2** | Parent Specimen 4 - Parent Specimen ID At Visit 2 | Parent Specimen 4 - Parent Specimen ID At Visit 2 | Char |
| 01. Principal | **spec_col_par4_id_v3** | Parent Specimen 4 - Parent Specimen ID At Visit 3 | Parent Specimen 4 - Parent Specimen ID At Visit 3 | Char |
| 01. Principal | **spec_col_par4_spec_dt_scr2** | Parent Specimen 4 - Specimen Collection Date At Screen 2 | Parent Specimen 4 - Specimen Collection Date At Screen 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par4_spec_dt_v1** | Parent Specimen 4 - Specimen Collection Date At Visit 1 | Parent Specimen 4 - Specimen Collection Date At Visit 1 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par4_spec_dt_v2** | Parent Specimen 4 - Specimen Collection Date At Visit 2 | Parent Specimen 4 - Specimen Collection Date At Visit 2 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par4_spec_dt_v3** | Parent Specimen 4 - Specimen Collection Date At Visit 3 | Parent Specimen 4 - Specimen Collection Date At Visit 3 | SAS Date .M="Missing" .R="Not Randomized" |
| 01. Principal | **spec_col_par4_spec_temp_scr2** | Parent Specimen 4 - Storage Temperature At Screen 2 | Parent Specimen 4 - Storage Temperature At Screen 2 | Numeric .M="Missing" .R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **spec_col_par4_spec_temp_v1** | Parent Specimen 4 - Storage Temperature At Visit 1 | Parent Specimen 4 - Storage Temperature At Visit 1 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par4_spec_temp_v2** | Parent Specimen 4 - Storage Temperature At Visit 2 | Parent Specimen 4 - Storage Temperature At Visit 2 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par4_spec_temp_v3** | Parent Specimen 4 - Storage Temperature At Visit 3 | Parent Specimen 4 - Storage Temperature At Visit 3 | Numeric<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par4_spec_time_scr2** | Parent Specimen 4 - Time Specimen Collected At Screen 2 | Parent Specimen 4 - Time Specimen Collected At Screen 2 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par4_spec_time_v1** | Parent Specimen 4 - Time Specimen Collected At Visit 1 | Parent Specimen 4 - Time Specimen Collected At Visit 1 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par4_spec_time_v2** | Parent Specimen 4 - Time Specimen Collected At Visit 2 | Parent Specimen 4 - Time Specimen Collected At Visit 2 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par4_spec_time_v3** | Parent Specimen 4 - Time Specimen Collected At Visit 3 | Parent Specimen 4 - Time Specimen Collected At Visit 3 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par4_spectype_scr2** | Parent Specimen 4 - Specimen Collection Type At Screen 2 | Parent Specimen 4 - Specimen Collection Type At Screen 2 | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par4_spectype_v1** | Parent Specimen 4 - Specimen Collection Type At Visit 1 | Parent Specimen 4 - Specimen Collection Type At Visit 1 | .M="Missing"<br>.R="Not Randomized"<br>1="Blood" |
| 01. Principal | **spec_col_par4_spectype_v2** | Parent Specimen 4 - Specimen Collection Type At Visit 2 | Parent Specimen 4 - Specimen Collection Type At Visit 2 | .M="Missing"<br>.R="Not Randomized"<br>1="Blood" |
| 01. Principal | **spec_col_par4_spectype_v3** | Parent Specimen 4 - Specimen Collection Type At Visit 3 | Parent Specimen 4 - Specimen Collection Type At Visit 3 | .M="Missing"<br>.R="Not Randomized"<br>1="Blood" |
| 01. Principal | **spec_col_par4_vactype_scr2** | Parent Specimen 4 - Parent Specimen Vacutainer Type At Screen 2 | Parent Specimen 4 - Parent Specimen Vacutainer Type At Screen 2 | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_col_par4_vactype_v1** | Parent Specimen 4 - Parent Specimen Vacutainer Type At Visit 1 | Parent Specimen 4 - Parent Specimen Vacutainer Type At Visit 1 | .M="Missing"<br>.R="Not Randomized"<br>2="Lavender" |
| 01. Principal | **spec_col_par4_vactype_v2** | Parent Specimen 4 - Parent Specimen Vacutainer Type At Visit 2 | Parent Specimen 4 - Parent Specimen Vacutainer Type At Visit 2 | .M="Missing"<br>.R="Not Randomized"<br>2="Lavender" |
| 01. Principal | **spec_col_par4_vactype_v3** | Parent Specimen 4 - Parent Specimen Vacutainer Type At Visit 3 | Parent Specimen 4 - Parent Specimen Vacutainer Type At Visit 3 | .M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_visit_dt_scr2** | Visit Date At Screen 2 | Visit Date At Screen 2 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **spec_visit_dt_v1** | Visit Date At Visit 1 | Visit Date At Visit 1 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_visit_dt_v2** | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **spec_visit_dt_v3** | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Time<br>.M="Missing"<br>.R="Not Randomized" |

# Section 37: Agent Interruption

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **agint_amt_missed** | Amount Of Agent Missed (# Of Capsules) | Amount Of Agent Missed (# Of Capsules) | Numeric<br>.F="No Record For This Visit"<br>.R="Not Randomized" |
| 01. Principal | **agint_comments** | Comments | Comments | Char |
| 01. Principal | **agint_reason** | Reason Stopped | Reason Stopped | .F="No Record For This Visit"<br>.R="Not Randomized"<br>4="AE/SAE, specify"<br>5="Other, specify" |
| 01. Principal | **agint_reason_spec** | Reason Stopped, Specify | Reason Stopped, Specify | Char |
| 01. Principal | **agint_restart** | Was Agent Restarted? | Was Agent Restarted? | .F="No Record For This Visit"<br>.R="Not Randomized"<br>1="Yes" |
| 01. Principal | **agint_restart_dt** | If Yes, Specify Date Restarted | If Yes, Specify Date Restarted | SAS Date<br>.F="No Record For This Visit"<br>.R="Not Randomized" |
| 01. Principal | **agint_start_dt** | Start Date Of Interruption (Date Of First Dose Missed) | Start Date Of Interruption (Date Of First Dose Missed) | SAS Date<br>.F="No Record For This Visit"<br>.R="Not Randomized" |

# Section 38: Agent Return & Compliance

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | agrc_amt_missing_v2 | Amount Of Agent Missing/Not Accounted For This Period (# Of Capsules) At Visit 2 | Amount Of Agent Missing/Not Accounted For This Period (# Of Capsules) At Visit 2 | Numeric<br>.R="Not Randomized" |
| 01. Principal | agrc_amt_missing_v3 | Amount Of Agent Missing/Not Accounted For This Period (# Of Capsules) At Visit 3 | Amount Of Agent Missing/Not Accounted For This Period (# Of Capsules) At Visit 3 | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | agrc_amt_previous_v2 | Amount Of Agent Provided At Previous Visit (# Of Capsules) At Visit 2 | Amount Of Agent Provided At Previous Visit (# Of Capsules) At Visit 2 | Numeric<br>.R="Not Randomized" |
| 01. Principal | agrc_amt_previous_v3 | Amount Of Agent Provided At Previous Visit (# Of Capsules) At Visit 3 | Amount Of Agent Provided At Previous Visit (# Of Capsules) At Visit 3 | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | agrc_amt_returned_v2 | Amount Of Agent Returned At This Visit (# Of Capsules) At Visit 2 | Amount Of Agent Returned At This Visit (# Of Capsules) At Visit 2 | Numeric<br>.R="Not Randomized" |
| 01. Principal | agrc_amt_returned_v3 | Amount Of Agent Returned At This Visit (# Of Capsules) At Visit 3 | Amount Of Agent Returned At This Visit (# Of Capsules) At Visit 3 | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | agrc_amt_taken_v2 | Amount Of Agent Used During This Period (# Of Capsules) At Visit 2 | Amount Of Agent Used During This Period (# Of Capsules) At Visit 2 | Numeric<br>.R="Not Randomized" |
| 01. Principal | agrc_amt_taken_v3 | Amount Of Agent Used During This Period (# Of Capsules) At Visit 3 | Amount Of Agent Used During This Period (# Of Capsules) At Visit 3 | Numeric<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | agrc_comments_v2 | Comments At Visit 2 | Comments At Visit 2 | Char |
| 01. Principal | agrc_comments_v3 | Comments At Visit 3 | Comments At Visit 3 | Char |
| 01. Principal | agrc_visit_dt_v2 | Visit Date At Visit 2 | Visit Date At Visit 2 | SAS Date<br>.R="Not Randomized" |
| 01. Principal | agrc_visit_dt_v3 | Visit Date At Visit 3 | Visit Date At Visit 3 | SAS Date<br>.N="N/A"<br>.R="Not Randomized" |

# Section 39: Hospital Readmissions

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **hospreadm_admission_dt1-5** | Date Of Admission [1-5] | Date Of Admission [1-5] | SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" |
| 01. Principal | **hospreadm_admission_reason1-5** | Primary Reason For Admission [1-5] | Primary Reason For Admission [1-5] | Char |
| 01. Principal | **hospreadm_admission_spec_reason1-5** | If Yes, Specify The Primary Reason [1-5] | If Yes, Specify The Primary Reason [1-5] | Char |
| 01. Principal | **hospreadm_discharge_dt1-5** | Date Of Discharge [1-5] | Date Of Discharge [1-5] | SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized" |
| 01. Principal | **hospreadm_offstudy1-5** | Has Anything Changed In The Patient's Medical History That Requires Them To Come Off Study [1-5] | Has Anything Changed In The Patient's Medical History That Requires Them To Come Off Study [1-5] | .F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" |

# Section 40: Off Study

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | **offst_comment** | Comments | Comments | Char |
| 01. Principal | **offst_contact_dt** | Date Of Last Contact | Date Of Last Contact | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **offst_dt** | Off Study Date | Off Study Date | SAS Date<br>.R="Not Randomized" |
| 01. Principal | **offst_end_dt** | Agent End Date | Agent End Date | SAS Date<br>.M="Missing"<br>.N="N/A"<br>.R="Not Randomized" |
| 01. Principal | **offst_reason** | Reason Off Study | Reason Off Study | .R="Not Randomized"<br>0="Study Complete"<br>1="Ineligible"<br>2="Lost to follow-up"<br>3="Other, specify" |
| 01. Principal | **offst_reason_other** | Reason Off Study Other, Specify | Reason Off Study Other, Specify | Char |
| 01. Principal | **offst_time** | Off Study Time | Off Study Time | SAS Time<br>.N="N/A"<br>.R="Not Randomized" |

# Section 41: Participant Contact Form

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **parcnct_ae_report1-34** | Did The Participant Report Any Symptoms Or Adverse Events? [1-34] | Did The Participant Report Any Symptoms Or Adverse Events? [1-34] | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>2="Too early to evaluate" |
| 01. Principal | **parcnct_comment1-34** | Comments [1-34] | Comments [1-34] | Char |
| 01. Principal | **parcnct_conmed _report1-34** | Were Any Changes In Concomitant Medications Reported? [1-34] | Were Any Changes In Concomitant Medications Reported? [1-34] | .M="Missing"<br>.N="Not Applicable"<br>.R="Not Randomized"<br>0="No"<br>1="Yes" |
| 01. Principal | **parcnct_contact_ dt1-34** | Date Of Contact [1-34] | Date Of Contact [1-34] | SAS Date<br>.M="Missing"<br>.R="Not Randomized" |
| 01. Principal | **parcnct_is_comp liant1-34** | Is The Participant Compliant With Protocol Intervention Per Telephone Conversation Or Email? [1-34] | Is The Participant Compliant With Protocol Intervention Per Telephone Conversation Or Email? [1-34] | .M="Missing"<br>.R="Not Randomized"<br>0="No"<br>1="Yes"<br>9="Unknown" |