MAY2017-09-01 - ENHANCED PERSON: DATA DICTIONARY

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Document Summary

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MAY2017-09-01 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
arm	Treatment Arm	Treatment Arm	.F="No Form" 1="Dolcanatide" 2="Placebo"
rave_id	RAVE ID	RAVE ID	Numeric
subject	Participant ID	Participant ID	Char

Section 2: Demographics

Variable	Label	Description	Format Text
age_at_screening	Age At Screening	Age At Screening	Numeric
country_code	Country Code	Country Code	Char "US"="US"
ethnicity	Ethnicity	Ethnicity	0="Not Hispanic or Latino" 1="Hispanic or Latino"
gender	Gender	Gender	0="Male" 1="Female"
pay_method	Payment Method	Payment Method	1="Medicaid" 2="Medicare" 3="No means of payment (no insurance)" 4="Private insurance" 5="Self pay (no insurance" 9="Unkown"
race	Race	Race	1="White" 2="Black or African American" 3="Asian"

Section 3: Primary Endpoints

Variable	Label	Description	Format Text
primary_allergy	Allergies?	Allergies?	0="No" 1="Yes"
primary_bbpss_bsl	Boston Bowel Preparation Scale Score Baseline	Boston Bowel Preparation Scale Score Baseline	Numeric .N="Not Applicable"
primary_bbpss_int	Boston Bowel Preparation Scale Score Intervention	Boston Bowel Preparation Scale Score Intervention	Numeric .N="Not Applicable"
primary_biop1_cgmp_diff	Difference In Mean cGMP Levels From Baseline And Intervention Biopsy Site #1	Difference In Mean cGMP Levels From Baseline And Intervention Biopsy Site #1	Numeric .N="Not Applicable"
primary_biop2_cgmp_diff	Difference In Mean cGMP Levels From Baseline And Intervention Biopsy Site #2	Difference In Mean cGMP Levels From Baseline And Intervention Biopsy Site #2	Numeric .N="Not Applicable"
primary_bmi	BMI (kg/m^2)	BMI (kg/m^2)	Numeric
primary_bowel_prep_bsl	Was Bowel Prep Adequate? Baseline	Was Bowel Prep Adequate? Baseline	.N="Not Applicable" 1="Yes"
primary_bowel_prep_int	Was Bowel Prep Adequate? Intervention	Was Bowel Prep Adequate? Intervention	.N="Not Applicable" 0="No" 1="Yes"
primary_day0_biop1_cgmp	Mean cGMP Levels From Biopsy #1 At Day 0	Mean cGMP Levels From Biopsy #1 At Day 0	Numeric .N="Not Applicable"
primary_day0_biop2_cgmp	Mean cGMP Levels From Biopsy #2 At Day 0	Mean cGMP Levels From Biopsy #2 At Day 0	Numeric .N="Not Applicable"
primary_day0_overall_cgmp	Overall Mean cGMP Levels At Day 0	Overall Mean cGMP Levels At Day 0	Numeric .N="Not Applicable"
primary_day7_biop1_cgmp	Mean cGMP Levels From Biopsy #1 At Day 7	Mean cGMP Levels From Biopsy #1 At Day 7	Numeric .N="Not Applicable"
primary_day7_biop2_cgmp	Mean cGMP Levels From Biopsy #2 At Day 7	Mean cGMP Levels From Biopsy #2 At Day 7	Numeric .N="Not Applicable"
primary_day7_overall_cgmp	Overall Mean cGMP Levels At Day 7	Overall Mean cGMP Levels At Day 7	Numeric .N="Not Applicable"
primary_ecg	ECG Results	ECG Results	1="Normal" 3="Abnormal, Not Clinically Significant"
primary_ecogps	Performance Status (ECOG)	Performance Status (ECOG)	Numeric
primary_end_dt	Off Study Date	Off Study Date	SAS Date
primary_endo_num_2_to_4_bsl	Number Of 2-4mm Polyps Baseline	Number Of 2-4mm Polyps Baseline	Numeric .N="Not Applicable"
primary_endo_num_2_to_4_int	Number Of 2-4mm Polyps Intervention	Number Of 2-4mm Polyps Intervention	Numeric .N="Not Applicable"
primary_endo_num_5_to_9_bsl	Number Of 5-9mm Polyps Baseline	Number Of 5-9mm Polyps Baseline	Numeric .N="Not Applicable"
primary_endo_num_5_to_9_int	Number Of 5-9mm Polyps Intervention	Number Of 5-9mm Polyps Intervention	Numeric .N="Not Applicable"

Variable	Label	Description	Format Text
primary_endo_num_larger_10_bsl	Number Of > 10mm Polyps Baseline	Number Of > 10mm Polyps Baseline	Numeric .N="Not Applicable"
primary_endo_num_larger_10_int	Number Of > 10mm Polyps Intervention	Number Of > 10mm Polyps Intervention	Numeric .N="Not Applicable"
primary_endo_polyps_rem_bsl	(If Any Polyps > 2 mm) Were All Rectal Polyps > 2mm Removed? Baseline	(If Any Polyps > 2 mm) Were All Rectal Polyps > 2mm Removed? Baseline	.N="Not Applicable" 0="No"
primary_endo_polyps_rem_int	(If Any Polyps > 2 mm) Were All Rectal Polyps > 2mm Removed? Intervention	(If Any Polyps > 2 mm) Were All Rectal Polyps > 2mm Removed? Intervention	.N="Not Applicable" 0="No" 1="Yes" 9="N/A"
primary_endoscopy_bsl	Endoscopy Completed Baseline	Endoscopy Completed Baseline	.N="Not Applicable" 1="Yes"
primary_endoscopy_int	Endoscopy Completed Intervention	Endoscopy Completed Intervention	.N="Not Applicable" 0="No" 1="Yes"
primary_endoscopy_result_bsl	Endoscopy Result Baseline	Endoscopy Result Baseline	.N="Not Applicable" 1="Normal" 2="Abnormal, Specify"
primary_endoscopy_result_int	Endoscopy Result Intervention	Endoscopy Result Intervention	.N="Not Applicable" 1="Normal" 2="Abnormal, Specify"
primary_endpoint_evaluable	Primary Endpoint Evaluable	Primary Endpoint Evaluable	0="No" 1="Yes"
primary_fail_screen_reason	Screen Fail Reason	Screen Fail Reason	.N="Not Applicable" 1="Did not meet other eligibility criteria, specify" 2="Participant decision, specify" 3="Other, specify"
primary_fail_screen_reason_spec	Screen Fail Reason, Specify	Screen Fail Reason, Specify	Char
primary_first_dose_dt	First Agent Dose Date	First Agent Dose Date	SAS Date .N="Not Applicable"
primary_last_dose_dt	Last Agent Dose Date	Last Agent Dose Date	SAS Date .N="Not Applicable"
primary_last_reg_step	Last Registration Step	Last Registration Step	0="Pre-Registration" 1="Registration/Randomization"
primary_meet_screening	Meets Screening Requirements	Meets Screening Requirements	0="No" 1="Yes"
primary_off_study_reason	Off Study Reason	Off Study Reason	1="Study Complete" 2="Ineligible" 3="Adverse Event" 4="Participant Withdrawal" 5="Other"
primary_overall_cgmp_diff	Difference In Overall Mean cGMP Levels	Difference In Overall Mean cGMP Levels	Numeric .N="Not Applicable"
primary_preregistration_dt	Pre-Registration Date	Pre-Registration Date	SAS Date
primary_registration_dt	Registration Date	Registration Date	SAS Date .N="Not Applicable"
primary_screen_dt	Screen Date	Screen Date	SAS Date

Section 4: Participant Enrollment

Variable	Label	Description	Format Text
subject_enroll_dt	Enrollment Date	Enrollment Date	SAS Date
subject_enroll_lead_organization	Lead Organization	Lead Organization	Char "CPN"="CPN"
subject_enroll_protocol	Protocol	Protocol	Char "MAY2017-09-01"="MAY2017-09-01"
subject_enroll_source_app	Source Application	Source Application	1="Remote Registration"
subject_enroll_study_inst	Study Institution	Study Institution	1="Thomas Jefferson University Hospital"
subject_enroll_study_site_num	Study Institution ID Number	Study Institution ID Number	Char "PA121"="PA121"
subject_enroll_time	Enrollment Time	Enrollment Time	Numeric

Section 5: Pre-Registration Checklist

Variable	Label	Description	Format Text
pre_chklist_age	Age At Pre-Checklist Form Date	Age At Pre-Checklist Form Date	Numeric
pre_chklist_agent_auth	Study Agent Is Available And Drug Shipment Authorization	Study Agent Is Available And Drug Shipment Authorization Has Been Granted To The Registering Site	1="Yes"
pre_chklist_auto_register	Registration Office Personnel Will Automatically Register Participants	Registration Office Personnel Will Automatically Register Participants Separately To The Translational Components Of The Study	1="Yes"
pre_chklist_biobank	Participant Permission For Specimens To Be Kept In A Biobank For Use In Future Studies	Participant Permission For Specimens To Be Kept In A Biobank For Use In Future Studies	0="No" 1="Yes"
pre_chklist_bsl_symptoms_doc	All Baseline Symptoms Must Be Documented	All Baseline Symptoms Must Be Documented	.N="Not Applicable" 1="Yes"
pre_chklist_case	Case Number	Case Number	Numeric
pre_chklist_collect_spec	Participant Permission To Collect And Use Specimens For This Protocol	Participant Permission To Collect And Use Specimens For Studies Described In This Protocol	0="No" 1="Yes"
pre_chklist_consent_dt	Consent Date	Consent Date	Numeric
pre_chklist_contact_doctor	Participant Permission For Study Doctor To Contact Their Physician With Results	Participant Permission For Study Doctor To Contact Their Physician With Results	0="No" 1="Yes"
pre_chklist_created_dt	Created Date	Created Date	SAS Date
pre_chklist_disclose_auth	Existence Of Authorization For Use And Disclosure Of Protected Health Information	Existence Of Authorization For Use And Disclosure Of Protected Health Information	1="Yes"
pre_chklist_dr_auth	Authorized Doctor/Representative To Contact About Future Research	Authorized Doctor/Representative To Contact About Future Research	.M="Missing"
pre_chklist_drug_info	Participant Permission For Alcohol/Tobacco Information To Be Used For Future Research	Participant Permission For Alcohol/Tobacco Information To Be Used For Future Research	0="No" 1="Yes"
pre_chklist_eligible	Is Participant Eligible?	Is Participant Eligible?	1="Yes"

Variable	Label	Description	Format Text
pre_chklist_eval_in_guide	Baseline Evaluations Must Be Completed Within Guidelines	Baseline Evaluations Must Be Completed Within Guidelines	.N="Not Applicable" 1="Yes"
pre_chklist_prev_id	Previous Study ID	Previous Study ID	Char
pre_chklist_prev_study	Previous Study?	Previous Study?	0="No" 1="Yes"
pre_chklist_signed_consent	Consent Form Signed And Dated	Consent Form Signed And Dated	1="Yes"
pre_chklist_spec_auth	Authorized Specimen Research	Authorized Specimen Research	0="No" 1="Yes"
pre_chklist_version	Form Version	Form Version	Numeric

Section 6: Pre-Registration Inclusion/Exclusion

Variable	Label	Description	Format Text
pre_excl_alcohol	Current Use Of >= 3 Alcoholic Drinks A Day	Current Use Of >= 3 Alcoholic Drinks A Day	0="No"
pre_excl_allergic_similar	History Of Allergic Reactions To Similar Compounds	History Of Allergic Reactions To Similar Compounds	0="No"
pre_excl_anti_coagulant	Use Of Anti-Coagulants Or Anti-Platelet Within 5 Days Prior To Sigmoidoscopy	Use Of Anti-Coagulants Or Anti-Platelet Within 5 Days Prior To Sigmoidoscopy	0="No"
pre_excl_hist_adenoma	History Of Advanced Adenomas Or Colorectal Cancer	History Of Advanced Adenomas Or Colorectal Cancer	0="No"
pre_excl_hist_bleeding	History Of Bleeding/Coagulation Problems	History Of Bleeding/Coagulation Problems	0="No"
pre_excl_hist_celiac	History Of Celiac Disease	History Of Celiac Disease	0="No"
pre_excl_hist_diff	History Of Difficult Sigmoidoscopy Or Abnormal Colorectal Anatomy	History Of Difficult Sigmoidoscopy Or Abnormal Colorectal Anatomy	0="No"
pre_excl_hist_gastroparesis	History Of Gastroparesis	History Of Gastroparesis	0="No"
pre_excl_hist_gi	History Of G.I. Tract Surgery	History Of G.I. Tract Surgery	0="No"
pre_excl_hist_ibs	Previous Diagnosis Of Irritable Bowel Syndrome, Chronic Constipation, Bowel Disorders, or Colonic Motility Disorder	Previous Diagnosis Of Irritable Bowel Syndrome, Chronic Constipation, Bowel Disorders, or Colonic Motility Disorder	0="No"
pre_excl_hist_polyposis	Family History Of Polyposis Syndrome Or Colorectal Cancer	Family History Of Polyposis Syndrome Or Colorectal Cancer	0="No"
pre_excl_ibs	Inflammatory Bowel Disease	Inflammatory Bowel Disease	0="No"
pre_excl_ill	Uncontrolled Current Illness	Uncontrolled Current Illness	0="No"
pre_excl_laxatives	Current Use Of Laxatives More Than 3 Times Per Week	Current Use Of Laxatives More Than 3 Times Per Week	0="No"
pre_excl_malignancy	Any Malignancy Within 3 Years Of Baseline	Any Malignancy Within 3 Years Of Baseline	0="No"
pre_excl_obstruction	Known Or Suspected Mechanical Gastrointestinal Obstruction	Known Or Suspected Mechanical Gastrointestinal Obstruction	0="No"
pre_excl_oth_agents	Any Other Investigational Agents Currently	Any Other Investigational Agents Currently	0="No"

Variable	Label	Description	Format Text
pre_excl_oth_condition	Any Medical Condition Judged By The Investigator To Constitute A Risk To Safe Participation	Any Medical Condition Judged By The Investigator To Constitute A Risk To Safe Participation	0="No"
pre_excl_pregnant	Pregnant Or Lactating Women	Pregnant Or Lactating Women	0="No" 9="N/A"
pre_excl_smoke	Current Use Of >= 5 Cigarettes A Day	Current Use Of >= 5 Cigarettes A Day	0="No"
pre_excl_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric
pre_incl_able_consent	Able And Willing To Sign Consent	Able And Willing To Sign Consent	1="Yes"
pre_incl_age_range	Age Between 18 And 65	Age Between 18 And 65	1="Yes"
pre_incl_bmi	Body Mass Index <35 kg/m3	Body Mass Index <35 kg/m3	1="Yes"
pre_incl_contraception	Willing To Use Adequate Contraception	Willing To Use Adequate Contraception	1="Yes"
pre_incl_icf_sign_dt	Informed Consent Form Sign Date	Informed Consent Form Sign Date	SAS Date
pre_incl_icf_signed	Informed Consent Form Signed	Informed Consent Form Signed	1="Yes"
pre_incl_no_grapefruit	Willing To Abstain From Grapefruit Juice	Willing To Abstain From Grapefruit Juice	1="Yes"
pre_incl_provide_spec	Willing To Provide Blood And Tissue Specimen	Willing To Provide Blood And Tissue Specimen	1="Yes"
pre_incl_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric
preg_test_collect_dt1-2	Pregnancy Test Specimen Collection Date	Pregnancy Test Specimen Collection Date	SAS Date .F="No Form" .N="Not Applicable"
preg_test_result1-2	Pregnancy Test Results	Pregnancy Test Results	.F="No Form" .N="Not Applicable" 0="Negative"
preg_test_specimen_type1-2	Pregnancy Test Specimen Type	Pregnancy Test Specimen Type	.F="No Form" .N="Not Applicable" 1="Urine"
preg_test_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"

Section 7: Blood Chemistry Lab Results

Variable	Label	Description	Format Text
lab_c_albumin_clinsig_v1-3	Lab Chemistry: Albumin Serum (g/dL) Clinically Significant	Lab Chemistry: Albumin Serum (g/dL) Clinically Significant	.F="No Form" 0="No"
lab_c_albumin_labdone_v1-3	Lab Chemistry: Albumin Serum (g/dL) Lab Test Done	Lab Chemistry: Albumin Serum (g/dL) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_albumin_oor_v1-3	Lab Chemistry: Albumin Serum (g/dL) Out Of Range	Lab Chemistry: Albumin Serum (g/dL) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_c_albumin_value_v1-3	Lab Chemistry: Albumin Serum (g/dL) Value	Lab Chemistry: Albumin Serum (g/dL) Value	Numeric .F="No Form"
lab_c_alkaline_p_clinsig_v1-3	Lab Chemistry: Alkaline Phosphatase Serum ([iU]/L) Clinically Significant	Lab Chemistry: Alkaline Phosphatase Serum ([iU]/L) Clinically Significant	.F="No Form" 0="No"
lab_c_alkaline_p_labdone_v1-3	Lab Chemistry: Alkaline Phosphatase Serum ([iU]/L) Lab Test Done	Lab Chemistry: Alkaline Phosphatase Serum ([iU]/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_alkaline_p_oor_v1-3	Lab Chemistry: Alkaline Phosphatase Serum ([iU]/L) Out Of Range	Lab Chemistry: Alkaline Phosphatase Serum ([iU]/L) Out Of Range	.F="No Form" 0="No"
lab_c_alkaline_p_value_v1-3	Lab Chemistry: Alkaline Phosphatase Serum ([iU]/L) Value	Lab Chemistry: Alkaline Phosphatase Serum ([iU]/L) Value	Numeric .F="No Form"
lab_c_alt_clinsig_v1-3	Lab Chemistry: Alanine Aminotransferase (ALT or SGPT) Serum ([iU]/L) Clinically Significant	Lab Chemistry: Alanine Aminotransferase (ALT or SGPT) Serum ([iU]/L) Clinically Significant	.F="No Form" 0="No"
lab_c_alt_labdone_v1-3	Lab Chemistry: Alanine Aminotransferase (ALT or SGPT) Serum ([iU]/L) Lab Test Done	Lab Chemistry: Alanine Aminotransferase (ALT or SGPT) Serum ([iU]/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_alt_oor_v1-3	Lab Chemistry: Alanine Aminotransferase (ALT or SGPT) Serum ([iU]/L) Out Of Range	Lab Chemistry: Alanine Aminotransferase (ALT or SGPT) Serum ([iU]/L) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_c_alt_value_v1-3	Lab Chemistry: Alanine Aminotransferase (ALT or SGPT) Serum ([iU]/L) Value	Lab Chemistry: Alanine Aminotransferase (ALT or SGPT) Serum ([iU]/L) Value	Numeric .F="No Form"
lab_c_aptt_clinsig_v1-3	Lab Chemistry: APTT (seconds) Clinically Significant	Lab Chemistry: APTT (seconds) Clinically Significant	.F="No Form" 0="No"
lab_c_aptt_labdone_v1-3	Lab Chemistry: APTT (seconds) Lab Test Done	Lab Chemistry: APTT (seconds) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_aptt_oor_v1-3	Lab Chemistry: APTT (seconds) Out Of Range	Lab Chemistry: APTT (seconds) Out Of Range	.F="No Form" 0="No" 1="Yes"

Variable	Label	Description	Format Text
lab_c_aptt_value_v1-3	Lab Chemistry: APTT (seconds) Value	Lab Chemistry: APTT (seconds) Value	Numeric .F="No Form"
lab_c_ast_clinsig_v1-3	Lab Chemistry: Aspartate Aminotransferase (AST or SGOT) Serum([iU]/L) Clinically Significant	Lab Chemistry: Aspartate Aminotransferase (AST or SGOT) Serum([iU]/L) Clinically Significant	.F="No Form" 0="No"
lab_c_ast_labdone_v1-3	Lab Chemistry: Aspartate Aminotransferase (AST or SGOT) Serum([iU]/L) Lab Test Done	Lab Chemistry: Aspartate Aminotransferase (AST or SGOT) Serum([iU]/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_ast_oor_v1-3	Lab Chemistry: Aspartate Aminotransferase (AST or SGOT) Serum([iU]/L) Out Of Range	Lab Chemistry: Aspartate Aminotransferase (AST or SGOT) Serum([iU]/L) Out Of Range	.F="No Form" 0="No"
lab_c_ast_value_v1-3	Lab Chemistry: Aspartate Aminotransferase (AST or SGOT) Serum([iU]/L) Value	Lab Chemistry: Aspartate Aminotransferase (AST or SGOT) Serum([iU]/L) Value	Numeric .F="No Form"
lab_c_bicarbonate_clinsig_v1-3	Lab Chemistry: Bicarbonate Serum (mmol/L) Clinically Significant	Lab Chemistry: Bicarbonate Serum (mmol/L) Clinically Significant	.F="No Form" 0="No"
lab_c_bicarbonate_labdone_v1-3	Lab Chemistry: Bicarbonate Serum (mmol/L) Lab Test Done	Lab Chemistry: Bicarbonate Serum (mmol/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_bicarbonate_oor_v1-3	Lab Chemistry: Bicarbonate Serum (mmol/L) Out Of Range	Lab Chemistry: Bicarbonate Serum (mmol/L) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_c_bicarbonate_value_v1-3	Lab Chemistry: Bicarbonate Serum (mmol/L) Value	Lab Chemistry: Bicarbonate Serum (mmol/L) Value	Numeric .F="No Form"
lab_c_bilirubin_clinsig_v1-3	Lab Chemistry: Bilirubin Total Serum (mg/dL) Clinically Significant	Lab Chemistry: Bilirubin Total Serum (mg/dL) Clinically Significant	.F="No Form" 0="No"
lab_c_bilirubin_labdone_v1-3	Lab Chemistry: Bilirubin Total Serum (mg/dL) Lab Test Done	Lab Chemistry: Bilirubin Total Serum (mg/dL) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_bilirubin_oor_v1-3	Lab Chemistry: Bilirubin Total Serum (mg/dL) Out Of Range	Lab Chemistry: Bilirubin Total Serum (mg/dL) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_c_bilirubin_value_v1-3	Lab Chemistry: Bilirubin Total Serum (mg/dL) Value	Lab Chemistry: Bilirubin Total Serum (mg/dL) Value	Numeric .F="No Form"
lab_c_bun_clinsig_v1-3	Lab Chemistry: Blood Urea Nitrogen (BUN) Serum (mg/dL) Clinically Significant	Lab Chemistry: Blood Urea Nitrogen (BUN) Serum (mg/dL) Clinically Significant	.F="No Form" 0="No"
lab_c_bun_labdone_v1-3	Lab Chemistry: Blood Urea Nitrogen (BUN) Serum (mg/dL) Lab Test Done	Lab Chemistry: Blood Urea Nitrogen (BUN) Serum (mg/dL) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_bun_oor_v1-3	Lab Chemistry: Blood Urea Nitrogen (BUN) Serum (mg/dL) Out Of Range	Lab Chemistry: Blood Urea Nitrogen (BUN) Serum (mg/dL) Out Of Range	.F="No Form" 0="No" 1="Yes"

Variable	Label	Description	Format Text
lab_c_bun_value_v1-3	Lab Chemistry: Blood Urea Nitrogen (BUN) Serum (mg/dL) Value	Lab Chemistry: Blood Urea Nitrogen (BUN) Serum (mg/dL) Value	Numeric .F="No Form"
lab_c_calcium_clinsig_v1-3	Lab Chemistry: Calcium Serum (mg/dL) Clinically Significant	Lab Chemistry: Calcium Serum (mg/dL) Clinically Significant	.F="No Form" 0="No"
lab_c_calcium_labdone_v1-3	Lab Chemistry: Calcium Serum (mg/dL) Lab Test Done	Lab Chemistry: Calcium Serum (mg/dL) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_calcium_oor_v1-3	Lab Chemistry: Calcium Serum (mg/dL) Out Of Range	Lab Chemistry: Calcium Serum (mg/dL) Out Of Range	.F="No Form" 0="No"
lab_c_calcium_value_v1-3	Lab Chemistry: Calcium Serum (mg/dL) Value	Lab Chemistry: Calcium Serum (mg/dL) Value	Numeric .F="No Form"
lab_c_chloride_clinsig_v1-3	Lab Chemistry: Chloride Serum (mmol/L) Clinically Significant	Lab Chemistry: Chloride Serum (mmol/L) Clinically Significant	.F="No Form" 0="No"
lab_c_chloride_labdone_v1-3	Lab Chemistry: Chloride Serum (mmol/L) Lab Test Done	Lab Chemistry: Chloride Serum (mmol/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_chloride_oor_v1-3	Lab Chemistry: Chloride Serum (mmol/L) Out Of Range	Lab Chemistry: Chloride Serum (mmol/L) Out Of Range	.F="No Form" 0="No"
lab_c_chloride_value_v1-3	Lab Chemistry: Chloride Serum (mmol/L) Value	Lab Chemistry: Chloride Serum (mmol/L) Value	Numeric .F="No Form"
lab_c_comments_v1-3	Lab Chemistry Comments	Lab Chemistry Comments	Char
lab_c_creatinine_clinsig_v1-3	Lab Chemistry: Creatinine Serum (mg/dL) Clinically Significant	Lab Chemistry: Creatinine Serum (mg/dL) Clinically Significant	.F="No Form" 0="No"
lab_c_creatinine_labdone_v1-3	Lab Chemistry: Creatinine Serum (mg/dL) Lab Test Done	Lab Chemistry: Creatinine Serum (mg/dL) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_creatinine_oor_v1-3	Lab Chemistry: Creatinine Serum (mg/dL) Out Of Range	Lab Chemistry: Creatinine Serum (mg/dL) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_c_creatinine_value_v1-3	Lab Chemistry: Creatinine Serum (mg/dL) Value	Lab Chemistry: Creatinine Serum (mg/dL) Value	Numeric .F="No Form"
lab_c_fasting_v1-3	Fasting?	Fasting?	.F="No Form" 1="Yes"
lab_c_fsh_clinsig_v1-3	Lab Chemistry: FSH Clinically Significant	Lab Chemistry: FSH Clinically Significant	.F="No Form" .N="Not Applicable" 0="No"
lab_c_fsh_labdone_v1-3	Lab Chemistry: FSH Lab Test Done	Lab Chemistry: FSH Lab Test Done	.F="No Form" .N="Not Applicable" 0="Not Obtained"
lab_c_fsh_oor_v1-3	Lab Chemistry: FSH Out Of Range	Lab Chemistry: FSH Out Of Range	.F="No Form" .N="Not Applicable" 0="No"
lab_c_fsh_value_v1-3	Lab Chemistry: FSH Value	Lab Chemistry: FSH Value	Numeric .F="No Form" .N="Not Applicable"

Variable	Label	Description	Format Text
lab_c_glucose_clinsig_v1-3	Lab Chemistry: Glucose Serum (mg/dL) Clinically Significant	Lab Chemistry: Glucose Serum (mg/dL) Clinically Significant	.F="No Form" 0="No"
lab_c_glucose_labdone_v1-3	Lab Chemistry: Glucose Serum (mg/dL) Lab Test Done	Lab Chemistry: Glucose Serum (mg/dL) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_glucose_oor_v1-3	Lab Chemistry: Glucose Serum (mg/dL) Out Of Range	Lab Chemistry: Glucose Serum (mg/dL) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_c_glucose_value_v1-3	Lab Chemistry: Glucose Serum (mg/dL) Value	Lab Chemistry: Glucose Serum (mg/dL) Value	Numeric .F="No Form"
lab_c_inr_clinsig_v1-3	Lab Chemistry: INR Clinically Significant	Lab Chemistry: INR Clinically Significant	.F="No Form" .N="Not Applicable" 0="No"
lab_c_inr_labdone_v1-3	Lab Chemistry: INR Lab Test Done	Lab Chemistry: INR Lab Test Done	.F="No Form" .N="Not Applicable" 0="Not Obtained"
lab_c_inr_oor_v1-3	Lab Chemistry: INR Out Of Range	Lab Chemistry: INR Out Of Range	.F="No Form" .N="Not Applicable" 0="No" 1="Yes"
lab_c_inr_value_v1-3	Lab Chemistry: INR Value	Lab Chemistry: INR Value	Numeric .F="No Form" .N="Not Applicable"
lab_c_potassium_clinsig_v1-3	Lab Chemistry: Potassium Serum (mmol/L) Clinically Significant	Lab Chemistry: Potassium Serum (mmol/L) Clinically Significant	.F="No Form" 0="No"
lab_c_potassium_labdone_v1-3	Lab Chemistry: Potassium Serum (mmol/L) Lab Test Done	Lab Chemistry: Potassium Serum (mmol/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_potassium_oor_v1-3	Lab Chemistry: Potassium Serum (mmol/L) Out Of Range	Lab Chemistry: Potassium Serum (mmol/L) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_c_potassium_value_v1-3	Lab Chemistry: Potassium Serum (mmol/L) Value	Lab Chemistry: Potassium Serum (mmol/L) Value	Numeric .F="No Form"
lab_c_prothrombin_clinsig_v1-3	Lab Chemistry: Prothrombin Time (PT) Blood (seconds) Clinically Significant	Lab Chemistry: Prothrombin Time (PT) Blood (seconds) Clinically Significant	.F="No Form" .N="Not Applicable" 0="No"
lab_c_prothrombin_labdone_v1-3	Lab Chemistry: Prothrombin Time (PT) Blood (seconds) Lab Test Done	Lab Chemistry: Prothrombin Time (PT) Blood (seconds) Lab Test Done	.F="No Form" .N="Not Applicable" 0="Not Obtained"
lab_c_prothrombin_oor_v1-3	Lab Chemistry: Prothrombin Time (PT) Blood (seconds) Out Of Range	Lab Chemistry: Prothrombin Time (PT) Blood (seconds) Out Of Range	.F="No Form" .N="Not Applicable" 0="No" 1="Yes"
lab_c_prothrombin_value_v1-3	Lab Chemistry: Prothrombin Time (PT) Blood (seconds) Value	Lab Chemistry: Prothrombin Time (PT) Blood (seconds) Value	Numeric .F="No Form" .N="Not Applicable"
lab_c_sample_col_dt_v1-3	Sample Collection Date	Sample Collection Date	SAS Date .F="No Form"

Variable	Label	Description	Format Text
lab_c_sodium_clinsig_v1-3	Lab Chemistry: Sodium Serum (mmol/L) Clinically Significant	Lab Chemistry: Sodium Serum (mmol/L) Clinically Significant	.F="No Form" 0="No"
lab_c_sodium_labdone_v1-3	Lab Chemistry: Sodium Serum (mmol/L) Lab Test Done	Lab Chemistry: Sodium Serum (mmol/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_sodium_oor_v1-3	Lab Chemistry: Sodium Serum (mmol/L) Out Of Range	Lab Chemistry: Sodium Serum (mmol/L) Out Of Range	.F="No Form" 0="No"
lab_c_sodium_value_v1-3	Lab Chemistry: Sodium Serum (mmol/L) Value	Lab Chemistry: Sodium Serum (mmol/L) Value	Numeric .F="No Form"
lab_c_target_days_from_bsl_v1-3	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
lab_c_total_prot_clinsig_v1-3	Lab Chemistry: Total Protein Serum (g/dL) Clinically Significant	Lab Chemistry: Total Protein Serum (g/dL) Clinically Significant	.F="No Form" 0="No"
lab_c_total_prot_labdone_v1-3	Lab Chemistry: Total Protein Serum (g/dL) Lab Test Done	Lab Chemistry: Total Protein Serum (g/dL) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_c_total_prot_oor_v1-3	Lab Chemistry: Total Protein Serum (g/dL) Out Of Range	Lab Chemistry: Total Protein Serum (g/dL) Out Of Range	.F="No Form" 0="No"
lab_c_total_prot_value_v1-3	Lab Chemistry: Total Protein Serum (g/dL) Value	Lab Chemistry: Total Protein Serum (g/dL) Value	Numeric .F="No Form"

Section 8: Blood Hematology Lab Results

Variable	Label	Description	Format Text
lab_h_anc_clinsig_v1-3	Lab Hematology: Neutrophils (ANC) # Blood (B/L) Clinically Significant	Lab Hematology: Neutrophils (ANC) # Blood (B/L) Clinically Significant	.F="No Form" 0="No"
lab_h_anc_labdone_v1-3	Lab Hematology: Neutrophils (ANC) # Blood (B/L) Lab Test Done	Lab Hematology: Neutrophils (ANC) # Blood (B/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_h_anc_oor_v1-3	Lab Hematology: Neutrophils (ANC) # Blood (B/L) Out Of Range	Lab Hematology: Neutrophils (ANC) # Blood (B/L) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_h_anc_value_v1-3	Lab Hematology: Neutrophils (ANC) # Blood (B/L) Value	Lab Hematology: Neutrophils (ANC) # Blood (B/L) Value	Numeric .F="No Form"
lab_h_basophils_clinsig_v1-3	Lab Hematology: Basophils # Blood (B/L) Clinically Significant	Lab Hematology: Basophils # Blood (B/L) Clinically Significant	.F="No Form" 0="No"
lab_h_basophils_labdone_v1-3	Lab Hematology: Basophils # Blood (B/L) Lab Test Done	Lab Hematology: Basophils # Blood (B/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_h_basophils_oor_v1-3	Lab Hematology: Basophils # Blood (B/L) Out Of Range	Lab Hematology: Basophils # Blood (B/L) Out Of Range	.F="No Form" 0="No"
lab_h_basophils_value_v1-3	Lab Hematology: Basophils # Blood (B/L) Value	Lab Hematology: Basophils # Blood (B/L) Value	Numeric .F="No Form"
lab_h_comments_v1-3	Lab Hematology Comments	Lab Hematology Comments	Char
lab_h_eosinophils_clinsig_v1-3	Lab Hematology: Eosinophils # Blood (B/L) Clinically Significant	Lab Hematology: Eosinophils # Blood (B/L) Clinically Significant	.F="No Form" 0="No"
lab_h_eosinophils_labdone_v1-3	Lab Hematology: Eosinophils # Blood (B/L) Lab Test Done	Lab Hematology: Eosinophils # Blood (B/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_h_eosinophils_oor_v1-3	Lab Hematology: Eosinophils # Blood (B/L) Out Of Range	Lab Hematology: Eosinophils # Blood (B/L) Out Of Range	.F="No Form" 0="No"
lab_h_eosinophils_value_v1-3	Lab Hematology: Eosinophils # Blood (B/L) Value	Lab Hematology: Eosinophils # Blood (B/L) Value	Numeric .F="No Form"
lab_h_fasting_v1-3	Fasting?	Fasting?	Numeric .F="No Form"
lab_h_hematocrit_clinsig_v1-3	Lab Hematology: Hematocrit % Blood (%) Clinically Significant	Lab Hematology: Hematocrit % Blood (%) Clinically Significant	.F="No Form" 0="No"
lab_h_hematocrit_labdone_v1-3	Lab Hematology: Hematocrit % Blood (%) Lab Test Done	Lab Hematology: Hematocrit % Blood (%) Lab Test Done	.F="No Form" .N="Not Applicable"

Variable	Label	Description	Format Text
lab_h_hematocrit_oor_v1-3	Lab Hematology: Hematocrit % Blood (%) Out Of Range	Lab Hematology: Hematocrit % Blood (%) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_h_hematocrit_value_v1-3	Lab Hematology: Hematocrit % Blood (%) Value	Lab Hematology: Hematocrit % Blood (%) Value	Numeric .F="No Form"
lab_h_hemoglobin_clinsig_v1-3	Lab Hematology: Hemoglobin Blood (g/dL) Clinically Significant	Lab Hematology: Hemoglobin Blood (g/dL) Clinically Significant	.F="No Form" 0="No"
lab_h_hemoglobin_labdone_v1-3	Lab Hematology: Hemoglobin Blood (g/dL) Lab Test Done	Lab Hematology: Hemoglobin Blood (g/dL) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_h_hemoglobin_oor_v1-3	Lab Hematology: Hemoglobin Blood (g/dL) Out Of Range	Lab Hematology: Hemoglobin Blood (g/dL) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_h_hemoglobin_value_v1-3	Lab Hematology: Hemoglobin Blood (g/dL) Value	Lab Hematology: Hemoglobin Blood (g/dL) Value	Numeric .F="No Form"
lab_h_lympho_clinsig_v1-3	Lab Hematology: Lymphocytes # Blood (B/L) Clinically Significant	Lab Hematology: Lymphocytes # Blood (B/L) Clinically Significant	.F="No Form" 0="No"
lab_h_lympho_labdone_v1-3	Lab Hematology: Lymphocytes # Blood (B/L) Lab Test Done	Lab Hematology: Lymphocytes # Blood (B/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_h_lympho_oor_v1-3	Lab Hematology: Lymphocytes # Blood (B/L) Out Of Range	Lab Hematology: Lymphocytes # Blood (B/L) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_h_lympho_value_v1-3	Lab Hematology: Lymphocytes # Blood (B/L) Value	Lab Hematology: Lymphocytes # Blood (B/L) Value	Numeric .F="No Form"
lab_h_monocytes_clinsig_v1-3	Lab Hematology: Monocytes # Blood (B/L) Clinically Significant	Lab Hematology: Monocytes # Blood (B/L) Clinically Significant	.F="No Form" 0="No"
lab_h_monocytes_labdone_v1-3	Lab Hematology: Monocytes # Blood (B/L) Lab Test Done	Lab Hematology: Monocytes # Blood (B/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_h_monocytes_oor_v1-3	Lab Hematology: Monocytes # Blood (B/L) Out Of Range	Lab Hematology: Monocytes # Blood (B/L) Out Of Range	.F="No Form" 0="No"
lab_h_monocytes_value_v1-3	Lab Hematology: Monocytes # Blood (B/L) Value	Lab Hematology: Monocytes # Blood (B/L) Value	Numeric .F="No Form"
lab_h_platelet_clinsig_v1-3	Lab Hematology: Platelets Blood (B/L) Clinically Significant	Lab Hematology: Platelets Blood (B/L) Clinically Significant	.F="No Form" 0="No"
lab_h_platelet_labdone_v1-3	Lab Hematology: Platelets Blood (B/L) Lab Test Done	Lab Hematology: Platelets Blood (B/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_h_platelet_oor_v1-3	Lab Hematology: Platelets Blood (B/L) Out Of Range	Lab Hematology: Platelets Blood (B/L) Out Of Range	.F="No Form" 0="No"
lab_h_platelet_value_v1-3	Lab Hematology: Platelets Blood (B/L) Value	Lab Hematology: Platelets Blood (B/L) Value	Numeric .F="No Form"

Variable	Label	Description	Format Text
lab_h_rbc_clinsig_v1-3	Lab Hematology: Red Blood Cells (RBC) # Blood (T/L) Clinically Significant	Lab Hematology: Red Blood Cells (RBC) # Blood (T/L) Clinically Significant	.F="No Form" 0="No"
lab_h_rbc_labdone_v1-3	Lab Hematology: Red Blood Cells (RBC) # Blood (T/L) Lab Test Done	Lab Hematology: Red Blood Cells (RBC) # Blood (T/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_h_rbc_oor_v1-3	Lab Hematology: Red Blood Cells (RBC) # Blood (T/L) Out Of Range	Lab Hematology: Red Blood Cells (RBC) # Blood (T/L) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_h_rbc_value_v1-3	Lab Hematology: Red Blood Cells (RBC) # Blood (T/L) Value	Lab Hematology: Red Blood Cells (RBC) # Blood (T/L) Value	Numeric .F="No Form"
lab_h_sample_col_dt_v1-3	Sample Collection Date	Sample Collection Date	SAS Date .F="No Form"
lab_h_target_days_from_bsl_v1-3	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
lab_h_wbc_clinsig_v1-3	Lab Hematology: White Blood Cells (WBC) # Blood (B/L) Clinically Significant	Lab Hematology: White Blood Cells (WBC) # Blood (B/L) Clinically Significant	.F="No Form" 0="No"
lab_h_wbc_labdone_v1-3	Lab Hematology: White Blood Cells (WBC) # Blood (B/L) Lab Test Done	Lab Hematology: White Blood Cells (WBC) # Blood (B/L) Lab Test Done	.F="No Form" .N="Not Applicable"
lab_h_wbc_oor_v1-3	Lab Hematology: White Blood Cells (WBC) # Blood (B/L) Out Of Range	Lab Hematology: White Blood Cells (WBC) # Blood (B/L) Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_h_wbc_value_v1-3	Lab Hematology: White Blood Cells (WBC) # Blood (B/L) Value	Lab Hematology: White Blood Cells (WBC) # Blood (B/L) Value	Numeric .F="No Form"

Section 9: Urine Lab Results

Variable	Label	Description	Format Text
lab_u_barbiturate_clinsig_v1-3	Lab Urine: Barbiturate Clinically Significant	Lab Urine: Barbiturate Clinically Significant	.F="No Form" 0="No"
lab_u_barbiturate_labdone_v1-3	Lab Urine: Barbiturate Lab Test Done	Lab Urine: Barbiturate Lab Test Done	.F="No Form" .N="Not Applicable"
lab_u_barbiturate_oor_v1-3	Lab Urine: Barbiturate Out Of Range	Lab Urine: Barbiturate Out Of Range	.F="No Form" 0="No"
lab_u_barbiturate_result_v1-3	Lab Urine: Barbiturate Results	Lab Urine: Barbiturate Results	.F="No Form" 0="Negative"
lab_u_barbiturate_value_v1-3	Lab Urine: Barbiturate Value	Lab Urine: Barbiturate Value	Numeric .F="No Form" .N="Not Applicable"
lab_u_benzo_clinsig_v1-3	Lab Urine: Benzodiazepine Clinically Significant	Lab Urine: Benzodiazepine Clinically Significant	.F="No Form" 0="No"
lab_u_benzo_labdone_v1-3	Lab Urine: Benzodiazepine Lab Test Done	Lab Urine: Benzodiazepine Lab Test Done	.F="No Form" .N="Not Applicable"
lab_u_benzo_oor_v1-3	Lab Urine: Benzodiazepine Out Of Range	Lab Urine: Benzodiazepine Out Of Range	.F="No Form" 0="No"
lab_u_benzo_result_v1-3	Lab Urine: Benzodiazepine Results	Lab Urine: Benzodiazepine Results	.F="No Form" 0="Negative"
lab_u_benzo_value_v1-3	Lab Urine: Benzodiazepine Value	Lab Urine: Benzodiazepine Value	Numeric .F="No Form" .N="Not Applicable"
lab_u_cannabinoid_clinsig_v1-3	Lab Urine: Cannabinoid Clinically Significant	Lab Urine: Cannabinoid Clinically Significant	.F="No Form" 0="No"
lab_u_cannabinoid_labdone_v1-3	Lab Urine: Cannabinoid Lab Test Done	Lab Urine: Cannabinoid Lab Test Done	.F="No Form" .N="Not Applicable"
lab_u_cannabinoid_oor_v1-3	Lab Urine: Cannabinoid Out Of Range	Lab Urine: Cannabinoid Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_u_cannabinoid_result_v1-3	Lab Urine: Cannabinoid Results	Lab Urine: Cannabinoid Results	.F="No Form" 0="Negative" 1="Positive"
lab_u_cannabinoid_value_v1-3	Lab Urine: Cannabinoid Value	Lab Urine: Cannabinoid Value	Numeric .F="No Form" .N="Not Applicable"
lab_u_cocaine_clinsig_v1-3	Lab Urine: Cocaine Clinically Significant	Lab Urine: Cocaine Clinically Significant	.F="No Form" 0="No"
lab_u_cocaine_labdone_v1-3	Lab Urine: Cocaine Lab Test Done	Lab Urine: Cocaine Lab Test Done	.F="No Form" .N="Not Applicable"
lab_u_cocaine_oor_v1-3	Lab Urine: Cocaine Out Of Range	Lab Urine: Cocaine Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_u_cocaine_result_v1-3	Lab Urine: Cocaine Results	Lab Urine: Cocaine Results	.F="No Form" 0="Negative" 1="Positive"

Variable	Label	Description	Format Text
lab_u_cocaine_value_v1-3	Lab Urine: Cocaine Value	Lab Urine: Cocaine Value	Numeric .F="No Form" .N="Not Applicable"
lab_u_comments_v1-3	Lab Urine Comments	Lab Urine Comments	Char
lab_u_glucose_clinsig_v1-3	Lab Urine: Glucose Urine Clinically Significant	Lab Urine: Glucose Urine Clinically Significant	.F="No Form" 0="No"
lab_u_glucose_labdone_v1-3	Lab Urine: Glucose Urine Lab Test Done	Lab Urine: Glucose Urine Lab Test Done	.F="No Form" .N="Not Applicable"
lab_u_glucose_oor_v1-3	Lab Urine: Glucose Urine Out Of Range	Lab Urine: Glucose Urine Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_u_glucose_result_v1-3	Lab Urine: Glucose Urine Results	Lab Urine: Glucose Urine Results	.F="No Form" .N="Not Applicable" 0="Negative"
lab_u_glucose_value_v1-3	Lab Urine: Glucose Urine Value	Lab Urine: Glucose Urine Value	Numeric .F="No Form" .N="Not Applicable" 99.1="1+"
lab_u_ketones_clinsig_v1-3	Lab Urine: Ketones Urine Clinically Significant	Lab Urine: Ketones Urine Clinically Significant	.F="No Form" 0="No"
lab_u_ketones_labdone_v1-3	Lab Urine: Ketones Urine Lab Test Done	Lab Urine: Ketones Urine Lab Test Done	.F="No Form" .N="Not Applicable"
lab_u_ketones_oor_v1-3	Lab Urine: Ketones Urine Out Of Range	Lab Urine: Ketones Urine Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_u_ketones_result_v1-3	Lab Urine: Ketones Urine Results	Lab Urine: Ketones Urine Results	.F="No Form" .N="Not Applicable" 0="Negative"
lab_u_ketones_value_v1-3	Lab Urine: Ketones Urine Value	Lab Urine: Ketones Urine Value	Numeric .F="No Form" .N="Not Applicable" 99="Trace" 99.1="1+"
lab_u_opiate_clinsig_v1-3	Lab Urine: Opiate Clinically Significant	Lab Urine: Opiate Clinically Significant	.F="No Form" 0="No"
lab_u_opiate_labdone_v1-3	Lab Urine: Opiate Lab Test Done	Lab Urine: Opiate Lab Test Done	.F="No Form" .N="Not Applicable"
lab_u_opiate_oor_v1-3	Lab Urine: Opiate Out Of Range	Lab Urine: Opiate Out Of Range	.F="No Form" 0="No"
lab_u_opiate_result_v1-3	Lab Urine: Opiate Results	Lab Urine: Opiate Results	.F="No Form" 0="Negative"
lab_u_opiate_value_v1-3	Lab Urine: Opiate Value	Lab Urine: Opiate Value	Numeric .F="No Form" .N="Not Applicable"
lab_u_ph_clinsig_v1-3	Lab Urine: pH Urine Clinically Significant	Lab Urine: pH Urine Clinically Significant	.F="No Form" 0="No"
lab_u_ph_labdone_v1-3	Lab Urine: pH Urine Lab Test Done	Lab Urine: pH Urine Lab Test Done	.F="No Form" .N="Not Applicable"

Variable	Label	Description	Format Text
lab_u_ph_oor_v1-3	Lab Urine: pH Urine Out Of Range	Lab Urine: pH Urine Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_u_ph_result_v1-3	Lab Urine: pH Urine Results	Lab Urine: pH Urine Results	.F="No Form" .N="Not Applicable"
lab_u_ph_value_v1-3	Lab Urine: pH Urine Value	Lab Urine: pH Urine Value	Numeric .F="No Form"
lab_u_prot_qual_clinsig_v1-3	Lab Urine: Protein Qualitative Urine Clinically Significant	Lab Urine: Protein Qualitative Urine Clinically Significant	.F="No Form" 0="No"
lab_u_prot_qual_labdone_v1-3	Lab Urine: Protein Qualitative Urine Lab Test Done	Lab Urine: Protein Qualitative Urine Lab Test Done	.F="No Form" .N="Not Applicable"
lab_u_prot_qual_oor_v1-3	Lab Urine: Protein Qualitative Urine Out Of Range	Lab Urine: Protein Qualitative Urine Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_u_prot_qual_result_v1-3	Lab Urine: Protein Qualitative Urine Results	Lab Urine: Protein Qualitative Urine Results	.F="No Form" .N="Not Applicable" 0="Negative"
lab_u_prot_qual_value_v1-3	Lab Urine: Protein Qualitative Urine Value	Lab Urine: Protein Qualitative Urine Value	Numeric .F="No Form" .N="Not Applicable" 99.1="1+" 99.2="2+"
lab_u_rbc_clinsig_v1-3	Lab Urine: Red Blood Cells (RBC) Microscopy # Urine Clinically Significant	Lab Urine: Red Blood Cells (RBC) Microscopy # Urine Clinically Significant	.F="No Form" 0="No"
lab_u_rbc_labdone_v1-3	Lab Urine: Red Blood Cells (RBC) Microscopy # Urine Lab Test Done	Lab Urine: Red Blood Cells (RBC) Microscopy # Urine Lab Test Done	.F="No Form" .N="Not Applicable"
lab_u_rbc_oor_v1-3	Lab Urine: Red Blood Cells (RBC) Microscopy # Urine Out Of Range	Lab Urine: Red Blood Cells (RBC) Microscopy # Urine Out Of Range	.F="No Form" 0="No" 1="Yes"
lab_u_rbc_result_v1-3	Lab Urine: Red Blood Cells (RBC) Microscopy # Urine Results	Lab Urine: Red Blood Cells (RBC) Microscopy # Urine Results	.F="No Form" .N="Not Applicable" 0="Negative"
lab_u_rbc_value_v1-3	Lab Urine: Red Blood Cells (RBC) Microscopy # Urine Value	Lab Urine: Red Blood Cells (RBC) Microscopy # Urine Value	Numeric .F="No Form" .N="Not Applicable" 99.1="1+" 99.2="2+" 99.3="3+"
lab_u_sample_col_dt_v1-3	Sample Collection Date	Sample Collection Date	SAS Date .F="No Form"
lab_u_specific_g_clinsig_v1-3	Lab Urine: Specific Gravity Urine Clinically Significant	Lab Urine: Specific Gravity Urine Clinically Significant	.F="No Form" 0="No"
lab_u_specific_g_labdone_v1-3	Lab Urine: Specific Gravity Urine Lab Test Done	Lab Urine: Specific Gravity Urine Lab Test Done	.F="No Form" .N="Not Applicable"
lab_u_specific_g_oor_v1-3	Lab Urine: Specific Gravity Urine Out Of Range	Lab Urine: Specific Gravity Urine Out Of Range	.F="No Form" 0="No" 1="Yes"

Variable	Label	Description	Format Text
lab_u_specific_g_result_v1-3	Lab Urine: Specific Gravity Urine Results	Lab Urine: Specific Gravity Urine Results	.F="No Form" .N="Not Applicable"
lab_u_specific_g_value_v1-3	Lab Urine: Specific Gravity Urine Value	Lab Urine: Specific Gravity Urine Value	Numeric .F="No Form"
lab_u_target_days_from_bsl_v1-3	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"

Section 10: Baseline Events

Variable	Label	Description	Format Text
ev_bsl_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
event_bsl_comp_dt	If Off Study And Completed WIWI Questionnaire, Date Completed	If Off Study And Completed WIWI Questionnaire, Date Completed	SAS Date .F="No Form" .N="Not Applicable"
event_bsl_protocol	What Protocol Intervention Will The Participant Receive For The First Cycle?	What Protocol Intervention Will The Participant Receive For The First Cycle?	.F="No Form" 1="Day 1" 99="No Treatment (Off Study)"
event_bsl_wiwi	(If No Treatment(Off Study)), Did The Participant Complete The Was It Worth It (WIWI) Questionnaire?	(If No Treatment(Off Study)), Did The Participant Complete The Was It Worth It (WIWI) Questionnaire?	.F="No Form" .N="Not Applicable" 0="No"

Section 11: Alcohol Questionnaire Baseline

Variable	Label	Description	Format Text
acl_bsl_years_drink_spec	Other Specify, Years Drinking Regularly	How Many Years Have You Been Drinking (Or Did You Drink) Regularly? (If No Answer)	.M="Missing" .N="Not Applicable" 8="Choose not to answer" 9="Don't Know/Not sure"
alc_binge_days	In The Past 30 Days, On How Many Days Did You Have 5 Or More Drinks Per Day?	In The Past 30 Days, On How Many Days Did You Have 5 Or More Drinks Per Day?	Numeric .F="No Form" .N="Not Applicable"
alc_binge_days_spec	Other Specify, Days With 5 Or More Drinks	In The Past 30 Days, On How Many Days Did You Have 5 Or More Drinks Per Day? (Specify)	.F="No Form" .N="Not Applicable"
alc_bsl_age_drinking	At What Age Did You Begin Drinking Regularly?	At What Age Did You Begin Drinking Regularly?	Numeric .M="Missing" .N="Not Applicable"
alc_bsl_age_drinking_spec	Other Specify, Age Started Drinking Regularly	At What Age Did You Begin Drinking Regularly? (If No Answer)	.M="Missing" .N="Not Applicable" 9="Don't Know/Not sure"
alc_bsl_beer_use	Do You Drink Beer?	Do You Drink Beer?	.N="Not Applicable" 0="No" 1="Yes" 8="Choose not to answer"
alc_bsl_binge_days	In The Past 12 Months, On How Many Days Did You Have 5 Or More Drinks Of Any Alcoholic Beverage?	In The Past 12 Months, On How Many Days Did You Have 5 Or More Drinks Of Any Alcoholic Beverage?	Numeric .M="Missing" .N="Not Applicable"
alc_bsl_binge_days_spec	Other Specify, Days With 5 Or More Drinks	In The Past 12 Months, On How Many Days Did You Have 5 Or More Drinks Of Any Alcoholic Beverage? (If No Answer)	.M="Missing" .N="Not Applicable" 9="Don't Know/Not sure"
alc_bsl_drink_freq	In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcoholic Beverage?	In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcoholic Beverage?	Numeric .M="Missing" .N="Not Applicable"
alc_bsl_drink_freq_spec	Other Specify, Average Days Drinking In Past 12 Months	In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcoholic Beverage? (If More Than 0)	.M="Missing" .N="Not Applicable" 1="Week" 2="Month" 3="Year" 9="Don't know/Not sure"
alc_bsl_drinks_day	In The Past 12 Months, On Those Days That You Drank Alcoholic How Many Drinks Did You Have Per Day?	In The Past 12 Months, On Those Days That You Drank Alcoholic How Many Drinks Did You Have Per Day?	Numeric .M="Missing" .N="Not Applicable"

Variable	Label	Description	Format Text
alc_bsl_drinks_day_spec	Other Specify, Drinks Per Day In Past 12 Months	In The Past 12 Months, On Those Days That You Drank Alcoholic How Many Drinks Did You Have Per Day? (If No Answer)	.M="Missing" .N="Not Applicable" 8="Choose not to answer" 9="Don't Know/Not sure"
alc_bsl_everyday_binge	Have You Ever Drank 5 Or More Drinks Of Any Kind Of Alcoholic Beverage Almost Every Day?	Was There Ever A Time Or Times In Your Life When You Drank 5 Or More Drinks Of Any Kind Of Alcoholic Beverage Almost Every Day?	.M="Missing" .N="Not Applicable" 0="No" 9="Don't know/Not sure"
alc_bsl_had_12_drinks_ever	In Your Entire Life, Have You Had At Least 12 Drinks Of Any Kind Of Alcoholic Beverage?	In Your Entire Life, Have You Had At Least 12 Drinks Of Any Kind Of Alcoholic Beverage?	Numeric
alc_bsl_liquor_use	Do You Drink Liquor?	Do You Drink Liquor?	.N="Not Applicable" 0="No" 1="Yes" 8="Choose not to answer"
alc_bsl_most_drank	At The Heaviest Point, About How Many Drinks Did You Drink A Day On The Average?	At The Heaviest Point, Either Now Or In The Past, On The Days When You Drank, About How Many Drinks Did You Drink A Day On The Average?	Numeric .M="Missing" .N="Not Applicable"
alc_bsl_most_drank_spec	Other Specify, Heaviest Point Drinks Per Day Average	At The Heaviest Point, Either Now Or In The Past, On The Days When You Drank, About How Many Drinks Did You Drink A Day On The Average? (If No Answer)	.M="Missing" .N="Not Applicable" 8="Choose not to answer" 9="Don't Know/Not sure"
alc_bsl_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric
alc_bsl_time_since_drank	If You Don't Currently Drink, How Long Has It Been Since You Last Drank Regularly?	If You Do Not Currently Drink Alcoholic Beverages, But Did In The Past, How Long Has It Been Since You Last Drank Regularly?	.M="Missing" .N="Not Applicable" 0="Within the past month (0 to 1 month ago)" 1="Between 1 and 3 months (1 to 3 months ago)" 3="Between 6 and 12 months (6 to 12 months ago)" 4="Between 1 and 5 years (1 to 5 years ago)" 7="Never drank regularly" 8="Choose not to answer" 9="Don't know/Not sure"
alc_bsl_wine_cooler_use	Do You Drink Wine Coolers?	Do You Drink Wine Coolers?	.N="Not Applicable" 0="No" 1="Yes" 8="Choose not to answer"
alc_bsl_wine_use	Do You Drink Wine?	Do You Drink Wine?	.N="Not Applicable" 0="No" 1="Yes" 8="Choose not to answer"
alc_bsl_years_drink	How Many Years Have You Been Drinking (Or Did You Drink) Regularly?	How Many Years Have You Been Drinking (Or Did You Drink) Regularly?	Numeric .M="Missing" .N="Not Applicable"

Section 12: Tobacco Questionnaire Baseline

Variable	Label	Description	Format Text
tob_bsl_100_cigs	Have You Smoked At Least 100 Cigarettes (5 Packs) In Your Entire Life?	Have You Smoked At Least 100 Cigarettes (5 Packs) In Your Entire Life?	0="No"
tob_bsl_2nd_hand_smoke	Second-Hand Smoke Exposure	(Answered Section) Second-Hand Smoke Exposure	1="Checked"
tob_bsl_age_first_smoke	How Old Were You When You First Smoked A Cigarette?	How Old Were You When You First Smoked A Cigarette?	Numeric .N="Not Applicable"
tob_bsl_age_first_smoke_reg	How Old Were You When You First Began Smoking Cigarettes Regularly?	How Old Were You When You First Began Smoking Cigarettes Regularly?	Numeric .N="Not Applicable"
tob_bsl_age_first_smoke_reg_spec	Other Specify, Age When You First Smoked A Cigarette	How Old Were You When You First Began Smoking Cigarettes Regularly? Specify	.N="Not Applicable"
tob_bsl_age_first_smoke_spec	Other Specify, Age When You First Smoked A Cigarette	How Old Were You When You First Smoked A Cigarette? Specify	.N="Not Applicable"
tob_bsl_child_smoke_live	Have You Ever Lived In A Place Where Other People Smoked Cigarettes Indoors?	Have You Ever Lived In A Place Where Other People Smoked Cigarettes Indoors?	.N="Not Applicable" 0="No" 1="Yes" 9="Choose not to answer"
tob_bsl_child_smoke_years	(If Yes), In Total, For About How Many Years?	(If Yes), In Total, For About How Many Years?	Numeric .N="Not Applicable"
tob_bsl_cig_after_wake	How Soon After You Wake Up Do You Smoke Your First Cigarette?	How Soon After You Wake Up Do You Smoke Your First Cigarette?	.N="Not Applicable"
tob_bsl_cigs_per_day	On Average, When You Smoked, About How Many Cigarettes Do/Did You Smoke A Day?	On Average, When You Smoked, About How Many Cigarettes Do/Did You Smoke A Day?	Numeric .N="Not Applicable"
tob_bsl_cigs_per_day_spec	Other Specify, Cigarettes Per Day	On Average, When You Smoked, About How Many Cigarettes Do/Did You Smoke A Day? Specify	.N="Not Applicable"
tob_bsl_current_smoke	Do You Now Smoke Cigarettes?	Do You Now Smoke Cigarettes?	.N="Not Applicable"
tob_bsl_days_last_cig	1-7 Days Since Last Cigarette	1-7 Days Since Last Cigarette	.N="Not Applicable"
tob_bsl_ever_other_forms	Have You Ever Used Other Forms Of Tobacco, Not Including Cigarettes?	Have You Ever Used Other Forms Of Tobacco, Not Including Cigarettes?	0="No"
tob_bsl_freq_other_forms	How Often Do You/Did You Use Other Forms Of Tobacco?	(Answered Section) How Often Do You/Did You Use Other Forms Of Tobacco?	1="Checked"

Variable	Label	Description	Format Text
tob_bsl_how_long_other_forms	How Long Has It Been Since You Last Used Other Forms Of Tobacco Regularly?	How Long Has It Been Since You Last Used Other Forms Of Tobacco Regularly?	.N="Not Applicable"
tob_bsl_how_long_since_cig	How Long Has It Been Since You Last Smoked A Cigarette?	(Answered Section) How Long Has It Been Since You Last Smoked A Cigarette?	1="Checked"
tob_bsl_last_time_smoked	Last Time Smoked (Choose Not To Answer)	(Answered Section) Last Time Smoked (Choose Not To Answer)	.N="Not Applicable"
tob_bsl_less_1_month_cig	Less Than 1 Month Since Last Cigarette	Less Than 1 Month Since Last Cigarette	.N="Not Applicable"
tob_bsl_less_1_year_cig	Less Than 1 Year Since Last Cigarette	Less Than 1 Year Since Last Cigarette	.N="Not Applicable"
tob_bsl_live_with_smoker	Are You Currently Living With A Smoker?	Are You Currently Living With A Smoker?	0="No" 1="Yes" 9="Choose not to answer"
tob_bsl_live_with_smoker_30_day	In The Past 30 Days, Have You Lived In A Place Where Other People Smoked Cigarettes Indoors?	In The Past 30 Days, Have You Lived In A Place Where Other People Smoked Cigarettes Indoors?	0="No" 1="Yes" 9="Choose not to answer"
tob_bsl_more_1_year_cig	More Than 1 Year Since Last Cigarette	More Than 1 Year Since Last Cigarette	.N="Not Applicable"
tob_bsl_num_days_last_cig	(If Yes) Number Of Days Since Last Cigarette	(If Yes) Number Of Days Since Last Cigarette	Numeric .N="Not Applicable"
tob_bsl_num_months_last_cig	(If Yes) Number Of Months Since Last Cigarette	(If Yes) Number Of Months Since Last Cigarette	Numeric .N="Not Applicable"
tob_bsl_num_years_last_cig	(If Yes) Number Of Years Since Last Cigarette	(If Yes) Number Of Years Since Last Cigarette	Numeric .N="Not Applicable"
tob_bsl_other_forms	Use Of Other Forms Of Tobacco	(Answered Section) Use Of Other Forms Of Tobacco	1="Checked"
tob_bsl_other_forms_daily	Other Forms Of Tobacco: Every Day	Other Forms Of Tobacco: Every Day	.N="Not Applicable"
tob_bsl_other_forms_num_days	Other Forms Of Tobacco: (If Yes), Number Of Days	Other Forms Of Tobacco: (If Yes), Number Of Days	.N="Not Applicable"
tob_bsl_other_forms_num_per_day	Other Forms Of Tobacco: (If Yes), Number Of Times Per Day	Other Forms Of Tobacco: (If Yes), Number Of Times Per Day	Numeric .N="Not Applicable"
tob_bsl_other_forms_per	Other Forms Of Tobacco: (If Yes), Per __	Other Forms Of Tobacco: (If Yes), Per __	Numeric .N="Not Applicable"
tob_bsl_other_forms_since_last	Since Your Last Visit, Have You Used Other Forms Of Tobacco, Not Including Cigarettes? (Choose Not To Answer)	Since Your Last Visit, Have You Used Other Forms Of Tobacco, Not Including Cigarettes? (Choose Not To Answer)	.N="Not Applicable"
tob_bsl_other_forms_some_days	Other Forms Of Tobacco: Some Days	Other Forms Of Tobacco: Some Days	.N="Not Applicable"
tob_bsl_other_forms_spec	Other Forms Of Tobacco: Usage Specify	Other Forms Of Tobacco: Usage Specify	Numeric .N="Not Applicable"

Variable	Label	Description	Format Text
tob_bsl_smoke_today	I Smoked A Cigarette Today (At Least One Puff)	I Smoked A Cigarette Today (At Least One Puff)	.N="Not Applicable"
tob_bsl_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric
tob_bsl_tobacco_product	Tobacco Product	Tobacco Product	.N="Not Applicable"
tob_bsl_tobacco_use	Tobacco Use	Tobacco Use	.N="Not Applicable"
tob_bsl_unknown_last_cig	Don't Know/Don't Remember Last Time Smoked Cigarette	Don't Know/Don't Remember Last Time Smoked Cigarette	.N="Not Applicable"
tob_bsl_weeks_last_cig	(If Yes) Number Of Weeks Since Last Cigarette	(If Yes) Number Of Weeks Since Last Cigarette	Numeric .N="Not Applicable"
tob_bsl_which_other_forms	Which Of The Following Products Have You Ever Used Regularly?	(Answered Section) Which Of The Following Products Have You Ever Used Regularly?	1="Checked"
tob_bsl_work_smoke_inside	Have You Ever Worked In A Place Where Other People Smoked Cigarettes Indoors?	Have You Ever Worked In A Place Where Other People Smoked Cigarettes Indoors?	.N="Not Applicable" 0="No" 1="Yes" 9="Choose not to answer"
tob_bsl_work_smoke_inside_30	In The Past 30 Days, Have You Worked In A Place Where Other People Smoked Cigarettes Indoors?	In The Past 30 Days, Have You Worked In A Place Where Other People Smoked Cigarettes Indoors?	0="No" 1="Yes" 9="Choose not to answer"
tob_bsl_work_smoke_inside_yrs	Have You Ever Worked In A Place Where Other People Smoked Cigarettes Indoors? For About How Many Years?	Have You Ever Worked In A Place Where Other People Smoked Cigarettes Indoors? For About How Many Years?	Numeric .N="Not Applicable"
tob_bsl_years_smoked	How Many Total Years Have You Smoked (Did You Smoke) Cigarettes?	How Many Total Years Have You Smoked (Did You Smoke) Cigarettes?	Numeric .N="Not Applicable"
tob_bsl_years_smoked_spec	Other Specify, Years Smoked Cigarettes	How Many Total Years Have You Smoked (Did You Smoke) Cigarettes? Specify	.N="Not Applicable"

Section 13: Registration Steps

Variable	Label	Description	Format Text
step_event_desc1-2	Step Event Description	Step Event Description	.N="Not Applicable" 0="Pre-Registration" 1="Registration/Randomization"
step_event_dt1-2	Step Event Date	Step Event Date	SAS Date .N="Not Applicable"
step_event_time1-2	Step Event Time	Step Event Time	Numeric .N="Not Applicable"

Section 14: Registration Checklist

Variable	Label	Description	Format Text
reg_chklist_ab_anc	ANC Value	ANC Value	Numeric .F="No Form"
reg_chklist_alt	ALT	ALT	Numeric .F="No Form"
reg_chklist_alt_low	ALT (SGPT) <= 1.5 x Institutional Upper Limit Of Normal (ULN)	ALT (SGPT) <= 1.5 x Institutional Upper Limit Of Normal (ULN)	.F="No Form" 1="Yes"
reg_chklist_alt_upper_limit	ALT Upper Limit	ALT Upper Limit	Numeric .F="No Form"
reg_chklist_ast	AST Value	AST Value	Numeric .F="No Form"
reg_chklist_ast_low	AST (SGOT) <= 1.5 x Institutional Upper Limit Of Normal (ULN)	AST (SGOT) <= 1.5 x Institutional Upper Limit Of Normal (ULN)	.F="No Form" 1="Yes"
reg_chklist_ast_upper_limit	AST Upper Normal Limit	AST Upper Normal Limit	Numeric .F="No Form"
reg_chklist_bili_lower_limit	Bilirubin Lower Limit	Bilirubin Lower Limit	Numeric .F="No Form"
reg_chklist_bili_upper_limit	Bilirubin Upper Limit	Bilirubin Upper Limit	Numeric .F="No Form"
reg_chklist_bilirubin	Bilirubin Value	Bilirubin Value	Numeric .F="No Form"
reg_chklist_bmi_low	Body Mass Index < 35Kg/m	Body Mass Index < 35Kg/m	.F="No Form" 1="Yes"
reg_chklist_bsl_eval_in_guide	Baseline Evaluations Must Be Completed Within Guidelines	Baseline Evaluations Must Be Completed Within Guidelines	.F="No Form" .N="Not Applicable" 1="Yes"
reg_chklist_bsl_symptoms_doc	All Baseline Symptoms Must Be Documented And Graded	All Baseline Symptoms Must Be Documented And Graded	.F="No Form" .N="Not Applicable" 1="Yes"
reg_chklist_case	Case Number	Case Number	Numeric .F="No Form"
reg_chklist_creat_upper_limit	Creatinine Upper Normal Limit	Creatinine Upper Normal Limit	Numeric .F="No Form"
reg_chklist_created_dt	Created Date	Created Date	SAS Date .F="No Form"
reg_chklist_creatinine	Creatinine Value	Creatinine Value	Numeric .F="No Form"
reg_chklist_creatinine_low	Creatinine <= Institutional Upper Limit Of Normal (ULN)	Creatinine <= Institutional Upper Limit Of Normal (ULN)	.F="No Form" 1="Yes"
reg_chklist_eligible	Is Participant Eligible?	Is Participant Eligible?	.F="No Form" 1="Yes"

Variable	Label	Description	Format Text
reg_chklist_intervention_14	Intervention Cannot Begin Prior To Registration And Must Begin <= 14 Days After	Intervention Cannot Begin Prior To Registration And Must Begin <= 14 Days After	.F="No Form" 1="Yes"
reg_chklist_intervention_at_cpn	Intervention Must Commence At A CPN Institution Under CPN Clinician Supervision	Intervention Must Commence At A CPN Institution Under CPN Clinician Supervision	.F="No Form" 1="Yes"
reg_chklist_leukocyte	Leukocytes	Leukocytes	Numeric .F="No Form"
reg_chklist_leukocytes_high	Leukocytes >= 3x10^3/microliter (B/L)	Leukocytes >= 3x10^3/microliter (B/L)	.F="No Form" 1="Yes"
reg_chklist_neutrophil_high	Absolute Neutrophil Count >= 1.5x10^3/microliter (B/L)	Absolute Neutrophil Count >= 1.5x10^3/microliter (B/L)	.F="No Form" 1="Yes"
reg_chklist_platelet	Platelets	Platelets	Numeric .F="No Form"
reg_chklist_platelets_high	Platelets >= 100x10^3/microliter (B/L)	Platelets >= 100x10^3/microliter (B/L)	.F="No Form" 1="Yes"
reg_chklist_version	Version	Version	Numeric .F="No Form"

Section 15: Registration Inclusion/Exclusion

Variable	Label	Description	Format Text
reg_exc_fail_drug_screen	Use Of Any Illicit Or Illegal Substances Detected By Urinary Drug Screen	Use Of Any Illicit Or Illegal Substances Detected By Urinary Drug Screen	.F="No Form" 0="No"
reg_exc_sigmoid	Sigmoidoscopy Findings Requiring Clinical Intervention	Sigmoidoscopy Findings Requiring Clinical Intervention	.F="No Form" 0="No"
reg_exc_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
reg_inc_no_adenomas	No Findings In Rectum Of Advanced Adenoma, Chronic Inflammation, Or Cancer	No Findings In Rectum Of Advanced Adenoma, Chronic Inflammation, Or Cancer	.F="No Form" 1="Yes"
reg_inc_normal	Normal Organ Function And Normal Lab Findings	Normal Organ Function And Normal Lab Findings	.F="No Form" 1="Yes"
reg_inc_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"

Section 16: Screen Information

Variable	Label	Description	Format Text
screen_criteria_not_met	If No, Which Screening Criteria Not Met?	If No, Which Screening Criteria Not Met?	.N="Not Applicable" 1="Did not meet other eligibility criteria, specify" 2="Participant decision, specify" 3="Other, specify"
screen_criteria_not_met_spec	If No, Which Screening Criteria Not Met? Specify	If No, Which Screening Criteria Not Met? Specify	Char
screen_dt	Screen Completion Date	Screen Completion Date	SAS Date
screen_meet_criteria	Does Participant Meet Screening Criteria?	Does Participant Meet Screening Criteria?	0="No" 1="Yes"
screen_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric

Section 17: Physical Exam

Variable	Label	Description	Format Text
phys_abdomen_v1-3	Physical Exam Status: Abdomen	Physical Exam Status: Abdomen	.N="Not Applicable" 1="Normal"
phys_allergies_v1-3	Allergies?	Allergies?	.F="No Form" 0="No" 1="Yes"
phys_allergy_spec_v1-3	Allergies, Specify	Allergies, Specify	Char
phys_appearance_v1-3	Physical Exam Status: Appearance	Physical Exam Status: Appearance	.N="Not Applicable" 1="Normal"
phys_bmi_v1-3	BMI (kg/m^2)	BMI (kg/m^2)	Numeric .F="No Form" .N="Not Applicable"
phys_cardio_v1-3	Physical Exam Status: Cardiovascular	Physical Exam Status: Cardiovascular	.N="Not Applicable" 1="Normal"
phys_comments_v1-3	Physical Exam Comments	Physical Exam Comments	Char
phys_diastolic_v1-3	Diastolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Numeric .F="No Form"
phys_ecg_result_v1-3	ECG Results	ECG Results	.F="No Form" .N="Not Applicable" 1="Normal" 3="Abnormal, Not Clinically Significant"
phys_ecog_stat_v1-3	Performance Status (ECOG)	Performance Status (ECOG)	Numeric .F="No Form" .N="Not Applicable"
phys_evaluation_dt_v1-3	Physical Exam Evaluation Date	Physical Exam Evaluation Date	SAS Date .F="No Form"
phys_ex_target_days_from_bsl_v1-3	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
phys_heent_v1-3	Physical Exam Status: H/E/E/N/T	Physical Exam Status: H/E/E/N/T	.N="Not Applicable" 1="Normal"
phys_height_v1-3	Height (cm)	Height (cm)	Numeric .F="No Form" .N="Not Applicable"
phys_musculoskeletal_v1-3	Physical Exam Status: Musculoskeletal	Physical Exam Status: Musculoskeletal	.N="Not Applicable" 1="Normal"
phys_oth_eval_spec	Other Body System Specify	Other Body System Specify	Char
phys_oth_eval_stat	Other Body System Status	Other Body System Status	.N="Not Applicable" 2="Abnormal"
phys_pulse_v1-3	Pulse	Pulse	Numeric .F="No Form"
phys_resp_v1-3	Physical Exam Status: Respiratory	Physical Exam Status: Respiratory	.N="Not Applicable" 1="Normal"

Variable	Label	Description	Format Text
phys_skin_v1-3	Physical Exam Status: Skin	Physical Exam Status: Skin	.N="Not Applicable" 1="Normal"
phys_systolic_v1-3	Systolic Blood Pressure (mmHg)	Systolic Blood Pressure (mmHg)	Numeric .F="No Form"
phys_temperature_v1-3	Temperature (C)	Temperature (C)	Numeric .F="No Form" .N="Not Applicable"
phys_thyroid_v1-3	Physical Exam Status: Thyroid	Physical Exam Status: Thyroid	.N="Not Applicable" 1="Normal"
phys_visit_with_abnormality	Visit Number With Documented Abnormality	Visit Number With Documented Abnormality	Numeric .N="Not Applicable"
phys_weight_v1-3	Weight (kg)	Weight (kg)	Numeric .F="No Form"

Section 18: Medical and Surgical History

Variable	Label	Description	Format Text
med_hist_body_sys_spec1-6	Body System/Site, Specify	Body System/Site, Specify	Char
med_hist_body_system1-6	Body System/Site	Body System/Site	.N="Not Applicable" 1="Abdomen" 2="Dermatologic" 3="HEENT" 4="Immune" 5="Musculoskeletal" 6="Psychologic" 7="Respiratory" 9="Other"
med_hist_comments1-6	Medical/Surgical History Comments	Medical/Surgical History Comments	Char
med_hist_description1-6	Description	Description	Char
med_hist_diagnosis1-6	Diagnosis/Surgical Procedure	Diagnosis/Surgical Procedure	Char
med_hist_dx_month1-6	Month Of Diagnosis/Surgery	Month Of Diagnosis/Surgery	Numeric .N="Not Applicable"
med_hist_dx_year1-6	Year Of Diagnosis/Surgery	Year Of Diagnosis/Surgery	Numeric .N="Not Applicable"
med_hist_evaluation_dt	Medical/Surgical History Evaluation Date	Medical/Surgical History Evaluation Date	SAS Date
med_hist_none_reported	No Medical/Surgical History Reported	No Medical/Surgical History Reported	0="Unchecked" 1="Checked"
med_hist_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric
num_med_surg_hist	Number of Medical/Surgical Histories Reported	Number of Medical/Surgical Histories Reported	Numeric

Section 19: Endoscopy

Variable	Label	Description	Format Text
endo_target_days_from_bsl_v1-2	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
endoscopy_all_polyp_rem_v1-2	(If Any Polyps > 2 mm) Were All Rectal Polyps > 2mm Removed?	(If Any Polyps > 2 mm) Were All Rectal Polyps > 2mm Removed?	.F="No Form" .N="Not Applicable" 0="No" 1="Yes" 2="N/A"
endoscopy_bbpss_v1-2	Boston Bowel Preparation Scale Score	Boston Bowel Preparation Scale Score	Numeric .F="No Form"
endoscopy_bowel_prep_v1-2	Was Bowel Preparation Adequate?	Was Bowel Preparation Adequate?	.F="No Form" 0="No" 1="Yes"
endoscopy_comments_v1-2	Endoscopy Comments	Endoscopy Comments	Char
endoscopy_comp_v1-2	Endoscopy Completed	Endoscopy Completed	.F="No Form" 1="Yes"
endoscopy_dt_v1-2	Endoscopy Date	Endoscopy Date	SAS Date .F="No Form"
endoscopy_end_time_v1-2	Endoscopy End Time	Endoscopy End Time	Numeric .F="No Form"
endoscopy_last_meal_dt_v1-2	Last Meal Date	Last Meal Date	SAS Date .F="No Form"
endoscopy_last_meal_time_v1-2	Last Meal Time	Last Meal Time	Numeric .F="No Form"
endoscopy_num_2_to_4_v1-2	Number Of 2-4 mm Polyps	Number Of 2-4 mm Polyps	Numeric .F="No Form" .N="Not Applicable"
endoscopy_num_5_to_9_v1-2	Number of 5-9 mm Polyps	Number of 5-9 mm Polyps	Numeric .F="No Form" .N="Not Applicable"
endoscopy_num_larger_10_v1-2	Number Of >10 mm Polyps	Number Of >10 mm Polyps	Numeric .F="No Form" .N="Not Applicable"
endoscopy_result_v1-2	Endoscopy Results	Endoscopy Results	.F="No Form" .N="Not Applicable" 1="Normal" 2="Abnormal, specify"
endoscopy_results_spec_v1-2	Endoscopy Results, Specify	Endoscopy Results, Specify	Char
endoscopy_start_time_v1-2	Endoscopy Start Time	Endoscopy Start Time	Numeric .F="No Form"

Section 20: Treatment Assignment

Variable	Label	Description	Format Text
treat_assign_event1-2	Event	Event	.N="Not Applicable" 0="Pre-Registration" 1="Registration/Randomization"
treat_assign_event_dt1-2	Event Date - Pre-Registration	Event Date - Pre-Registration	SAS Date .N="Not Applicable"
treat_assign_event_dt1-2	Event Date - Registration/Randomization	Event Date - Registration/Randomization	SAS Date .N="Not Applicable"
treat_assign_event_time1-2	Event Time - Pre-Registration	Event Time - Pre-Registration	Numeric .N="Not Applicable"
treat_assign_event_time1-2	Event Time - Registration/Randomization	Event Time - Registration/Randomization	Numeric .N="Not Applicable"

Section 21: Treatment Events

Variable	Label	Description	Format Text
ev_tx_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
event_tx_comments	Event TX Comments	Event TX Comments	Char
event_tx_participant_cont	Will The Participant Continue To The Day 13/Early Termination Follow-Up Period?	Will The Participant Continue To The Day 13/Early Termination Follow-Up Period?	.F="No Form" 1="Yes"
event_tx_phys_exam	Was The Overall Physical Exam Performed?	Was The Overall Physical Exam Performed?	.F="No Form" 0="No" 1="Yes"

Section 22: End Active Treatment

Variable	Label	Description	Format Text
end_at_agent_end_dt	Agent End Date	Agent End Date	SAS Date .N="Not Applicable"
end_at_agent_not_obt	Agent Not Obtained	Agent Not Obtained	0="No" 1="Yes"
end_at_comments	End Active Treatment Comments	End Active Treatment Comments	Char
end_at_off_study_dt	Off Study Date	Off Study Date	SAS Date
end_at_reason	End Active Treatment Reason	End Active Treatment Reason	1="Study Complete" 2="Ineligible" 3="Adverse Event" 4="Participant Withdrawal" 5="Other"
end_at_reason_spec	End Active Treatment Reason, Specify	End Active Treatment Reason, Specify	Char
end_at_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric

Section 23: Intervention Form Data

Variable	Label	Description	Format Text
prot_data_agent_admin1-7	Agent Administered?	Agent Administered?	.F="No Form" 0="No" 1="Yes"
prot_data_comments	Protocol Data Comments	Protocol Data Comments	Char
prot_data_compliant	Compliant?	Compliant?	.F="No Form" 0="No" 1="Yes"
prot_data_dose	Dose (mg)	Dose (mg)	Numeric .F="No Form"
prot_data_dose_dt1-7	Dose Date	Dose Date	SAS Date .F="No Form" .N="Not Applicable"
prot_data_dose_time1-7	Dose Time	Dose Time	Numeric .F="No Form" .N="Not Applicable"
prot_data_fasting1-7	Fasting?	Fasting?	.F="No Form" .N="Not Applicable" 0="No" 1="Yes"
prot_data_hrs_since_last1-7	Hours Since Last Meal	Hours Since Last Meal	Numeric .F="No Form" .N="Not Applicable"
prot_data_last_meal_dt1-7	Last Meal Date	Last Meal Date	SAS Date .F="No Form" .N="Not Applicable"
prot_data_last_meal_time1-7	Last Meal Time	Last Meal Time	Numeric .F="No Form" .N="Not Applicable"
prot_data_not_comp_spec	If Not Compliant, Specify	If Not Compiant, Specify	Char
prot_data_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
prot_int_comp_wiwi	Completed Was It Worth It Questionnaire	Completed Was It Worth It Questionnaire	.F="No Form" 1="Yes"
prot_int_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
prot_int_uresolved_ae	Are There Any Unresolved Adverse Events?	Are There Any Unresolved Adverse Events?	.F="No Form" 0="No"
prot_int_wiwi_dt	Was It Worth It Questionnaire Completion Date	Was It Worth It Questionnaire Completion Date	SAS Date .F="No Form"

Section 24: Concomitant Medication

Variable	Label	Description	Format Text
conmed_continuing 1-4	Continuing Taking Medication?	Continuing Taking Medication?	.N="Not Applicable" 0="No" 1="Yes"
conmed_dose1-4	Medication Dose	Medication Dose	Numeric .N="Not Applicable"
conmed_end_dt1-4	Medication End Date	Medication End Date	SAS Date .N="Not Applicable"
conmed_freq1-4	Medication Frequency	Medication Frequency	Char
conmed_indication1 -4	Indication	Indication	Numeric .N="Not Applicable" 999="Other Specify"
conmed_indication_ spec1-4	Indication, Specify	Indication, Specify	Char
conmed_name1-4	Medication Name	Medication Name	Char
conmed_start_dt1-4	Medication Start Date	Medication Start Date	SAS Date .N="Not Applicable"
conmed_target_day s_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric
conmed_units1-4	Medication Units	Medication Units	Char
has_conmed	Has Concomitant Medication	Has Concomitant Medication	0="No" 1="Yes"
num_conmed	Number of Concomitant Medications	Number of Concomitant Medications	Numeric

Section 25: Alcohol Questionnaire

Variable	Label	Description	Format Text
alc_drink_days	During The Past 30 Days, How Many Days Per Week Did You Drink Any Alcoholic Beverages?	During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages?	Numeric .F="No Form" .M="Missing"
alc_drink_days_spec	Other Specify, Drinks Per Day In Last 30 Days	During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages? (Specify)	.F="No Form" .M="Missing" 1="Week" 2="Month"
alc_drink_last_30	During The Past 30 Days, Did You Drink Any Alcoholic Beverages?	During The Past 30 Days, Did You Drink Any Alcoholic Beverages?	.F="No Form" 0="No" 1="Yes"
alc_drinks_per_day	On The Days When You Drank, On Average, About How Many Drinks Did You Have?	On The Days When You Drank, On Average, About How Many Drinks Did You Have?	Numeric .F="No Form" .M="Missing"
alc_drinks_per_day_spec	Other Specify, Average Drinks Per Day	On The Days When You Drank, On Average, About How Many Drinks Did You Have? (Specify)	.F="No Form" .N="Not Applicable"
alc_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"

Section 27: Tobacco Questionnaire

Variable	Label	Description	Format Text
tob_cigs_per_day	On Average, When You Smoked, About How Many Cigarettes Do/Did You Smoke A Day?	On Average, When You Smoked, About How Many Cigarettes Do/Did You Smoke A Day?	Numeric .F="No Form" .N="Not Applicable"
tob_cigs_per_day_spec	On Average, When You Smoked, About How Many Cigarettes Do/Did You Smoke A Day? Specify	On Average, When You Smoked, About How Many Cigarettes Do/Did You Smoke A Day? Specify	Numeric .F="No Form" .N="Not Applicable"
tob_current_smoke	Do You Now Smoke Cigarettes?	Do You Now Smoke Cigarettes?	.F="No Form" 3="Not at all"
tob_days_last_cig	1-7 Days Since Last Cigarette	1-7 Days Since Last Cigarette	.F="No Form" .N="Not Applicable" 0="No"
tob_ever_other_forms	Since Your Last Visit, Have You Used Other Forms Of Tobacco, Not Including Cigarettes?	Since Your Last Visit, Have You Used Other Forms Of Tobacco, Not Including Cigarettes?	.F="No Form" 0="No"
tob_how_long_other_forms	How Long Has It Been Since You Last Used Other Forms Of Tobacco Regularly?	How Long Has It Been Since You Last Used Other Forms Of Tobacco Regularly?	.F="No Form" .N="Not Applicable"
tob_last_time_smoked	Last Time Smoked (Choose Not To Answer)	(Answered Section) Last Time Smoked (Choose Not To Answer)	.F="No Form" 0="Unchecked" 1="Checked"
tob_less_1_month_cig	Less Than 1 Month Since Last Cigarette	Less Than 1 Month Since Last Cigarette	.F="No Form" .N="Not Applicable" 0="No"
tob_less_1_year_cig	Less Than 1 Year Since Last Cigarette	Less Than 1 Year Since Last Cigarette	.F="No Form" .N="Not Applicable" 0="No"
tob_more_1_year_cig	More Than 1 Year Since Last Cigarette	More Than 1 Year Since Last Cigarette	.F="No Form" .N="Not Applicable" 0="No" 1="Yes"
tob_num_days_last_cig	(If Yes) Number Of Days Since Last Cigarette	(If Yes) Number Of Days Since Last Cigarette	Numeric .F="No Form" .N="Not Applicable"
tob_num_months_last_cig	(If Yes) Number Of Months Since Last Cigarette	(If Yes) Number Of Months Since Last Cigarette	Numeric .F="No Form" .N="Not Applicable"
tob_num_years_last_cig	(If Yes) Number Of Years Since Last Cigarette	(If Yes) Number Of Years Since Last Cigarette	Numeric .F="No Form" .N="Not Applicable"
tob_other_forms_daily	Other Forms Of Tobacco: Every Day	Other Forms Of Tobacco: Every Day	Numeric .F="No Form" .N="Not Applicable"

Variable	Label	Description	Format Text
tob_other_forms_freq	How Often Do You/Did You Use Other Forms Of Tobacco?	(Answered Section) How Often Do You/Did You Use Other Forms Of Tobacco?	.F="No Form" 1="Checked"
tob_other_forms_num_days	Other Forms Of Tobacco: (If Yes), Number Of Days	Other Forms Of Tobacco: (If Yes), Number Of Days	Numeric .F="No Form" .N="Not Applicable"
tob_other_forms_num_per_day	Other Forms Of Tobacco: (If Yes), Number Of Times Per Day	Other Forms Of Tobacco: (If Yes), Number Of Times Per Day	Numeric .F="No Form" .N="Not Applicable"
tob_other_forms_per	Other Forms Of Tobacco: (If Yes), Per __	Other Forms Of Tobacco: (If Yes), Per __	Numeric .F="No Form" .N="Not Applicable"
tob_other_forms_some_days	Other Forms Of Tobacco: Some Days	Other Forms Of Tobacco: Some Days	Numeric .F="No Form" .N="Not Applicable"
tob_other_forms_spec	Other Forms Of Tobacco: Usage Specify	Other Forms Of Tobacco: Usage Specify	Numeric .F="No Form" .N="Not Applicable"
tob_other_forms_types_since_last	Since Your Last Visit, Which Of The Following Products Have You Used?	(Answered Section) Since Your Last Visit, Which Of The Following Products Have You Used?	.F="No Form" 1="Checked"
tob_smoke_after_study_end	Did You Smoke After The End Of Study Treatment	Did You Smoke After The End Of Study Treatment	.F="No Form" .N="Not Applicable" 3="Did not smoke at all"
tob_smoke_during_study	Did You Smoke During Study Treatment	Did You Smoke During Study Treatment	.F="No Form" .N="Not Applicable" 3="Did not smoke at all"
tob_smoke_since_last_visit	Did You Smoke Since Your Last Visit To This Clinic	Did You Smoke Since Your Last Visit To This Clinic	.F="No Form" .N="Not Applicable" 3="Did not smoke at all"
tob_smoke_today	I Smoked A Cigarette Today (At Least One Puff)	(Answered Section) I Smoked A Cigarette Today (At Least One Puff)	.F="No Form" .N="Not Applicable" 0="Unchecked"
tob_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
tob_time_frame_freq	During Each Of The Following Time Frames (Last Time You Smoked), Please Indicate Whether You Smoked Cigarettes Every Day, Some Days, Or Not At All.	(Answered Section) During Each Of The Following Time Frames (Last Time You Smoked), Please Indicate Whether You Smoked Cigarettes Every Day, Some Days, Or Not At All.	.F="No Form" 1="Checked"
tob_time_since_last_sig	How Long Has It Been Since You Last Smoked A Cigarette (Even One Or Two Puffs)?	How Long Has It Been Since You Last Smoked A Cigarette (Even One Or Two Puffs)?	.F="No Form" 1="Yes"
tob_tobacco_product	Tobacco Product	Tobacco Product	.F="No Form" .N="Not Applicable"
tob_tobacco_use	Tobacco Use	Tobacco Use	.F="No Form" .N="Not Applicable"

Variable	Label	Description	Format Text
tob_unknown_last_cig	Don't Know/Don't Remember Last Time Smoked Cigarette	Don't Know/Don't Remember Last Time Smoked Cigarette	.F="No Form" .N="Not Applicable" 0="No" 1="Yes"
tob_weeks_last_cig	(If Yes) Number Of Weeks Since Last Cigarette	(If Yes) Number Of Weeks Since Last Cigarette	Numeric .F="No Form" .N="Not Applicable"

Section 28: CGMP Results

Variable	Label	Description	Format Text
cgmp_average_1_v1	cGMP Average Site 1 Day 0	cGMP Average Site 1 Day 0	Numeric .F="No Form"
cgmp_average_1_v2	cGMP Average Site 1 Day 7	cGMP Average Site 1 Day 7	Numeric .F="No Form"
cgmp_average_2_v1	cGMP Average Site 2 Day 0	cGMP Average Site 2 Day 0	Numeric .F="No Form"
cgmp_average_2_v2	cGMP Average Site 2 Day 7	cGMP Average Site 2 Day 7	Numeric .F="No Form"
cgmp_biop_site_1_1_v1	cGMP Biopsy Site 1-1 Day 0	cGMP Biopsy Site 1-1 Day 0	Numeric .F="No Form"
cgmp_biop_site_1_1_v2	cGMP Biopsy Site 1-1 Day 7	cGMP Biopsy Site 1-1 Day 7	Numeric .F="No Form" .M="Missing"
cgmp_biop_site_1_2_v1	cGMP Biopsy Site 1-2 Day 0	cGMP Biopsy Site 1-2 Day 0	Numeric .F="No Form"
cgmp_biop_site_1_2_v2	cGMP Biopsy Site 1-2 Day 7	cGMP Biopsy Site 1-2 Day 7	Numeric .F="No Form"
cgmp_biop_site_1_3_v1	cGMP Biopsy Site 1-3 Day 0	cGMP Biopsy Site 1-3 Day 0	Numeric .F="No Form"
cgmp_biop_site_1_3_v2	cGMP Biopsy Site 1-3 Day 7	cGMP Biopsy Site 1-3 Day 7	Numeric .F="No Form" .M="Missing"
cgmp_biop_site_2_1_v1	cGMP Biopsy Site 2-1 Day 0	cGMP Biopsy Site 2-1 Day 0	Numeric .F="No Form"
cgmp_biop_site_2_1_v2	cGMP Biopsy Site 2-1 Day 7	cGMP Biopsy Site 2-1 Day 7	Numeric .F="No Form"
cgmp_biop_site_2_2_v1	cGMP Biopsy Site 2-2 Day 0	cGMP Biopsy Site 2-2 Day 0	Numeric .F="No Form"
cgmp_biop_site_2_2_v2	cGMP Biopsy Site 2-2 Day 7	cGMP Biopsy Site 2-2 Day 7	Numeric .F="No Form"
cgmp_biop_site_2_3_v1	cGMP Biopsy Site 2-3 Day 0	cGMP Biopsy Site 2-3 Day 0	Numeric .F="No Form"
cgmp_biop_site_2_3_v2	cGMP Biopsy Site 2-3 Day 7	cGMP Biopsy Site 2-3 Day 7	Numeric .F="No Form"
cgmp_bite_v1	cGMP Bite Day 0	cGMP Bite Day 0	.F="No Form" 1="Bite 2/Bite 3" 2="Bite 2/Bite 5" 3="Bite 3/Bite 5"
cgmp_bite_v2	cGMP Bite Day 7	cGMP Bite Day 7	.F="No Form" 1="Bite 2/Bite 3" 2="Bite 2/Bite 5" 3="Bite 3/Bite 5"
cgmp_overall_average_v1	cGMP Overall Average Day 0	cGMP Overall Average Day 0	Numeric .F="No Form"

Variable	Label	Description	Format Text
cgmp_overall_average_v2	cGMP Overall Average Day 7	cGMP Overall Average Day 7	Numeric .F="No Form"
cgmp_std_dev_v1	cGMP Standard Deviation Day 0	cGMP Standard Deviation Day 0	Numeric .F="No Form"
cgmp_std_dev_v2	cGMP Standard Deviation Day 7	cGMP Standard Deviation Day 7	Numeric .F="No Form"
cgmp_variance_v1	cGMP Variance Day 0	cGMP Variance Day 0	Numeric .F="No Form"
cgmp_variance_v2	cGMP Variance Day 7	cGMP Variance Day 7	Numeric .F="No Form"

Section 29: CGMP Averages

Variable	Label	Description	Format Text
cgmp_biopsy_1_mean_v1	cGMP Biopsy Site 1 Mean Day 0	cGMP Biopsy Site 1 Mean Day 0	Numeric .F="No Form"
cgmp_biopsy_1_mean_v2	cGMP Biopsy Site 1 Mean Day 7	cGMP Biopsy Site 1 Mean Day 7	Numeric .F="No Form"
cgmp_biopsy_2_mean_v1	cGMP Biopsy Site 2 Mean Day 0	cGMP Biopsy Site 2 Mean Day 0	Numeric .F="No Form"
cgmp_biopsy_2_mean_v2	cGMP Biopsy Site 2 Mean Day 7	cGMP Biopsy Site 2 Mean Day 7	Numeric .F="No Form"
cgmp_overall_mean_v1	cGMP Overall Mean Day 0	cGMP Overall Mean Day 0	Numeric .F="No Form"
cgmp_overall_mean_v2	cGMP Overall Mean Day 7	cGMP Overall Mean Day 7	Numeric .F="No Form"

Section 30: Was It Worth It Questionnaire

Variable	Label	Description	Format Text
wiwi_comments	Was It Worth It Comments	Was It Worth It Comments	Char
wiwi_did_not_comp	Check Here If You Prefer Not To Complete This Questionnaire	Check Here If You Prefer Not To Complete This Questionnaire	.F="No Form" 0="Unchecked"
wiwi_improve_one_thing	If There Was One Thing That Could Have Been Done To Improve Your Experience In This Research Study, What Would It Be?	If There Was One Thing That Could Have Been Done To Improve Your Experience In This Research Study, What Would It Be?	Char
wiwi_life_quality_improve	Overall, Did Your Quality Of Life Change By Participating In This Research Study?	Overall, Did Your Quality Of Life Change By Participating In This Research Study?	.F="No Form" 1="It improved" 2="It stayed the same"
wiwi_not_add_resp	Check Here If You Prefer Not To Have Your Responses Added To Responses From Participants In Other Clinical Trials	Check Here If You Prefer Not To Have Your Responses Added To Responses From Participants In Other Clinical Trials	.F="No Form" 0="Unchecked"
wiwi_overall_experience	Overall, How Was Your Experience Of Participating In This Research Study?	Overall, How Was Your Experience Of Participating In This Research Study?	.F="No Form" 1="Better than I expected" 2="The same as I expected" 3="Worse than I expected"
wiwi_participate_again	If You Had To Do It Over, Would You Participate In This Research Study Again?	If You Had To Do It Over, Would You Participate In This Research Study Again?	.F="No Form" 0="No" 1="Yes" 2="Uncertain"
wiwi_recommend	Would You Recommend Participating In This Research Study To Others?	Would You Recommend Participating In This Research Study To Others?	.F="No Form" 0="No" 1="Yes" 2="Uncertain"
wiwi_talk_about_concerns	Would You Like To Talk To Someone About Your Concerns?	Would You Like To Talk To Someone About Your Concerns?	.F="No Form" 0="No" 1="Yes"
wiwi_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
wiwi_time_point	Time Point	Time Point	.F="No Form" 1="Yes" 2="Uncertain"
wiwi_was_it_worthwile	Was It Worthwhile For You To Participate In This Research Study?	Was It Worthwhile For You To Participate In This Research Study?	.F="No Form" 1="Yes" 2="Uncertain"

Section 31: Specimen Tissue Submission Form

Variable	Label	Description	Format Text
spec_t_target_days_from_bsl1-2	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form" .N="Not Applicable"
spec_tissue_comments1-2	Specimen Tissue Comments	Specimen Tissue Comments	Char
spec_tissue_dt_sent1-2	Date Tissue Samples Sent To Lab	Date Tissue Samples Sent To Lab	SAS Date .F="No Form" .N="Not Applicable"
spec_tissue_num_samples1-2	Number Of Biopsy Samples Collected	Number Of Biopsy Samples Collected	Numeric .F="No Form" .N="Not Applicable"
spec_tissue_store_cond1-2	Specimen Tissue Storage Conditions	Specimen Tissue Storage Conditions	.F="No Form" .N="Not Applicable" 1="Stored per protocol"

Section 32: Supporting Documentation

Variable	Label	Description	Format Text
num_support_docs	Number of Support Documents Recorded	Number of Support Documents Recorded	Numeric .F="No Form"
sup_doc_target_days_from_bsl	Days From Baseline That Form Was Supposed To Be Completed	Days From Baseline That Form Was Supposed To Be Completed	Numeric .F="No Form"
support_doc_attachment1-3	Attachment Name	Attachment Name	Char
support_doc_dt1-3	Date Of Assessment	Date Of Assessment	SAS Date .F="No Form" .N="Not Applicable"
support_doc_rep_type1-3	Report Type	Report Type	.F="No Form" .N="Not Applicable" 1="Endoscopy Report" 2="Pathology Report" 3="Other"
support_doc_rep_type_spec1-3	Report Type, Specify	Report Type, Specify	Char