

MAY2016-07-01 - Enhanced Person Data Dictionary

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Document Summary

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MAY2016-07-01 - Enhanced Person: Data Dictionary

Section 1: Identifiers

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

Section 2: Demographics

Class	Variable	Label	Description	Format Text
01. Principal	country	Country Of Residence		1="US" 2="PR"
01. Principal	demo_pay_method	Method Of Payment		1="Private Insurance" 2="Medicaid" 3="Medicare" 4="Medicare And Private Insurance" 9="Other"
01. Principal	demo_protocol	Protocol		Char
01. Principal	demo_site	Site		Char
01. Principal	demo_site_num	Site Number		Char
01. Principal	ethnicity	Ethnicity		0="Not Hispanic Or Latino" 1="Hispanic Or Latino"
01. Principal	gender	Gender		0="Female" 1="Male"
01. Principal	race	Race		1="White" 2="Black Or African American" 3="American Indian or Alaska Native" 9="Not Reported"

Section 3: Analysis

Class	Variable	Label	Description	Format Text
01. Principal	analysis_ae_gr2to3	Grade 2-3 Adverse Event		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	analysis_ae_rash	Rash Acneiform/Maculo-Papular		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	analysis_ae_rl3	Adverse Event, At Least Possibly Related		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	analysis_age	Age		Numeric .R="Not Randomized"
01. Principal	analysis_apc_genetic	APC Genetic Mutation		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	analysis_aspirin	Aspirin Use		.R="Not Randomized" 1="No Regular Use" 2="D81 mg Day"
01. Principal	analysis_bmi	BMI (kg/m ²)		Numeric .R="Not Randomized"
01. Principal	analysis_endatrsn	Off Study Reason		Char
01. Principal	analysis_ethnicity	Ethnicity		.R="Not Randomized" 0="Not Hispanic Or Latino" 1="Hispanic Or Latino"
01. Principal	analysis_eval	Evaluable For Primary Endpoint 1: Percent Change In Duodenal Polyp Burden (mm)		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	analysis_fap	FAP		.R="Not Randomized" 1="Classic" 2="Attenuated"
01. Principal	analysis_height	Height (cm)		Numeric .R="Not Randomized"
01. Principal	analysis_intstart_dt	Intervention Start Date		SAS Date .R="Not Randomized"
01. Principal	analysis_lifedrinks	In Your Entire Life, Have You Had At Least 12 Drinks Of Any Kind Of Alcoholic Beverage?		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	analysis_lowergi	Lower GI Status		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_polypdiam_absdiff	Absolute Change In Lower GI Polyp Burden (mm)		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	analysis_polytpdi am_bsl	Baseline Lower GI Polyp Burden (mm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_polytpdi am_mo6	Month 6 Lower GI Polyp Burden (mm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_polytpdi am_pctdiff	Percent Change In Lower GI Polyp Burden (mm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_polytpnu m_absdiff	Absolute Change In Lower GI Polyp Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_polytpnu m_bsl	Baseline Lower GI Polyp Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_polytpnu m_mo6	Month 6 Lower GI Polyp Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_polytpnu m_pctdiff	Percent Change In Lower GI Polyp Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_race	Race		.R="Not Randomized" 1="White" 2="Black Or African American" 9="Not Reported"
01. Principal	analysis_reg_dt	Registration Date		SAS Date .R="Not Randomized"
01. Principal	analysis_severity	Severity Of Duodenal Polyposis		.R="Not Randomized" 1="Spigelman 2" 2="Spigelman 3"
01. Principal	analysis_sex	Sex		.R="Not Randomized" 0="Female" 1="Male"
01. Principal	analysis_smoke1 00	Have You Smoked At Least 100 Cigarettes (5 Packs = 100 Cigarettes) In Your Entire Life?		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	analysis_specpro t_mo6	Month 6 Specimen Collection Protocol		.M="Missing" .R="Not Randomized" 1="Spigelman 2" 2="Spigelman 3"
01. Principal	analysis_sschg	Change In Spigelman Stage		.R="Not Randomized" 1="Downstaged" 2="Upstaged" 3="Unchanged" 9="Not Applicable"
01. Principal	analysis_totdia_a bsdif	Absolute Change In Duodenal Polyp Burden (mm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_totdia_b sl	Baseline Duodenal Polyp Burden (mm)		Numeric .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	analysis_totdia_mo6	Month 6 Duodenal Polyp Burden (mm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_totdia_pctdiff	Percent Change In Duodenal Polyp Burden (mm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_totduo_absdiff	Absolute Change In Duodenal Polyp Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_totduo_bsl	Baseline Duodenal Polyp Number		Numeric .R="Not Randomized"
01. Principal	analysis_totduo_mo6	Month 6 Duodenal Polyp Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_totduo_pctdiff	Percent Change In Duodenal Polyp Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	analysis_weight	Weight (kg)		Numeric .R="Not Randomized"

Section 4: Pre-Registration Checklist

Class	Variable	Label	Description	Format Text
01. Principal	chklist_pre_able_to_cosent	Ability To Understand And The Willingness To Sign A Written Informed Consent Document.		1="Yes"
01. Principal	chklist_pre_age	Age		Numeric
01. Principal	chklist_pre_agent_avail	Study Agent Is Available And Drug Shipment Authorization Has Been Granted To The Registering Site.		1="Yes"
01. Principal	chklist_pre_alc_tob_share	Participant Has Given Permission For Information From The Alcohol And Tobacco Use Assessment To Be Used In Future Health Research.		1="Yes"
01. Principal	chklist_pre_anticoag	Use Of Anticoagulation Medications, Including But Not Limited To Coumadin, Warfarin, Plavix.		0="No" 9="Not Applicable"
01. Principal	chklist_pre_auth_disc	Existence Of Authorization For Use And Disclosure Of Protected Health Information.		1="Yes" 9="Not Applicable"
01. Principal	chklist_pre_auth_res	Participant Has Given Permission To His/Her Doctor To Contact Them In The Future To Ask Them To Take Part In More Research.		1="Yes"
01. Principal	chklist_pre_biospec_oth_res	Participant Has Given Permission To Collect And Store Blood, Urine, And Tissue For Future Use In Research To Learn About, Prevent, Treat, Or Cure Cancer And Other Health Problems.		0="No" 1="Yes"
01. Principal	chklist_pre_biospec_other_inst	Participant Has Given Permission To Send Blood, Urine, And Tissue Specimens To Researchers At Outside Institutions.		1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	chklist_pre_biospec_protocol	Participant Has Given Permission To Collect And Store Blood, Urine And Tissue For Research Specified In This Protocol.		.M="Missing" 1="Yes"
01. Principal	chklist_pre_case_id	Case Number		Numeric
01. Principal	chklist_pre_consent_dt	Date Informed Consent Signed		SAS Date
01. Principal	chklist_pre_consent_signed	Consent Form Signed And Dated.		1="Yes"
01. Principal	chklist_pre_contact_dr	Participant Has Given Permission To Contact Him/Her Or His/Her Physician To Learn About The Results Of These Studies.		1="Yes"
01. Principal	chklist_pre_ctep	TAC/TAD Code		0="TAC-0 (Signed Informed Consent Document And Before Intervention)"
01. Principal	chklist_pre_cyp3a4	Use Of CYP3A4 Inducers		0="No"
01. Principal	chklist_pre_dc_number	Data Center Assigned Protocol Number		Char
01. Principal	chklist_pre_elig	Is The Participant Eligible For Inclusion On This Study?		1="Yes"
01. Principal	chklist_pre_enroll_dt	Enrollment Date		SAS Date
01. Principal	chklist_pre_eres_number	ERES Number		Char
01. Principal	chklist_pre_evaluation_guidelines	Baseline (Screening) Evaluations Must Be Completed Within The Guidelines Specified On The Schedule Of Events.		1="Yes"
01. Principal	chklist_pre_fap	Diagnosis Of Familial Adenomatous Polyposis (FAP) Or Attenuated Familial Adenomatous Polyposis (AFAP)		1="Yes"
01. Principal	chklist_pre_gi_surg	History Of Any Upper GI Surgery That Does Not Permit Access To Or Evaluation Of A 10 cm Segment Of The Duodenum That Includes The Duodenal Bulb		.M="Missing" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	chklist_pre_hist_allergy	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Erlotinib		0="No"
01. Principal	chklist_pre_in_age_range	Age 18 To 69		1="Yes"
01. Principal	chklist_pre_invasive_malign	History Of Invasive Malignancy <=3 Years Prior To Pre-Registration. Exception: Adequately Treated Carcinoma Of The Cervix, Carcinoma In Situ, Or Basal Or Squamous Cell Carcinomas Of The Skin.		0="No"
01. Principal	chklist_pre_oth_agents	Use Of Any Other Investigational Agents <=12 Weeks Prior To Pre-Registration		0="No"
01. Principal	chklist_pre_potent_cyp3a4	Use Of Potent CYP3A4 Inhibitors		0="No"
01. Principal	chklist_pre_pre_reg	Has The Participant Been Pre-Registered Previously To This Study?		0="No" 1="Yes"
01. Principal	chklist_pre_prev_id	If Yes: Prior Participant CPN ID Number:		Char
01. Principal	chklist_pre_prior_erlotinib	Any Prior Treatment With Erlotinib Or Other Agent Whose Primary Mechanism Of Action Is Known To Inhibit EGFR		0="No"
01. Principal	chklist_pre_reg_participants	Registration Office Personnel Will Automatically Register Participants Separately To The Translational Research Components Of The Study. run		1="Yes"
01. Principal	chklist_pre_study_id	Internal Study Number		Numeric
01. Principal	chklist_pre_uncontrolled_ill	Uncontrolled Intercurrent Illness Or Recent Surgical Procedure That In The Opinion Of The Investigative Team Would Limit Compliance With Study Requirements?		0="No"
01. Principal	chklist_pre_version_num	Version Number		Numeric

Class	Variable	Label	Description	Format Text
01. Principal	chklist_pre_willing_biospec	Willing To Provide Mandatory Biospecimens As Specified In The Protocol		1="Yes"
01. Principal	chklist_pre_willing_no_nsaids	Willing To Discontinue Taking NSAIDS For 30 Days Prior To Initiation Of And During Intervention.		1="Yes"
01. Principal	chklist_pre_willing_no_smoke	Willing To Discontinue Smoking For The Duration Of Study Intervention		1="Yes"

Section 5: Pre-Registration Eligibility Criteria

Class	Variable	Label	Description	Format Text
01. Principal	prechk_age_at_entry	Age At Entry		Numeric
01. Principal	prechk_age_range	Age (18 To 69)		1="Yes"
01. Principal	prechk_allergic_similar	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Erlotinib		0="No"
01. Principal	prechk_anticoag_meds	Individuals On Anticoagulation Medications Who Cannot Safely Discontinue The Medication For At Least 48 Hours Prior To The Study Endoscopy		0="No"
01. Principal	prechk_col_biopic	Participant Has Given Permission To Collect And Store Blood, Urine, And/Or Tissue Specimens And Related Information In A Biobank For Future Use In Research To Learn About, Prevent, Treat, Or Cure Cancer		0="No" 1="Yes"
01. Principal	prechk_contact_results	Participant Has Given Permission To Contact Him/Her Or His/Her Physician To Learn About The Results Of These Studies.		0="No" 1="Yes"
01. Principal	prechk_cyp3a4_inducer	Use Of Potent CYP3A4 Inducers, Including But Not Limited To Rifampicin, Rifabutin, Rifapentine, Phenytoin, Carbamazepine, Phenobarbital, And St. John's Wort'		0="No"
01. Principal	prechk_cyp3a4_inhib	Use Of Potent CYP3A4 Inhibitors, Including But Not Limited To Ketoconazole, Atazanavir, Clarithromycin, Indinavir, Itraconazole, Nefazodone...		0="No"

Class	Variable	Label	Description	Format Text
01. Principal	prechk_fap	Diagnosis Of Familial Adenomatous Polyposis (FAP) Or Attenuated Familial Adenomatous Polyposis (AFAP)		0="No" 1="Yes"
01. Principal	prechk_future_re s	Participant Has Given Permission For His/Her Doctor To Contact Them In The Future To Ask Them To Take Part In More Research		0="No" 1="Yes"
01. Principal	prechk_inv_mali gnancy	History Of Invasive Malignancy D 3 Years Prior To Pre-Registration.		0="No"
01. Principal	prechk_oth_inv_ agents	Use Of Any Other Investigational Agents 12 Weeks Prior To Pre-Registration		0="No"
01. Principal	prechk_prior_egf r	Any Prior Treatment With Erlotinib Or Other Agent Whose Primary Mechanism Of Action Is Known To Inhibit EGFR		0="No"
01. Principal	prechk_recurr_ill ness	Uncontrolled Intercurrent Illness Or Recent Surgical Procedure That Would Limit Compliance With Study Requirements		0="No"
01. Principal	prechk_share_re s_info	Participant Has Given Permission To Give His/Her Blood, Urine, And/Or Tissue Specimens And Related Information To Researchers At Outside Institutions.		0="No" 1="Yes"
01. Principal	prechk_target_da ys	Target Days From Baseline		Numeric
01. Principal	prechk_tob_alc_ q_use	Participant Has/Has Not Given Permission For Information From The Alcohol And Tobacco Use Assessment To Be Used In Future Health Research		0="No" 1="Yes"
01. Principal	prechk_up_gi_su rg	History Of Any Upper GI Surgery That Does Not Permit Access To Or Evaluation Of A 10 cm Segment Of The Duodenum That Includes The Duodenal Bulb		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	prechk_will_biospecimen	Willing To Provide Mandatory Biospecimens As Specified In The Protocol		1="Yes"
01. Principal	prechk_will_discnsaids	Willing To Discontinue Taking Nsaids For 30 Days Prior To Initiation Of And During Intervention.		1="Yes"
01. Principal	prechk_will_discsmoking	Willing To Discontinue Smoking For The Duration Of Study Intervention		1="Yes"
01. Principal	prechk_will_signicf	Able To Understand And The Willingness To Sign A Written Informed Consent Document		1="Yes"

Section 6: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	phyexam_abdomen_spec_v0-3	Abdomen Status: Abnormal Specify		Char
01. Principal	phyexam_abdomen_v0-3	Abdomen Status		.M="Missing" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phyexam_allergy_spec_v0-3	Does The Participant Have Any Allergies? Specify		Char
01. Principal	phyexam_allergy_v0-3	Does The Participant Have Any Allergies?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	phyexam_appearance_spec_v0-3	Appearance Status: Abnormal Specify		Char
01. Principal	phyexam_appearance_v0-3	Appearance Status		.M="Missing" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phyexam_cardio_spec_v0-3	Cardiovascular Status: Abnormal Specify		Char
01. Principal	phyexam_cardio_v0-3	Cardiovascular Status		.M="Missing" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phyexam_comments_v0-3	Physical Exam Comments		Char
01. Principal	phyexam_diastolic_bp_v0-3	Diastolic (mm Hg)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phyexam_ecog_score_v0-3	Performance Status (ECGO)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phyexam_eval_dt_v0-3	Evaluation Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	phyexam_height_v0-3	Height (cm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phyexam_muscle_spec_v0-3	Musculoskeletal Status: Abnormal Specify		Char

Class	Variable	Label	Description	Format Text
01. Principal	phyexam_musc_v0-3	Musculoskeletal Status		.M="Missing" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phyexam_pulse_v0-3	Pulse (bpm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phyexam_resp_spec_v0-3	Respiratory Status: Abnormal Specify		Char
01. Principal	phyexam_resp_v0-3	Respiratory Status		.M="Missing" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phyexam_skin_spec_v0-3	Skin Status: Abnormal Specify		Char
01. Principal	phyexam_skin_v0-3	Skin Status		.M="Missing" .R="Not Randomized" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	phyexam_systolic_bp_v0-3	Systolic (mm Hg)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phyexam_target_days_v0-3	Target Days From Baseline		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phyexam_temperature_v0-3	Body Temperature (C)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phyexam_visit_v0-3	Visit Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phyexam_weight_v0-3	Weight (kg)		Numeric .M="Missing" .R="Not Randomized"

Section 7: Medical And Surgical History

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_body_system1-44	Body System/Site		.M="Missing" .R="Not Randomized" 1="Abdomen" 2="Dermatologic" 3="H/E/E/N/T" 4="Immune" 5="Musculoskeletal" 6="Psychologic" 7="Respiratory" 8="Gastrointestinal" 9="Genitourinary" 10="Neurologic" 11="Cardiovascular" 12="Hematopoietic/Lymph Node(s)" 13="Pelvis" 14="Breasts" 15="Neck" 16="Endocrine/Metabolic" 99="Other"
01. Principal	medsurg_body_system_spec1-44	Body System/Site Specify		Char
01. Principal	medsurg_comments1-44	Medical And Surgical History Comments		Char
01. Principal	medsurg_dx_day1-44	Date Of Diagnosis/Surgery (Day Of The Month)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	medsurg_dx_dt1-44	Date Of Diagnosis/Surgery		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	medsurg_dx_month1-44	Date Of Diagnosis/Surgery (Month)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	medsurg_dx_proc1-44	Diagnosis/Surgical Procedure		Char
01. Principal	medsurg_dx_year1-44	Date Of Diagnosis/Surgery (Year)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	medsurg_eval_dt1-44	Evaluation Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	medsurg_target_days	Medical And Surgical History Target Days From Baseline		Numeric .R="Not Randomized"
01. Principal	medsurg_tx_comments1-44	Comments (Provide Treatment And/Or Comments)		Char

Section 8: Alcohol Baseline Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	alc_bsl_5_in_a_day	In The Past 30 Days, On How Many Days Did You Have 5 Or More Drinks Per Day?		Numeric .M="Missing" .R="Not Randomized"
01. Principal	alc_bsl_5_in_a_day_spec	In The Past 30 Days, On How Many Days Did You Have 5 Or More Drinks Per Day? Other Specify		Numeric .M="Missing" .R="Not Randomized" 8="Choose Not To Answer" 9="Don't Know/Not Sure"
01. Principal	alc_bsl_age_drink	At What Age Did You Begin Drinking Regularly?		Numeric .M="Missing" .R="Not Randomized"
01. Principal	alc_bsl_age_drink_spec	At What Age Did You Begin Drinking Regularly? Other Specify		Numeric .M="Missing" .R="Not Randomized"
01. Principal	alc_bsl_at_least_12	In Your Entire Life, Have You Had At Least 12 Drinks Of Any Kind Of Alcoholic Beverage?		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	alc_bsl_beer_use	Alcohol Use - Beer		Numeric .M="Missing" .R="Not Randomized"
01. Principal	alc_bsl_binge_daily	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" .R="Not Randomized" 0="No" 1="Yes" 9="Don't Know/Not Sure"
01. Principal	alc_bsl_comments	Alcohol Questionnaire Baseline Comments		Char
01. Principal	alc_bsl_drink_freq	In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcoholic Beverage?		Numeric .M="Missing" .R="Not Randomized"
01. Principal	alc_bsl_drink_freq_spec	In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcoholic Beverage? Other Specify		.M="Missing" .R="Not Randomized" 1="Week" 2="Month" 3="Year" 9="Don't Know/Not Sure"
01. Principal	alc_bsl_drinks_per_day	In The Past 12 Months, On Those Days That You Drank Alcoholic Beverages, On Average, How Many Drinks Did You Have Per Day?		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	alc_bsl_drinks_d ay_spec	In The Past 12 Months, On Those Days That You Drank Alcoholic Beverages, On Average, How Many Drinks Did You Have Per Day? Other Specify		Numeric .M="Missing" .R="Not Randomized"
01. Principal	alc_bsl_liquor_u se	Alcohol Use - Liquor		Numeric .M="Missing" .R="Not Randomized"
01. Principal	alc_bsl_most_dr ank	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" .R="Not Randomized"
01. Principal	alc_bsl_most_dr ank_spec	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? Other Specify		Numeric .M="Missing" .R="Not Randomized" 8="Choose Not To Answer" 9="Don't Know/Not Sure"
01. Principal	alc_bsl_target_d ays	Target Days From Baseline		Numeric .R="Not Randomized"
01. Principal	alc_bsl_time_sin ce_drank	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" .R="Not Randomized" 0="Within The Past Month (0 To 1 Month Ago)" 1="Between 1 And 3 Months (1 To 3 Months Ago)" 2="Between 3 And 6 Months (3 To 6 Months Ago)" 4="Between 1 And 5 Years (1 To 5 Years Ago)" 5="Between 5 And 15 Years (5 To 15 Years Ago)" 6="More Than 15 Years Ago" 7="Never Drank Regularly" 8="Choose Not To Answer" 9="Don't Know/Not Sure"
01. Principal	alc_bsl_types_dr ank_check	What Type(s) Of Alcohol Do You Drink?		.R="Not Randomized" 1="Checked"
01. Principal	alc_bsl_wine_co oler_use	Alcohol Use - Wine Cooler		Numeric .M="Missing" .R="Not Randomized"
01. Principal	alc_bsl_wine_us e	Alcohol Use - Wine		Numeric .M="Missing" .R="Not Randomized"
01. Principal	alc_bsl_years_dri nk	How Many Years Have You Been Drinking (Or Did You Drink) Regularly?		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	alc_bsl_years_drink_spec	How Many Years Have You Been Drinking (Or Did You Drink) Regularly? Other Specify		Numeric .M="Missing" .R="Not Randomized" 9="Don't Know/Not Sure"

Section 9: Tobacco Baseline Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	tob_bsl_age_first_spec	How Old Were You When You First Smoked A Cigarette Specify		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tob_bsl_age_reg	How Old Were You When You First Began Smoking Cigarettes Regularly?		Numeric .N="N/A" .R="Not Randomized"
01. Principal	tob_bsl_age_reg_smoke	How Old Were You When You First Began Smoking Cigarettes Regularly? Specify		.M="Missing" .R="Not Randomized" 7="Have Never Smoked Cigarettes Regularly" 9="Don't Know/Not Sure"
01. Principal	tob_bsl_age_smoked	How Old Were You When You First Smoked A Cigarette		Numeric .N="N/A" .R="Not Randomized"
01. Principal	tob_bsl_bidis	Other Tobacco Products Used Regularly: Bidis		.M="Missing" .R="Not Randomized" 0="No" 8="Choose Not To Answer"
01. Principal	tob_bsl_child_liv_e_smk	Thinking Of All Your Childhood And Adult Years, Have You Ever Lived In A Place Where Other People Smoked Cigarettes Indoors?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_child_smk_yrs	In Total, For About How Many Years Have You Lived In A Place Where Other People Smoked Cigarettes Indoors?		Numeric .N="N/A" .R="Not Randomized"
01. Principal	tob_bsl_choose_not_ans	Choose Not To Answer		.M="Missing" .R="Not Randomized" 0="Unchecked"
01. Principal	tob_bsl_cig_last_month	Cigarette In Less Than 1 Month		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_bsl_cig_last_week	Cigarette In The Last 1-7 Days		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_bsl_cig_last_year	Cigarette In Less Than 1 Year		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	tob_bsl_cig_more_1_year	Cigarette In More Than 1 Year		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_bsl_cig_today	I Smoked A Cigarette Today		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_bsl_cigarettes	Other Tobacco Products Used Regularly: Cigarettes		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_cigars	Other Tobacco Products Used Regularly: Traditional Cigars, Cigarillos, Or Filtered Cigars		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_cigs_day	On Average, When You Smoked, About How Many Cigarettes Do You Smoke A Day?		Numeric .N="N/A" .R="Not Randomized"
01. Principal	tob_bsl_clove_cig	Other Tobacco Products Used Regularly: Clove Cigarettes Or Kreteks		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_comments	Tobacco Baseline Questionnaire Comments		Char
01. Principal	tob_bsl_days_last_cig	Number Of Days Since Last Cigarette		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tob_bsl_do_not_know	Don't Know/Don't Remember		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_bsl_e_cig	Other Tobacco Products Used Regularly: E-Cigarettes Or Other Electronic Nicotine Delivery System		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_hookah	Other Tobacco Products Used Regularly: Hookah		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_live_30_smoker	In The Past 30 Days, Have You Lived In A Place Where Other People Smoked Cigarettes Indoors?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"

Class	Variable	Label	Description	Format Text
01. Principal	tob_bsl_live_with_smoker	Are You Currently Living With A Smoker?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_months_last_cig	Number Of Months Since Last Cigarette		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tob_bsl_oth_daily	Other Tobacco Use Every Day		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_bsl_oth_last_use	If You Do Not Currently Use Other Forms Of Tobacco, But Did In The Past, How Long Has It Been Since You Last Used Other Forms Of Tobacco Regularly?		.M="Missing" .R="Not Randomized" 0="Within The Past Month (0 To 1 Month Ago)" 1="Between 1 And 3 Months (1 To 3 Months Ago)" 4="Between 1 And 5 Years (1 To 5 Years Ago)" 5="Between 5 And 15 Years (5 To 15 Years Ago)" 6="More Than 15 Years Ago" 7="Never Drank Regularly" 8="Choose Not To Answer"
01. Principal	tob_bsl_oth_not_answer	Choose Not To Answer		.M="Missing" .R="Not Randomized" 0="Unchecked" 1="Checked"
01. Principal	tob_bsl_oth_some_days	Other Tobacco Use Some Days		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_bsl_oth_times_per_day	Other Tobacco Use Number Of Times Per Day		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tob_bsl_oth_tob_spec	Other Tobacco Use, Specify		Char
01. Principal	tob_bsl_oth_tob_use	Have You Ever Used Other Forms Of Tobacco, Not Including Cigarettes?		.R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_oth_use_days	Other Tobacco Use Number Of Days		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tob_bsl_oth_use_per	Other Tobacco Use Per		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tob_bsl_other	Other Tobacco Products Used Regularly: Other		.M="Missing" .R="Not Randomized" 0="No" 8="Choose Not To Answer"

Class	Variable	Label	Description	Format Text
01. Principal	tob_bsl_paan	Other Tobacco Products Used Regularly: Paan With Tobacco, Gutka, Zarda, Khaini		.M="Missing" .R="Not Randomized" 0="No" 8="Choose Not To Answer"
01. Principal	tob_bsl_pipe	Other Tobacco Products Used Regularly: Pipes		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_smoke_100_cigs	Have You Smoked At Least 100 Cigarettes In Your Entire Life?		.R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_smoke_now	Do You Now Smoke Cigarettes?		.M="Missing" .R="Not Randomized" 1="Everyday" 2="Some Days" 3="Not At All"
01. Principal	tob_bsl_smokeless	Other Tobacco Products Used Regularly: Smokeless Tobacco (Like Dip, Chew, Or Snuff)		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_snus	Other Tobacco Products Used Regularly: Snus		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_target_days	Target Days From Baseline		Numeric .R="Not Randomized"
01. Principal	tob_bsl_wake_first_cig	How Soon After You Wake Up Do You Smoke Your First Cigarette?		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tob_bsl_water_pipe	Other Tobacco Products Used Regularly: Water Pipe		.M="Missing" .R="Not Randomized" 0="No" 8="Choose Not To Answer"
01. Principal	tob_bsl_weeks_last_cig	Number Of Weeks Since Last Cigarette		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tob_bsl_work_30_smoke	In The Past 30 Days, Have You Worked In A Place Where Other People Smoked Cigarettes Indoors?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"
01. Principal	tob_bsl_work_smoke	Thinking Of All The Years You Have Worked, Have You Ever Worked In A Place Where Other People Smoked Cigarettes Indoors?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Choose Not To Answer"

Class	Variable	Label	Description	Format Text
01. Principal	tob_bsl_years_last_cig	Number Of Years Since Last Cigarette		Numeric .N="N/A" .R="Not Randomized"
01. Principal	tob_bsl_years_smoked	How Many Total Years Have You Smoked (Or Did You Smoke) Cigarettes? Specify		Numeric .N="N/A" .R="Not Randomized"
01. Principal	tob_bsl_years_work_smoke	In Total, For About How Many Years Have You Worked In A Place Where Other People Smoked Cigarettes Indoors?		Numeric .N="N/A" .R="Not Randomized"

Section 10: Blood Lab Chemistry Results

Class	Variable	Label	Description	Format Text
01. Principal	labreschem_albumin_clin_sig_v0-4	Albumin: Clinically Significant		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_albumin_oor_v0-4	Albumin: Out Of Range		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_albumin_res_v0-4	Albumin: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_albumin_units_v0-4	Albumin: Units		Char
01. Principal	labreschem_aminotransferase_clin_sig_v0-4	Alanine Aminotransferase (ALT or SGPT): Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_aminotransferase_oor_v0-4	Alanine Aminotransferase (ALT or SGPT): Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_aminotransferase_res_v0-4	Alanine Aminotransferase (ALT or SGPT): Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_aminotransferase_units_v0-4	Alanine Aminotransferase (ALT or SGPT): Units		Char
01. Principal	labreschem_aspartate_aminotransferase_clin_sig_v0-4	Aspartate Aminotransferase (AST or SGOT): Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labreschem_aspartate_aminotransferase_oor_v0-4	Aspartate Aminotransferase (AST or SGOT): Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_aspartate_aminotransferase_res_v0-4	Aspartate Aminotransferase (AST or SGOT): Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_aspartate_aminotransferase_units_v0-4	Aspartate Aminotransferase (AST or SGOT): Units		Char
01. Principal	labreschem_bicarbonate_clin_sig_v0-4	Bicarbonate: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labreschem_bicarbonate_oor_v0-4	Bicarbonate: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	labreschem_bicarb_res_v0-4	Bicarbonate: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_bicarb_units_v0-4	Bicarbonate: Units		Char
01. Principal	labreschem_bilirubin_clin_sig_v0-4	Bilirubin Total: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_bilirubin_oor_v0-4	Bilirubin Total: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_bilirubin_res_v0-4	Bilirubin Total: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_bilirubin_units_v0-4	Bilirubin Total: Units		Char
01. Principal	labreschem_bun_clin_sig_v0-4	Blood Urea Nitrogen (BUN): Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_bun_oor_v0-4	Blood Urea Nitrogen (BUN): Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_bun_res_v0-4	Blood Urea Nitrogen (BUN): Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_bun_units_v0-4	Blood Urea Nitrogen (BUN): Units		Char
01. Principal	labreschem_calcium_clin_sig_v0-4	Calcium: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_calcium_oor_v0-4	Calcium: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_calcium_res_v0-4	Calcium: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_calcium_units_v0-4	Calcium: Units		Char
01. Principal	labreschem_chloride_clin_sig_v0-4	Chloride: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labreschem_chloride_oor_v0-4	Chloride: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	labreschem_chloride_res_v0-4	Chloride: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_chloride_units_v0-4	Chloride: Units		Char
01. Principal	labreschem_comments_v0-4	Blood Chemistry Comments		Char
01. Principal	labreschem_creat_clin_sig_v0-4	Creatinine: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_creat_oor_v0-4	Creatinine: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_creat_res_v0-4	Creatinine: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_creat_units_v0-4	Creatinine: Units		Char
01. Principal	labreschem_done_v0-4	Blood Chemistry Done?		.M="Missing" .R="Not Randomized" 1="Not Obtained"
01. Principal	labreschem_fasting_v0-4	Fasting?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	labreschem_glucose_clin_sig_v0-4	Glucose: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_glucose_oor_v0-4	Glucose: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_glucose_res_v0-4	Glucose: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_glucose_units_v0-4	Glucose: Units		Char
01. Principal	labreschem_phosphatase_clin_sig_v0-4	Alkaline Phosphatase: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_phosphatase_oor_v0-4	Alkaline Phosphatase: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_phosphatase_res_v0-4	Alkaline Phosphatase: Results		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	labreschem_phosph_units_v0-4	Alkaline Phosphatase: Units		Char
01. Principal	labreschem_potass_clin_sig_v0-4	Potassium: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labreschem_potass_oor_v0-4	Potassium: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_potass_res_v0-4	Potassium: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_potass_units_v0-4	Potassium: Units		Char
01. Principal	labreschem_prot ein_clin_sig_v0-4	Total Protein: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_prot ein_oor_v0-4	Total Protein: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_prot ein_res_v0-4	Total Protein: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_prot ein_units_v0-4	Total Protein: Units		Char
01. Principal	labreschem_samp_col_dt_v0-4	Sample Collection Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	labreschem_sodium_clin_sig_v0-4	Sodium: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labreschem_sodium_oor_v0-4	Sodium: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labreschem_sodium_res_v0-4	Sodium: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_sodium_units_v0-4	Sodium: Units		Char
01. Principal	labreschem_target_day_v0-4	Blood Chemistry Target Days		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labreschem_visit_v0-4	Blood Chemistry Visit Number		Numeric .M="Missing" .R="Not Randomized"

Section 11: Blood Lab Hematology Results

Class	Variable	Label	Description	Format Text
01. Principal	labresheme_basop_clin_sig_v0-3	Basophils # Blood: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_basop_oor_v0-3	Basophils # Blood: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_basop_res_v0-3	Basophils # Blood: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_basop_units_v0-3	Basophils # Blood: Units		Char
01. Principal	labresheme_comments_v0-3	Blood Hematology Comments		Char
01. Principal	labresheme_done_v0-3	Blood Hematology Done?		.M="Missing" .R="Not Randomized" 1="Not Obtained"
01. Principal	labresheme_eosino_clin_sig_v0-3	Eosinophils # Blood: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labresheme_eosino_oor_v0-3	Eosinophils # Blood: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_eosino_res_v0-3	Eosinophils # Blood: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_eosino_units_v0-3	Eosinophils # Blood: Units		Char
01. Principal	labresheme_hemato_clin_sig_v0-3	Hematocrit % Blood: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labresheme_hemato_oor_v0-3	Hematocrit % Blood: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_hemato_res_v0-3	Hematocrit % Blood: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_hemato_units_v0-3	Hematocrit % Blood: Units		Char
01. Principal	labresheme_hemoglobin_clin_sig_v0-3	Hemoglobin Blood: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	labresheme_hemog_oor_v0-3	Hemoglobin Blood: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_hemog_res_v0-3	Hemoglobin Blood: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_hemog_units_v0-3	Hemoglobin Blood: Units		Char
01. Principal	labresheme_lympho_clin_sig_v0-3	Lymphocytes # Blood: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_lympho_oor_v0-3	Lymphocytes # Blood: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_lympho_res_v0-3	Lymphocytes # Blood: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_lympho_units_v0-3	Lymphocytes # Blood: Units		Char
01. Principal	labresheme_monoc_clin_sig_v0-3	Monocytes # Blood: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_monoc_oor_v0-3	Monocytes # Blood: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_monoc_res_v0-3	Monocytes # Blood: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_monoc_units_v0-3	Monocytes # Blood: Units		Char
01. Principal	labresheme_neutro_clin_sig_v0-3	Neutrophils (ANC) # Blood: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_neutro_oor_v0-3	Neutrophils (ANC) # Blood: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_neutro_res_v0-3	Neutrophils (ANC) # Blood: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_neutro_units_v0-3	Neutrophils (ANC) # Blood: Units		Char
01. Principal	labresheme_platelet_clin_sig_v0-3	Platelets Blood: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	labresheme_plat_elet_oor_v0-3	Platelets Blood: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_plat_elet_res_v0-3	Platelets Blood: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_plat_elet_units_v0-3	Platelets Blood: Units		Char
01. Principal	labresheme_rbc_clin_sig_v0-3	Red Blood Cells (RBC) # Blood: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labresheme_rbc_oor_v0-3	Red Blood Cells (RBC) # Blood: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_rbc_res_v0-3	Red Blood Cells (RBC) # Blood: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_rbc_units_v0-3	Red Blood Cells (RBC) # Blood: Units		Char
01. Principal	labresheme_samp_col_dt_v0-3	Sample Collection Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	labresheme_target_days_v0-3	Blood Hematology Target Days		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_visit_v0-3	Blood Hematology Visit		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_wbc_clin_sig_v0-3	White Blood Cells (WBC) # Blood: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_wbc_oor_v0-3	White Blood Cells (WBC) # Blood: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresheme_wbc_res_v0-3	White Blood Cells (WBC) # Blood: Results		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresheme_wbc_units_v0-3	White Blood Cells (WBC) # Blood: Units		Char

Section 12: Urine Lab Results

Class	Variable	Label	Description	Format Text
01. Principal	labresurine_appear_col_oth	Was Urine Appearance Collected		.M="Missing" .R="Not Randomized" 1="Yes"
01. Principal	labresurine_appear_col_v0-3	Was Urine Appearance Collected		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresurine_appearance_oth	Urine Appearance Result		Char
01. Principal	labresurine_appearance_v0-3	Urine Appearance Result		Char
01. Principal	labresurine_comments_oth	Lab Urine Comments		Char
01. Principal	labresurine_comments_v0-3	Lab Urine Comments		Char
01. Principal	labresurine_cotclin_sig_oth	Cotinine Urine: Clinically Significant		.M="Missing" .R="Not Randomized"
01. Principal	labresurine_cotclin_sig_v0-3	Cotinine Urine: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresurine_cotoor_oth	Cotinine Urine: Out Of Range		.M="Missing" .R="Not Randomized"
01. Principal	labresurine_cotoor_v0-3	Cotinine Urine: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresurine_cotires_oth	Cotinine Urine: Results		Char
01. Principal	labresurine_cotires_v0-3	Cotinine Urine: Results		Char
01. Principal	labresurine_cotunits_oth	Cotinine Urine: Units		Char
01. Principal	labresurine_cotunits_v0-3	Cotinine Urine: Units		Char
01. Principal	labresurine_doned_oth	Was Lab Specimen Collected?		.M="Missing" .R="Not Randomized" 1="Not Obtained"
01. Principal	labresurine_doned_v0-3	Was Lab Specimen Collected?		.M="Missing" .R="Not Randomized" 1="Not Obtained"
01. Principal	labresurine_glucose_clin_sig_oth	Glucose: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	labresurine_glucose_clin_sig_v0-3	Glucose: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresurine_glucose_oor_oth	Glucose: Out Of Range		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labresurine_glucose_oor_v0-3	Glucose: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresurine_glucose_res_oth	Glucose: Results		Char
01. Principal	labresurine_glucose_res_v0-3	Glucose: Results		Char
01. Principal	labresurine_glucose_units_oth	Glucose: Units		Char
01. Principal	labresurine_glucose_units_v0-3	Glucose: Units		Char
01. Principal	labresurine_hemo_done_oth	Was Urine Hemoglobin Collected?		.M="Missing" .R="Not Randomized" 1="Yes"
01. Principal	labresurine_hemo_done_v0-3	Was Urine Hemoglobin Collected?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresurine_hemo_res_oth	Urine Hemoglobin Result		.M="Missing" .R="Not Randomized" 0="Negative"
01. Principal	labresurine_hemo_res_v0-3	Urine Hemoglobin Result		.M="Missing" .R="Not Randomized" 0="Negative" 1="Positive"
01. Principal	labresurine_ph_clin_sig_oth	pH: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labresurine_ph_clin_sig_v0-3	pH: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labresurine_ph_or_oth	pH: Out Of Range		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labresurine_ph_or_v0-3	pH: Out Of Range		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labresurine_ph_res_oth	pH: Results		Char
01. Principal	labresurine_ph_res_v0-3	pH: Results		Char
01. Principal	labresurine_ph_units_oth	pH: Units		Char

Class	Variable	Label	Description	Format Text
01. Principal	labresurine_ph_units_v0-3	pH: Units		Char
01. Principal	labresurine_protein_clin_sig_oth	Protein: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labresurine_protein_clin_sig_v0-3	Protein: Clinically Significant		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresurine_protein_oor_oth	Protein: Out Of Range		.M="Missing" .R="Not Randomized" 0="No"
01. Principal	labresurine_protein_oor_v0-3	Protein: Out Of Range		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	labresurine_protein_res_oth	Protein: Results		Char
01. Principal	labresurine_protein_res_v0-3	Protein: Results		Char
01. Principal	labresurine_protein_units_oth	Protein: Units		Char
01. Principal	labresurine_protein_units_v0-3	Protein: Units		Char
01. Principal	labresurine_sample_collection_date_oth	Sample Collection Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	labresurine_sample_collection_date_v0-3	Sample Collection Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	labresurine_target_days_oth	Lab Urine Target Days		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresurine_target_days_v0-3	Lab Urine Target Days		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresurine_visit_oth	Lab Urine Visit		Numeric .M="Missing" .R="Not Randomized"
01. Principal	labresurine_visit_v0-3	Lab Urine Visit		Numeric .M="Missing" .R="Not Randomized"

Section 13: Pregnancy Test Results

Class	Variable	Label	Description	Format Text
01. Principal	preg_test_comments_oth	Pregnancy Test Comments		Char
01. Principal	preg_test_comments_v0	Pregnancy Test Comments		Char
01. Principal	preg_test_comments_v2	Pregnancy Test Comments		Char
01. Principal	preg_test_comments_v3	Pregnancy Test Comments		Char
01. Principal	preg_test_results_oth	Pregnancy Test Results		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Positive"
01. Principal	preg_test_results_v0	Pregnancy Test Results		.F="No Record For This Visit" .R="Not Randomized" 0="Negative" 2="Not Applicable" 3="Not Obtained"
01. Principal	preg_test_results_v2	Pregnancy Test Results		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Negative" 2="Not Applicable" 3="Not Obtained"
01. Principal	preg_test_results_v3	Pregnancy Test Results		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Negative" 2="Not Applicable"
01. Principal	preg_test_spec_col_dt_oth	Specimen Collection Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	preg_test_spec_col_dt_v0	Specimen Collection Date		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	preg_test_spec_col_dt_v2	Specimen Collection Date		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	preg_test_spec_col_dt_v3	Specimen Collection Date		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	preg_test_target_days_oth	Target Days		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	preg_test_target_days_v0	Target Days		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	preg_test_target_days_v2	Target Days		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	preg_test_target_days_v3	Target Days		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	preg_test_test_type_oth	Pregnancy Test Type		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Serum"
01. Principal	preg_test_test_type_v0	Pregnancy Test Type		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Serum" 2="Urine"
01. Principal	preg_test_test_type_v2	Pregnancy Test Type		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Serum" 2="Urine"
01. Principal	preg_test_test_type_v3	Pregnancy Test Type		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Serum" 2="Urine"
01. Principal	preg_test_visit_oth	Visit Number		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	preg_test_visit_v0	Visit Number		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	preg_test_visit_v2	Visit Number		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	preg_test_visit_v3	Visit Number		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 14: Subject Enrollment

Class	Variable	Label	Description	Format Text
01. Principal	sub_enroll_curr_site_id	Current Site CTEP ID		Char
01. Principal	sub_enroll_dt	Enrollment Date		SAS Date
01. Principal	sub_enroll_group_data	Registering Membership		Char
01. Principal	sub_enroll_inst_name	Lead Organization		Char
01. Principal	sub_enroll_project_id	Protocol		Char
01. Principal	sub_enroll_pt_id	Patient ID		Char
01. Principal	sub_enroll_site	Site		Char
01. Principal	sub_enroll_site_id	Enrolling Site CTEP ID		Char
01. Principal	sub_enroll_site_num	Site Number		Char
01. Principal	sub_enroll_source_app	Source Application		1="Remote Registration" 2="Research Registration"
01. Principal	sub_enroll_time	Enrollment Time		SAS Time

Section 15: Screening

Class	Variable	Label	Description	Format Text
01. Principal	screen_comments	Screen Comments		Char
01. Principal	screen_date	Screen Completion Date		SAS Date
01. Principal	screen_fail_reason	If No, Which Screening Criteria Not Met?		.N="N/A" 1="Participant Decision Specify" 2="Investigator Decision Specify" 3="Did Not Meet Spigelman Score Criteria Specify" 4="Did Not Meet Other Eligibility Criteria Specify" 5="Other Specify"
01. Principal	screen_fail_reason_spec	If No, Which Screening Criteria Not Met? Specify		Char
01. Principal	screen_meet_criteria	Does Participant Meet Screening Criteria?		0="No" 1="Yes"
01. Principal	screen_target_days	Target Days From Baseline		Numeric

Section 16: Registration Checklist

Class	Variable	Label	Description	Format Text
01. Principal	chklist_reg_african_amer	Is this participant an African-American?		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	chklist_reg_alk_phos	Alkaline Phosphatase		Numeric .R="Not Randomized"
01. Principal	chklist_reg_alk_unl	Alkaline Phosphatase UNL		Numeric .R="Not Randomized"
01. Principal	chklist_reg_alt	ALT/SGPT		Numeric .R="Not Randomized"
01. Principal	chklist_reg_alt_qual	ALT/SGPT < =2 x UNL		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_alt_unl	ALT/SGPT UNL		Numeric .R="Not Randomized"
01. Principal	chklist_reg_arm	Arm		.R="Not Randomized" 1="A"
01. Principal	chklist_reg_ast	AST/SGOT		Numeric .R="Not Randomized"
01. Principal	chklist_reg_ast_qual	AST/SGOT < =2 x UNL		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_ast_unl	AST/SGOT UNL		Numeric .R="Not Randomized"
01. Principal	chklist_reg_bili_qual	Total Bilirubin < =1.5 x UNL		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_bone_marrow	Adequate Bone Marrow And Organ Function:		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_contraception	Willing To Use Adequate Contraception To Avoid Pregnancy Or Impregnation Until 2 Weeks After Discontinuing Study Agent		.R="Not Randomized" 1="Yes" 9="Not Applicable"
01. Principal	chklist_reg_creat	Creatinine		Numeric .R="Not Randomized"
01. Principal	chklist_reg_creat_qual	Creatinine UNL		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_creat_unl	Creatinine UNL+		Numeric .R="Not Randomized"
01. Principal	chklist_reg_ctep_arm	TAC/TAD Code		.R="Not Randomized" 1="TAC-1 (Erlotinib 350 mg PO Once Per Week x 6 Months)"
01. Principal	chklist_reg_ecog_qual	ECOG Performance Status < =1		.R="Not Randomized" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	chklist_reg_ecog_status	ECOG performance status 0 Or 1		Numeric .R="Not Randomized"
01. Principal	chklist_reg_elig	Is The Participant Eligible For Inclusion On This Study?		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_enroll_dt	Enrollment Date		SAS Date .R="Not Randomized"
01. Principal	chklist_reg_gi_bleeding	Gastrointestinal Bleeding.		.R="Not Randomized" 0="No"
01. Principal	chklist_reg_gi_drugs	Regular (> =2 Times Per Week) Use Of Drugs That Alter The pH Of The GI Tract		.R="Not Randomized" 0="No"
01. Principal	chklist_reg_hemoglobin_qual	Hemoglobin > =11.5 g/dL		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_hgb	Hemoglobin (> =11.5)		Numeric .R="Not Randomized"
01. Principal	chklist_reg_hgd_hist	Histologically-Confirmed High Grade Dysplasia (HGD), Cancer, Or Polyp Burden That Is Not Quantifiable.		.R="Not Randomized" 0="No"
01. Principal	chklist_reg_intervention_cpns	Intervention Must Take Place At A CPN Institution And Under The Supervision Of A CPN Clinician.		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_invitation_after_registration	Intervention Cannot Begin Prior To Registration And Must Begin < =14 Days From Registration.		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_leukocytes	If Yes, Leukocytes (WBC)		Numeric .R="Not Randomized"
01. Principal	chklist_reg_not_pregnant	Not Pregnant Or Breast Feeding.		Numeric .R="Not Randomized"
01. Principal	chklist_reg_pathology_reports_dx_sent	Pathology Reports Confirming Diagnoses Must Be Sent < =30 Days Post Registration To The CPN QAS at CPN Operations Office		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_phosphorus_qual	Alkaline Phosphatase < =1.5 x UNL		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_platelet	Platelet count (> =100)		Numeric .R="Not Randomized"
01. Principal	chklist_reg_platelet_qual	Platelet Count > =100 x 10 ⁹ /L		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_spigelman	Spigelman 2-3		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_total_bilirubin	Total bilirubin run		Numeric .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	chklist_reg_tot_bili_unl	Total bilirubin UNL		Numeric .R="Not Randomized"
01. Principal	chklist_reg_urine	Urinary Testing Results Within Institutional Limits Of Normal Or Deemed Clinically Significant		.R="Not Randomized" 1="Yes"
01. Principal	chklist_reg_version_num	Version Number		Numeric .R="Not Randomized"
01. Principal	chklist_reg_wbc_qual	Leukocytes (WBC) > =3,000/mL (> =2,500/mL for African-American participants)		.R="Not Randomized" 1="Yes"

Section 17: Events At Baseline

Class	Variable	Label	Description	Format Text
01. Principal	event_bsl_comments	Baseline Events Comments		Char
01. Principal	event_bsl_comp_dt	Date Completed		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	event_bsl_dose_start_dt	Date Of First Dose		SAS Date .R="Not Randomized"
01. Principal	event_bsl_proceed	Will The Participant Proceed To Protocol Intervention For The First Visit?		.R="Not Randomized" 1="Yes"
01. Principal	event_bsl_target_days	Baseline Events Target Days From Baseline		Numeric .R="Not Randomized"
01. Principal	event_bsl_wiwi_comp	Did The Participant Complete The Was It Worth It (WIWI) Questionnaire?		.M="Missing" .R="Not Randomized" 0="No" 9="Not Applicable"

Section 18: Registration Eligibility Criteria

Class	Variable	Label	Description	Format Text
01. Principal	reg_adequate_alt	Adequate Bone Marrow And Organ Function: ALT/SGPT 2 X Institutional Upper Limit Of Normal (ULN)		.R="Not Randomized" 1="Yes"
01. Principal	reg_adequate_ast	Adequate Bone Marrow And Organ Function: AST/SGOT 2 X Institutional Upper Limit Of Normal (ULN)		.R="Not Randomized" 1="Yes"
01. Principal	reg_adequate_bili	Adequate Bone Marrow And Organ Function: Total Bilirubin D 1.5 X Institutional Upper Limit Of Normal (ULN)		.R="Not Randomized" 1="Yes"
01. Principal	reg_adequate_creat	Adequate Bone Marrow And Organ Function: Creatinine Institutional Upper Limit Of Normal		.R="Not Randomized" 1="Yes"
01. Principal	reg_adequate_hemo	Adequate Bone Marrow And Organ Function: Hemoglobin 11.5 G/Dl		.R="Not Randomized" 1="Yes"
01. Principal	reg_adequate_leuko	Adequate Bone Marrow And Organ Function: Leukocytes (WBC) 3,000/UI (2,500/UI For African-American Participants).		.R="Not Randomized" 1="Yes"
01. Principal	reg_adequate_phos	Adequate Bone Marrow And Organ Function: Alkaline Phosphatase D 1.5 X Institutional Upper Limit Of Normal (ULN)		.R="Not Randomized" 1="Yes"
01. Principal	reg_adequate_platelet	Adequate Bone Marrow And Organ Function: Platelet Count 100 X 109/L		.R="Not Randomized" 1="Yes"
01. Principal	reg_adequate_urine	Adequate Bone Marrow And Organ Function: Urinary Test Results Within Institutional Limits Of Normal Or Deemed Not Clinically Significant		.R="Not Randomized" 1="Yes"
01. Principal	reg_apc_genetic	APC Genetic Mutation		.R="Not Randomized" 0="No" 1="Yes" 2="Not Known, Not Reported"

Class	Variable	Label	Description	Format Text
01. Principal	reg_aspirin	Baseline Aspirin Use:		.R="Not Randomized" 1="No Regular Use" 2="d81 mg Day"
01. Principal	reg_conf_hg_dysplasia	Histologically-Confirmed High Grade Dysplasia (Hgd), Cancer, Or Polyp Burden That Is Not Quantifiable		.R="Not Randomized" 0="No"
01. Principal	reg_contraception	Willing To Use Adequate Contraception To Avoid Pregnancy Or Impregnation Until 2 Weeks After Discontinuing Study Agent		.R="Not Randomized" 1="Yes" 9="Not Applicable"
01. Principal	reg_ecog_perf	Ecog Performance Status D1		.R="Not Randomized" 1="Yes"
01. Principal	reg_fap	FAP		.R="Not Randomized" 1="Classic" 2="Attenuated"
01. Principal	reg_gastro_bleed	Gastrointestinal Bleeding		.R="Not Randomized" 0="No"
01. Principal	reg_gi_drug_use	Regular (2 Times Per Week) Use Of Drugs That Alter The Ph Of The GI Tract, Such As Proton Pump Inhibitors (PPI) And Antacids		.R="Not Randomized" 0="No"
01. Principal	reg_not_pregnant	Not Pregnant Or Breast Feeding		.R="Not Randomized" 1="Yes" 9="Not Applicable"
01. Principal	reg_severity	Severity Of Duodenal Polyposis		.R="Not Randomized" 1="Spigelman 2" 2="Spigelman 3"
01. Principal	reg_spigelman	Spigelman 2-3		.R="Not Randomized" 1="Yes"
01. Principal	reg_target_days	Target Days From Baseline		Numeric .R="Not Randomized"

Section 19: Step Information

Class	Variable	Label	Description	Format Text
01. Principal	step_info_arm1-2	Arm Name		.M="Missing" 1="A"
01. Principal	step_info_date1-2	Event Date		SAS Date .M="Missing"
01. Principal	step_info_even_desc1-2	Event Description		Char
01. Principal	step_info_num1-2	Registration Step		Numeric .M="Missing"
01. Principal	step_info_time1-2	Event Time		Numeric .M="Missing"
01. Principal	step_info_tracking_num1-2	Tracking Number		Numeric .M="Missing"

Section 20: Pre-Intervention Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	symp_bsl_day1-3	Onset Day		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	symp_bsl_dt1-3	Onset Date		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	symp_bsl_eval_d t	Evaluation Date		SAS Date .R="Not Randomized"
01. Principal	symp_bsl_grade 1-3	Symptoms Grade		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	symp_bsl_month 1-3	Onset Month		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	symp_bsl_none	No Pre-Intervention Symptoms Reported		.R="Not Randomized" 0="Unchecked" 1="Checked"
01. Principal	symp_bsl_target _days	Target Days From Baseline		Numeric .R="Not Randomized"
01. Principal	symp_bsl_verbat im1-3	Symptoms Verbatim Text		Char
01. Principal	symp_bsl_visit	Visit Number		Numeric .R="Not Randomized"
01. Principal	symp_bsl_visit_c omments	Visit Symptoms Comments		Char
01. Principal	symp_bsl_visit_c omments1-3	Doctor Symptoms Comments		Char
01. Principal	symp_bsl_year1- 3	Onset Year		Numeric .M="Missing" .N="N/A" .R="Not Randomized"

Section 21: Treatment Assignment

Class	Variable	Label	Description	Format Text
01. Principal	trt_arm_assign_dt1-2	Date Of Intervention/Treatment Assignment		SAS Date .M="Missing"
01. Principal	trt_arm_event_desc1-2	Event Description		Char
01. Principal	trt_arm_event_time1-2	Event Time		SAS Time .M="Missing"
01. Principal	trt_arm_name1-2	Arm Name		.M="Missing" .N="N/A" 1="A"
01. Principal	trt_arm_step_num1-2	Step Number		Numeric .M="Missing"

Section 22: Pouch Exam

Class	Variable	Label	Description	Format Text
01. Principal	pouch_area_examined1-6	Was Area Examined?		.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	pouch_biopsy_done1-6	Biopsies Taken		.M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	pouch_comments1-6	Biopsies Comments		Char
01. Principal	pouch_polyp_diameter1-6	Average Diameter (mm)		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pouch_polyp_location1-6	Location		.M="Missing" .N="N/A" .R="Not Randomized" 1="Pouch" 2="Rectum" 3="Small Bowel"
01. Principal	pouch_polyp_number1-6	Number Of Polyps		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pouch_polyp_size1-6	Size Range (mm-mm)		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pouch_rectal_reman_length1-6	Rectal Remnant Length (cm)		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	pouch_rectal_remanant1-6	Rectal Remnant		.M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	pouch_target_days1-6	Target Days From Baseline		Numeric .N="N/A" .R="Not Randomized"
01. Principal	pouch_visit1-6	Visit Number		Numeric .N="N/A" .R="Not Randomized"

Section 23: Specimen Submission: Blood

Class	Variable	Label	Description	Format Text
01. Principal	spec_bld_col_dt_v0_1-3	Date Specimen Collected		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_col_dt_v2_1-3	Date Specimen Collected		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_col_dt_v3_1-3	Date Specimen Collected		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_comments_v0_1-3	Blood Specimen Comments		Char
01. Principal	spec_bld_comments_v2_1-3	Blood Specimen Comments		Char
01. Principal	spec_bld_comments_v3_1-3	Blood Specimen Comments		Char
01. Principal	spec_bld_container_v0_1-3	Container Or Additive		.R="Not Randomized" 1="EDTA Purple Top (10mL)" 2="Red Top (10mL)"
01. Principal	spec_bld_container_v2_1-3	Container Or Additive		.M="Missing" .R="Not Randomized" 1="EDTA Purple Top (10mL)" 2="Red Top (10mL)"
01. Principal	spec_bld_container_v3_1-3	Container Or Additive		.M="Missing" .R="Not Randomized" 1="EDTA Purple Top (10mL)" 2="Red Top (10mL)"
01. Principal	spec_bld_not_col_rsn_v0_1-3	Not Collected Reason		.M="Missing" .R="Not Randomized" 3="Unsuccessful Blood Draw"
01. Principal	spec_bld_not_col_rsn_v2_1-3	Not Collected Reason		.M="Missing" .R="Not Randomized" 1="Institution Error" 2="Patient Did Not Keep Appointment"
01. Principal	spec_bld_not_col_rsn_v3_1-3	Not Collected Reason		.M="Missing" .R="Not Randomized"
01. Principal	spec_bld_num_v0_1-3	Number Of Specimens Collected		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_num_v2_1-3	Number Of Specimens Collected		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_num_v3_1-3	Number Of Specimens Collected		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_rsn_spec_v0_1-3	Not Collected Reason Other Specify		Char

Class	Variable	Label	Description	Format Text
01. Principal	spec_bld_rsn_spec_v2_1-3	Not Collected Reason Other Specify		Char
01. Principal	spec_bld_rsn_spec_v3_1-3	Not Collected Reason Other Specify		Char
01. Principal	spec_bld_ship_dt_v0_1-3	Date Specimen Shipped		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_ship_dt_v2_1-3	Date Specimen Shipped		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_ship_dt_v3_1-3	Date Specimen Shipped		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_storage_v0_1-3	If Samples Were Not Shipped On The Day Of Collection Under What Conditions Were The Specimens Stored?		.M="Missing" .R="Not Randomized" 1="Stored Per Protocol" 2="Not Applicable"
01. Principal	spec_bld_storage_v2_1-3	If Samples Were Not Shipped On The Day Of Collection Under What Conditions Were The Specimens Stored?		.M="Missing" .R="Not Randomized" 1="Stored Per Protocol" 2="Not Applicable"
01. Principal	spec_bld_storage_v3_1-3	If Samples Were Not Shipped On The Day Of Collection Under What Conditions Were The Specimens Stored?		.M="Missing" .R="Not Randomized" 1="Stored Per Protocol" 2="Not Applicable"
01. Principal	spec_bld_store_spec_v0_1-3	If Samples Were Not Shipped On The Day Of Collection Under What Conditions Were The Specimens Stored? Specify		Char
01. Principal	spec_bld_store_spec_v2_1-3	If Samples Were Not Shipped On The Day Of Collection Under What Conditions Were The Specimens Stored? Specify		Char
01. Principal	spec_bld_store_spec_v3_1-3	If Samples Were Not Shipped On The Day Of Collection Under What Conditions Were The Specimens Stored? Specify		Char
01. Principal	spec_bld_target_days_v0	Target Days From Baseline		Numeric .R="Not Randomized"
01. Principal	spec_bld_target_days_v2	Target Days From Baseline		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	spec_bld_target_days_v3	Target Days From Baseline		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_type_v0_1-3	Specimen Type		.R="Not Randomized" 1="Whole Blood Processed Into Plasma And Buffy Coat" 2="Whole Blood Processed Into Platelet Poor Plasma And Buffy Coat" 3="Whole Blood Processed Into Serum"
01. Principal	spec_bld_type_v2_1-3	Specimen Type		.M="Missing" .R="Not Randomized" 1="Whole Blood Processed Into Plasma And Buffy Coat" 2="Whole Blood Processed Into Platelet Poor Plasma And Buffy Coat" 3="Whole Blood Processed Into Serum"
01. Principal	spec_bld_type_v3_1-3	Specimen Type		.M="Missing" .R="Not Randomized" 1="Whole Blood Processed Into Plasma And Buffy Coat" 2="Whole Blood Processed Into Platelet Poor Plasma And Buffy Coat" 3="Whole Blood Processed Into Serum"
01. Principal	spec_bld_visit_v0	Visit Number		Numeric .R="Not Randomized"
01. Principal	spec_bld_visit_v2	Visit Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_visit_v3	Visit Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_bld_was_col_v0_1-3	Was Specimen Collected?		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	spec_bld_was_col_v2_1-3	Was Specimen Collected?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	spec_bld_was_col_v3_1-3	Was Specimen Collected?		.M="Missing" .R="Not Randomized" 1="Yes"

Section 24: Specimen Submission: Tissue

Class	Variable	Label	Description	Format Text
01. Principal	spec_tiss_col_dt_v0_1-6	Date Specimen Collected		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_tiss_col_dt_v3_1-6	Date Specimen Collected		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_tiss_comments_v0_1-6	Tissue Specimen Comments		Char
01. Principal	spec_tiss_comments_v3_1-6	Tissue Specimen Comments		Char
01. Principal	spec_tiss_container_v0_1-6	Container Or Additive		.R="Not Randomized" 1="Frozen" 2="RNAlater"
01. Principal	spec_tiss_container_v3_1-6	Container Or Additive		.M="Missing" .R="Not Randomized" 1="Frozen" 2="RNAlater"
01. Principal	spec_tiss_not_col_rsn_v0_1-6	Not Collected Reason		.M="Missing" .R="Not Randomized" 1="Insufficient/Scant Sample" 2="Not Available" 3="Sample Not Required" 4="Other"
01. Principal	spec_tiss_not_col_rsn_v3_1-6	Not Collected Reason		.M="Missing" .R="Not Randomized" 2="Not Available" 3="Sample Not Required" 4="Other"
01. Principal	spec_tiss_num_v0_1-6	Number Of Specimens Collected		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_tiss_num_v3_1-6	Number Of Specimens Collected		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_tiss_protocol_v0_1-6	Specimen Collection Protocol		.M="Missing" .R="Not Randomized" 1="Rectal Stump Or Intact Rectum" 2="Spigelman 2" 3="Spigelman 3"
01. Principal	spec_tiss_protocol_v3_1-6	Specimen Collection Protocol		.M="Missing" .R="Not Randomized" 2="Spigelman 2" 3="Spigelman 3"
01. Principal	spec_tiss_rsn_spec_v0_1-6	Not Collected Reason Other Specify		Char
01. Principal	spec_tiss_rsn_spec_v3_1-6	Not Collected Reason Other Specify		Char

Class	Variable	Label	Description	Format Text
01. Principal	spec_tiss_ship_d t_v0_1-6	Date Specimen Shipped		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_tiss_ship_d t_v3_1-6	Date Specimen Shipped		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_tiss_storag e_v0_1-6	If Samples Were Not Shipped On The Day Of Collection Under What Conditions Were The Specimens Stored?		.R="Not Randomized" 1="Stored Per Protocol" 2="Not Applicable"
01. Principal	spec_tiss_storag e_v3_1-6	If Samples Were Not Shipped On The Day Of Collection Under What Conditions Were The Specimens Stored?		.M="Missing" .R="Not Randomized" 1="Stored Per Protocol" 2="Not Applicable"
01. Principal	spec_tiss_target _days_v0	Target Days From Baseline		Numeric .R="Not Randomized"
01. Principal	spec_tiss_target _days_v3	Target Days From Baseline		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_tiss_type_v 0_1-6	Specimen Type		.R="Not Randomized" 1="Normal Duodenal Mucosa" 2="Duodenal Polyp" 3="Rectal Mucosa"
01. Principal	spec_tiss_type_v 3_1-6	Specimen Type		.M="Missing" .R="Not Randomized" 3="Rectal Mucosa"
01. Principal	spec_tiss_visit_v 0	Visit Number		Numeric .R="Not Randomized"
01. Principal	spec_tiss_visit_v 3	Visit Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_tiss_was_c ol_v0_1-6	Was Specimen Collected?		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	spec_tiss_was_c ol_v3_1-6	Was Specimen Collected?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Section 25: Specimen Submission: Urine

Class	Variable	Label	Description	Format Text
01. Principal	spec_urine_col_dt_v0/2/3	Date Specimen Collected		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_urine_comments_v0/2/3	Urine Specimen Comments		Char
01. Principal	spec_urine_not_col_rsn_v0/2/3	Not Collected Reason		.M="Missing" .R="Not Randomized" 1="Institution Error" 2="Patient Did Not Keep Appointment" 3="Patient Unable To Submit Sample" 4="Other"
01. Principal	spec_urine_number_v0/2/3	Number Of Specimens Collected		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_urine_rsn_spec_v0/2/3	Not Collected Reason Other, Specify		Char
01. Principal	spec_urine_ship_dt_v0/2/3	Date Specimen Shipped		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_urine_target_days_v0/2/3	Target Days From Baseline		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_urine_type_v0/2/3	Specimen Type		.M="Missing" .R="Not Randomized" 1="Urine"
01. Principal	spec_urine_visit_v0/2/3	Visit Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	spec_urine_was_col_v0/2/3	Was Specimen Collected?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Section 26: Upper GI Endoscopy Map

Class	Variable	Label	Description	Format Text
01. Principal	upgimap_colectomy1-78	Colectomy?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	upgimap_colectomy_age1-78	Colectomy What Age?		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	upgimap_comments1-78	Upper GI Map Comments		Char
01. Principal	upgimap_polyp_count1-78	Polyp Count		Numeric .M="Missing" .R="Not Randomized"
01. Principal	upgimap_segment_num1-78	Segment Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	upgimap_size1-78	Size (mm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	upgimap_target_days1-78	Target Days From Baseline		Numeric .M="Missing" .R="Not Randomized"
01. Principal	upgimap_total1-78	Total		Numeric .M="Missing" .R="Not Randomized"
01. Principal	upgimap_total_diam1-78	Total Sum Of Polyp Diameters		Numeric .M="Missing" .R="Not Randomized"
01. Principal	upgimap_totaloduodenal1-78	Total Number Of Duodenal Polyps		Numeric .M="Missing" .R="Not Randomized"
01. Principal	upgimap_visit_number1-78	Visit Number		Numeric .M="Missing" .R="Not Randomized"

Section 27: Upper GI Pathology Specimens

Class	Variable	Label	Description	Format Text
01. Principal	upgipath_biopsy_size1-12	Biopsy Size (mm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	upgipath_bottle_num1-12	Bottle Number		Char
01. Principal	upgipath_comments1-12	Upper GI Path Comments		Char
01. Principal	upgipath_image_num1-12	Image Number		Char
01. Principal	upgipath_location1-12	Location		Numeric .M="Missing" .R="Not Randomized" 99="Other"
01. Principal	upgipath_location_specify1-12	Location: Specify		Char
01. Principal	upgipath_shape1-12	Shape		.M="Missing" .R="Not Randomized" 1="Normal" 2="Sessile" 3="Pedunculated"
01. Principal	upgipath_target_days1-12	Target Days From Baseline		Numeric .M="Missing" .R="Not Randomized"
01. Principal	upgipath_visit1-12	Visit Number		Numeric .M="Missing" .R="Not Randomized"

Section 28: Upper GI Endoscopy Specimens

Class	Variable	Label	Description	Format Text
01. Principal	upgispec_biopsy_size1-16	Biopsy Size (mm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	upgispec_bottle_num1-16	Bottle Number		Char
01. Principal	upgispec_comments1-16	Upper GI Specimen Collection Comments		Char
01. Principal	upgispec_location1-16	Location		Numeric .M="Missing" .R="Not Randomized" 99="Other"
01. Principal	upgispec_location_specify1-16	Location: Specify		Char
01. Principal	upgispec_sample_type1-16	Sample Type		.M="Missing" .R="Not Randomized" 1="Frozen" 2="RNAlater"
01. Principal	upgispec_shape1-16	Shape		.M="Missing" .R="Not Randomized" 1="Normal" 2="Sessile"
01. Principal	upgispec_target_days1-16	Target Days From Baseline		Numeric .M="Missing" .R="Not Randomized"
01. Principal	upgispec_tissue_type1-16	Tissue Type		.M="Missing" .R="Not Randomized" 1="Normal" 2="Polyp"
01. Principal	upgispec_visit1-16	Visit Number		Numeric .M="Missing" .R="Not Randomized"

Section 29: Concomitant Medication

Class	Variable	Label	Description	Format Text
01. Principal	conmed_agent_name1-44	Agent Name		Char
01. Principal	conmed_any	Is The Participant Taking Any Concomitant Medications?		0="No" 1="Yes"
01. Principal	conmed_comments1-44	Concomitant Medication Comments		Char
01. Principal	conmed_continue1-44	Continuing?		.M="Missing" .N="N/A" 0="No" 1="Yes" 9="Unknown"
01. Principal	conmed_dose1-44	Dose		Numeric .M="Missing" .N="N/A"
01. Principal	conmed_freq1-44	Frequency		Char
01. Principal	conmed_freq_spec1-44	Frequency Specify		Char

Class	Variable	Label	Description	Format Text
01. Principal	conmed_indication1-44	Indication		.M="Missing" .N="N/A" 2="Acidity" 4="Allergic Reaction" 5="Allergy" 7="Anemia" 8="Anesthesia" 9="Anorexia" 11="Anticoagulation" 13="Anxiety" 16="Arrhythmia" 17="Arthralgia" 18="Arthritis" 20="Asthma" 22="Attention Deficit Hyperactivity Disorder (ADHD)" 23="Benign Prostatic Hyperplasia" 24="Bipolar Disorder" 25="Birth Control" 29="Bronchitis" 32="Cardiac" 33="Cellulitis" 36="Cns Disease" 38="Congestion" 39="Conjunctivitis" 40="Constipation" 42="Cough" 43="Dehydration" 44="Depression" 45="Dermatitis" 46="Diabetes" 47="Diarrhea" 49="Dyspepsia" 51="Dyspnea" 53="Earache" 60="Erectile Dysfunction" 66="Fever" 69="Flu Symptoms" 72="Gastric Ulcer" 73="Gastritis" 74="Gastroesophageal Reflux Disease" 75="Gastrointestinal Distress" 77="Glaucoma" 83="Headache" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] conmed_indication1-44			[...continued] 92="Hormonal Manipulation" 95="Hypercholesterolemia" 98="Hyperlipidemia" 100="Hypertension" 109="Hypothyroidism" 112="Indigestion" 113="Induce Sedation" 114="Infection" 115="Inflammation" 117="Insomnia" 118="Itching" 124="Local Anesthesia" 130="Mood" 131="Mouth Sores" 133="Muscle Spasm" 138="Nasal Symptom" 139="Nausea" 140="Nausea And Vomiting" 141="Neuropathy" 143="Nutrition" 145="Pain" 152="Pharyngitis" 157="Post Traumatic Stress Disorder" 160="Preprocedure/Diagnostic Testing" 161="Pretreatment" 162="Prophylaxis" 163="Pruritus" 166="Pulmonary Embolus" 167="Rash" 169="Reflux" 172="Respiratory Distress/Dyspnea" 173="Restless Leg Syndrome" 175="Rhinitis" 176="Rhinorrhea" 180="Sinusitis" 181="Skin Irritation" 182="Sleep" 183="Sleep Apnea" 184="Smoking Cessation" 187="Supplement" 192="Urinary" 198="Vertigo" 199="Vitamins" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	[...continued] conmed_indication1-44			[...continued] 200="Vomiting" 202="Weight Loss" 999="Other Specify"
01. Principal	conmed_indication_spec1-44	Indication Specify		Char
01. Principal	conmed_start_day1-44	Start Date(Day Of The Month)		Numeric .M="Missing" .N="N/A"
01. Principal	conmed_start_dt1-44	Start Date		SAS Date .M="Missing" .N="N/A"
01. Principal	conmed_start_month1-44	Start Date(Month)		Numeric .M="Missing" .N="N/A"
01. Principal	conmed_start_year1-44	Start Date(Year)		Numeric .M="Missing" .N="N/A"
01. Principal	conmed_stop_day1-44	Stop Date (Day Of The Month)		Numeric .M="Missing" .N="N/A"
01. Principal	conmed_stop_dt1-44	Stop Date		SAS Date .M="Missing" .N="N/A"
01. Principal	conmed_stop_month1-44	Stop Date (Month)		Numeric .M="Missing" .N="N/A"
01. Principal	conmed_stop_year1-44	Stop Date (Year)		Numeric .M="Missing" .N="N/A"
01. Principal	conmed_target_days	Target Days From Baseline		Numeric
01. Principal	conmed_units1-44	Units		Char

Section 30: Alcohol Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	alc_avg_drinks	On The Days When You Drank, On Average, About How Many Drinks Did You Have?		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	alc_avg_drinks_spec	On The Days When You Drank, On Average, About How Many Drinks Did You Have? Other Specify		.F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	alc_comments	Alcohol Questionnaire Comments		Char
01. Principal	alc_drink_past_30	During The Past 30 Days, Did You Drink Any Alcoholic Beverages?		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	alc_drink_past_30_days	During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages?		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	alc_drink_past_30_days_spec	During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages? Other Specify		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 8="Don't Know/Not Sure"

Section 31: End Active Treatment

Class	Variable	Label	Description	Format Text
01. Principal	end_at_agent_end_dt	Agent End Date		Numeric .N="N/A"
01. Principal	end_at_comments	End Active Treatment Comments		Char
01. Principal	end_at_contact_dt	Date Of Last Visit Or Contact		Numeric
01. Principal	end_at_not_obt	Agent Not Obtained (Only If The Participant Did Not Start Study Agent)		0="Unchecked" 1="Checked"
01. Principal	end_at_off_dt	Off Study Date		Numeric
01. Principal	end_at_reason	Off Study Reason		1="Study Complete" 2="Ineligible" 3="Adverse Event" 4="Physician Decision" 5="Lost To Follow-Up"
01. Principal	end_at_reason_spec	Off Study Reason Specify		Char
01. Principal	end_at_target_days	End Active Treatment Target Days From Baseline		Numeric .M="Missing"

Section 32: Events During Treatment

Class	Variable	Label	Description	Format Text
01. Principal	event_tx_ae_assessed_1-5	Were Adverse Events Assessed During This Reporting Period?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes, And Reportable Adverse Events Occurred" 2="Yes, But No Reportable Adverse Events Occurred"
01. Principal	event_tx_comments_1-5	Treatment Events Comments		Char
01. Principal	event_tx_comp_dt_1-5	Date Completed		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	event_tx_cont_1-5	Will The Participant Continue To The Next Visit?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	event_tx_contact_dt_1-5	Date Of Most Recent Contact		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	event_tx_target_days_1-5	Target Days From Baseline		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	event_tx_wiwi_comp_1-5	Did The Participant Complete The Was It Worth It (WIWI) Questionnaire?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 9="Not Applicable"

Section 33: Protocol Intervention Data

Class	Variable	Label	Description	Format Text
01. Principal	protdata_agent_admin_v2_1-15	Was Agent Administered?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	protdata_agent_admin_v3_1-15	Was Agent Administered?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	protdata_agent_name_v2_1-15	Agent Name		.M="Missing" .R="Not Randomized" 1="Erlotinib"
01. Principal	protdata_agent_name_v3_1-15	Agent Name		.M="Missing" .R="Not Randomized" 1="Erlotinib"
01. Principal	protdata_agent_start_dt_v2_1-15	Date Agent Started		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	protdata_agent_start_dt_v3_1-15	Date Agent Started		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	protdata_agent_stop_dt_v2_1-15	Date Agent Stopped		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	protdata_agent_stop_dt_v3_1-15	Date Agent Stopped		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	protdata_comments_v2_1-15	Protocol Data Comments		Char
01. Principal	protdata_comments_v3_1-15	Protocol Data Comments		Char
01. Principal	protdata_dose_dt_v2_1-15	Dose Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	protdata_dose_dt_v3_1-15	Dose Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	protdata_dose_num_v2_1-15	Agent Dose Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_dose_num_v3_1-15	Agent Dose Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_dose_time_v2_1-15	Dose Time (Hours:Minutes:Am Or Pm)		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	protdata_dose_time_v3_1-15	Dose Time (Hours:Minutes:Am Or Pm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_dose_v2_1-15	Dose (mg)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_dose_v3_1-15	Dose (mg)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_fasting_v2_1-15	Fasting		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	protdata_fasting_v3_1-15	Fasting		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	protdata_last_meal_dt_v2_1-15	Last Meal Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	protdata_last_meal_dt_v3_1-15	Last Meal Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	protdata_last_meal_hours_v2_1-15	Number Of Hours Since Last Meal		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_last_meal_hours_v3_1-15	Number Of Hours Since Last Meal		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_last_meal_time_v2_1-15	Last Meal Time (Hours:Minutes:Am Or Pm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_last_meal_time_v3_1-15	Last Meal Time (Hours:Minutes:Am Or Pm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_num_pills_coll_v2_1-15	Number Of Pills Collected At This Visit		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_num_pills_coll_v3_1-15	Number Of Pills Collected At This Visit		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_num_pills_prev_v2_1-15	Number Of Pills Dispensed At Previous Visit		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_num_pills_prev_v3_1-15	Number Of Pills Dispensed At Previous Visit		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_target_days_v2_1-15	Target Days From Baseline		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_target_days_v3_1-15	Target Days From Baseline		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	protdata_visit_nu m_v2_1-15	Visit Number		Numeric .M="Missing" .R="Not Randomized"
01. Principal	protdata_visit_nu m_v3_1-15	Visit Number		Numeric .M="Missing" .R="Not Randomized"

Section 34: Post-Intervention Evaluation

Class	Variable	Label	Description	Format Text
01. Principal	protintr_ae_asse ssed	Were Adverse Events Assessed During This Reporting Period?		.F="No Record For This Visit" .R="Not Randomized" 1="Yes, And Reportable Adverse Events Occurred" 2="Yes, But No Reportable Adverse Events Occurred"
01. Principal	protintr_commen ts	Protocol Interruptions Comments		Char
01. Principal	protintr_comp_fu	Has The Participant Completed Their Last Follow-Up Visit?		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	protintr_comp_wi wi	Was It Worth It Questionnaire Completed?		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	protintr_comp_wi wi_dt	Was It Worth It Questionnaire Date Completed		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	protintr_target_d ays	Target Days From Baseline		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	protintr_visit	Visit Number		Numeric .F="No Record For This Visit" .R="Not Randomized"

Section 35: Tobacco Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	tob_bidis	Other Tobacco Products Used Regularly: Bidis		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	tob_bsl_years_smoked_spec	How Many Total Years Have You Smoked (Or Did You Smoke) Cigarettes? Specify		Numeric .M="Missing" .R="Not Randomized" 9="Don't Know/Not Sure"
01. Principal	tob_choose_not_ans	Choose Not To Answer		.F="No Record For This Visit" .R="Not Randomized" 0="Unchecked" 1="Checked"
01. Principal	tob_cig_last_month	Cigarette In Less Than 1 Month		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_cig_last_week	Cigarette In The Last 1-7 Days		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	tob_cig_last_year	Cigarette In Less Than 1 Year		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_cig_more_1_year	Cigarette In More Than 1 Year		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_cig_per_day_spec	Cigarettes Per Day Specify		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	tob_cig_today	I Smoked A Cigarette Today		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_cigarettes	Other Tobacco Products Used Regularly: Cigarettes		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	tob_cigars	Other Tobacco Products Used Regularly: Traditional Cigars, Cigarillos, Or Filtered Cigars		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	tob_cigs_day	On Average, When You Smoked, About How Many Cigarettes Do You Smoke A Day?		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	tob_clove_cig	Other Tobacco Products Used Regularly: Clove Cigarettes Or Kreteks		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	tob_comments	Tobacco Questionnaire Comments		Char
01. Principal	tob_days_last_cig	Number Of Days Since Last Cigarette		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	tob_do_not_know	Don't Know/Don't Remember		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_e_cig	Other Tobacco Products Used Regularly: E-Cigarettes Or Other Electronic Nicotine Delivery System		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	tob_hookah	Other Tobacco Products Used Regularly: Hookah		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	tob_months_last_cig	Number Of Months Since Last Cigarette		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	tob_oth_daily	Other Tobacco Use Every Day		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Yes"
01. Principal	tob_oth_last_use	If You Do Not Currently Use Other Forms Of Tobacco, But Did In The Past, How Long Has It Been Since You Last Used Other Forms Of Tobacco Regularly?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	tob_oth_not_answer	Choose Not To Answer		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Unchecked"
01. Principal	tob_oth_some_days	Other Tobacco Use Some Days		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	tob_oth_timse_day	Other Tobacco Use Number Of Times Per Day		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	tob_oth_tob_spec	Other Tobacco Use, Specify		Char
01. Principal	tob_oth_tob_use	Since Your Last Visit, Have You Used Other Forms Of Tobacco, Not Including Cigarettes?		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	tob_oth_use_days	Other Tobacco Use Number Of Days		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	tob_oth_use_per	Other Tobacco Use Per		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	tob_other	Other Tobacco Products Used Regularly: Other		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Yes"
01. Principal	tob_paan	Other Tobacco Products Used Regularly: Paan With Tobacco, Gutka, Zarda, Khaini		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	tob_pipe	Other Tobacco Products Used Regularly: Pipes		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	tob_smoke_after_end	Smoke After The End Of Study Treatment?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 2="Smoked Some Days" 3="Did Not Smoke At All" 4="Not Applicable (I Have Not Completed The Study Treatment)" 8="Choose Not To Answer" 9="Don't Know/Not Sure"
01. Principal	tob_smoke_during_study	Smoke During Study Treatment?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Smoked Every Day" 2="Smoked Some Days" 3="Did Not Smoke At All" 4="Not Applicable" 8="Choose Not To Answer"

Class	Variable	Label	Description	Format Text
01. Principal	tob_smoke_last_visit	Smoke Since Your Last Visit To This Clinic?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Smoked Every Day" 2="Smoked Some Days" 3="Did Not Smoke At All" 4="Not Applicable (This Is My First Visit To This Clinic)" 8="Choose Not To Answer" 9="Don't Know/Not Sure"
01. Principal	tob_smoke_now	Do You Now Smoke Cigarettes?		.F="No Record For This Visit" .R="Not Randomized" 1="Everyday" 2="Some Days" 3="Not At All"
01. Principal	tob_smokeless	Other Tobacco Products Used Regularly: Smokeless Tobacco (Like Dip, Chew, Or Snuff)		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	tob_snus	Other Tobacco Products Used Regularly: Snus		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	tob_target_days	Target Days From Baseline		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tob_visit	Visit Number		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	tob_water_pipe	Other Tobacco Products Used Regularly: Water Pipe		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No"
01. Principal	tob_weeks_last_cig	Number Of Weeks Since Last Cigarette		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	tob_years_last_cig	Number Of Years Since Last Cigarette		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 36: Was It Worth It? Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	wiwi_comments	Was It Worth It Questionnaire Comments		Char
01. Principal	wiwi_do_over	If You Had To Do It Over, Would You Participate In This Research Study Again?		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	wiwi_improve_what	If There Was One Thing That Could Have Been Done To Improve Your Experience In This Research Study, What Would It Be?		Char
01. Principal	wiwi_life_change	Overall, Did Your Quality Of Life Change By Participating In This Research Study?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="It Improved" 2="It Stayed The Same" 3="It Got Worse"
01. Principal	wiwi_overall	Overall, How Was Your Experience Of Participating In This Research Study?		.F="No Record For This Visit" .R="Not Randomized" 1="Better Than I Expected" 2="The Same As I Expected" 3="Worse Than I Expected"
01. Principal	wiwi_recommend	Would You Recommend Participating In This Research Study To Others?		.F="No Record For This Visit" .R="Not Randomized" 1="Yes" 9="Uncertain"
01. Principal	wiwi_talk_concerns	Would You Like To Talk To Someone About Your Concerns?		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	wiwi_target_days	Target Days From Baseline		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	wiwi_timepoint	Time Point		.F="No Record For This Visit" .R="Not Randomized" 1="Early Termination" 2="Follow-Up"
01. Principal	wiwi_worthwhile	Was It Worthwhile For You To Participate In This Research Study?		.F="No Record For This Visit" .R="Not Randomized" 1="Yes" 9="Uncertain"

Section 37: Supporting Documentation

Class	Variable	Label	Description	Format Text
01. Principal	support_doc_attachment1-29	Attachment		Char
01. Principal	support_doc_comments1-29	Supporting Documents Comments		Char
01. Principal	support_doc_dt1-29	Date Of Assessment		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	support_doc_report_type1-29	Report Type		.M="Missing" .N="N/A" .R="Not Randomized" 1="Clinic Note" 2="Laboratory Report" 3="Pathology Report" 4="Other"
01. Principal	support_doc_target_days1-29	Target Days From Baseline		Numeric .N="N/A" .R="Not Randomized"
01. Principal	support_doc_type_spec1-29	Specify Report Type		Char
01. Principal	support_doc_visit_num1-29	Visit Number		Numeric .N="N/A" .R="Not Randomized"

Section 38: Phone Contact

Class	Variable	Label	Description	Format Text
01. Principal	phone_ae_reported1-4	Were Any Adverse Events Reported?		.M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	phone_attempt1-4	Was A Follow-Up Phone Call Attempted?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	phone_attempt_dt1-4	Date Follow-Up Phone Call Attempted		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	phone_comments1-4	Follow-Up Phone Call Comments		Char
01. Principal	phone_comp1-4	Was A Follow-Up Phone Call Completed?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	phone_comp_dt1-4	Date Follow-Up Phone Call Completed		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	phone_conmed_change1-4	Did The Participant Report Any Changes To Concomitant Medications?		.M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	phone_target_days1-4	Target Days From Baseline		Numeric .M="Missing" .R="Not Randomized"
01. Principal	phone_visit1-4	Visit Number		Numeric .M="Missing" .R="Not Randomized"