

UWI2016-08-01 - Enhanced Person Data Dictionary

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UWI2016-08-01 - Enhanced Person: Data Dictionary

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	build_dt	Build Date		SAS Date
01. Principal	Sequence_No_	Participant ID		Char

Section 3: Registration

Class	Variable	Label	Description	Format Text
01. Principal	reg_age	Age - [Registration]		Numeric
01. Principal	reg_biobank_agree	Participant Agrees That Her Samples And Related Information May Be Kept In A Biobank For Use In Future Health Research - [Registration]		0="No" 1="Yes"
01. Principal	reg_dr_contact	Participant Agrees That Her Study Doctor, Or Their Representative, May Contact Her Or Her Physician To See If She Wishes To Participate In Other Research In The Future - [Registration]		0="No" 1="Yes"
01. Principal	reg_dt	Registration Date - [Registration]		SAS Date
01. Principal	reg_ethnicity	Ethnicity - [Registration]		0="Not Hispanic or Latino" 1="Hispanic or Latino" 2="Not Reported"
01. Principal	reg_gender	Gender - [Registration]		1="Female"
01. Principal	reg_gene_sci_db	Participant Agrees That Her Genetic And Health Information Can Be Released, With No Direct Identifiers, Into Scientific Databases - [Registration]		0="No" 1="Yes"
01. Principal	reg_icf_dt	Informed Consent Date - [Registration]		SAS Date
01. Principal	reg_institution	Registering Institution - [Registration]		Char
01. Principal	reg_protocol_number	DCP Protocol Number - [Registration]		Char
01. Principal	reg_race	Race - [Registration]		1="White" 2="Black or African American" 3="Asian" 4="American Indian or Alaska Native" 5="Native Hawaiian or Other Pacific Islander" 6="Not Reported" 7="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	reg_tob_alc_info	The Information From My Tobacco And Alcohol Use Questionnaires May Be Used In Future Health Research - [Registration]		0="No" 1="Yes"

Section 4: Screening

Class	Variable	Label	Description	Format Text
01. Principal	screen_bio_consent_na	Biopsy Consent (N/A) - [Screening]		1="Not Applicable"
01. Principal	screen_biop_consent_dt	Date Of Biopsy Consent - [Screening]		SAS Date .M="Missing"
01. Principal	screen_comments	Comments - [Screening]		Char
01. Principal	screen_dt	Screening Date - [Screening]		SAS Date
01. Principal	screen_part_find_study1	How Did The Participant Find Out About The Study? - [Screening]		.N="N/A" 1="Physician" 2="Nurse"
01. Principal	screen_part_find_study2	How Did The Participant Find Out About The Study? (Other, Specify) - [Screening]		0="No" 1="Yes"
01. Principal	screen_part_find_study_spec	How Did The Participant Find Out About The Study, Other, Specify - [Screening]		Char
01. Principal	screen_partic_meet_crit	Does The Participant Meet The Screening Criteria? - [Screening]		0="No" 1="Yes"
01. Principal	screen_refer1	Who Referred The Participant? (Physician) - [Screening]		0="No" 1="Yes"
01. Principal	screen_refer2	Who Referred The Participant? (Other, Specify) - [Screening]		0="No" 1="Yes"
01. Principal	screen_refer_spec	Referral Other, Specify - [Screening]		Char
01. Principal	screen_tele_consent_dt	Date Of Telephone Consent - [Screening]		SAS Date .M="Missing"
01. Principal	screen_tele_consent_na	Telephone Consent (N/A) - [Screening]		.M="Missing" 1="Not Applicable"

Section 5: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	bsymptom_num	Total Number Of Observations - [Baseline Symptoms]		Numeric .R="Not Randomized"
01. Principal	bsymptoms_any	Did Participant Have Any Baseline Symptoms? - [Baseline Symptoms]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bsymptoms_comments1-14	Comments - # - [Baseline Symptoms]		Char
01. Principal	bsymptoms_ctcae_term1-14	CTCAE Term (v4.0) - # - [Baseline Symptoms]		Char
01. Principal	bsymptoms_grade1-14	Symptom Grade - # - [Baseline Symptoms]		.M="Missing" .N="N/A" .R="Not Randomized" 0="No Symptoms" 1="Mild" 2="Moderate" 3="Severe" 4="Life Threatening" 5="Lethal" 9="Ungradeable"
01. Principal	bsymptoms_ongoing1-14	Ongoing - # - [Baseline Symptoms]		.M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	bsymptoms_onset_dt1-14	Onset Date - # - [Baseline Symptoms]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	bsymptoms_onset_dt_acc1-14	Onset Date (Accuracy) - # - [Baseline Symptoms]		.M="Missing" .N="N/A" .R="Not Randomized" 1="Day" 2="Week" 3="Month" 4="Year" 5="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bsymptoms_soc 1-14	MedDRA System Organ Class (SOC) (V12.0) - # - [Baseline Symptoms]		.M="Missing" .N="No Adverse Events Reported" .R="Not Randomized" 1="Blood and Lymphatic System Disorders" 2="Cardiac Disorders" 3="Congenital, Familial and Genetic Disorders" 4="Ear and Labyrinth Disorders" 5="Endocrine Disorders" 6="Eye Disorders" 7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 9="Hepatobiliary Disorders" 10="Immune System Disorders" 11="Infections and Infestations" 12="Injury, Poisoning and Procedural Complications" 13="Investigations" 14="Metabolism and Nutrition Disorders" 15="Musculoskeletal and Connective Tissue Disorders" 16="Neoplasms Benign, Malignant and Unspecified (Including Cysts and Polyps)" 17="Nervous System Disorders" 18="Pregnancy, Puerperium and Perinatal Conditions" 19="Psychiatric Disorders" 20="Renal and Urinary Disorders" 21="Reproductive System and Breast Disorders" 22="Respiratory, Thoracic and Mediastinal Disorders" 23="Skin and Subcutaneous Tissue Disorders" 24="Social Circumstances" 25="Surgical and Medical Procedures" 26="Vascular Disorders" 99="No Toxicity Group Associated With CTCAE Term"
01. Principal	bsymptoms_stop _dt1-14	Stop Date - # - [Baseline Symptoms]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	bsymptoms_verb atim1-14	Symptom Description (Verbatim Term) - # - [Baseline Symptoms]		Char

Section 6: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	conmed_continuing1-21	Continuing? - # - [Concomitant Medications]		.N="N/A" 0="No" 1="Yes" 2="Unknown"
01. Principal	conmed_dose1-21	Dose - # - [Concomitant Medications]		Numeric .N="N/A"
01. Principal	conmed_dose_unknown1-21	Dose Unknown? - # - [Concomitant Medications]		.N="N/A" 0="No" 1="Yes"
01. Principal	conmed_end_dt1-21	End Date - # - [Concomitant Medications]		SAS Date .N="N/A"
01. Principal	conmed_end_dt_acc1-21	End Date (Accuracy) - # - [Concomitant Medications]		.N="N/A" 1="Day" 2="Week" 3="Month" 4="Year" 5="Unknown"
01. Principal	conmed_freq1-21	Frequency - # - [Concomitant Medications]		Char
01. Principal	conmed_medication1-21	Medication - # - [Concomitant Medications]		Char
01. Principal	conmed_num	Total Number Of Concomitant Medications - [Concomitant Medications]		Numeric
01. Principal	conmed_reason1-21	Reason - # - [Concomitant Medications]		Char
01. Principal	conmed_rep_dt1-21	Medication Report Date - # - [Concomitant Medications]		SAS Date .N="N/A"
01. Principal	conmed_start_dt1-21	Start Date - # - [Concomitant Medications]		SAS Date .M="Missing" .N="N/A"
01. Principal	conmed_start_dt_acc1-21	Start Date (Accuracy) - # - [Concomitant Medications]		.N="N/A" 1="Day" 2="Week" 3="Month" 4="Year" 5="Unknown"
01. Principal	conmed_units1-21	Units - # - [Concomitant Medications]		Char

Section 7: Exclusion

Class	Variable	Label	Description	Format Text
01. Principal	excl_any_hormonal_treat	Has Been On Any Hormonal Treatment For CAH/EIN Or Grade 1 Endometrial Carcinoma In Last 3 Months - [Exclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	excl_bone_density_issue	Women With Severe Bone Density Issues/Osteoporosis - [Exclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	excl_form_version	Form Version - [Exclusion]		Char
01. Principal	excl_gastro_condition	Any Gastrointestinal Condition Causing Malabsorption Or Obstruction - [Exclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	excl_hormone_replacement	Use Hormone Replacement Therapy, Phytoestrogen Supplements, Progestin, Tamoxifen Or Aromatase Inhibitor Within The Prior 3 Months - [Exclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	excl_hypersensitive	Known Hypersensitivity To Exemestane Or Its Excipients - [Exclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	excl_intercurrent_ill	Known Intercurrent Illness Or Psychiatric Illness/Social Situations That Will Limit Compliance With Study Requirements - [Exclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	excl_no_biopsy	Unwilling Or Unable To Undergo Research Biopsy During The Baseline (Pre-Surgical) Clinic Visit, Or Inadequate Research Biopsy Obtained During The Baseline (Pre-Surgical) Clinic Visit - [Exclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	excl_not_surgical_candidate	Not A Surgical Candidate Or Surgery Is Not Scheduled Within 43 Days From Starting The Study Drug. - [Exclusion]		.M="Missing" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	excl_oth_inv_agents	Receiving Any Other Investigational Agents - [Exclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	excl_prev_treat_malig	Participants Who Had Curatively Treated Invasive Malignancies For Which All Treatments Ended Within 1 Year Prior To The Study - [Exclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	excl_prob_metastatic	Evidence Or High Suspicion Of Metastatic Disease At Enrollment - [Exclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	excl_strong_cyp3a4	Concomitant Use Of Strong CYP3A4 Inducers - [Exclusion]		.M="Missing" 0="No" 1="Yes"

Section 8: Inclusion

Class	Variable	Label	Description	Format Text
01. Principal	incl_able_icf	Ability To Understand And The Willingness To Sign A Written Informed Consent Document - [Inclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	incl_able_oral_meds	Able And Willing To Take Oral Medications - [Inclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	incl_age_crit	Age >50 (v2/v3) Or >45 (v4/v6) Years - [Inclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	incl_bmi_min_20	BMI > 20 - [Inclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	incl_ecog_perf_stat	ECOG Performance Status > 1 - [Inclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	incl_form_version	Form Version - [Inclusion]		Char
01. Principal	incl_hist_proven	Females With A Histologically Proven CAH/ EIN Or Grade I Endometrial Carcinoma (EC) For Which Surgery Is Planned - [Inclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	incl_no_prior_tx	No Prior Treatment For CAH/EIN/EC - [Inclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	incl_normal_organisms	Participants Must Have Normal Organ And Marrow Function - [Inclusion]		.M="Missing" 0="No" 1="Yes"
01. Principal	incl_post_menopause	Post-Menopausal - [Inclusion]		.M="Missing" 0="No" 1="Yes"

Section 9: Intervention Administration

Class	Variable	Label	Description	Format Text
01. Principal	int_admin_agent	Agent/Placebo - [Intervention Administration]		.R="Not Randomized" 1="Exemestane"
01. Principal	int_admin_agent _dose	Dose (mg Every Day) - [Intervention Administration]		Numeric .R="Not Randomized"
01. Principal	int_admin_agent _prov_dt	Date Agent Provided (To Participant) - [Intervention Administration]		SAS Date .R="Not Randomized"
01. Principal	int_admin_agent _start_dt	Date Agent Started - [Intervention Administration]		SAS Date .R="Not Randomized"

Section 10: MDS

Class	Variable	Label	Description	Format Text
01. Principal	mds_country_code	Country Code - [MDS]		1="USA"
01. Principal	mds_enroll_dt	Enrollment Date - [MDS]		SAS Date
01. Principal	mds_payment_method	Participant Method Of Payment - [MDS]		1="Medicaid" 2="Medicare" 3="Medicare and Private Insurance" 4="Military Sponsored (including CHAMPUS & TriCare)" 5="Military or Veterans Sponsored, NOS" 6="Private Insurance" 7="Self-Pay (No insurance)" 8="Unknown" 9="Veterans Sponsored" 10="No Means of Payment (No Insurance)" 11="Managed Care/Medicare" 12="State Supplemental Health Insurance" 13="Other"
01. Principal	mds_reg_consortium	Registering Consortium - [MDS]		Char
01. Principal	mds_tac_code	Treatment Assignment Code (TAC) - [MDS]		0="TAC-0" 1="TAC1"

Section 11: Clinical Pathology

Class	Variable	Label	Description	Format Text
01. Principal	clin_path_comments	Comments - [Clinical Pathology]		Char
01. Principal	clin_path_dx_dt	Diagnosis Date - [Clinical Pathology]		SAS Date .R="Not Randomized"
01. Principal	clin_path_dx_path	Diagnosis Pathology - [Clinical Pathology]		.R="Not Randomized" 1="Grade 1 Endometrial Cancer" 2="Grade 2 Endometrial Cancer" 3="Endometrial Intraepithelial Neoplasia" 4="Complex Atypical Hyperplasia"
01. Principal	clin_path_surg_dt	Surgery Date - [Clinical Pathology]		SAS Date .R="Not Randomized"
01. Principal	clin_path_surg_path	Surgery Pathology - [Clinical Pathology]		.R="Not Randomized" 0="No Visible Legion" 1="Grade 1 Endometrial Cancer" 2="Grade 2 Endometrial Cancer" 3="Endometrial Intraepithelial Neoplasia" 4="Complex Atypical Hyperplasia" 5="High Grade Endometrial Cancer"

Section 12: Baseline Surgical And Medical History

Class	Variable	Label	Description	Format Text
01. Principal	bmedsurg_all_normal	All Body Systems Are Normal? (No Baseline Symptoms) - [Baseline Surgical And Medical History]		.M="Missing" 0="No" 1="Yes"
01. Principal	bmedsurg_allergies	Does The Participant Have Any Allergies? - [Baseline Surgical And Medical History]		.M="Missing" 0="No" 1="Yes"
01. Principal	bmedsurg_allergies_spec	Does The Participant Have Any Allergies?, Specify - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_breast_comment	Breast Comments - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_breast_stat	Breast Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_cardio_comment	Cardiovascular Comments - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_cardio_stat	Cardiovascular Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_dermat_comment	Dermatologic Comments - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_dermat_stat	Dermatologic Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_diagnosis	Diagnosis - [Baseline Surgical And Medical History]		.M="Missing" 1="Grade 1 Endometrial Cancer" 2="Grade 2 Endometrial Cancer" 3="Endometrial Intraepithelial Neoplasia" 4="Complex Atypical Hyperplasia"
01. Principal	bmedsurg_diagnosis_dt	Diagnosis Date - [Baseline Surgical And Medical History]		SAS Date .M="Missing"
01. Principal	bmedsurg_endocrine_comment	Endocrine/Metabolic Comments - [Baseline Surgical And Medical History]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bmedsurg_endocrine_stat	Endocrine/Metabolic Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_gastro_comment	Gastrointestinal Comments - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_gastro_stat	Gastrointestinal Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_genito_comment	Genitourinary Comments - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_genito_stat	Genitourinary Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_heent_comment	H/E/E/N/T Comments - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_heent_stat	H/E/E/N/T Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_hema_comment	Hematopoietic Comments - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_hema_stat	Hematopoietic Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_musculo_comment	Musculoskeletal Comments - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_musculo_stat	Musculoskeletal Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_neck_comment	Neck Comments - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_neck_stat	Neck Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_neuro_comment	Neurologic Comments - [Baseline Surgical And Medical History]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bmedsurg_neuro_stat	Neurologic Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_oth_body_sys1-4	Specific Other Body System/Site - # - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_oth_body_sys_num	Number Of Other Baseline Histories - [Baseline Surgical And Medical History]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	bmedsurg_oth_body_sys_spec1-4	Specific Other Body System/Site Comments - # - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_oth_body_sys_stat1-4	Specific Other Body System/Site Status Normal? - # - [Baseline Surgical And Medical History]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	bmedsurg_resp_comment	Respiratory Comments - [Baseline Surgical And Medical History]		Char
01. Principal	bmedsurg_resp_stat	Respiratory Body System Normal? - [Baseline Surgical And Medical History]		.M="Missing" 0="Not Assessed" 1="Normal" 2="Abnormal"

Section 13: Alcohol Questionnaire (Baseline)

Class	Variable	Label	Description	Format Text
01. Principal	alc_bsl_5_drinks_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? - [Alcohol Questionnaire (Baseline)]		.M="Missing" .N="N/A" 0="No" 1="Yes" 2="Don't Know/Not Sure" 3="Refused"
01. Principal	alc_bsl_5_drinks_day	In The Past 12 Months, On How Many Days Did You Have 5 Or More Drinks Of Any Alcoholic Beverage? - [Alcohol Questionnaire (Baseline)]		Numeric .M="Missing" .N="N/A"
01. Principal	alc_bsl_5_drinks_day_refuse	Refused Or Don't Know/Not Sure, How Many Days Drank 5 Or More Alcohol Drinks Per Day In The Past 12 Months - [Alcohol Questionnaire (Baseline)]		.N="N/A" 1="Don't Know/Not Sure" 2="Refused"
01. Principal	alc_bsl_age_drink_reg	At What Age Did You Begin Drinking Regularly? - [Alcohol Questionnaire (Baseline)]		Numeric .M="Missing" .N="N/A"
01. Principal	alc_bsl_age_drink_reg_refuse	Refused Or Don't Know/Not Sure, At What Age Did You Begin Drinking Regularly? - [Alcohol Questionnaire (Baseline)]		.N="N/A" 1="Don't Know/Not Sure" 2="Refused"
01. Principal	alc_bsl_beer	What Type(s) Of Alcohol Do You Drink? (Beer) - [Alcohol Questionnaire (Baseline)]		.N="N/A" 0="No" 1="Yes"
01. Principal	alc_bsl_drinks_day	In The Past 12 Months, On Those Days That You Drank Alcoholic Beverages, On Average, How Many Drinks Did You Have Per Day? - [Alcohol Questionnaire (Baseline)]		Numeric .M="Missing" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	alc_bsl_drinks_d ay_refuse	Refused Or Don't Know/Not Sure, How Many Alcohol Drinks Per Day In The Past 12 Months - [Alcohol Questionnaire (Baseline)]		.N="N/A" 1="Don't Know/Not Sure" 2="Refused"
01. Principal	alc_bsl_ever_dri nk_12	In Your Entire Life, Have You Had At Least 12 Drinks Of Any Kind Of Alcoholic Beverage? - [Alcohol Questionnaire (Baseline)]		.M="Missing" 0="No" 1="Yes" 2="Don't Know/Not Sure" 3="Refused"
01. Principal	alc_bsl_heavy_dr ink_freq	At The Heaviest Point, Either Now Or In The Past, On The Days When You Drank, About How Many Drinks Did You Drink On The Average? - [Alcohol Questionnaire (Baseline)]		Numeric .M="Missing" .N="N/A"
01. Principal	alc_bsl_heavy_dr ink_freq_refuse	Refused Or Don't Know/Not Sure, At The Heaviest Point, About How Many Drinks Did You Drink On The Average? - [Alcohol Questionnaire (Baseline)]		.N="N/A" 1="Don't Know/Not Sure" 2="Refused"
01. Principal	alc_bsl_how_ofte n	In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcoholic Beverage? - [Alcohol Questionnaire (Baseline)]		Numeric .N="N/A"
01. Principal	alc_bsl_how_ofte n_freq	In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcoholic Beverage? Frequency - [Alcohol Questionnaire (Baseline)]		.N="N/A" 1="Day" 2="Week" 3="Month" 4="Year" 5="Don't Know/Not Sure" 6="Refused"

Class	Variable	Label	Description	Format Text
01. Principal	alc_bsl_last_drunk_reg	If You Do Not Currently Drink Alcoholic Beverages, But Did In The Past, How Long Has It Been Since You Last Drank Regularly - [Alcohol Questionnaire (Baseline)]		.M="Missing" .N="N/A" 1="Within the Past Month (0 to 1 Month Ago)" 2="Between 1 and 3 Months (1 to 3 Months Ago)" 3="Between 3 and 6 Months (3 to 6 Months Ago)" 4="Between 6 and 12 Months (6 to 12 Months Ago)" 5="Between 1 and 5 Years (1 to 5 Years Ago)" 6="Between 5 and 15 Years (5 to 15 years Ago)" 7="More Than 15 Years Ago" 8="Don't Know/Not Sure" 9="Never Drank Regularly"
01. Principal	alc_bsl_liquor	What Type(s) Of Alcohol Do You Drink? (Liquor) - [Alcohol Questionnaire (Baseline)]		.N="N/A" 0="No" 1="Yes"
01. Principal	alc_bsl_wine	What Type(s) Of Alcohol Do You Drink? (Wine) - [Alcohol Questionnaire (Baseline)]		.N="N/A" 0="No" 1="Yes"
01. Principal	alc_bsl_wine_cooler	What Type(s) Of Alcohol Do You Drink? (Wine Cooler) - [Alcohol Questionnaire (Baseline)]		.N="N/A" 0="No" 1="Yes"
01. Principal	alc_bsl_years_drink_reg	How Many Years Have You Been Drinking (Or Did You Drink) Regularly? - [Alcohol Questionnaire (Baseline)]		Numeric .M="Missing" .N="N/A"
01. Principal	alc_bsl_years_drink_reg_refuse	Refused Or Don't Know/Not Sure, How Many Years Have You Been Drinking (Or Did You Drink) Regularly? - [Alcohol Questionnaire (Baseline)]		.N="N/A" 1="Don't Know/Not Sure" 2="Refused"

Section 14: Tobacco Questionnaire (Baseline)

Class	Variable	Label	Description	Format Text
01. Principal	tob_bsl_30_live_in	In The Past 30 Days, Have You Lived In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Questionnaire (Baseline)]		.M="Missing" 0="No" 1="Yes"
01. Principal	tob_bsl_30_work_in	In The Past 30 Days, Have You Worked In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Questionnaire (Baseline)]		.M="Missing" 0="No" 1="Yes"
01. Principal	tob_bsl_age_smoke_first	How Old Were You When You First Smoked A Cigarette? - [Tobacco Questionnaire (Baseline)]		Numeric .N="N/A"
01. Principal	tob_bsl_age_smoke_reg	How Old Were You When You First Began Smoking Cigarettes Regularly? - [Tobacco Questionnaire (Baseline)]		Numeric .M="Missing" .N="N/A"
01. Principal	tob_bsl_cig_day	On Average When You Have Smoked, About How Many Cigarettes Do You Smoke A Day? - [Tobacco Questionnaire (Baseline)]		Numeric .N="N/A"
01. Principal	tob_bsl_cig_wake_time	How Soon After You Wake Up Do You Smoke Your First Cigarette? - [Tobacco Questionnaire (Baseline)]		.M="Missing" .N="N/A" 1="Within 30 Minutes" 2="After 30 Minutes"
01. Principal	tob_bsl_last_cig	How Long Has It Been Since You Last Smoked A Cigarette? - [Tobacco Questionnaire (Baseline)]		.N="N/A" 1="I Smoked a Cigarette Today (At Least One Puff)" 2="1-7 Days" 3="Less Than 1 Month" 4="Less Than 1 Year" 5="More Than 1 Year" 6="Don't Know/Don't Remember"

Class	Variable	Label	Description	Format Text
01. Principal	tob_bsl_last_cig_yrs	Number (Years), How Long Has It Been Since You Last Smoked A Cigarette? - [Tobacco Questionnaire (Baseline)]		Numeric .M="Missing"
01. Principal	tob_bsl_live_smoke_in	Thinking Of All Your Childhood And Adult Years, Have You Ever Lived In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Questionnaire (Baseline)]		.M="Missing" 0="No" 1="Yes"
01. Principal	tob_bsl_live_smoke_in_yrs	Lived In A Place Where Other People Smoked Cigarettes Indoors? In Total, For About How Many Years? - [Tobacco Questionnaire (Baseline)]		Numeric .N="N/A"
01. Principal	tob_bsl_live_smoker_curr	Are You Currently Living With A Smoker? - [Tobacco Questionnaire (Baseline)]		.M="Missing" 0="No" 1="Yes"
01. Principal	tob_bsl_never_smoke_reg	Never Smoked Regularly - [Tobacco Questionnaire (Baseline)]		.N="N/A" 1="Check Here if You have Never Smoked Cigarettes Regularly"
01. Principal	tob_bsl_oth_tob	Have You Ever Used Other Forms Of Tobacco, Not Including Cigarettes? - [Tobacco Questionnaire (Baseline)]		.M="Missing" 0="No" 1="Yes" 2="Don't Know/Not Sure"
01. Principal	tob_bsl_oth_tob_freq	Number Within Timeframe, How Often Do You/Did You Use Other Forms Of Tobacco? - [Tobacco Questionnaire (Baseline)]		Numeric .M="Missing" .N="N/A"
01. Principal	tob_bsl_oth_tob_often	How Often Do You/Did You Use Other Forms Of Tobacco? - [Tobacco Questionnaire (Baseline)]		.M="Missing" .N="N/A" 0="Not At All" 1="Some Days" 2="Every Day"
01. Principal	tob_bsl_oth_tob_timeframe	Timeframe, How Often Do You/Did You Use Other Forms Of Tobacco? - [Tobacco Questionnaire (Baseline)]		.M="Missing" .N="N/A" 1="Days Per Week" 2="Days Per Year"

Class	Variable	Label	Description	Format Text
01. Principal	tob_bsl_oth_type	Which Of The Following Products Have You Ever Used Regularly? - [Tobacco Questionnaire (Baseline)]		=" .M="Missing" .N="N/A" 1="Smokeless tobacco, like dip, chew or snuff" 2="Cigarettes" 3="E-cigarettes or other electronic nicotine delivery system" 4="Traditional cigars, cigarillos or filtered cigars" 5="Waterpipe" 6="Pipes" 7="Hookah" 8="Clove cigarettes or kreteks" 9="Bidis" 10="Snus" 11="Paan with tobacco, gutka, zarda, khaini" 12="Other, Please Specify"
01. Principal	tob_bsl_oth_type_spec	Which Of The Following Products Have You Ever Used Regularly? Other, Specify - [Tobacco Questionnaire (Baseline)]		Char
01. Principal	tob_bsl_smoke_100	Have You Smoked At Least 100 Cigarettes In Your Entire Life? - [Tobacco Questionnaire (Baseline)]		.M="Missing" 0="No" 1="Yes" 2="Don't Know/Not Sure"
01. Principal	tob_bsl_smoke_cig_now	Do You Now Smoke Cigarettes? - [Tobacco Questionnaire (Baseline)]		.N="N/A" 0="Not At All" 1="Some Days" 2="Every Day"
01. Principal	tob_bsl_time_since_oth_tob	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? - [Tobacco Questionnaire (Baseline)]		.N="N/A" 1="Within the Past Month (0 to 1 Month Ago)" 2="Between 1 and 3 Months (1 to 3 Months Ago)" 3="Between 3 and 6 Months (3 to 6 Months Ago)" 4="Between 6 and 12 Months (6 to 12 Months Ago)" 5="Between 1 and 5 Years (1 to 5 Years Ago)" 6="Between 5 and 15 Years (5 to 15 years Ago)" 7="More Than 15 Years Ago" 8="Don't Know/Not Sure" 9="Never Drank Regularly"

Class	Variable	Label	Description	Format Text
01. Principal	tob_bsl_work_s moke_in	Thinking Of All The Years You Have Worked, Have You Ever Worked In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Questionnaire (Baseline)]		.M="Missing" 0="No" 1="Yes"
01. Principal	tob_bsl_work_s moke_in_yrs	Worked In A Place Where Other People Smoked Cigarettes Indoors? In Total, For About How Many Years? - [Tobacco Questionnaire (Baseline)]		Numeric .N="N/A"
01. Principal	tob_bsl_yrs_smo ke_cig	How Many Total Years Have You Smoked Cigarettes? - [Tobacco Questionnaire (Baseline)]		Numeric .N="N/A"

Section 15: Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_albumin_clin_sig_v1/bldchem_albumin_clin_sig_v4	Albumin Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_albumin_comm_v1/bldchem_albumin_comm_v4	Albumin Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_albumin_not_obt_v1/bldchem_albumin_not_obt_v4	Albumin Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_albumin_oor_v1/bldchem_albumin_oor_v4	Albumin Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_albumin_result_v1/bldchem_albumin_result_v4	Albumin Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_alkpho_clin_sig_v1/bldchem_alkpho_clin_sig_v4	Alkaline Phosphatase Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_alkpho_comm_v1/bldchem_alkpho_comm_v4	Alkaline Phosphatase Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_alkpho_not_obt_v1/bldchem_alkpho_not_obt_v4	Alkaline Phosphatase Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_alkpho_oor_v1/bldchem_alkpho_oor_v4	Alkaline Phosphatase Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_alkpho_result_v1/bldchem_alkpho_result_v4	Alkaline Phosphatase Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_alt_clin_sig_v1/bldchem_alt_clin_sig_v4	SGPT/ALT Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_alt_comm_v1/bldchem_alt_comm_v4	SGPT/ALT Comments - Visit # - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_alt_not_obt_v1/bldchem_alt_not_obt_v4	SGPT/ALT Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_alt_oor_v1/bldchem_alt_oor_v4	SGPT/ALT Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_alt_result_v1/bldchem_alt_result_v4	SGPT/ALT Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_ast_clin_sig_v1/bldchem_ast_clin_sig_v4	SGOT/AST Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_ast_comm_v1/bldchem_ast_comm_v4	SGOT/AST Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_ast_not_obt_v1/bldchem_ast_not_obt_v4	SGOT/AST Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_ast_oor_v1/bldchem_ast_oor_v4	SGOT/AST Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_ast_result_v1/bldchem_ast_result_v4	SGOT/AST Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_bicarb_clin_sig_v1/bldchem_bicarb_clin_sig_v4	Bicarbonate Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_bicarb_comm_v1/bldchem_bicarb_comm_v4	Bicarbonate Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_bicarb_not_obt_v1/bldchem_bicarb_not_obt_v4	Bicarbonate Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_bicarb_oor_v1/bldchem_bicarb_oor_v4	Bicarbonate Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_bicarb_result_v1/bldchem_bicarb_result_v4	Bicarbonate Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_bili_clin_sig_v1/bldchem_bili_clin_sig_v4	Bilirubin Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_bili_comm_v1/bldchem_bili_comm_v4	Bilirubin Comments - Visit # - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bili_not_obt_v1/bldchem_bili_not_obt_v4	Bilirubin Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_bili_oor_v1/bldchem_bili_oor_v4	Bilirubin Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_bili_result_v1/bldchem_bili_result_v4	Bilirubin Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_bun_clin_sig_v1/bldchem_bun_clin_sig_v4	BUN Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_bun_comm_v1/bldchem_bun_comm_v4	BUN Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_bun_not_obt_v1/bldchem_bun_not_obt_v4	BUN Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_bun_oor_v1/bldchem_bun_oor_v4	BUN Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_bun_result_v1/bldchem_bun_result_v4	BUN Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_calc_clin_sig_v1/bldchem_calc_clin_sig_v4	Calcium Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_calc_comm_v1/bldchem_calc_comm_v4	Calcium Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_calc_not_obt_v1/bldchem_calc_not_obt_v4	Calcium Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_calc_oor_v1/bldchem_calc_oor_v4	Calcium Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_calc_result_v1/bldchem_calc_result_v4	Calcium Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_chloride_clin_sig_v1/bldchem_chloride_clin_sig_v4	Chloride Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_chloride_comm_v1/bldchem_chloride_comm_v4	Chloride Comments - Visit # - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_chloride_not_obt_v1/bldchem_chloride_not_obt_v4	Chloride Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_chloride_oor_v1/bldchem_chloride_oor_v4	Chloride Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_chloride_result_v1/bldchem_chloride_result_v4	Chloride Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_coll_dt_v1/bldchem_coll_dt_v4	Date Specimen Collected - Visit # - [Blood Chemistry]		SAS Date .M="Missing" .N="N/A"
01. Principal	bldchem_creatinine_clin_sig_v1/bldchem_creatinine_clin_sig_v4	Creatinine Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_creatinine_comments_v1/bldchem_creatinine_comments_v4	Creatinine Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_creatinine_not_obt_v1/bldchem_creatinine_not_obt_v4	Creatinine Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_creatinine_oor_v1/bldchem_creatinine_oor_v4	Creatinine Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_creatinine_result_v1/bldchem_creatinine_result_v4	Creatinine Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_estradiol_clin_sig_v1/bldchem_estradiol_clin_sig_v4	Estradiol Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_estradiol_comments_v1/bldchem_estradiol_comments_v4	Estradiol Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_estradiol_not_obt_v1/bldchem_estradiol_not_obt_v4	Estradiol Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_estradiol_oor_v1/bldchem_estradiol_oor_v4	Estradiol Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_estradiol_result_v1/bldchem_estradiol_result_v4	Estradiol Result - Visit # - [Blood Chemistry]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_fasting_v1/bldchem_fasting_v4	Fasting? - Visit # - [Blood Chemistry]		.N="N/A" 0="No" 1="Yes" 2="Unknown"
01. Principal	bldchem_fsh_clin_sig_v1/bldchem_fsh_clin_sig_v4	FSH Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_fsh_comm_v1/bldchem_fsh_comm_v4	FSH Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_fsh_not_obt_v1/bldchem_fsh_not_obt_v4	FSH Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_fsh_oor_v1/bldchem_fsh_oor_v4	FSH Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_fsh_result_v1/bldchem_fsh_result_v4	FSH Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_glucose_clin_sig_v1/bldchem_glucose_clin_sig_v4	Glucose Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_glucose_comm_v1/bldchem_glucose_comm_v4	Glucose Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_glucose_not_obt_v1/bldchem_glucose_not_obt_v4	Glucose Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_glucose_oor_v1/bldchem_glucose_oor_v4	Glucose Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_glucose_result_v1/bldchem_glucose_result_v4	Glucose Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_k_clin_sig_v1/bldchem_k_clin_sig_v4	Potassium Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_k_comm_v1/bldchem_k_comm_v4	Potassium Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_k_not_obt_v1/bldchem_k_not_obt_v4	Potassium Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_k_oor_v1/bldchem_k_oor_v4	Potassium Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_k_result_v1/bldchem_k_result_v4	Potassium Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_na_clin_sig_v1/bldchem_na_clin_sig_v4	Sodium Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_na_comm_v1/bldchem_na_comm_v4	Sodium Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_na_not_obt_v1/bldchem_na_not_obt_v4	Sodium Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_na_oor_v1/bldchem_na_oor_v4	Sodium Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_na_result_v1/bldchem_na_result_v4	Sodium Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_proges_clin_sig_v1/bldchem_proges_clin_sig_v4	Progesterone Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_proges_comm_v1/bldchem_proges_comm_v4	Progesterone Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_proges_not_obt_v1/bldchem_proges_not_obt_v4	Progesterone Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"
01. Principal	bldchem_proges_oor_v1/bldchem_proges_oor_v4	Progesterone Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_proges_result_v1/bldchem_proges_result_v4	Progesterone Result - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_prot_clin_sig_v1/bldchem_prot_clin_sig_v4	Protein Clinically Significant - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_prot_comm_v1/bldchem_prot_comm_v4	Protein Comments - Visit # - [Blood Chemistry]		Char
01. Principal	bldchem_prot_not_obt_v1/bldchem_prot_not_obt_v4	Protein Not Obtained - Visit # - [Blood Chemistry]		.N="N/A" 1="Not Obtained"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_prot_oor_v1/bldchem_prot_oor_v4	Protein Out Of Range - Visit # - [Blood Chemistry]		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	bldchem_prot_result_v1/bldchem_prot_result_v4	Protein Result - Visit # - [Blood Chemistry]		Char

Section 16: Blood Hematology

Class	Variable	Label	Description	Format Text
01. Principal	bldhema_baso_clin_sig_v1/bldhema_baso_clin_sig_v4	Absolute Baseline Clinically Significant - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_baso_comm_v1/bldhema_baso_comm_v4	Absolute Baseline Comments - Visit # - [Blood Hematology]		Char
01. Principal	bldhema_baso_not_obt_v1/bldhema_baso_not_obt_v4	Absolute Baseline Not Obtained - Visit # - [Blood Hematology]		.N="N/A" 1="Not Obtained"
01. Principal	bldhema_baso_out_of_range_v1/bldhema_baso_out_of_range_v4	Absolute Baseline Out Of Range - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_baso_result_v1/bldhema_baso_result_v4	Absolute Baseline Result - Visit # - [Blood Hematology]		Numeric .N="N/A"
01. Principal	bldhema_coll_dt_v1/bldhema_coll_dt_v4	Date Specimen Collected - Visit # - [Blood Hematology]		SAS Date .N="N/A"
01. Principal	bldhema_eosin_clin_sig_v1/bldhema_eosin_clin_sig_v4	Absolute Eosinophils Clinically Significant - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_eosin_comm_v1/bldhema_eosin_comm_v4	Absolute Eosinophils Comments - Visit # - [Blood Hematology]		Char
01. Principal	bldhema_eosin_not_obt_v1/bldhema_eosin_not_obt_v4	Absolute Eosinophils Not Obtained - Visit # - [Blood Hematology]		.N="N/A" 1="Not Obtained"
01. Principal	bldhema_eosin_out_of_range_v1/bldhema_eosin_out_of_range_v4	Absolute Eosinophils Out Of Range - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_eosin_result_v1/bldhema_eosin_result_v4	Absolute Eosinophils Result - Visit # - [Blood Hematology]		Numeric .N="N/A"
01. Principal	bldhema_hema_clin_sig_v1/bldhema_hema_clin_sig_v4	Hematocrit Clinically Significant - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_hema_comm_v1/bldhema_hema_comm_v4	Hematocrit Comments - Visit # - [Blood Hematology]		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldhema_hema_not_obt_v1/bldhema_hema_not_obt_v4	Hematocrit Not Obtained - Visit # - [Blood Hematology]		.N="N/A" 1="Not Obtained"
01. Principal	bldhema_hema_oor_v1/bldhema_hema_oor_v4	Hematocrit Out Of Range - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_hema_result_v1/bldhema_hema_result_v4	Hematocrit Result - Visit # - [Blood Hematology]		Numeric .N="N/A"
01. Principal	bldhema_hemo_clin_sig_v1/bldhema_hemo_clin_sig_v4	Hemoglobin Clinically Significant - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_hemo_comm_v1/bldhema_hemo_comm_v4	Hemoglobin Comments - Visit # - [Blood Hematology]		Char
01. Principal	bldhema_hemo_not_obt_v1/bldhema_hemo_not_obt_v4	Hemoglobin Not Obtained - Visit # - [Blood Hematology]		.N="N/A" 1="Not Obtained"
01. Principal	bldhema_hemo_oor_v1/bldhema_hemo_oor_v4	Hemoglobin Out Of Range - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_hemo_result_v1/bldhema_hemo_result_v4	Hemoglobin Result - Visit # - [Blood Hematology]		Numeric .N="N/A"
01. Principal	bldhema_lympho_clin_sig_v1/bldhema_lympho_clin_sig_v4	Absolute Lymphocytes Clinically Significant - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_lympho_comm_v1/bldhema_lympho_comm_v4	Absolute Lymphocytes Comments - Visit # - [Blood Hematology]		Char
01. Principal	bldhema_lympho_not_obt_v1/bldhema_lympho_not_obt_v4	Absolute Lymphocytes Not Obtained - Visit # - [Blood Hematology]		.N="N/A" 1="Not Obtained"
01. Principal	bldhema_lympho_oor_v1/bldhema_lympho_oor_v4	Absolute Lymphocytes Out Of Range - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_lympho_result_v1/bldhema_lympho_result_v4	Absolute Lymphocytes Result - Visit # - [Blood Hematology]		Numeric .N="N/A"
01. Principal	bldhema_mono_clin_sig_v1/bldhema_mono_clin_sig_v4	Absolute Monocytes Clinically Significant - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bldhema_mono_comm_v1/bldhema_mono_comm_v4	Absolute Monocytes Comments - Visit # - [Blood Hematology]		Char
01. Principal	bldhema_mono_not_obt_v1/bldhema_mono_not_obt_v4	Absolute Monocytes Not Obtained - Visit # - [Blood Hematology]		.N="N/A" 1="Not Obtained"
01. Principal	bldhema_mono_oor_v1/bldhema_mono_oor_v4	Absolute Monocytes Out Of Range - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_mono_result_v1/bldhema_mono_result_v4	Absolute Monocytes Result - Visit # - [Blood Hematology]		Numeric .N="N/A"
01. Principal	bldhema_neutro_clin_sig_v1/bldhema_neutro_clin_sig_v4	Absolute Neutrophils Clinically Significant - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_neutro_comm_v1/bldhema_neutro_comm_v4	Absolute Neutrophils Comments - Visit # - [Blood Hematology]		Char
01. Principal	bldhema_neutro_not_obt_v1/bldhema_neutro_not_obt_v4	Absolute Neutrophils Not Obtained - Visit # - [Blood Hematology]		.N="N/A" 1="Not Obtained"
01. Principal	bldhema_neutro_oor_v1/bldhema_neutro_oor_v4	Absolute Neutrophils Out Of Range - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_neutro_result_v1/bldhema_neutro_result_v4	Absolute Neutrophils Result - Visit # - [Blood Hematology]		Numeric .N="N/A"
01. Principal	bldhema_platelet_clin_sig_v1/bldhema_platelet_clin_sig_v4	Platelets Clinically Significant - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_platelet_comm_v1/bldhema_platelet_comm_v4	Platelets Comments - Visit # - [Blood Hematology]		Char
01. Principal	bldhema_platelet_not_obt_v1/bldhema_platelet_not_obt_v4	Platelets Not Obtained - Visit # - [Blood Hematology]		.N="N/A" 1="Not Obtained"
01. Principal	bldhema_platelet_oor_v1/bldhema_platelet_oor_v4	Platelets Out Of Range - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_platelet_result_v1/bldhema_platelet_result_v4	Platelets Result - Visit # - [Blood Hematology]		Numeric .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	bldhema_wbc_clin_sig_v1/bldhema_wbc_clin_sig_v4	WBC Clinically Significant - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_wbc_comm_v1/bldhema_wbc_comm_v4	WBC Comments - Visit # - [Blood Hematology]		Char
01. Principal	bldhema_wbc_not_obt_v1/bldhema_wbc_not_obt_v4	WBC Not Obtained - Visit # - [Blood Hematology]		.N="N/A" 1="Not Obtained"
01. Principal	bldhema_wbc_oor_v1/bldhema_wbc_oor_v4	WBC Out Of Range - Visit # - [Blood Hematology]		.N="N/A" 0="No" 1="Yes"
01. Principal	bldhema_wbc_result_v1/bldhema_wbc_result_v4	WBC Result - Visit # - [Blood Hematology]		Numeric .N="N/A"

Section 17: Contact

Class	Variable	Label	Description	Format Text
01. Principal	contact_ae_v2-3	Did The Participant Report Any Symptoms Or Adverse Events? - Visit # - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	contact_compliant_v2-3	Is The Participant Compliant With The Protocol Intervention - Visit # - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	contact_conmed_v2-3	Were Any Changes In Concomitant Medications Reported? - Visit # - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	contact_dt_v2-3	Date Of Contact - Visit # - [Contact]		SAS Date .R="Not Randomized"
01. Principal	contact_time_v2-3	Contact Time - Visit # - [Contact]		SAS Time .R="Not Randomized"
01. Principal	contact_type_v2-3	Contact Type - Visit # - [Contact]		.R="Not Randomized" 1="Home Cell" 2="Home Phone" 3="Work Phone" 4="Work Cell" 5="Email" 6="Work Email" 7="Regular Mail"

Section 18: Compliance

Class	Variable	Label	Description	Format Text
01. Principal	comp_agent_inte rrupt	Was Agent Interrupted During This Period? - [Compliance]		.R="Not Randomized" 0="No" 1="Yes" 2="N/A"
01. Principal	comp_agent_inte rrupt_num	If Yes, Indicate Number Of Interruptions This Period - [Compliance]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	comp_agent_mis sing	Amount Of Agent Missing - [Compliance]		Numeric .R="Not Randomized"
01. Principal	comp_agent_pro v_last	Amount Of Agent Provided At Last Visit - [Compliance]		Numeric .R="Not Randomized"
01. Principal	comp_agent_pro vided	Was Agent Provided At This Visit - [Compliance]		.R="Not Randomized" 0="No" 1="Yes"
01. Principal	comp_agent_retu rned	Amount Of Agent Returned This Visit - [Compliance]		Numeric .R="Not Randomized"
01. Principal	comp_agent_tak en	Amount Of Agent Taken During This Visit - [Compliance]		Numeric .R="Not Randomized"
01. Principal	comp_dispense_ dt	Date Of Dispense Of Agent - [Compliance]		SAS Date .R="Not Randomized"
01. Principal	comp_first_dose_ dt	First Dose Taken This Period - Date - [Compliance]		SAS Date .R="Not Randomized"
01. Principal	comp_first_dose_ time	First Dose Taken This Period - Time - [Compliance]		SAS Time .R="Not Randomized"
01. Principal	comp_last_dose_ dt	Last Dose Taken This Period - Date - [Compliance]		SAS Date .R="Not Randomized"
01. Principal	comp_last_dose_ time	Last Dose Taken This Period - Time - [Compliance]		SAS Time .R="Not Randomized"
01. Principal	comp_not_compl iant_spec	If No, Specify Reason For Noncompliance - [Compliance]		Char
01. Principal	comp_partic_co mpliant	Is The Participant Compliant With The Protocol Intervention - [Compliance]		.R="Not Randomized" 0="No" 1="Yes" 2="Unknown"

Section 19: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	pe_abdomen_comm_v1/pe_abdomen_comm_v4	Abdomen Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_abdomen_stat_v1/pe_abdomen_stat_v4	Abdomen Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_appear_comm_v1/pe_appear_comm_v4	Appearance Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_appear_stat_v1/pe_appear_stat_v4	Appearance Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_breast_comm_v1/pe_breast_comm_v4	Breasts Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_breast_stat_v1/pe_breast_stat_v4	Breasts Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_chest_comm_v1/pe_chest_comm_v4	Chest Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_chest_stat_v1/pe_chest_stat_v4	Chest Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_ecog_perf_stat_v1/pe_ecog_perf_stat_v4	ECOG Performance Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Fully Active" 1="Restricted"
01. Principal	pe_exam_dt_v1/pe_exam_dt_v4	Examination Date - Visit # - [Physical Exam]		SAS Date .R="Not Randomized"
01. Principal	pe_form_stat_v1/pe_form_stat_v4	Form Status - Visit # - [Physical Exam]		.R="Not Randomized" 1="Completed" 2="Amended"
01. Principal	pe_heart_comm_v1/pe_heart_comm_v4	Heart Comments - Visit # - [Physical Exam]		Char

Class	Variable	Label	Description	Format Text
01. Principal	pe_heart_stat_v1 /pe_heart_stat_v4	Heart Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_heent_comm_v1 /pe_heent_comm_v4	H/E/E/N/T Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_heent_stat_v1 /pe_heent_stat_v4	H/E/E/N/T Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_lungs_comm_v1 /pe_lungs_comm_v4	Lungs Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_lungs_stat_v1 /pe_lungs_stat_v4	Lungs Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_lymph_comm_v1 /pe_lymph_comm_v4	Lymph Nodes Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_lymph_stat_v1 /pe_lymph_stat_v4	Lymph Nodes Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_musculo_comm_v1 /pe_musculo_comm_v4	Musculoskeletal Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_musculo_stat_v1 /pe_musculo_stat_v4	Musculoskeletal Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_neuro_comm_v1 /pe_neuro_comm_v4	Neurological Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_neuro_stat_v1 /pe_neuro_stat_v4	Neurological Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_oth_body_sys_norm_v1_1-2	Other Body System Normal/Abnormal - # - Visit # - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"

Class	Variable	Label	Description	Format Text
01. Principal	pe_oth_body_sy s_norm_v4	Other Body System Normal/Abnormal - Visit 4 (Surgery Visit) - [Physical Exam]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_oth_body_sy s_v1_1-2	Other Body System - # - Visit # - [Physical Exam]		Char
01. Principal	pe_oth_body_sy s_v4	Other Body System - Visit 4 (Surgery Visit) - [Physical Exam]		Char
01. Principal	pe_pelvis_comm _v1/pe_pelvis_co mm_v4	Pelvis Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_pelvis_stat_v 1/pe_pelvis_stat_ v4	Pelvis Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_same_as_bsl _v4	Same As Baseline - Visit # - [Physical Exam]		.R="Not Randomized" 0="No" 1="Yes" 2="N/A"
01. Principal	pe_skin_comm_v 1/pe_skin_comm _v4	Skin Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_skin_stat_v1/ pe_skin_stat_v4	Skin Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_thyroid_com m_v1/pe_thyroid _comm_v4	Thyroid Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_thyroid_stat_ v1/pe_thyroid_st at_v4	Thyroid Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_vascular_com m_v1/pe_vascula r_comm_v4	Vascular Comments - Visit # - [Physical Exam]		Char
01. Principal	pe_vascular_stat _v1/pe_vascular_ stat_v4	Vascular Status - Visit # - [Physical Exam]		.M="Missing" .R="Not Randomized" 0="Not Assessed" 1="Normal" 2="Abnormal"
01. Principal	pe_visit_dt_v1/pe _visit_dt_v4	Visit Date - Visit # - [Physical Exam]		SAS Date .R="Not Randomized"

Section 20: Off Study

Class	Variable	Label	Description	Format Text
01. Principal	off_agent_end_dt	Agent End Date - [Off Study]		SAS Date .N="N/A"
01. Principal	off_comments	Comments - [Off Study]		Char
01. Principal	off_last_cont_dt	Date Of Last Contact - [Off Study]		SAS Date .M="Missing"
01. Principal	off_off_follow_up_dt	Date Off Follow-Up - [Off Study]		SAS Date .M="Missing" .N="N/A"
01. Principal	off_off_follow_up_na	Date Off Follow-Up Not Applicable - [Off Study]		.M="Missing" 1="Not Applicable"
01. Principal	off_off_study_dt	Date Off Study - [Off Study]		SAS Date
01. Principal	off_on_follow_up_dt	Date On Follow-Up - [Off Study]		SAS Date .M="Missing" .N="N/A"
01. Principal	off_on_follow_up_na	Date On Follow-Up Not Applicable - [Off Study]		.M="Missing" 1="Not Applicable"
01. Principal	off_reason_off_study	Reason Off Study - [Off Study]		1="Study Complete" 2="Ineligible"

Section 21: Agent Interruption

Class	Variable	Label	Description	Format Text
01. Principal	agent_int_num_v2-4	Number Of Interruptions For Visit - Visit # - [Agent Interruption]		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	agent_int_num_v2_1-2	Interruption Number - Visit # - [Agent Interruption]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	agent_int_num_v3_1-2	Interruption Number - Visit # - [Agent Interruption]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	agent_int_num_v4_1-2	Interruption Number - Visit # - [Agent Interruption]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	agent_int_reas_restart_v2_1-2	Reason Restarted, Specify - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Investigator Decision, Specify" 2="Participant Decision, Specify"
01. Principal	agent_int_reas_restart_v3_1-2	Reason Restarted, Specify - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Investigator Decision, Specify" 2="Participant Decision, Specify"
01. Principal	agent_int_reas_restart_v4_1-2	Reason Restarted, Specify - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Investigator Decision, Specify" 2="Participant Decision, Specify"
01. Principal	agent_int_reas_stop_spec_v2_1-2	Reason Stopped, Specify - Visit # - [Agent Interruption]		Char
01. Principal	agent_int_reas_stop_spec_v3_1-2	Reason Stopped, Specify - Visit # - [Agent Interruption]		Char
01. Principal	agent_int_reas_stop_spec_v4_1-2	Reason Stopped, Specify - Visit # - [Agent Interruption]		Char
01. Principal	agent_int_reas_stop_v2_1-2	Reason Stopped - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Investigator Decision, Specify" 2="Participant Decision, Specify" 3="AE/SAE, Specify" 4="Other, Specify"

Class	Variable	Label	Description	Format Text
01. Principal	agent_int_reas_s top_v3_1-2	Reason Stopped - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Investigator Decision, Specify" 2="Participant Decision, Specify" 3="AE/SAE, Specify" 4="Other, Specify"
01. Principal	agent_int_reas_s top_v4_1-2	Reason Stopped - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Investigator Decision, Specify" 2="Participant Decision, Specify" 3="AE/SAE, Specify" 4="Other, Specify"
01. Principal	agent_int_restart _dt_acc_v2_1-2	Date Restarted, Specify (Accuracy) - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Day" 2="Week" 3="Month" 4="Year" 5="Unknown"
01. Principal	agent_int_restart _dt_acc_v3_1-2	Date Restarted, Specify (Accuracy) - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Day" 2="Week" 3="Month" 4="Year" 5="Unknown"
01. Principal	agent_int_restart _dt_acc_v4_1-2	Date Restarted, Specify (Accuracy) - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Day" 2="Week" 3="Month" 4="Year" 5="Unknown"
01. Principal	agent_int_restart _dt_v2_1-2	Date Restarted, Specify - Visit # - [Agent Interruption]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	agent_int_restart _dt_v3_1-2	Date Restarted, Specify - Visit # - [Agent Interruption]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	agent_int_restart _dt_v4_1-2	Date Restarted, Specify - Visit # - [Agent Interruption]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	agent_int_restart ed_v2_1-2	Was Agent Restarted? - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	agent_int_restarted_v3_1-2	Was Agent Restarted? - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	agent_int_restarted_v4_1-2	Was Agent Restarted? - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	agent_int_stopped_t_acc_v2_1-2	Date Stopped, Specify (Accuracy) - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Day" 2="Week" 3="Month" 4="Year" 5="Unknown"
01. Principal	agent_int_stopped_t_acc_v3_1-2	Date Stopped, Specify (Accuracy) - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Day" 2="Week" 3="Month" 4="Year" 5="Unknown"
01. Principal	agent_int_stopped_t_acc_v4_1-2	Date Stopped, Specify (Accuracy) - Visit # - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Day" 2="Week" 3="Month" 4="Year" 5="Unknown"
01. Principal	agent_int_stopped_t_v2_1-2	Date Stopped, Specify - Visit # - [Agent Interruption]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	agent_int_stopped_t_v3_1-2	Date Stopped, Specify - Visit # - [Agent Interruption]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	agent_int_stopped_t_v4_1-2	Date Stopped, Specify - Visit # - [Agent Interruption]		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Section 22: Vitals

Class	Variable	Label	Description	Format Text
01. Principal	vitals_bmi_v1/vitals_bmi_v4	BMI - Visit # - [Vitals]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	vitals_comments_v1/vitals_comments_v4	Comments - Visit # - [Vitals]		Char
01. Principal	vitals_diastolic_v1/vitals_diastolic_v4	Diastolic Blood Pressure (mmHg) - Visit # - [Vitals]		Numeric .R="Not Randomized"
01. Principal	vitals_height_v1/vitals_height_v4	Height (cm) - Visit # - [Vitals]		Numeric .M="Missing" .R="Not Randomized"
01. Principal	vitals_pulse_v1/vitals_pulse_v4	Pulse Rate (bpm) - Visit # - [Vitals]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	vitals_resp_rate_v1/vitals_resp_rate_v4	Respiration Rate - Visit # - [Vitals]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	vitals_systolic_v1/vitals_systolic_v4	Systolic Blood Pressure (mmHg) - Visit # - [Vitals]		Numeric .R="Not Randomized"
01. Principal	vitals_temp_v1/vitals_temp_v4	Temperature (C) - Visit # - [Vitals]		Numeric .N="N/A" .R="Not Randomized"
01. Principal	vitals_time_assess_v1/vitals_time_assess_v4	Time Assessed - Visit # - [Vitals]		SAS Time .N="N/A" .R="Not Randomized"
01. Principal	vitals_visit_dt_v1/vitals_visit_dt_v4	Visit Date - Visit # - [Vitals]		SAS Date .R="Not Randomized"
01. Principal	vitals_weight_v1/vitals_weight_v4	Weight (kg) - Visit # - [Vitals]		Numeric .M="Missing" .R="Not Randomized"

Section 23: Alcohol Questionnaire (Follow-up)

Class	Variable	Label	Description	Format Text
01. Principal	alc_fup_5_drinks_day	In The Past 12 Months, On How Many Days Did You Have 5 Or More Drinks Of Any Alcoholic Beverage? - [Alcohol Questionnaire (Baseline)]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	alc_fup_5_drinks_day_refuse	Refused Or Don't Know/Not Sure, How Many Days Drank 5 Or More Alcohol Drinks Per Day In The Past 12 Months - [Alcohol Questionnaire (Baseline)]		.N="N/A" .R="Not Randomized" 1="Don't Know/Not Sure" 2="Refused"
01. Principal	alc_fup_drink_past_30	During The Past 30 Days, Did You Drink Any Alcoholic Beverages? - [Alcohol Questionnaire (Follow-up)]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="Don't Know/Not Sure" 3="Refused"
01. Principal	alc_fup_drinks_day	On The Days When You Drank, On Average, About How Many Drinks Did You Have? - [Alcohol Questionnaire (Follow-up)]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	alc_fup_drinks_day_refuse	Refused Or Don't Know/Not Sure, On The Days When You Drank, On Average, About How Many Drinks Did You Have? - [Alcohol Questionnaire (Follow-up)]		.N="N/A" .R="Not Randomized" 1="Don't Know/Not Sure" 2="Refused"
01. Principal	alc_fup_how_often	During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages, On The Average? - [Alcohol Questionnaire (Follow-up)]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	alc_fup_how_of ten_freq	During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages, On The Average? Frequency - [Alcohol Questionnaire (Follow-up)]		.N="N/A" .R="Not Randomized" 1="Day" 2="Week" 3="Month" 4="Year" 5="Don't Know/Not Sure" 6="Refused"

Section 24: Tobacco Questionnaire (Follow Up)

Class	Variable	Label	Description	Format Text
01. Principal	tob_fup_cig_day	On Average When You Smoked, About How Many Cigarettes Do You Smoke A Day? - [Tobacco Questionnaire (Follow Up)]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	tob_fup_long_last_smoke	How Long Has It Been Since You Last Smoked A Cigarette? - [Tobacco Questionnaire (Follow Up)]		.M="Missing" .N="N/A" .R="Not Randomized" 1="I smoked a cigarette today (at least one puff)." 2="1-7 days" 3="Less than 1 month" 4="Less than 1 year" 5="More than 1 year." 6="Don't know/Don't remember"
01. Principal	tob_fup_long_last_smoke_yrs	How Long Has It Been Since You Last Smoked A Cigarette? Years - [Tobacco Questionnaire (Follow Up)]		Numeric .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	tob_fup_now_smoke	Do You Now Smoke Cigarettes? - [Tobacco Questionnaire (Follow Up)]		.M="Missing" .R="Not Randomized" 0="Not At All" 1="Some Days" 2="Every Day" 3="Never Smoked"
01. Principal	tob_fup_oth_prod_use	Since Your Last Visit, Which Of The Following Products Have You Used? - [Tobacco Questionnaire (Follow Up)]		="" .N="N/A" .R="Not Randomized" 1="Smokeless tobacco, like dip, chew or snuff" 2="Cigarettes" 3="E-cigarettes or other electronic nicotine delivery system" 4="Traditional cigars, cigarillos or filtered cigars" 5="Waterpipe" 6="Pipes" 7="Hookah" 8="Clove cigarettes or kreteks" 9="Bidis" 10="Snus" 11="Paan with tobacco, gutka, zarda, khaini" 12="Other, Please Specify"

Class	Variable	Label	Description	Format Text
01. Principal	tob_fup_oth_pro d_use_yrs	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? - [Tobacco Questionnaire (Follow Up)]		.N="N/A" .R="Not Randomized" 1="Within the Past Month (0 to 1 Month Ago)" 2="Between 1 and 3 Months (1 to 3 Months Ago)" 3="Between 3 and 6 Months (3 to 6 Months Ago)" 4="Between 6 and 12 Months (6 to 12 Months Ago)" 5="Between 1 and 5 Years (1 to 5 Years Ago)" 6="Between 5 and 15 Years (5 to 15 years Ago)" 7="More Than 15 Years Ago" 8="Don't Know/Not Sure" 9="Never Drank Regularly"
01. Principal	tob_fup_oth_tob freq	How Often Do You/Did You Use Other Forms Of Tobacco? - [Tobacco Questionnaire (Follow Up)]		.N="N/A" .R="Not Randomized" 0="Not At All" 1="Some Days" 2="Every Day" 3="Never Smoked"
01. Principal	tob_fup_smoke_ after_study	After The End Of Study Treatment, How Often Did You Smoke Cigarettes - [Tobacco Questionnaire (Follow Up)]		.N="N/A" .R="Not Randomized" 1="Smoked Every Day" 2="Smoked Some Days" 3="Did Not Smoke At All" 4="Don't Know/Not Sure" 5="Not Applicable"
01. Principal	tob_fup_smoke_ after_visit	Since Your Last Visit To This Clinic, How Often Did You Smoke Cigarettes - [Tobacco Questionnaire (Follow Up)]		.N="N/A" .R="Not Randomized" 1="Smoked Every Day" 2="Smoked Some Days" 3="Did Not Smoke At All" 4="Don't Know/Not Sure" 5="Not Applicable"
01. Principal	tob_fup_smoke_ during_study	During Study Treatment, How Often Did You Smoke Cigarettes? - [Tobacco Questionnaire (Follow Up)]		.N="N/A" .R="Not Randomized" 1="Smoked Every Day" 2="Smoked Some Days" 3="Did Not Smoke At All" 4="Don't Know/Not Sure"
01. Principal	tob_fup_smoke_ since_last	Since Your Last Visit, Have You Used Other Forms Of Tobacco, Not Including Cigarettes? - [Tobacco Questionnaire (Follow Up)]		.M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Section 25: Verification

Class	Variable	Label	Description	Format Text
01. Principal	verif_form_dt	Form Date - [Verification]		SAS Date

Section 26: Specimen Acquisition (Blood)

Class	Variable	Label	Description	Format Text
01. Principal	spec_bld_agent_last_dt_v1/spec_bld_agent_last_dt_v4	Date Last Study Agent Taken - Visit # - [Specimen Acquisition (Blood)]		SAS Date .N="N/A"
01. Principal	spec_bld_agent_last_time_v1/spec_bld_agent_last_time_v4	Time Last Study Agent Taken - Visit # - [Specimen Acquisition (Blood)]		SAS Time .N="N/A"
01. Principal	spec_bld_collect_dt_v1/spec_bld_collect_dt_v4	Date Specimen Collected - Visit # - [Specimen Acquisition (Blood)]		SAS Date .N="N/A"
01. Principal	spec_bld_collect_time_v1/spec_bld_collect_time_v4	Time Specimen Collected - Visit # - [Specimen Acquisition (Blood)]		SAS Time .N="N/A"
01. Principal	spec_bld_label_v1/spec_bld_label_v4	Specimen Label - Visit # - [Specimen Acquisition (Blood)]		.N="N/A" 1="6mL Greentop"
01. Principal	spec_bld_not_obt_v1/spec_bld_not_obt_v4	Specimen Not Obtained - Visit # - [Specimen Acquisition (Blood)]		.N="N/A" 1="Not Obtained"
01. Principal	spec_bld_store_temp_v1/spec_bld_store_temp_v4	Storage Temperature (C) - Visit # - [Specimen Acquisition (Blood)]		.M="Missing" .N="N/A" 1="-70/-80"

Section 27: Specimen Acquisition (Tissue)

Class	Variable	Label	Description	Format Text
01. Principal	spec_tissue_agent_last_dt_v4_1-2	Date Last Study Agent Taken - # - Visit # - [Specimen Acquisition (Tissue)]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_tissue_agent_last_time_v4_1-2	Time Last Study Agent Taken - # - Visit # - [Specimen Acquisition (Tissue)]		SAS Time .N="N/A" .R="Not Randomized"
01. Principal	spec_tissue_coll_dt_v1_1-3	Date Specimen Collected - # - Visit # - [Specimen Acquisition (Tissue)]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	spec_tissue_coll_dt_v4_1-2	Date Specimen Collected - # - Visit # - [Specimen Acquisition (Tissue)]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_tissue_coll_time_v1_1-3	Time Specimen Collected - # - Visit # - [Specimen Acquisition (Tissue)]		SAS Time .N="N/A" .R="Not Randomized"
01. Principal	spec_tissue_coll_time_v4_1-2	Time Specimen Collected - # - Visit # - [Specimen Acquisition (Tissue)]		SAS Time .N="N/A" .R="Not Randomized"
01. Principal	spec_tissue_comments_v1_1-3	Comments - # - Visit # - [Specimen Acquisition (Tissue)]		Char
01. Principal	spec_tissue_comments_v4_1-2	Comments - # - Visit # - [Specimen Acquisition (Tissue)]		Char
01. Principal	spec_tissue_num_v1/4	Number Of Tissue Specimens Taken - Visit # - [Specimen Acquisition (Tissue)]		Numeric .R="Not Randomized"
01. Principal	spec_tissue_ship_dt_v1_1-3	Specimen Shipping Date - # - Visit # - [Specimen Acquisition (Tissue)]		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	spec_tissue_ship_dt_v4_1-2	Specimen Shipping Date - # - Visit # - [Specimen Acquisition (Tissue)]		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	spec_tissue_store_temp_v1_1-3	Storage Temperature - # - Visit # - [Specimen Acquisition (Tissue)]		.M="Missing" .N="N/A" .R="Not Randomized" 1="-70/-80"

Class	Variable	Label	Description	Format Text
01. Principal	spec_tissue_storage_temp_v4_1-2	Storage Temperature - # - Visit # - [Specimen Acquisition (Tissue)]		.M="Missing" .R="Not Randomized" 1="-70/-80"
01. Principal	spec_tissue_type_v1_1-3	Tissue Type - # - Visit # - [Specimen Acquisition (Tissue)]		.N="N/A" .R="Not Randomized" 1="Endometrial Biopsy" 2="Hysterectomy" 3="Vaginal Cell From Tampon"
01. Principal	spec_tissue_type_v4_1-2	Tissue Type - # - Visit # - [Specimen Acquisition (Tissue)]		.R="Not Randomized" 1="Endometrial Biopsy" 2="Hysterectomy" 3="Vaginal Cell From Tampon"

Section 28: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_num	Number Of Adverse Events Experienced During The Study - [Adverse Events]		Numeric .F="No Record For This Visit" .R="Not Randomized"