

MDA2013-02-02 - Enhanced Person Data Dictionary

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Document Summary

Property	Value
Document Title	MDA2013-02-02 - Enhanced Person: Data Dictionary
Date Created	05/20/2024
Sections	44
Entries	1302
Document Filename	dictionary_enhanced_prsn.rtf

MDA2013-02-02 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	arm	Treatment Arm		.N="N/A" 1="Placebo" 2="Aspirin"
01. Principal	MRNO	MRNO		Numeric

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	Accession	Accession		Numeric
01. Principal	Agent_Dose	Agent Dose (325 mg QD x 12 Months)		Numeric .N="N/A"
01. Principal	enroll_dt	Participant Enrollment Date		SAS Date .M="Missing"
01. Principal	Institution	Institution		Char
01. Principal	tac_code	Treatment Assignment Code (TAC)		0="TAC-0" 1="Tac1"
01. Principal	Trial	Trial Name run		Char

Section 3: Demographics

Class	Variable	Label	Description	Format Text
01. Principal	ethnicity	Ethnicity		2="Not Hispanic Or Latino" 3="Not Reported" 4="Unknown"
01. Principal	gender	Gender		1="Male" 2="Female"
01. Principal	race	Race		1="White" 2="Unknown" 9="Not Reported"
01. Principal	reg_country	Participant Country Code		1="USA" 2="CAN"
01. Principal	reg_race_selected	Race Selected		0="False" 1="True"

Section 4: Registration

Class	Variable	Label	Description	Format Text
01. Principal	reg_agree_biobank	Participant Agreed That Their Samples And Related Information May Be Kept At A Biobank		.M="Missing" 0="No" 1="Yes"
01. Principal	reg_consortium	Registering Consortium		Char
01. Principal	reg_future_res	Participant Agreed That Their Doctor May Contact Them In The Future To Take Part In Other Research		.M="Missing" 0="No" 1="Yes"
01. Principal	reg_oth_pay_method	Other Method Of Payment		Char
01. Principal	reg_pay_method 1-4	Payment Method		.N="N/A" 1="Managed Care/Medicare" 2="Medicaid" 3="Medicare" 4="Medicare And Private Insurance" 5="Private Insurance" 6="Veterans Sponsored" 7="Other" 9="Unknown"
01. Principal	reg_pay_selected 1-4	Payment Selected		.N="N/A" 0="False" 1="True"
01. Principal	reg_tac_0	TAC-0 (Signed Informed Consent Document And Before Intervention)		1="Yes"
01. Principal	regist_dt	Registration Date		SAS Date
01. Principal	regist_time	Registration Time		SAS Time

Section 5: Screening

Class	Variable	Label	Description	Format Text
01. Principal	screen_2_dt	Screening 2 Date		SAS Date .N="N/A"
01. Principal	screen_aspirin_contra	Contraindication To Aspirin Use		0="No" 1="Yes"
01. Principal	screen_dt	Screening Date		SAS Date
01. Principal	screen_form_version	Form Version Number		Char
01. Principal	screen_inable_aspirin	Inability To Tolerate Aspirin		0="No" 1="Yes"
01. Principal	screen_med_contra	Medical Contraindications		0="No" 1="Yes"
01. Principal	screen_meet_req	Does The Participant Meet Screening Criteria?		0="No" 1="Yes"
01. Principal	screen_reg_nsaid	Regular Aspirin/NSAID Use X 3 Months		0="No" 1="Yes"

Section 6: Inclusion Criteria

Class	Variable	Label	Description	Format Text
01. Principal	inclu_age_18	Age 18 Or Older		0="No" 1="Yes" 2="N/A"
01. Principal	inclu_be_ablation	Documentation Of Complete Ablation OF BE		0="No" 1="Yes" 2="N/A"
01. Principal	inclu_be_dx	Known Diagnosis Of Histologically-Confirmed BE		0="No" 1="Yes" 2="N/A"
01. Principal	inclu_contraceptives	Willing To Use Contraceptives		0="No" 1="Yes" 2="N/A"
01. Principal	inclu_ecog_stat	ECOG Performance Status Better Than 2		0="No" 1="Yes" 2="N/A"
01. Principal	inclu_form_num	Inclusion Form Version Number		Char
01. Principal	inclu_no_nsaid	No Chronic Use Of Aspirin Or NSAIDs Or Selective COX-2 Inhibitors		0="No" 1="Yes" 2="N/A"
01. Principal	inclu_norm_organ	Normal Organ And Marrow Function		0="No" 1="Yes" 2="N/A"
01. Principal	inclu_not_preg	Negative Serum Pregnancy Test		0="No" 1="Yes" 2="N/A"
01. Principal	inclu_sign_icf	Ability To Understand And Willingness To Sign A Written Informed Consent Document		0="No" 1="Yes" 2="N/A"
01. Principal	inclu_tissue_sample	Willingness To Provide Tissue Samples For Research Purposes		0="No" 1="Yes" 2="N/A"
01. Principal	inclu_visit_dt	Inclusion Visit Date		SAS Date

Section 7: Exclusion Criteria

Class	Variable	Label	Description	Format Text
01. Principal	elig_abst_nsaid	Inability To Abstain From NSAID And Selective COX-2 Inhibitor Therapy		Numeric
01. Principal	elig_allergic	Allergic Reactions To Aspirin Or Compounds Similar To Study Agent		Numeric
01. Principal	elig_anticoag	Current Or Planned Use Of Anticoagulant Drugs		Numeric
01. Principal	elig_biop_be	Surveillance Biopsies Demonstrating Residual BE		Numeric
01. Principal	elig_breast_feeding	Breast Feeding Women		Numeric .V="Not In Form Version"
01. Principal	elig_cnc_dx_24	Cancer Diagnosis Within 12 Or 24 Months Prior To Randomization (24 For Pre v7A2, 12 For v7A2 And v9A4)		Numeric
01. Principal	elig_cnc_tx_12	Cancer Treatment Within 12 Months Prior To Randomization		Numeric
01. Principal	elig_eso_stricture	Presence Of An Esophageal Stricture		Numeric
01. Principal	elig_form_num	Eligibility Form Version Number		Char
01. Principal	elig_hiv	Patients With Human Immunodeficiency Virus (HIV) Infection		Numeric
01. Principal	elig_intercur_ill	Uncontrolled Intercurrent Illness		Numeric
01. Principal	elig_oth_drugs	Taking Drugs From List		Numeric
01. Principal	elig_oth_inv	Other Investigational Agents Withing 3 Months Prior To Randomization		Numeric
01. Principal	elig_pep_ulcer	History Of Endoscopically Or Radiographically Diagnosed Peptic Ulcer Disease		Numeric .M="Missing"
01. Principal	elig_preg_bf	Pregnant Or Breastfeeding Women		Numeric .V="Not In Form Version"
01. Principal	elig_pregnant	Pregnant Women		Numeric .V="Not In Form Version"

Class	Variable	Label	Description	Format Text
01. Principal	elig_prior_fundo	Prior Fundoplication, Bariatric Surgery, Or Any Other Major Upper GI Surgery		Numeric
01. Principal	elig_renal_fail	Uncontrolled Renal Insufficiency Or Renal Failure		Numeric
01. Principal	elig_visit_dt	Eligibility Visit Date		SAS Date

Section 8: Participant Contact Form

Class	Variable	Label	Description	Format Text
01. Principal	parcon_compliant_v1/3/4/5/6/8	Is The Participant Compliant With Protocol Intervention Per Telephone Conversation?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	parcon_dt_v1/3/4/5/6/8	Date Of Contact		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	parcon_rep_ae_v1/3/4/5/6/8	Did The Participant Report Any Symptoms Or Adverse Events?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes (Complete AE CRF" 2="Too Early To Evaluate"
01. Principal	parcon_rep_conmed_v1/3/4/5/6/8	Were Any Changes In Concomitant Medications Reported? [Either New Medications Started Or Previous Medications Stopped]?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes (Complete Con Med CRF)" 2="N/A"
01. Principal	parcon_result_v1/3/4/5/6/8	Contact Result		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Spoke To Patient/Participant"
01. Principal	parcon_time_v1/3/4/5/6/8	Time Of Contact		SAS Time .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	parcon_type_v1/3/4/5/6/8	Contact Type		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Home Cell" 2="Home Phone" 3="Work Cell" 4="Work Phone"

Section 9: Ablation History

Class	Variable	Label	Description	Format Text
01. Principal	ablat_any_dk	Don't Know: TIM, MAX, CIRC, OR TGF		0="False" 1="True"
01. Principal	ablat_be_length	BE Length		Numeric .M="Missing"
01. Principal	ablat_be_recur_e ver	Has The Participant Ever Had BE Recurrence?		Numeric .M="Missing" .U="Unknown"
01. Principal	ablat_circ	Proximal Margin Of Contiguous Circumferential Disease (CIRC)		Numeric .M="Missing"
01. Principal	ablat_circ_dk	Don't Know: Contiguous Circumferential Disease (CIRC)		0="False" 1="True"
01. Principal	ablat_distal	Distal:		Numeric .M="Missing"
01. Principal	ablat_egd_dk	Don't Know EGDs		0="False" 1="True"
01. Principal	ablat_emr_dk	Endoscopic Mucosal Resection (EMR)		.M="Missing" 0="False" 1="True"
01. Principal	ablat_first_be_dt	First BE Clearance Date:		SAS Date
01. Principal	ablat_first_be_dt _dk	Don't Know 1st BE Date		0="False" 1="True"
01. Principal	ablat_first_rfa_dt	First RFA Date:		SAS Date
01. Principal	ablat_first_rfa_dt _dk	Don't know 1st RFA Date		0="False" 1="True"
01. Principal	ablat_halo_360_d k	Circumferential Radiofrequency Ablation (HALO 360)		.M="Missing" 0="False" 1="True"
01. Principal	ablat_halo_60_dk	Focal Bipolar Thermal Ablation (HALO 60)		.M="Missing" 0="False" 1="True"
01. Principal	ablat_halo_90_dk	Focal Bipolar Thermal Ablation (HALO 90)		0="False" 1="True"
01. Principal	ablat_halo_90_ult _dk	Focal Bipolar Thermal Ablation (HALO 90 Ultra)		.M="Missing" 0="False" 1="True"
01. Principal	ablat_max	Proximal Margin Of Contiguous Disease (MAX)		Numeric .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	ablat_max_dk	Don't Know: Contiguous Disease (MAX)		0="False" 1="True"
01. Principal	ablat_num_egd	Total Number Of EGDs Since Achieving CEIM (Including The First EGD That Demonstrated CEIM)		Numeric .M="Missing"
01. Principal	ablat_num_emr	Number Of Times (EMR)		Numeric .M="Missing"
01. Principal	ablat_num_halo_360	Number Of Times (HALO 360)		Numeric .M="Missing"
01. Principal	ablat_num_halo_60	Number Of Times (HALO 60)		Numeric .M="Missing"
01. Principal	ablat_num_halo_90	Number Of Times (HALO 90)		Numeric .M="Missing"
01. Principal	ablat_num_halo_90_ult	Number Of Times (HALO 90 Ultra)		Numeric .M="Missing"
01. Principal	ablat_num_rf	Number Of Times (RF Ablation)		Numeric .M="Missing"
01. Principal	ablat_proximal	Proximal:		Numeric .M="Missing"
01. Principal	ablat_rec_rfa_dt	Most Recent RFA Date		SAS Date .M="Missing"
01. Principal	ablat_rec_rfa_dt_dk	Don't Know Most Recent RFA Date		0="False" 1="True"
01. Principal	ablat_recurr_1_dk	Don't Know Recurrence 1		0="False" 1="True"
01. Principal	ablat_recurr_2_dk	Don't Know Recurrence 2		0="False" 1="True"
01. Principal	ablat_recurr_3_dk	Don't Know Recurrence 3		0="False" 1="True"
01. Principal	ablat_recurr_4_dk	Don't Know Recurrence 4		0="False" 1="True"
01. Principal	ablat_rf_dk	Radiofrequency Ablation (not otherwise specified)		.M="Missing" 0="False" 1="True"
01. Principal	ablat_sec_be_dt	Second BE Clearance Date (Date CEIM Confirmed)		SAS Date .M="Missing"
01. Principal	ablat_sec_be_dt_dk	Don't Know 2nd BE Date		0="False" 1="True"
01. Principal	ablat_sec_be_dt_na	NA 2nd BE Date		0="False" 1="True"
01. Principal	ablat_tgf	Top Of Gastric Folds (TGF)		Numeric .M="Missing"
01. Principal	ablat_tgf_dk	Don't Know: Gastric Folds (TGF)		0="False" 1="True"
01. Principal	ablat_tim	Top Of Intestinal Metaplasia (TIM)		Numeric .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	ablat_tim_dk	Don't Know: Top Of Intestinal Metaplasia (TIM)		0="False" 1="True"
01. Principal	ablat_visit_dt	Visit Date		SAS Date .M="Missing"

Section 10: Alcohol History

Class	Variable	Label	Description	Format Text
01. Principal	alc_age_beg_drink	At What Age Did You Begin Drinking Regularly?		Numeric .M="Missing" .N="N/A"
01. Principal	alc_last_drink	If You Do Not Currently Drink Alcoholic Beverages, But Did In The Past, How Long Has It Been Since You Last Drank Regularly (That Is, Every Day Or Some Days)?		.M="Missing" 1="(0 To 1 Month Ago) Within The Past Month" 2="(6 To 12 Months Ago) Between 3 And 6 Months" 3="(5 To 15 Years Ago) Between 5 And 15 Years" 4="More Than 15 Years Ago" 5="Never Drank Regularly"
01. Principal	alc_more_12_drink	During Your Entire Life, Have You Had At Least 12 Drinks Of Any Kind Of Alcoholic Beverage?		0="No, Never" 1="Yes" 2="Yes, But I Quit"
01. Principal	alc_num_days_drink	How Many Days Drinking Alcohol Per W/M/Y?		Numeric .M="Missing"
01. Principal	alc_num_days_drink_per	Period Of Time (How Many Days Drinking Alcohol Per W/M/Y?)		.M="Missing" 1="Week" 2="Month" 3="Year"
01. Principal	alc_visit_dt	Visit Date		SAS Date

Section 11: Baseline History Assessment

Class	Variable	Label	Description	Format Text
01. Principal	medh_be_comments	Comments BE		Char
01. Principal	medh_be_hist	Barrett's Esophagus (BE) (Please Provide Results)		.R="Not Randomized" 0="False" 1="True"
01. Principal	medh_be_onset_dt	Onset Date BE		Char
01. Principal	medh_be_res_other_spec	If Other BE Results, Specify:		Char
01. Principal	medh_be_results	BE Results		.M="Missing" .R="Not Randomized" 0="No Evidence Of Intestinal Metaplasia" 1="Intramucosal Adenocarcinoma" 2="Intestinal Metaplasia, Negative For Dysplasia" 3="Intestinal Metaplasia, Low Grade Dysplasia" 4="Intestinal Metaplasia, Indefinite For Dysplasia" 5="Intestinal Metaplasia, High Grade Dysplasia"
01. Principal	medh_be_source	Source: BE		.M="Missing" .R="Not Randomized" 1="Biopsies" 2="Resection" 3="Biopsies And Resection"
01. Principal	medh_be_therapy_comment	Comments BE Therapy		Char
01. Principal	medh_cimetidine_dose	Dose Cimetidine		Char
01. Principal	medh_cimetidine_frequency	Frequency Cimetidine		Char
01. Principal	medh_cimetidine	Cimetidine (Tagamet)		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	medh_endoscopy_exam_comment	Comments Endo Exam		Char
01. Principal	medh_esome_dose	Dose Esomeprazole		Numeric .M="Missing" .R="Not Randomized"
01. Principal	medh_esome	Esomeprazole (Nexium)		.M="Missing" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	medh_esome_freq	Frequency Esomeprazole		.M="Missing" .R="Not Randomized" 2="QD" 3="BID"
01. Principal	medh_esoph_comments	Comments Esophageal		Char
01. Principal	medh_esoph_onset_dt	Onset Date Esophageal		Char
01. Principal	medh_famo	Famotidine (Pepcid)		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	medh_famot_dose	Dose Famotidine		Char
01. Principal	medh_famot_freq	Frequency Famotidine		Char
01. Principal	medh_fudo_comments	Comments Fundoplication		Char
01. Principal	medh_fundo_hist	Fundoplication		.R="Not Randomized" 0="False" 1="True"
01. Principal	medh_fundo_onset_dt	Onset Date Fundoplication		Char
01. Principal	medh_niza	Nizatidine (Axid)		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	medh_niza_dose	Dose Nizatidine		Char
01. Principal	medh_niza_freq	Frequency Nizatidine		Char
01. Principal	medh_ome	Omeprazole (Prilosec, Rapinex)		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	medh_ome_dose	Dose Omeprazole		Numeric .M="Missing" .R="Not Randomized"
01. Principal	medh_ome_freq	Frequency Omeprazole		.M="Missing" .R="Not Randomized" 1="TID" 2="QD" 3="BID"
01. Principal	medh_other	Other		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	medh_other_dose	Dose Other		Numeric .M="Missing" .R="Not Randomized"
01. Principal	medh_other_freq	Frequency Other		.M="Missing" .R="Not Randomized" 1="TID" 2="QD" 3="BID"

Class	Variable	Label	Description	Format Text
01. Principal	medh_other_med	Other Medication		Char
01. Principal	medh_panto	Pantoprazole (Protonix)		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	medh_panto_dose	Dose Pantoprazole		Numeric .M="Missing" .R="Not Randomized"
01. Principal	medh_panto_freq	Frequency Pantoprazole		.M="Missing" .R="Not Randomized" 1="TID" 2="QD" 3="BID"
01. Principal	medh_prior_therapy	Any previous BE therapy		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	medh_prior_endoscopic	Any Prior Endoscopic Exams		.R="Not Randomized" 0="False" 1="True"
01. Principal	medh_prior_esodis	Prior Esophageal Disease		.R="Not Randomized" 0="False" 1="True"
01. Principal	medh_rabe	Rabeprazole (AcipHex)		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	medh_rabep_dose	Dose Rabeprazole		Char
01. Principal	medh_rabepr_freq	Frequency Rabeprazole		Char
01. Principal	medh_ranitidine	Ranitidine (Zantac)		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	medh_ranitidine_dose	Dose Ranitidine		Numeric .M="Missing" .R="Not Randomized"
01. Principal	medh_ranitidine_freq	Frequency Ranitidine		.M="Missing" .R="Not Randomized" 1="TID" 2="QD" 3="BID"
01. Principal	medh_reflux_comments	Comments Reflux		Char
01. Principal	medh_reflux_hist	Reflux / GERD		.R="Not Randomized" 0="False" 1="True"
01. Principal	medh_reflux_onset_dt	Onset Date Reflux		Char
01. Principal	medh_ulcer_comments	Comments Ulcer		Char

Class	Variable	Label	Description	Format Text
01. Principal	medh_ulcer_dt	Onset Date Ulcer		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	medh_ulcer_hist	Ulcers		.R="Not Randomized" 0="False" 1="True"
01. Principal	medh_ulcer_med	GERD/ulcer Medication		.R="Not Randomized" 0="False" 1="True"
01. Principal	medh_verif_dt	Verified Date		SAS Date .R="Not Randomized"

Section 12: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	base_sym_abdo_comm	Baseline Symptoms: Abdominal Pain/Cramping Comments		Char
01. Principal	base_sym_abdo_grade	Baseline Symptoms: Abdominal Pain/Cramping Grade		Char
01. Principal	base_sym_abdo_onset	Baseline Symptoms: Abdominal Pain/Cramping Onset Date		Char
01. Principal	base_sym_breath_comm	Baseline Symptoms: Shortness Of Breath Comments		Char
01. Principal	base_sym_breath_grade	Baseline Symptoms: Shortness Of Breath Grade		Char
01. Principal	base_sym_breath_onset	Baseline Symptoms: Shortness Of Breath Onset Date		Char
01. Principal	base_sym_bruise_comm	Baseline Symptoms: Easy Bruising/Bleeding Comments		Char
01. Principal	base_sym_bruise_grade	Baseline Symptoms: Easy Bruising/Bleeding Grade		Char
01. Principal	base_sym_bruise_onset	Baseline Symptoms: Easy Bruising/Bleeding Onset Date		Char
01. Principal	base_sym_consti_comm	Baseline Symptoms: Constipation Comments		Char
01. Principal	base_sym_consti_grade	Baseline Symptoms: Constipation Grade		Char
01. Principal	base_sym_consti_onset	Baseline Symptoms: Constipation Onset Date		Char
01. Principal	base_sym_cpain_comm	Baseline Symptoms: Chest Pain Comments		Char
01. Principal	base_sym_cpain_grade	Baseline Symptoms: Chest Pain Grade		Char
01. Principal	base_sym_cpain_onset	Baseline Symptoms: Chest Pain Onset Date		Char
01. Principal	base_sym_diarrhea_comm	Baseline Symptoms: Diarrhea Comments		Char

Class	Variable	Label	Description	Format Text
01. Principal	base_sym_diarrhea_grade	Baseline Symptoms: Diarrhea Grade		Char
01. Principal	base_sym_diarrhea_onset	Baseline Symptoms: Diarrhea Onset Date		Char
01. Principal	base_sym_dizzy_comm	Baseline Symptoms: Dizziness Comments		Char
01. Principal	base_sym_dizzy_grade	Baseline Symptoms: Dizziness Grade		Char
01. Principal	base_sym_dizzy_onset	Baseline Symptoms: Dizziness Onset Date		Char
01. Principal	base_sym_drowsy_comm	Baseline Symptoms: Drowsiness Comments		Char
01. Principal	base_sym_drowsy_grade	Baseline Symptoms: Drowsiness Grade		Char
01. Principal	base_sym_drowsy_onset	Baseline Symptoms: Drowsiness Onset Date		Char
01. Principal	base_sym_edema_comm	Baseline Symptoms: Edema Comments		Char
01. Principal	base_sym_edema_grade	Baseline Symptoms: Edema Grade		Char
01. Principal	base_sym_edema_onset	Baseline Symptoms: Edema Onset Date		Char
01. Principal	base_sym_gastro_comm	Baseline Symptoms: Gastrointestinal Bleeding Comments		Char
01. Principal	base_sym_gastro_grade	Baseline Symptoms: Gastrointestinal Bleeding Grade		Char
01. Principal	base_sym_gastro_onset	Baseline Symptoms: Gastrointestinal Bleeding Onset Date		Char
01. Principal	base_sym_has	Has Baseline Symptoms		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	base_sym_head_comm	Baseline Symptoms: Headache Comments		Char
01. Principal	base_sym_head_grade	Baseline Symptoms: Headache Grade		Char
01. Principal	base_sym_head_onset	Baseline Symptoms: Headache Onset Date		Char
01. Principal	base_sym_heartb_comm	Baseline Symptoms: Heartburn Comments		Char
01. Principal	base_sym_heartb_grade	Baseline Symptoms: Heartburn Grade		Char
01. Principal	base_sym_heartb_onset	Baseline Symptoms: Heartburn Onset Date		Char
01. Principal	base_sym_hemate_comm	Baseline Symptoms: Hematemesis Comments		Char

Class	Variable	Label	Description	Format Text
01. Principal	base_sym_hemat_e_grade	Baseline Symptoms: Hematemesis Grade		Char
01. Principal	base_sym_hemat_e_onset	Baseline Symptoms: Hematemesis Onset Date		Char
01. Principal	base_sym_hemato_comm	Baseline Symptoms: Hematochezia Comments		Char
01. Principal	base_sym_hemato_grade	Baseline Symptoms: Hematochezia Grade		Char
01. Principal	base_sym_hemato_onset	Baseline Symptoms: Hematochezia Onset Date		Char
01. Principal	base_sym_itch_comm	Baseline Symptoms: Itching Comments		Char
01. Principal	base_sym_itch_grade	Baseline Symptoms: Itching Grade		Char
01. Principal	base_sym_itch_onset	Baseline Symptoms: Itching Onset Date		Char
01. Principal	base_sym_lhead_comm	Baseline Symptoms: Lightheadedness Comments		Char
01. Principal	base_sym_lhead_grade	Baseline Symptoms: Lightheadedness Grade		Char
01. Principal	base_sym_lhead_onset	Baseline Symptoms: Lightheadedness Onset Date		Char
01. Principal	base_sym_melena_comm	Baseline Symptoms: Melena Comments		Char
01. Principal	base_sym_melena_grade	Baseline Symptoms: Melena Grade		Char
01. Principal	base_sym_melena_onset	Baseline Symptoms: Melena Onset Date		Char
01. Principal	base_sym_none_rep	Check Here If None Reported (No Baseline Symptoms)		.R="Not Randomized" 0="False" 1="True"
01. Principal	base_sym_palp_comm	Baseline Symptoms: Irregular Heart Rate/Palpitations Comments		Char
01. Principal	base_sym_palp_grade	Baseline Symptoms: Irregular Heart Rate/Palpitations Grade		Char
01. Principal	base_sym_palp_onset	Baseline Symptoms: Irregular Heart Rate/Palpitations Onset Date		Char
01. Principal	base_sym_vertigo_comm	Baseline Symptoms: Vertigo Comments		Char

Class	Variable	Label	Description	Format Text
01. Principal	base_sym_vertigo_grade	Baseline Symptoms: Vertigo Grade		Char
01. Principal	base_sym_vertigo_onset	Baseline Symptoms: Vertigo Onset Date		Char
01. Principal	base_sym_visit_dt	Visit Date		Numeric .R="Not Randomized"

Section 13: Cancer History

Class	Variable	Label	Description	Format Text
01. Principal	cnc_hist_bladder	Bladder		0="False" 1="True"
01. Principal	cnc_hist_bone	Bone		0="False" 1="True"
01. Principal	cnc_hist_brain	Brain		0="False" 1="True"
01. Principal	cnc_hist_breast	Breast		0="False" 1="True"
01. Principal	cnc_hist_cervix	Cervix		0="False" 1="True"
01. Principal	cnc_hist_chemo	Chemotherapy		0="False" 1="True"
01. Principal	cnc_hist_colon	Colon		0="False" 1="True"
01. Principal	cnc_hist_dx_dt	Date Of Diagnosis		SAS Date .N="N/A"
01. Principal	cnc_hist_end_dt	End Date:		SAS Date .M="Missing"
01. Principal	cnc_hist_end_dt 2	End Date:		SAS Date .N="N/A"
01. Principal	cnc_hist_endo	Endometrium		0="False" 1="True"
01. Principal	cnc_hist_esoph	Esophagus		0="False" 1="True"
01. Principal	cnc_hist_gall_bla d	Gall Bladder		0="False" 1="True"
01. Principal	cnc_hist_hnt	Head & Neck (Mouth, Nose, Throat)		0="False" 1="True"
01. Principal	cnc_hist_hormon es	Hormones		0="False" 1="True"
01. Principal	cnc_hist_kidney	Kidney		0="False" 1="True"
01. Principal	cnc_hist_leukemi a	Leukemia		0="False" 1="True"
01. Principal	cnc_hist_liver	Liver		0="False" 1="True"
01. Principal	cnc_hist_lung	Lung		0="False" 1="True"
01. Principal	cnc_hist_lympho ma	Lymphoma/Hodgkin's		0="False" 1="True"
01. Principal	cnc_hist_mesoth elioma	Mesothelioma		0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	cnc_hist_most_rec_dt	Most Recent:		SAS Date .N="N/A"
01. Principal	cnc_hist_mult_myeloma	Multiple myeloma		0="False" 1="True"
01. Principal	cnc_hist_none	None		0="False" 1="True"
01. Principal	cnc_hist_oth_cnc	Have You Ever Had Cancer (Other Than Basal/Squamous Cell Skin Cancer) Confirmed By A Doctor?		0="False" 1="True"
01. Principal	cnc_hist_other	Other		0="False" 1="True"
01. Principal	cnc_hist_other_spec	If Other, Please Specify		Char
01. Principal	cnc_hist_ovary	Ovary		0="False" 1="True"
01. Principal	cnc_hist_pancreas	Pancreas		0="False" 1="True"
01. Principal	cnc_hist_prim_dx	If Yes, How Many Primary Cancers Have You Been Diagnosed With?		Numeric .M="Missing"
01. Principal	cnc_hist_prostate	Prostate		0="False" 1="True"
01. Principal	cnc_hist_radiation	Radiation		0="False" 1="True"
01. Principal	cnc_hist_rectum	Rectum		0="False" 1="True"
01. Principal	cnc_hist_skin	Skin		0="False" 1="True"
01. Principal	cnc_hist_stomach	Stomach		0="False" 1="True"
01. Principal	cnc_hist_surgery	Surgery		0="False" 1="True"
01. Principal	cnc_hist_testis	Testis		0="False" 1="True"
01. Principal	cnc_hist_thyroid	Thyroid		0="False" 1="True"
01. Principal	cnc_hist_unknown	Unknown		0="False" 1="True"
01. Principal	cnc_hist_uterus	Uterus		0="False" 1="True"
01. Principal	cnc_hist_vagina	Vagina		0="False" 1="True"
01. Principal	cnc_hist_visit_dt	Visit Date		SAS Date

Section 14: Family History

Class	Variable	Label	Description	Format Text
01. Principal	famhx_any_rel_cnc_dx1-5	Have Any Of Your Living And Deceased First Degree Blood Relatives Been Diagnosed With Cancer [Other Than Basal/Squamous Cell Skin Cancer]?		.N="N/A" 0="No" 1="Yes" 9="Unknown"
01. Principal	famhx_first_deg_cnc1-5	How Many Of Your Living And Deceased First Degree Blood Relatives Been Diagnosed With Cancer [Other Than Basal/Squamous Cell Skin Cancer]?		Numeric .M="Missing" .N="N/A"
01. Principal	famhx_num	Number Of Family Members Mentioned		Numeric
01. Principal	famhx_num_brothers1-5	How Many Living And Deceased Blood-Related Brothers Do You Have?		Numeric .N="N/A"
01. Principal	famhx_num_daughters1-5	How Many Living And Deceased Blood-Related Daughters Do You Have?		Numeric .N="N/A"
01. Principal	famhx_num_sisters1-5	How Many Living And Deceased Blood-Related Sisters Do You Have?		Numeric .N="N/A"
01. Principal	famhx_num_sons1-5	How Many Living And Deceased Blood-Related Sons Do You Have?		Numeric .N="N/A"
01. Principal	famhx_oth_cnc_spec1-5	Relative's Cancer Type, Other Specify:		Char
01. Principal	famhx_rel_age_dx1-5	Relative's Age When Diagnosed:		Numeric .M="Missing" .N="N/A" .U="Unknown" 9999="Unknown"
01. Principal	famhx_rel_cnc_type1-5	Relative's Cancer:		Char

Class	Variable	Label	Description	Format Text
01. Principal	famhx_rel_type1-5	Relative type:		.M="Missing" .N="N/A" 1="Brother" 2="Sister" 3="Daughter" 4="Sone" 5="Father" 6="Mother"
01. Principal	famhx_visit_dt	Family History Visit Date		SAS Date

Section 15: Medical History

Class	Variable	Label	Description	Format Text
01. Principal	medhx_anemia	Anemia? (If Yes, Please Check Type) run		0="False" 1="True"
01. Principal	medhx_b12_def	Pernicious (Vitamin B12 Deficiency)		0="False" 1="True"
01. Principal	medhx_bone_dis	Osteomyelitis? Infection In The Bones		0="False" 1="True"
01. Principal	medhx_coll_vasc_dis	Collagen Vascular Disease? Such As Lupus Or Scleroderma		0="False" 1="True"
01. Principal	medhx_crohns	Crohn's Disease? Inflammation Into The Deeper Layers Of The Intestinal Walls And May Affect The Colon, Mouth, Esophagus, And Stomach		0="False" 1="True"
01. Principal	medhx_diabetes	Diabetes? Body Doesn't Make Enough Insulin Or Insulin That Is Made Doesn't Work		0="False" 1="True"
01. Principal	medhx_diverticulitis	Diverticulitis? Pouches In The Wall Of The Colon Become Inflamed Or Infected		.M="Missing" 0="False" 1="True"
01. Principal	medhx_ibs	Irritable Bowel Syndrome? Disorder Of The Bowel's Alternating Diarrhea And Constipation With Gassiniess And Cramping		0="False" 1="True"
01. Principal	medhx_inf_bowel_dis	Inflammatory Bowel Disease?		0="False" 1="True"
01. Principal	medhx_iron_ef	Iron Deficiency		0="False" 1="True"
01. Principal	medhx_other_dis	Other		0="False" 1="True"
01. Principal	medhx_pancreatitis	Pancreatitis? Inflamed Pancreas		.M="Missing" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	medhx_rheuma_arth	Rheumatoid Arthritis? Inflammatory Disease Of The Lining Of The Joint, That Results In Pain, Stiffness, Swelling, Deformity And Loss Of Function In The Joints.		0="False" 1="True"
01. Principal	medhx_thalassemia	Thalassemia Or Other Traits		0="False" 1="True"
01. Principal	medhx_thyroid_dis	Thyroid Disease? Thyroiditis Or Grave's Disease (Hypothyroidism)		0="False" 1="True"
01. Principal	medhx_tuberculosis	Tuberculosis?		0="False" 1="True"
01. Principal	medhx_visit_dt	Visit Date		SAS Date

Section 16: Surgical History

Class	Variable	Label	Description	Format Text
01. Principal	surg_hist_appendix	Appendix		0="False" 1="True"
01. Principal	surg_hist_esophagus	All Or Part Of Your Esophagus		0="False" 1="True"
01. Principal	surg_hist_gall_bladder	Gall Bladder		0="False" 1="True"
01. Principal	surg_hist_intestines	All Or Part Of Your Intestines, Colon, Or Rectum		0="False" 1="True"
01. Principal	surg_hist_liver	Part Of Your Liver		0="False" 1="True"
01. Principal	surg_hist_pancreas	Part Of Your Pancreas		0="False" 1="True"
01. Principal	surg_hist_stomach	All The Part Of Your Stomach		0="False" 1="True"
01. Principal	surg_hist_visit_date	Visit Date		SAS Date .M="Missing"

Section 17: Tobacco History

Class	Variable	Label	Description	Format Text
01. Principal	tob_age_begin_s moke	At What Age Did You Begin Smoking Regularly?		Numeric .M="Missing"
01. Principal	tob_cig_a_day	On The Average, About How Many Cigarettes A Day Do (Or Did) You Smoke? (1 Pack = 20 Cigarettes)		Numeric .M="Missing"
01. Principal	tob_how_long	If You Do Not Currently Smoke Cigarettes, But Did In The Past, How Long Has It Been Since You Last Smoked Regularly (That Is, Everyday Or Some Days)?		.N="N/A" 1="(1 To 5 Years Ago) Between 1 And 5 Years" 2="(5 To 15 Years Ago) Between 5 And 15 Years" 3="More Than 15 Years Ago" 4="Don't Know/Not Sure"
01. Principal	tob_quit_age	If You Have Quit Smoking: How Old Were You When You Quit?		Numeric .M="Missing"
01. Principal	tob_smoked_100 _cig	Have You Smoked 100 Cigarettes Or More During Your Entire Lifetime? (5 Packs = 100 Cigarettes)		0="No, Never" 1="Yes" 2="Yes, But I Quit"
01. Principal	tob_visit_dt	Visit Date		SAS Date

Section 18: Eligibility Verification

Class	Variable	Label	Description	Format Text
01. Principal	elig_comments	Comments		Char
01. Principal	elig_mdacc_id	MDACC Patient Identifier		Char
01. Principal	elig_rand_crit	Meets Randomization Criteria		0="No" 1="Yes"
01. Principal	elig_rand_dt	Randomization Date		SAS Date .N="N/A"
01. Principal	elig_reg_dt	Registration Date		SAS Date
01. Principal	elig_verif_dt	Verified Date		SAS Date
01. Principal	elig_verif_stat	Verification Status		1="Confirmed" 2="Ineligible" 3="Pending"

Section 19: Verification

Class	Variable	Label	Description	Format Text
01. Principal	verif_dt	Date Of Investigator Signature		SAS Date
01. Principal	verif_time	Time Of Investigator Signature		SAS Time

Section 20: Randomization

Class	Variable	Label	Description	Format Text
01. Principal	rand_dt	Randomization Date		SAS Date .M="Missing"
01. Principal	rand_elig	Eligibility Status: Is The Participant Eligible For Inclusion On This Protocol?		0="No" 1="Yes"
01. Principal	rand_id_num	Randomization Number		Char
01. Principal	rand_na	Not Applicable		0="False" 1="True"
01. Principal	rand_number	Randomization Number		Char
01. Principal	rand_tac1	TAC1 Aspirin/Placebo 325 mg PO QD x 12 Months		.M="Missing" 0="No" 1="Yes"

Section 21: Agent Interruption

Class	Variable	Label	Description	Format Text
01. Principal	agint_reason_restart_spec1-5	Reason Restarted Specify		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Participant Decision"
01. Principal	agint_reason_stop1-5	Reason Stopped		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Participant Decision" 9="Other, Specify"
01. Principal	agint_reason_stop_spec1-5	Reason Stopped Specify		Char
01. Principal	agint_restart1-5	Was Agent Restarted?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	agint_restart_dt1-5	If Yes (Restarted), Date Restarted		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	agint_stop_dt1-5	Date Stopped		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	agint_visit_dt1-5	Visit Date		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Section 22: BE Details

Class	Variable	Label	Description	Format Text
01. Principal	be_a12hete_fcon_v1_1-3	A12 HETE FCON		Numeric .M="Missing"
01. Principal	be_a12hete_fcon_v5_1-3	A12 HETE FCON		Numeric .M="Missing"
01. Principal	be_a12hete_fcon_v7_1-3	A12 HETE FCON		Numeric .M="Missing"
01. Principal	be_a12hete_mg_ng_v1_1-3	A12 HETE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a12hete_mg_ng_v5_1-3	A12 HETE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a12hete_mg_ng_v7_1-3	A12 HETE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a13hode_fcon_v1_1-3	A13 HODE FCON		Numeric .M="Missing"
01. Principal	be_a13hode_fcon_v5_1-3	A13 HODE FCON		Numeric .M="Missing"
01. Principal	be_a13hode_fcon_v7_1-3	A13 HODE FCON		Numeric .M="Missing"
01. Principal	be_a13hode_mg_ng_v1_1-3	A13 HODE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a13hode_mg_ng_v5_1-3	A13 HODE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a13hode_mg_ng_v7_1-3	A13 HODE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a13pge1_fcon_v1_1-3	A13 PGE FCON		Numeric .M="Missing"
01. Principal	be_a13pge1_fcon_v5_1-3	A13 PGE FCON		Numeric .M="Missing"
01. Principal	be_a13pge1_fcon_v7_1-3	A13 PGE FCON		Numeric .M="Missing"
01. Principal	be_a13pge1_mg_ng_v1_1-3	A13 PGE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a13pge1_mg_ng_v5_1-3	A13 PGE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a13pge1_mg_ng_v7_1-3	A13 PGE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a13pge2_fcon_v1_1-3	A13 PGE FCON		Numeric .M="Missing"
01. Principal	be_a13pge2_fcon_v5_1-3	A13 PGE FCON		Numeric .M="Missing"
01. Principal	be_a13pge2_fcon_v7_1-3	A13 PGE FCON		Numeric .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	be_a13pge2_mg_ng_v1_1-3	A13 PGE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a13pge2_mg_ng_v5_1-3	A13 PGE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a13pge2_mg_ng_v7_1-3	A13 PGE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a15hete_fcon_v1_1-3	A15 HETE FCON		Numeric .M="Missing"
01. Principal	be_a15hete_fcon_v5_1-3	A15 HETE FCON		Numeric .M="Missing"
01. Principal	be_a15hete_fcon_v7_1-3	A15 HETE FCON		Numeric .M="Missing"
01. Principal	be_a15hete_mg_ng_v1_1-3	A15 HETE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a15hete_mg_ng_v5_1-3	A15 HETE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a15hete_mg_ng_v7_1-3	A15 HETE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a5hete_fcon_v1_1-3	A5 HETE FCON		Numeric .M="Missing"
01. Principal	be_a5hete_fcon_v5_1-3	A5 HETE FCON		Numeric .M="Missing"
01. Principal	be_a5hete_fcon_v7_1-3	A5 HETE FCON		Numeric .M="Missing"
01. Principal	be_a5hete_mg_ng_v1_1-3	A5 HETE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a5hete_mg_ng_v5_1-3	A5 HETE (ng/mg)		Numeric .M="Missing"
01. Principal	be_a5hete_mg_ng_v7_1-3	A5 HETE (ng/mg)		Numeric .M="Missing"
01. Principal	be_cdx2_gapdh_v1_1-3	CDX2/GAPDH Ratio		Numeric .M="Missing"
01. Principal	be_cdx2_gapdh_v5_1-3	CDX2/GAPDH Ratio		Numeric .M="Missing"
01. Principal	be_cdx2_gapdh_v7_1-3	CDX2/GAPDH Ratio		Numeric .M="Missing"
01. Principal	be_cdx2_v1_1-3	CDX2		Numeric .M="Missing"
01. Principal	be_cdx2_v5_1-3	CDX2		Numeric .M="Missing"
01. Principal	be_cdx2_v7_1-3	CDX2		Numeric .M="Missing"
01. Principal	be_gapdh_v1_1-3	GAPDH		Numeric .M="Missing"
01. Principal	be_gapdh_v5_1-3	GAPDH		Numeric .M="Missing"
01. Principal	be_gapdh_v7_1-3	GAPDH		Numeric .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	be_ketoPGF1a_fcon_v1_1-3	Keto PGF 1a FCON		Numeric .M="Missing"
01. Principal	be_ketoPGF1a_fcon_v5_1-3	Keto PGF 1a FCON		Numeric .M="Missing"
01. Principal	be_ketoPGF1a_fcon_v7_1-3	Keto PGF 1a FCON		Numeric .M="Missing"
01. Principal	be_ketoPGF1a_ng_mg_v1_1-3	Keto PGF 1a (ng/mg)		Numeric .M="Missing"
01. Principal	be_ketoPGF1a_ng_mg_v5_1-3	Keto PGF 1a (ng/mg)		Numeric .M="Missing"
01. Principal	be_ketoPGF1a_ng_mg_v7_1-3	Keto PGF 1a (ng/mg)		Numeric .M="Missing"
01. Principal	be_location_v1_1-3	Location		1="A" 2="B" 3="C"
01. Principal	be_location_v5_1-3	Location		1="A" 2="B" 3="C"
01. Principal	be_location_v7_1-3	Location		1="A" 2="B" 3="C"
01. Principal	be_pgd2_fcon_v1_1-3	PGD 2 FCON		Numeric .M="Missing"
01. Principal	be_pgd2_fcon_v5_1-3	PGD 2 FCON		Numeric .M="Missing"
01. Principal	be_pgd2_fcon_v7_1-3	PGD 2 FCON		Numeric .M="Missing"
01. Principal	be_pgd2_ng_mg_v1_1-3	PGD 2 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pgd2_ng_mg_v5_1-3	PGD 2 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pgd2_ng_mg_v7_1-3	PGD 2 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pge1_fcon_v1_1-3	PGE 1 FCON		Numeric .M="Missing"
01. Principal	be_pge1_fcon_v5_1-3	PGE 1 FCON		Numeric .M="Missing"
01. Principal	be_pge1_fcon_v7_1-3	PGE 1 FCON		Numeric .M="Missing"
01. Principal	be_pge1_ng_mg_v1_1-3	PGE 1 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pge1_ng_mg_v5_1-3	PGE 1 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pge1_ng_mg_v7_1-3	PGE 1 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pge2_fcon_v1_1-3	PGE 2 FCON		Numeric .M="Missing"
01. Principal	be_pge2_fcon_v5_1-3	PGE 2 FCON		Numeric .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	be_pge2_fcon_v7_1-3	PGE 2 FCON		Numeric .M="Missing"
01. Principal	be_pge2_ng_mg_v1_1-3	PGE 2 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pge2_ng_mg_v5_1-3	PGE 2 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pge2_ng_mg_v7_1-3	PGE 2 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pge3_fcon_v1_1-3	PGE 3 FCON		Numeric .M="Missing"
01. Principal	be_pge3_fcon_v5_1-3	PGE 3 FCON		Numeric .M="Missing"
01. Principal	be_pge3_fcon_v7_1-3	PGE 3 FCON		Numeric .M="Missing"
01. Principal	be_pge3_ng_mg_v1_1-3	PGE 3 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pge3_ng_mg_v5_1-3	PGE 3 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pge3_ng_mg_v7_1-3	PGE 3 (ng/mg)		Numeric .M="Missing"
01. Principal	be_pgf2a_fcon_v1_1-3	PGF 2a FCON		Numeric .M="Missing"
01. Principal	be_pgf2a_fcon_v5_1-3	PGF 2a FCON		Numeric .M="Missing"
01. Principal	be_pgf2a_fcon_v7_1-3	PGF 2a FCON		Numeric .M="Missing"
01. Principal	be_pgf2a_ng_mg_v1_1-3	PGF 2a (ng/mg)		Numeric .M="Missing"
01. Principal	be_pgf2a_ng_mg_v5_1-3	PGF 2a (ng/mg)		Numeric .M="Missing"
01. Principal	be_pgf2a_ng_mg_v7_1-3	PGF 2a (ng/mg)		Numeric .M="Missing"
01. Principal	be_pp65_totp65c_orrtu_v1_1-3	P-P65/T-P65 Normalized To Tubulin		Numeric .M="Missing"
01. Principal	be_pp65_totp65c_orrtu_v5_1-3	P-P65/T-P65 Normalized To Tubulin		Numeric .M="Missing"
01. Principal	be_pp65_totp65c_orrtu_v7_1-3	P-P65/T-P65 Normalized To Tubulin		Numeric .M="Missing"
01. Principal	be_pp65_tp65_v1_1-3	P-P65/T-P65		Numeric .M="Missing"
01. Principal	be_pp65_tp65_v5_1-3	P-P65/T-P65		Numeric .M="Missing"
01. Principal	be_pp65_tp65_v7_1-3	P-P65/T-P65		Numeric .M="Missing"
01. Principal	be_pp65_tu_v1_1-3	P-P65/TU		Numeric .M="Missing"
01. Principal	be_pp65_tu_v5_1-3	P-P65/TU		Numeric .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	be_pp65_tu_v7_1-3	P-P65/TU		Numeric .M="Missing"
01. Principal	be_pp65_v1_1-3	P-P65		Numeric .M="Missing"
01. Principal	be_pp65_v5_1-3	P-P65		Numeric .M="Missing"
01. Principal	be_pp65_v7_1-3	P-P65		Numeric .M="Missing"
01. Principal	be_protein_mg_mL_v1_1-3	Protein (mg/mL)		Numeric .M="Missing"
01. Principal	be_protein_mg_mL_v5_1-3	Protein (mg/mL)		Numeric .M="Missing"
01. Principal	be_protein_mg_mL_v7_1-3	Protein (mg/mL)		Numeric .M="Missing"
01. Principal	be_record_id_v1_1-3	Record ID		Numeric
01. Principal	be_record_id_v5_1-3	Record ID		Numeric
01. Principal	be_record_id_v7_1-3	Record ID		Numeric
01. Principal	be_sample_name_v1_1-3	Sample Name		Char
01. Principal	be_sample_name_v5_1-3	Sample Name		Char
01. Principal	be_sample_name_v7_1-3	Sample Name		Char
01. Principal	be_sample_v1_1-3	Sample		Char
01. Principal	be_sample_v5_1-3	Sample		Char
01. Principal	be_sample_v7_1-3	Sample		Char
01. Principal	be_sampleid2_v1_1-3	Sample ID 2		Char
01. Principal	be_sampleid2_v5_1-3	Sample ID 2		Char
01. Principal	be_sampleid2_v7_1-3	Sample ID 2		Char
01. Principal	be_sampleid3_v1_1-3	Sample ID 3		Char
01. Principal	be_sampleid3_v5_1-3	Sample ID 3		Char
01. Principal	be_sampleid3_v7_1-3	Sample ID 3		Char
01. Principal	be_tp65_tu_v1_1-3	T-P65/TU		Numeric .M="Missing"
01. Principal	be_tp65_tu_v5_1-3	T-P65/TU		Numeric .M="Missing"

Class	Variable	Label	Description	Format Text
01. Principal	be_tp65_tu_v7_1-3	T-P65/TU		Numeric .M="Missing"
01. Principal	be_tp65_v1_1-3	T-P65		Numeric .M="Missing"
01. Principal	be_tp65_v5_1-3	T-P65		Numeric .M="Missing"
01. Principal	be_tp65_v7_1-3	T-P65		Numeric .M="Missing"
01. Principal	be_tu_v1_1-3	TU		Numeric .M="Missing"
01. Principal	be_tu_v5_1-3	TU		Numeric .M="Missing"
01. Principal	be_tu_v7_1-3	TU		Numeric .M="Missing"
01. Principal	be_txb2_fcon_v1_1-3	TXB 2 FCON		Numeric .M="Missing"
01. Principal	be_txb2_fcon_v5_1-3	TXB 2 FCON		Numeric .M="Missing"
01. Principal	be_txb2_fcon_v7_1-3	TXB 2 FCON		Numeric .M="Missing"
01. Principal	be_txb2_ng_mg_v1_1-3	TXB 2 (ng/mg)		Numeric .M="Missing"
01. Principal	be_txb2_ng_mg_v5_1-3	TXB 2 (ng/mg)		Numeric .M="Missing"
01. Principal	be_txb2_ng_mg_v7_1-3	TXB 2 (ng/mg)		Numeric .M="Missing"

Section 23: Biopsy Research Specimen

Class	Variable	Label	Description	Format Text
01. Principal	biop_a1_v1/7/9	Biopsy A1 (Formalin Fixed)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_a2_v1/7/9	Biopsy A2 (RNAlater)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_a3_v1/7/9	Biopsy A3 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_a4_v1/7/9	Biopsy A4 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_a5_v1/7/9	Biopsy A5 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_a6_v1/7/9	Biopsy A6 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_a7_v1/7/9	Biopsy A7 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_b1_v1/7/9	Biopsy B1 (Formalin fixed)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_b2_v1/7/9	Biopsy B2 (RNAlater)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_b3_v1/7/9	Biopsy B3 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"

Class	Variable	Label	Description	Format Text
01. Principal	biop_b4_v1/7/9	Biopsy B4 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_b5_v1/7/9	Biopsy B5 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_b6_v1/7/9	Biopsy B6 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_b7_v1/7/9	Biopsy B7 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_c1_v1/7/9	Biopsy C1 (Formalin fixed)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_c2_v1/7/9	Biopsy C2 (RNAlater)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_c3_v1/7/9	Biopsy C3 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_c4_v1/7/9	Biopsy C4 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_c5_v1/7/9	Biopsy C5 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_c6_v1/7/9	Biopsy C6 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"
01. Principal	biop_c7_v1/7/9	Biopsy C7 (Flash Frozen)		Numeric .M="Missing" .R="Not Randomized" 9998="1217 Kit 1061" 9999="Not Collected"

Class	Variable	Label	Description	Format Text
01. Principal	biop_visit_dt_v1/7/9	Biopsy Visit Date		SAS Date .M="Missing" .R="Not Randomized"

Section 24: Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_bili_clin_sig_v1/7	Blood Chemistry Clinically Significant: Bilirubin, Total		.M="Missing" .R="Not Randomized" 0="No" 9="Unknown"
01. Principal	bldchem_bili_comments_v1/7	Blood Chemistry Comments: Bilirubin, Total		Char
01. Principal	bldchem_bili_not_obt_v1/7	Blood Chemistry Not Obtained: Bilirubin, Total		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bili_oor_v1/7	Blood Chemistry Out Of Range: Bilirubin, Total		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_bili_results_v1/7	Blood Chemistry Results: Bilirubin, Total		Numeric .M="Missing" .R="Not Randomized" 9998=">89" 9999=">60"
01. Principal	bldchem_bili_units_v1/7	Blood Chemistry Units: Bilirubin, Total		Char
01. Principal	bldchem_creat_clin_sig_v1/7	Blood Chemistry Clinically Significant: Creatinine		.M="Missing" .R="Not Randomized" 0="No" 9="Unknown"
01. Principal	bldchem_creat_comments_v1/7	Blood Chemistry Comments: Creatinine		Char
01. Principal	bldchem_creat_not_obt_v1/7	Blood Chemistry Not Obtained: Creatinine		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_creat_oor_v1/7	Blood Chemistry Out Of Range: Creatinine		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_creat_results_v1/7	Blood Chemistry Results: Creatinine		Numeric .M="Missing" .R="Not Randomized" 9998=">89" 9999=">60"
01. Principal	bldchem_creat_units_v1/7	Blood Chemistry Units: Creatinine		Char
01. Principal	bldchem_gfr_clin_sig_v1/7	Blood Chemistry Clinically Significant: GFR		.M="Missing" .R="Not Randomized" 0="No" 9="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_gfr_comments_v1/7	Blood Chemistry Comments: GFR		Char
01. Principal	bldchem_gfr_not_obt_v1/7	Blood Chemistry Not Obtained: GFR		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_gfr_oor_v1/7	Blood Chemistry Out Of Range: GFR		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_gfr_results_v1/7	Blood Chemistry Results: GFR		Numeric .M="Missing" .R="Not Randomized" 9998=">89" 9999=">60"
01. Principal	bldchem_gfr_units_v1/7	Blood Chemistry Units: GFR		Char
01. Principal	bldchem_k_clin_sig_v1/7	Blood Chemistry Clinically Significant: Potassium		.M="Missing" .R="Not Randomized" 0="No" 9="Unknown"
01. Principal	bldchem_k_comments_v1/7	Blood Chemistry Comments: Potassium		Char
01. Principal	bldchem_k_not_obt_v1/7	Blood Chemistry Not Obtained: Potassium		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_k_oor_v1/7	Blood Chemistry Out Of Range: Potassium		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_k_results_v1/7	Blood Chemistry Results: Potassium		Numeric .M="Missing" .R="Not Randomized" 9998=">89" 9999=">60"
01. Principal	bldchem_k_units_v1/7	Blood Chemistry Units: Potassium		Char
01. Principal	bldchem_na_clin_sig_v1/7	Blood Chemistry Clinically Significant: Sodium		.M="Missing" .R="Not Randomized" 0="No" 9="Unknown"
01. Principal	bldchem_na_comments_v1/7	Blood Chemistry Comments: Sodium		Char
01. Principal	bldchem_na_not_obt_v1/7	Blood Chemistry Not Obtained: Sodium		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_na_oor_v1/7	Blood Chemistry Out Of Range: Sodium		.M="Missing" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	bldchem_na_results_v1/7	Blood Chemistry Results: Sodium		Numeric .M="Missing" .R="Not Randomized" 9998=">89" 9999=">60"
01. Principal	bldchem_na_units_v1/7	Blood Chemistry Units: Sodium		Char
01. Principal	bldchem_sgpt_clin_sig_v1/7	Blood Chemistry Clinically Significant: SGOT/AST		.M="Missing" .R="Not Randomized" 0="No" 9="Unknown"
01. Principal	bldchem_sgpt_comments_v1/7	Blood Chemistry Comments: SGOT/AST		Char
01. Principal	bldchem_sgpt_not_obt_v1/7	Blood Chemistry Not Obtained: SGOT/AST		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgpt_out_of_range_v1/7	Blood Chemistry Out Of Range: SGOT/AST		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgpt_results_v1/7	Blood Chemistry Results: SGOT/AST		Numeric .M="Missing" .R="Not Randomized" 9998=">89" 9999=">60"
01. Principal	bldchem_sgpt_units_v1/7	Blood Chemistry Units: SGOT/AST		Char
01. Principal	bldchem_sgpt_clin_sig_v1/7	Blood Chemistry Clinically Significant: SGPT/ALT		.M="Missing" .R="Not Randomized" 0="No" 9="Unknown"
01. Principal	bldchem_sgpt_comments_v1/7	Blood Chemistry Comments: SGPT/ALT		Char
01. Principal	bldchem_sgpt_not_obt_v1/7	Blood Chemistry Not Obtained: SGPT/ALT		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgpt_out_of_range_v1/7	Blood Chemistry Out Of Range: SGPT/ALT		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldchem_sgpt_results_v1/7	Blood Chemistry Results: SGPT/ALT		Numeric .M="Missing" .R="Not Randomized" 9998=">89" 9999=">60"
01. Principal	bldchem_sgpt_units_v1/7	Blood Chemistry Units: SGPT/ALT		Char
01. Principal	bldchem_visit_dt_v1/7	Blood Chemistry Visit Date		SAS Date .R="Not Randomized"

Section 25: Blood Hematology

Class	Variable	Label	Description	Format Text
01. Principal	bldhema_abs_neut_clin_sig_v1/7	Blood Hematology Clinically Significant: Absolute Neutrophils		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldhema_abs_neut_comments_v1/7	Blood Hematology Comments: Absolute Neutrophils		Char
01. Principal	bldhema_abs_neut_not_obt_v1/7	Blood Hematology Not Obtained: Absolute Neutrophils		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_abs_neut_oor_v1/7	Blood Hematology Out Of Range: Absolute Neutrophils		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_abs_neut_results_v1/7	Blood Hematology Results: Absolute Neutrophils		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldhema_abs_neut_units_v1/7	Blood Hematology Units: Absolute Neutrophils		Char
01. Principal	bldhema_bands_clin_sig_v1/7	Blood Hematology Clinically Significant: Bands		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldhema_bands_comments_v1/7	Blood Hematology Comments: Bands		Char
01. Principal	bldhema_bands_not_obt_v1/7	Blood Hematology Not Obtained: Bands		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_bands_oor_v1/7	Blood Hematology Out Of Range: Bands		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_bands_results_v1/7	Blood Hematology Results: Bands		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldhema_bands_units_v1/7	Blood Hematology Units: Bands		Char
01. Principal	bldhema_baso_clin_sig_v1/7	Blood Hematology Clinically Significant: Basophils		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	bldhema_baso_comments_v1/7	Blood Hematology Comments: Basophils		Char
01. Principal	bldhema_baso_not_obt_v1/7	Blood Hematology Not Obtained: Basophils		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_baso_out_v1/7	Blood Hematology Out Of Range: Basophils		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_baso_results_v1/7	Blood Hematology Results: Basophils		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldhema_baso_units_v1/7	Blood Hematology Units: Basophils		Char
01. Principal	bldhema_eosino_clin_sig_v1/7	Blood Hematology Clinically Significant: Eosinophils		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldhema_eosino_comments_v1/7	Blood Hematology Comments: Eosinophils		Char
01. Principal	bldhema_eosino_not_obt_v1/7	Blood Hematology Not Obtained: Eosinophils		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_eosino_out_v1/7	Blood Hematology Out Of Range: Eosinophils		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_eosino_results_v1/7	Blood Hematology Results: Eosinophils		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldhema_eosino_units_v1/7	Blood Hematology Units: Eosinophils		Char
01. Principal	bldhema_hema_clin_sig_v1/7	Blood Hematology Clinically Significant: Hematocrit		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldhema_hema_comments_v1/7	Blood Hematology Comments: Hematocrit		Char
01. Principal	bldhema_hema_not_obt_v1/7	Blood Hematology Not Obtained: Hematocrit		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_hema_out_v1/7	Blood Hematology Out Of Range: Hematocrit		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_hema_results_v1/7	Blood Hematology Results: Hematocrit		Numeric .M="Missing" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	bldhema_hema_units_v1/7	Blood Hematology Units: Hematocrit		Char
01. Principal	bldhema_hemo_clin_sig_v1/7	Blood Hematology Clinically Significant: Hemoglobin		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldhema_hemo_comments_v1/7	Blood Hematology Comments: Hemoglobin		Char
01. Principal	bldhema_hemo_not_obt_v1/7	Blood Hematology Not Obtained: Hemoglobin		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_hemo_oor_v1/7	Blood Hematology Out Of Range: Hemoglobin		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_hemo_results_v1/7	Blood Hematology Results: Hemoglobin		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldhema_hemo_units_v1/7	Blood Hematology Units: Hemoglobin		Char
01. Principal	bldhema_lymph_clin_sig_v1/7	Blood Hematology Clinically Significant: Lymphocytes		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldhema_lymph_comments_v1/7	Blood Hematology Comments: Lymphocytes		Char
01. Principal	bldhema_lymph_not_obt_v1/7	Blood Hematology Not Obtained: Lymphocytes		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_lymph_oor_v1/7	Blood Hematology Out Of Range: Lymphocytes		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_lymph_results_v1/7	Blood Hematology Results: Lymphocytes		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldhema_lymph_units_v1/7	Blood Hematology Units: Lymphocytes		Char
01. Principal	bldhema_mono_clin_sig_v1/7	Blood Hematology Clinically Significant: Monocytes		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldhema_mono_comments_v1/7	Blood Hematology Comments: Monocytes		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldhema_mono_not_obt_v1/7	Blood Hematology Not Obtained: Monocytes		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_mono_oor_v1/7	Blood Hematology Out Of Range: Monocytes		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_mono_results_v1/7	Blood Hematology Results: Monocytes		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldhema_mono_units_v1/7	Blood Hematology Units: Monocytes		Char
01. Principal	bldhema_neutro_clin_sig_v1/7	Blood Hematology Clinically Significant: Neutrophils		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldhema_neutro_comments_v1/7	Blood Hematology Comments: Neutrophils		Char
01. Principal	bldhema_neutro_not_obt_v1/7	Blood Hematology Not Obtained: Neutrophils		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_neutro_oor_v1/7	Blood Hematology Out Of Range: Neutrophils		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_neutro_results_v1/7	Blood Hematology Results: Neutrophils		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldhema_neutro_units_v1/7	Blood Hematology Units: Neutrophils		Char
01. Principal	bldhema_plate_clin_sig_v1/7	Blood Hematology Clinically Significant: Platelets		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldhema_plate_comments_v1/7	Blood Hematology Comments: Platelets		Char
01. Principal	bldhema_plate_not_obt_v1/7	Blood Hematology Not Obtained: Platelets		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_plate_oor_v1/7	Blood Hematology Out Of Range: Platelets		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_plate_results_v1/7	Blood Hematology Results: Platelets		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldhema_plate_units_v1/7	Blood Hematology Units: Platelets		Char

Class	Variable	Label	Description	Format Text
01. Principal	bldhema_rbc_clin_sig_v1/7	Blood Hematology Clinically Significant: RBC		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldhema_rbc_comments_v1/7	Blood Hematology Comments: RBC		Char
01. Principal	bldhema_rbc_not_obt_v1/7	Blood Hematology Not Obtained: RBC		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_rbc_oor_v1/7	Blood Hematology Out Of Range: RBC		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_rbc_results_v1/7	Blood Hematology Results: RBC		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldhema_rbc_units_v1/7	Blood Hematology Units: RBC		Char
01. Principal	bldhema_visit_2_dt_v1/7	Blood Hematology Visit Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	bldhema_visit_dt_v1/7	Blood Hematology Visit Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	bldhema_wbc_clin_sig_v1/7	Blood Hematology Clinically Significant: WBC		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 9="Unknown"
01. Principal	bldhema_wbc_comments_v1/7	Blood Hematology Comments: WBC		Char
01. Principal	bldhema_wbc_not_obt_v1/7	Blood Hematology Not Obtained: WBC		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_wbc_oor_v1/7	Blood Hematology Out Of Range: WBC		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	bldhema_wbc_results_v1/7	Blood Hematology Results: WBC		Numeric .M="Missing" .R="Not Randomized"
01. Principal	bldhema_wbc_units_v1/7	Blood Hematology Units: WBC		Char

Section 26: Other Labs

Class	Variable	Label	Description	Format Text
01. Principal	oth_lab_clin_sig1-20	Other Lab Tests: Clinically Significant		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Known" 9="Unknown"
01. Principal	oth_lab_num	Number Of Other Labs		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	oth_lab_oor1-20	Other Lab Tests: Out Of Range		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True" 2="NULL"
01. Principal	oth_lab_results1-20	Other Lab Tests: Results		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	oth_lab_test1-20	Other Lab Tests: Test		Char
01. Principal	oth_lab_units1-20	Other Lab Tests: Units		Char
01. Principal	oth_lab_visit_dt	Other Lab Tests: Visit Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 27: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	conmed_continuing1-32	Continuing		.M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	conmed_dose1-32	Dose		Char
01. Principal	conmed_freq1-32	Frequency		Char
01. Principal	conmed_freq_desc1-32	Frequency Description		Char
01. Principal	conmed_medication1-32	Medication		Char
01. Principal	conmed_num	Number Of Concomitant Medications		Numeric .R="Not Randomized"
01. Principal	conmed_oth_freq1-32	Other Frequency		Char
01. Principal	conmed_oth_units1-32	Other Units		Char
01. Principal	conmed_reason1-32	Reason		Char
01. Principal	conmed_rep_dt1-32	Medication Reported Date		SAS Date .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	conmed_start_dt1-32	Start Date		Char
01. Principal	conmed_stop_dt1-32	Stop Date		Char
01. Principal	conmed_units1-32	Units		Char
01. Principal	conmed_units_desc1-32	Units Description		Char

Section 28: Endoscopy Assessment

Class	Variable	Label	Description	Format Text
01. Principal	endo_cent_lev_v1_1-9	Centimeter Level Or Range Of Levels		Char
01. Principal	endo_cent_lev_v3_1-4	Centimeter Level Or Range Of Levels		Char
01. Principal	endo_cent_lev_v7_1-5	Centimeter Level Or Range Of Levels		Char
01. Principal	endo_cent_lev_v9_1-5	Centimeter Level Or Range Of Levels		Char
01. Principal	endo_diaph_pinch_v1_1-9	Diaphragmatic Pinch		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"
01. Principal	endo_diaph_pinch_v3_1-4	Diaphragmatic Pinch		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"
01. Principal	endo_diaph_pinch_v7_1-5	Diaphragmatic Pinch		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"
01. Principal	endo_diaph_pinch_v9_1-5	Diaphragmatic Pinch		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"
01. Principal	endo_esophagitis_v1_1-9	Esophagitis Using The LA Criteria		.M="Missing" .R="Not Randomized" 0="No Esophagitis" 1="Grade A" 3="Grade C"
01. Principal	endo_esophagitis_v3_1-4	Esophagitis Using The LA Criteria		.M="Missing" .R="Not Randomized" 0="No Esophagitis" 1="Grade A" 3="Grade C"
01. Principal	endo_esophagitis_v7_1-5	Esophagitis Using The LA Criteria		.M="Missing" .R="Not Randomized" 0="No Esophagitis" 1="Grade A" 3="Grade C"
01. Principal	endo_esophagitis_v9_1-5	Esophagitis Using The LA Criteria		.M="Missing" .R="Not Randomized" 0="No Esophagitis" 1="Grade A" 3="Grade C"

Class	Variable	Label	Description	Format Text
01. Principal	endo_ext_colu_e so_v1_1-9	If Yes: Extension Of Columnar Lined Esophagus:		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_ext_colu_e so_v3_1-4	If Yes: Extension Of Columnar Lined Esophagus:		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_ext_colu_e so_v7_1-5	If Yes: Extension Of Columnar Lined Esophagus:		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_ext_colu_e so_v9_1-5	If Yes: Extension Of Columnar Lined Esophagus:		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_ge_j_loc_v 1_1-9	Location Of The GE Junction		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_ge_j_loc_v 3_1-4	Location Of The GE Junction		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_ge_j_loc_v 7_1-5	Location Of The GE Junction		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_ge_j_loc_v 9_1-5	Location Of The GE Junction		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_has_be_v1 _1-9	Participant Has Barrett's Esophagus?		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	endo_has_be_v3 _1-4	Participant Has Barrett's Esophagus?		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	endo_has_be_v7 _1-5	Participant Has Barrett's Esophagus?		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	endo_has_be_v9 _1-5	Participant Has Barrett's Esophagus?		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	endo_hiat_hernia _v1_1-9	Hiatal Hernia		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	endo_hiat_hernia _v3_1-4	Hiatal Hernia		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	endo_hiat_hernia _v7_1-5	Hiatal Hernia		.M="Missing" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	endo_hiat_hernia_v9_1-5	Hiatal Hernia		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	endo_local_acc_v1_1-9	Local Accession Or Pathology Number		Char
01. Principal	endo_local_acc_v3_1-4	Local Accession Or Pathology Number		Char
01. Principal	endo_local_acc_v7_1-5	Local Accession Or Pathology Number		Char
01. Principal	endo_local_acc_v9_1-5	Local Accession Or Pathology Number		Char
01. Principal	endo_num_fixed_samp_v1_1-9	# Fixed Samples Placed In The Same Formalin Container %		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_num_fixed_samp_v3_1-4	# Fixed Samples Placed In The Same Formalin Container %		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_num_fixed_samp_v7_1-5	# Fixed Samples Placed In The Same Formalin Container %		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_num_fixed_samp_v9_1-5	# Fixed Samples Placed In The Same Formalin Container %		Numeric .M="Missing" .R="Not Randomized"
01. Principal	endo_path_dx_v1_1-9	Diagnosis From Pathology		Char
01. Principal	endo_path_dx_v3_1-4	Diagnosis From Pathology		Char
01. Principal	endo_path_dx_v7_1-5	Diagnosis From Pathology		Char
01. Principal	endo_path_dx_v9_1-5	Diagnosis From Pathology		Char
01. Principal	endo_slide_kit_num_v1_1-9	Slide Kit Number		Char
01. Principal	endo_slide_kit_num_v3_1-4	Slide Kit Number		Char
01. Principal	endo_slide_kit_num_v7_1-5	Slide Kit Number		Char
01. Principal	endo_slide_kit_num_v9_1-5	Slide Kit Number		Char
01. Principal	endo_squamo_jun_v1_1-9	Squamocolumnar Junction		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"
01. Principal	endo_squamo_jun_v3_1-4	Squamocolumnar Junction		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	endo_squamo_ju n_v7_1-5	Squamocolumnar Junction		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"
01. Principal	endo_squamo_ju n_v9_1-5	Squamocolumnar Junction		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"
01. Principal	endo_top_gas_fo ld_v1_1-9	Top of Gastric Folds [Endoscopic EG junction]		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"
01. Principal	endo_top_gas_fo ld_v3_1-4	Top of Gastric Folds [Endoscopic EG junction]		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"
01. Principal	endo_top_gas_fo ld_v7_1-5	Top of Gastric Folds [Endoscopic EG junction]		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"
01. Principal	endo_top_gas_fo ld_v9_1-5	Top of Gastric Folds [Endoscopic EG junction]		Numeric .M="Missing" .R="Not Randomized" .U="Unknown" 9999="Unknown"
01. Principal	endo_visit_dt_v1 _1-9	Visit Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	endo_visit_dt_v3 _1-4	Visit Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	endo_visit_dt_v7 _1-5	Visit Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	endo_visit_dt_v9 _1-5	Visit Date		SAS Date .M="Missing" .R="Not Randomized"

Section 29: Intervention Admin

Class	Variable	Label	Description	Format Text
01. Principal	int_admin_agent_prov_dt	Date Agent Provided (To Participant)		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	int_admin_visit_dt	Visit Date		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 30: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	phys_abs_comment_v1/2/7	Abdomen Comments (Required If Abnormal)		Char
01. Principal	phys_abs_status_v1/2/7	Abdomen Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_appear_comment_v1/2/7	Appearance Comments (Required If Abnormal)		Char
01. Principal	phys_appear_status_v1/2/7	Appearance Status		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	phys_bp_not_obt_v1/2/7	Blood Pressure Not Obtained		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_breast_comment_v1/2/7	Breasts Comments (Required If Abnormal)		Char
01. Principal	phys_breast_status_v1/2/7	Breasts Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_chest_comment_v1/2/7	Chest Comments (Required If Abnormal)		Char
01. Principal	phys_chest_status_v1/2/7	Chest Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_diastolic_bp_v1/2/7	Diastolic BP (mmHg)		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	phys_ecog_status_v1/2/7	ECOG Performance Status		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	phys_genital_comment_v1/2/7	Genitalia Comments (Required If Abnormal)		Char

Class	Variable	Label	Description	Format Text
01. Principal	phys_genital_status_v1/2/7	Genitalia Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_heart_comment_v1/2/7	Heart Comments (Required If Abnormal)		Char
01. Principal	phys_heart_status_v1/2/7	Heart Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_heent_comment_v1/2/7	H/E/E/N/T Comments (Required If Abnormal)		Char
01. Principal	phys_heent_status_v1/2/7	H/E/E/N/T Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_height_not_obt_v1/2/7	Height Not Obtained		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_height_unit_v1/2/7	Height Unit		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="cm" 2="in"
01. Principal	phys_height_v1/2/7	Height:		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	phys_lungs_comment_v1/2/7	Lungs Comments (Required If Abnormal)		Char
01. Principal	phys_lungs_status_v1/2/7	Lungs Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_lymph_comment_v1/2/7	Lymph Nodes Comments (Required If Abnormal)		Char

Class	Variable	Label	Description	Format Text
01. Principal	phys_lymph_status_v1/2/7	Lymph Nodes Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_musculo_comment_v1/2/7	Musculoskeletal Comments (Required If Abnormal)		Char
01. Principal	phys_musculo_status_v1/2/7	Musculoskeletal Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_neuro_comment_v1/2/7	Neurological Comments (Required If Abnormal)		Char
01. Principal	phys_neuro_status_v1/2/7	Neurological Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_none_exam_v1/2/7	Check Here If No Body Systems Were Examined		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="True"
01. Principal	phys_oth_body_sys_comm_v1_1-3	Comments (Required if Abnormal)		Char
01. Principal	phys_oth_body_sys_comm_v2_1-3	Comments (Required if Abnormal)		Char
01. Principal	phys_oth_body_sys_comm_v7_1-3	Comments (Required if Abnormal)		Char
01. Principal	phys_oth_body_sys_status_v1_1-3	Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal"
01. Principal	phys_oth_body_sys_status_v2_1-3	Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal"
01. Principal	phys_oth_body_sys_status_v7_1-3	Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Normal"

Class	Variable	Label	Description	Format Text
01. Principal	phys_oth_body_sys_v1_1-3	Other Body System: Specify		Char
01. Principal	phys_oth_body_sys_v2_1-3	Other Body System: Specify		Char
01. Principal	phys_oth_body_sys_v7_1-3	Other Body System: Specify		Char
01. Principal	phys_pelvis_comment_v1/2/7	Pelvis Comments (Required If Abnormal)		Char
01. Principal	phys_pelvis_status_v1/2/7	Pelvis Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_prostate_comment_v1/2/7	Prostate Comments (Required If Abnormal)		Char
01. Principal	phys_prostate_status_v1/2/7	Prostate Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_pulse_not_obt_v1/2/7	Pulse Not Obtained		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_pulse_v1/2/7	Pulse Rate:		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	phys_rectal_comment_v1/2/7	Rectal Comments (Required If Abnormal)		Char
01. Principal	phys_rectal_status_v1/2/7	Rectal Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_resp_not_obt_v1/2/7	Respiration Not Obtained		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_resp_rate_v1/2/7	Respiration Rate:		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	phys_skin_comment_v1/2/7	Skin Comments (Required If Abnormal)		Char

Class	Variable	Label	Description	Format Text
01. Principal	phys_skin_status_v1/2/7	Skin Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_systolic_bp_v1/2/7	Systolic BP (mmHg)		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	phys_temp_not_obt_v1/2/7	Temperature Not Obtained		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_temp_unit_v1/2/7	Temperature Unit		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="C" 2="F"
01. Principal	phys_temperature_v1/2/7	Temperature:		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	phys_thyroid_comment_v1/2/7	Thyroid Comments (Required If Abnormal)		Char
01. Principal	phys_thyroid_status_v1/2/7	Thyroid Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_vascular_comment_v1/2/7	Vascular Comments (Required If Abnormal)		Char
01. Principal	phys_vascular_status_v1/2/7	Vascular Status		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Not Examined" 1="Normal" 2="Abnormal"
01. Principal	phys_visit_dt_v1/2/7	Visit Date		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	phys_weight_not_obt_v1/2/7	Weight Not Obtained		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	phys_weight_unit_v1/2/7	Weight Unit		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="kg" 2="lb"

Class	Variable	Label	Description	Format Text
01. Principal	phys_weight_v1/ 2/7	Weight:		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 31: Pregnancy Tests

Class	Variable	Label	Description	Format Text
01. Principal	preg_specimen_dt_v1/2/3/7	Date Specimen Collected		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	preg_test_no_rsn_v1/2/3/7	Reason pregnancy data was not collected:		.M="Missing" .R="Not Randomized" 1="Participant Is Male" 2="Participant Is Female And Not Of Childbearing Potential"
01. Principal	preg_test_result_v1/2/3/7	Result		.M="Missing" .R="Not Randomized" 2="Negative" 3="Not Obtained"
01. Principal	preg_test_type_v1/2/3/7	Pregnancy Test Type		.M="Missing" .R="Not Randomized" 1="Urine"
01. Principal	preg_visit_dt_v1/2/3/7	Visit Date		SAS Date .M="Missing" .R="Not Randomized"

Section 32: Interval Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	qx_addtl_otc_since_last_v4-8	Do You Have Additional Over-The-Counter Medications To Report?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	qx_addtl_pres_since_last_v4-8	Do You Have Additional Types Of Prescription Medications To Report?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	qx_admin_dt_v4-8	When Were You Admitted?		SAS Date .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	qx_admint_dt_v4-8	When Were You Admitted?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="(mm/dd/yyyy)"
01. Principal	qx_angioplasty_v4-8	Diagnosis: Angioplasty		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_aspirin_dose_v4-8	What Was The Dose Per Pill Or Other Form?		Char
01. Principal	qx_aspirin_form_v4-8	In What Form Did You Take This Aspirin Medication?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Pill Tablet"
01. Principal	qx_aspirin_num_v4-8	How Many Pills/Gums/Other Forms Per Day Did You Take On Average On The Days When You Were Taking It?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Specify #"
01. Principal	qx_aspirin_oth_rsn_spec_v4-8	What Was The Reason You Were Taking It? Other Reason (Specify):		Char
01. Principal	qx_aspirin_rsn_v4-8	What Was The Reason You Were Taking It? (Choose The Primary Reason)		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Cold/Flu" 2="Headache" 3="Other Reason"
01. Principal	qx_aspirin_since_last_v4-8	Since Your Last Study Questionnaire, Have You Taken Aspirin Or Any Medications Containing Aspirin?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	qx_aspirin_type_spec_v4-8	Aspirin Taken (Specify):		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Alka-Seltzer" 2="Alka-Seltzer Plus" 3="Baby Aspirin (81 mg)"
01. Principal	qx_aspirin_weekly_freq_v4-8	How Often On A Weekly Basis, Were You Taking It?		Char
01. Principal	qx_asthma_v4-8	Diagnosis: Asthma		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_atrial_fib_v4-8	Diagnosis: Atrial Fibrillation		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_back_surg_v4-8	Diagnosis: Back Surgery		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_blad_inf_v4-8	Diagnosis: Bladder Infection		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_blood_stool_v4-8	Blood on stool?		.F="No Record For This Visit" .R="Not Randomized" 0="None" 1="Some" 2="Severe" 9="Don't Know"
01. Principal	qx_cancer_v4-8	Diagnosis: Cancer		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_chest_pain_v4-8	Diagnosis: Chest Pain		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_completed_by_v4-8	Completed By:		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Site Designee (Questionnaire As Source)" 2="Site Designee (Responses Entered Directly To eCRF, No Paper Source)"
01. Principal	qx_days_no_study_pill_v4-8	For How Many Days In Total Did You Not Take Your Pills?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 2="Specify"

Class	Variable	Label	Description	Format Text
01. Principal	qx_detached_retina_v4-8	Diagnosis: Detached Retina		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_diverticulitis_v4-8	Diagnosis: Diverticulitis		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_doctor_v4-8	Since Your Last Study Questionnaire, Have You Seen A Doctor Or Other Medical Personnel For Any Reason Or Visited A Clinic For A Same-Day Procedure?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	qx_fam_crc_v4-8	Diagnosis: Familial Colorectal Cancer Syndrome		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_flu_v4-8	Diagnosis: Flu Or Influenza-Like Illness		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_fracture_v4-8	Diagnosis: Fracture		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_gall_blad_v4-8	Diagnosis: Gall Bladder		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_heart_attack_v4-8	Diagnosis: Heart Attack		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_heartburn_v4-8	Heartburn?		.F="No Record For This Visit" .R="Not Randomized" 0="None" 1="Some" 2="Severe" 9="Don't Know"
01. Principal	qx_hepatitis_v4-8	Diagnosis: Hepatitis B Or C		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	qx_hernia_rep_v4-8	Diagnosis: Hernia Repair		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_hip_rep_v4-8	Diagnosis: Hip Replacement		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_hiv_v4-8	Diagnosis: HIV		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_hosp_to_rep_v4-8	Do You Have Another Hospitalization On A Different Date To Report?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	qx_hospital_name_desc_v4-8	What Was The Name Of The Hospital? (Description)		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_hospital_name_v4-8	What Was The Name Of The Hospital?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 1="Methodist Hospital - TMC" 2="UT MD Anderson Cancer Center"
01. Principal	qx_hospital_ov_v4-8	Since Your Last Study Questionnaire, Have You Been Hospitalized Overnight?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	qx_hysterectomy_v4-8	Diagnosis: Hysterectomy		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_infl_bowel_dis_v4-8	Diagnosis: Inflammatory Bowel Disease		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_intest_malabsorb_v4-8	Diagnosis: Chronic Intestinal Malabsorption Syndrome		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_itching_v4-8	Itching?		.F="No Record For This Visit" .R="Not Randomized" 0="None" 1="Some" 2="Severe" 9="Don't Know"

Class	Variable	Label	Description	Format Text
01. Principal	qx_kidney_dis_v4-8	Diagnosis: Kidney Disease		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_kidney_stone_v4-8	Diagnosis: Kidney Stone		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_knee_rep_v4-8	Diagnosis: Knee Replacement		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_loss_appetite_v4-8	Loss of Appetite?		.F="No Record For This Visit" .R="Not Randomized" 0="None" 1="Some" 2="Severe" 9="Don't Know"
01. Principal	qx_lost_bottle_v4-8	Lost Bottle		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_nausea_v4-8	Nausea or vomiting?		.F="No Record For This Visit" .R="Not Randomized" 0="None" 1="Some" 2="Severe" 9="Don't Know"
01. Principal	qx_num_aspirin_wkly_v4-8	How Often On A Weekly Basis, Were You Taking It? (Specify #) Days Per Week:		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	qx_num_days_not_take_v4-8	Specify Number Of Days:		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	qx_num_oth_pill_day_v4-8	How Many Pills/Gums/Other Forms Per Day Did You Take On Average On The Days When You Were Taking It? Specify #:		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	qx_otc_since_last_v4-8	Since Your Last Study Questionnaire, Have You Taken Any Over-The-Counter Medications, Other Than The Vitamins And Minerals?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	qx_other_no_reason_v4-8	Other		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_perc_symptom_v4-8	Perceived Symptom Or Side Effect		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_pneumonia_v4-8	Diagnosis: Pneumonia		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_pregnancy_v4-8	Diagnosis: Pregnancy		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_prescript_since_last_v4-8	Since Your Last Study Questionnaire, Have You Taken Any New Prescription Medications?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	qx_prost_enlarge_v4-8	Diagnosis: Prostate Enlargement		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_rec_study_bottle_v4-8	Have You Received This Study Pill Bottle?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_refuse_answer_v4-8	Refuse To Answer		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_same_day_doc_v4-8	Do You Have Another Dr. Visit Or Same-Day Procedure For A Different Purpose, Reason Or Diagnosis, Or The Same Purpose, Reason Or Diagnosis On A Different Date To Report?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	qx_seizures_v4-8	Seizures?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="None" 1="Some" 2="Severe" 9="Don't Know"

Class	Variable	Label	Description	Format Text
01. Principal	qx_sleep_apnea_v4-8	Diagnosis: Sleep Apnea		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_stom_cramps_v4-8	Stomach Cramps?		.F="No Record For This Visit" .R="Not Randomized" 0="None" 1="Some" 2="Severe" 9="Don't Know"
01. Principal	qx_study_bottle_damage_v4-8	Was This Bottle Damaged Or Was There Any Other Problem?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_study_bottle_num_v4-8	Study Bottle #?		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 99="N/A"
01. Principal	qx_study_bottle_usable_v4-8	Study Pill Bottle Usable?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_study_pill_start_dt_v4-8	Start Date:		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	qx_study_pills_week_v4-8	Since Your Last Study Questionnaire, In A Normal Week Of Pill Taking, How Many Study Pills Per Week Did You Take?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="None - Off Study Pills" 1="3 - 4 Pills" 2="5 - 6 Pills" 3="7 Pills"
01. Principal	qx_study_week_no_pills_v4-8	Since Your Last Study Questionnaire, Was There Any Period Of A Week Or More When You Did Not Take Your Study Pills?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="No" 1="Yes"
01. Principal	qx_take_study_pill_dt_v4-8	On What Date Did You Start Taking Pills From This Bottle?		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="Not Started Yet" 1="(mm/dd/yyyy)" 2="Specify"
01. Principal	qx_troub_breath_v4-8	Trouble Breathing?		.F="No Record For This Visit" .R="Not Randomized" 0="None" 1="Some" 2="Severe" 9="Don't Know"

Class	Variable	Label	Description	Format Text
01. Principal	qx_unrelated_ill_spec_v4-8	If Other, Please Specify:		Char
01. Principal	qx_unrelated_ill_v4-8	Unrelated Illness		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_vacation_v4-8	Vacation		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	qx_visit_dt_v4-8	Visit Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	qx_vitamin_d_trt_v4-8	Diagnosis: A Medical Condition Requiring Treatment With Vitamin D		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"

Section 33: Interval Questionnaire 2

Class	Variable	Label	Description	Format Text
01. Principal	qx2_dr_visit_dt_v4_1-5	Dr. Visit Date		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx2_dr_visit_dt_v5_1-5	Dr. Visit Date		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx2_dr_visit_dt_v6_1-5	Dr. Visit Date		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx2_dr_visit_dt_v7_1-5	Dr. Visit Date		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx2_dr_visit_dt_v8_1-5	Dr. Visit Date		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx2_dx_v4_1-5	Reason Or Diagnosis		Char
01. Principal	qx2_dx_v5_1-5	Reason Or Diagnosis		Char
01. Principal	qx2_dx_v6_1-5	Reason Or Diagnosis		Char
01. Principal	qx2_dx_v7_1-5	Reason Or Diagnosis		Char
01. Principal	qx2_dx_v8_1-5	Reason Or Diagnosis		Char
01. Principal	qx2_hosp_2_visit_dt_v4_1-5	Hospital/Clinic Visit Date		Char
01. Principal	qx2_hosp_2_visit_dt_v5_1-5	Hospital/Clinic Visit Date		Char
01. Principal	qx2_hosp_2_visit_dt_v6_1-5	Hospital/Clinic Visit Date		Char
01. Principal	qx2_hosp_2_visit_dt_v7_1-5	Hospital/Clinic Visit Date		Char
01. Principal	qx2_hosp_2_visit_dt_v8_1-5	Hospital/Clinic Visit Date		Char
01. Principal	qx2_hospital_v4_1-5	Hospital/Clinic		Char
01. Principal	qx2_hospital_v5_1-5	Hospital/Clinic		Char

Class	Variable	Label	Description	Format Text
01. Principal	qx2_hospital_v6_1-5	Hospital/Clinic		Char
01. Principal	qx2_hospital_v7_1-5	Hospital/Clinic		Char
01. Principal	qx2_hospital_v8_1-5	Hospital/Clinic		Char
01. Principal	qx2_purpose_v4_1-5	What Was The Purpose Of This Visit?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Checkup" 2="Follow-Up To A Earlier Diagnosis" 3="New Diagnosis"
01. Principal	qx2_purpose_v5_1-5	What Was The Purpose Of This Visit?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Checkup" 2="Follow-Up To A Earlier Diagnosis" 3="New Diagnosis"
01. Principal	qx2_purpose_v6_1-5	What Was The Purpose Of This Visit?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Checkup" 2="Follow-Up To A Earlier Diagnosis" 3="New Diagnosis"
01. Principal	qx2_purpose_v7_1-5	What Was The Purpose Of This Visit?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Checkup" 2="Follow-Up To A Earlier Diagnosis" 3="New Diagnosis"
01. Principal	qx2_purpose_v8_1-5	What Was The Purpose Of This Visit?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Checkup" 2="Follow-Up To A Earlier Diagnosis" 3="New Diagnosis"
01. Principal	qx2_reas_dx_v4_1-5	What Was The Reason Or Diagnosis?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Reason Or Diagnosis"
01. Principal	qx2_reas_dx_v5_1-5	What Was The Reason Or Diagnosis?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Reason Or Diagnosis"
01. Principal	qx2_reas_dx_v6_1-5	What Was The Reason Or Diagnosis?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Reason Or Diagnosis"

Class	Variable	Label	Description	Format Text
01. Principal	qx2_reas_dx_v7_1-5	What Was The Reason Or Diagnosis?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Reason Or Diagnosis"
01. Principal	qx2_reas_dx_v8_1-5	What Was The Reason Or Diagnosis?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Reason Or Diagnosis"
01. Principal	qx2_visit_dt_v4_1-5	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx2_visit_dt_v5_1-5	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx2_visit_dt_v6_1-5	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx2_visit_dt_v7_1-5	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx2_visit_dt_v8_1-5	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Section 34: Interval Questionnaire 3

Class	Variable	Label	Description	Format Text
01. Principal	qx3_med_how_of ten_spec_v4_1-1 4	Number Of Days, Specify		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx3_med_how_of ten_spec_v5_1-1 4	Number Of Days, Specify		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx3_med_how_of ten_spec_v6_1-1 4	Number Of Days, Specify		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx3_med_how_of ten_spec_v7_1-1 4	Number Of Days, Specify		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx3_med_how_of ten_spec_v8_1-1 4	Number Of Days, Specify		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx3_med_how_of ten_v4_1-14	How Often, On Average, On A Weekly Basis, Were You Taking It?		Char
01. Principal	qx3_med_how_of ten_v5_1-14	How Often, On Average, On A Weekly Basis, Were You Taking It?		Char
01. Principal	qx3_med_how_of ten_v6_1-14	How Often, On Average, On A Weekly Basis, Were You Taking It?		Char
01. Principal	qx3_med_how_of ten_v7_1-14	How Often, On Average, On A Weekly Basis, Were You Taking It?		Char
01. Principal	qx3_med_how_of ten_v8_1-14	How Often, On Average, On A Weekly Basis, Were You Taking It?		Char
01. Principal	qx3_med_name_ v4_1-14	Specify Prescription Medication		Char
01. Principal	qx3_med_name_ v5_1-14	Specify Prescription Medication		Char

Class	Variable	Label	Description	Format Text
01. Principal	qx3_med_name_v6_1-14	Specify Prescription Medication		Char
01. Principal	qx3_med_name_v7_1-14	Specify Prescription Medication		Char
01. Principal	qx3_med_name_v8_1-14	Specify Prescription Medication		Char
01. Principal	qx3_med_oth_rsn_v4_1-14	What Was The Reason You Were Taking It? Other Reason		Char
01. Principal	qx3_med_oth_rsn_v5_1-14	What Was The Reason You Were Taking It? Other Reason		Char
01. Principal	qx3_med_oth_rsn_v6_1-14	What Was The Reason You Were Taking It? Other Reason		Char
01. Principal	qx3_med_oth_rsn_v7_1-14	What Was The Reason You Were Taking It? Other Reason		Char
01. Principal	qx3_med_oth_rsn_v8_1-14	What Was The Reason You Were Taking It? Other Reason		Char
01. Principal	qx3_med_rsn_v4_1-14	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	qx3_med_rsn_v5_1-14	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	qx3_med_rsn_v6_1-14	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	qx3_med_rsn_v7_1-14	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	qx3_med_rsn_v8_1-14	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	qx3_med_take_v4_1-14	What Prescription Medication Did You Take?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Specify"
01. Principal	qx3_med_take_v5_1-14	What Prescription Medication Did You Take?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Specify"

Class	Variable	Label	Description	Format Text
01. Principal	qx3_med_take_v6_1-14	What Prescription Medication Did You Take?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Specify"
01. Principal	qx3_med_take_v7_1-14	What Prescription Medication Did You Take?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Specify"
01. Principal	qx3_med_take_v8_1-14	What Prescription Medication Did You Take?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Specify"
01. Principal	qx3_visit_dt_v4_1-14	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx3_visit_dt_v5_1-14	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx3_visit_dt_v6_1-14	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx3_visit_dt_v7_1-14	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx3_visit_dt_v8_1-14	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Section 35: Interval Questionnaire 4

Class	Variable	Label	Description	Format Text
01. Principal	qx4_days_week_spec_v4_1-2	Days Per Week Specify		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx4_days_week_spec_v5_1-2	Days Per Week Specify		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	qx4_days_week_spec_v6_1-2	Days Per Week Specify		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	qx4_days_week_spec_v7_1-2	Days Per Week Specify		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	qx4_days_week_spec_v8_1-2	Days Per Week Specify		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" .U="Unknown"
01. Principal	qx4_pres_med_name_v4_1-2	Specify Prescription Medication		Char
01. Principal	qx4_pres_med_name_v5_1-2	Specify Prescription Medication		Char
01. Principal	qx4_pres_med_name_v6_1-2	Specify Prescription Medication		Char
01. Principal	qx4_pres_med_name_v7_1-2	Specify Prescription Medication		Char
01. Principal	qx4_pres_med_name_v8_1-2	Specify Prescription Medication		Char
01. Principal	qx4_reason_spec_v4_1-2	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	qx4_reason_spec_v5_1-2	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char

Class	Variable	Label	Description	Format Text
01. Principal	qx4_reason_spec_v6_1-2	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	qx4_reason_spec_v7_1-2	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	qx4_reason_spec_v8_1-2	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	qx4_reason_v4_1-2	What Was The Reason You Were Taking It? Other Reason		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Allergies" 2="Nausea" 3="Sinus" 4="Supplement" 5="Vertigo"
01. Principal	qx4_reason_v5_1-2	What Was The Reason You Were Taking It? Other Reason		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Allergies" 2="Nausea" 3="Sinus" 4="Supplement" 5="Vertigo"
01. Principal	qx4_reason_v6_1-2	What Was The Reason You Were Taking It? Other Reason		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Allergies" 2="Nausea" 3="Sinus" 4="Supplement" 5="Vertigo"
01. Principal	qx4_reason_v7_1-2	What Was The Reason You Were Taking It? Other Reason		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Allergies" 2="Nausea" 3="Sinus" 4="Supplement" 5="Vertigo"
01. Principal	qx4_reason_v8_1-2	What Was The Reason You Were Taking It? Other Reason		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Allergies" 2="Nausea" 3="Sinus" 4="Supplement" 5="Vertigo"

Class	Variable	Label	Description	Format Text
01. Principal	qx4_visit_dt_v4_1-2	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx4_visit_dt_v5_1-2	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx4_visit_dt_v6_1-2	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx4_visit_dt_v7_1-2	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	qx4_visit_dt_v8_1-2	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Section 36: Your Health And Wellbeing

Class	Variable	Label	Description	Format Text
01. Principal	hwb_accomp_les1-7	Accomplished Less Than You Would Like		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	hwb_accomp_les_than_like1-7	Accomplished Less Than You Would Like		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	hwb_alot_energy1-7	Did You Have A Lot Of Energy?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="None Of The Time" 1="A Little Of The Time" 2="Some Of The Time" 3="Good Bit Of The Time" 4="Most Of The Time" 5="All Of The Time"
01. Principal	hwb_as_healthy1-7	I Am As Healthy As Anybody I Know		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Definitely False" 1="Mostly False" 2="Don't Know" 3="Mostly True" 4="Definitely True"
01. Principal	hwb_bending1-7	Bending, Kneeling, Or Stooping		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No, Not Limited At All" 1="Yes, Limited A Little" 2="Yes, Limited A Lot"
01. Principal	hwb_calm1-7	Have You Felt Calm And Peaceful?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="None Of The Time" 1="A Little Of The Time" 2="Some Of The Time" 3="Good Bit Of The Time" 4="Most Of The Time" 5="All Of The Time"
01. Principal	hwb_climb1-7	Climbing One Flight Of Stairs		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No, Not Limited At All" 1="Yes, Limited A Little" 2="Yes, Limited A Lot"

Class	Variable	Label	Description	Format Text
01. Principal	hwb_climb_sev1-7	Climbing Several Flights Of Stairs		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No, Not Limited At All" 1="Yes, Limited A Little" 2="Yes, Limited A Lot"
01. Principal	hwb_cut_time_oth_act1-7	Cut Down On The Amount Of Time You Spent On Work Or Other Activities		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	hwb_cut_work_time1-7	Cut Down On The Amount Of Time You Spent On Work Or Other Activities		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	hwb_diff_work1-7	Had Difficulty Performing The Work Or Other Activities (For Example, It Took Extra Effort)		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	hwb_downhearted1-7	Have You Felt Downhearted And Blue?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="None Of The Time" 1="A Little Of The Time" 2="Some Of The Time" 3="Good Bit Of The Time" 4="Most Of The Time" 5="All Of The Time"
01. Principal	hwb_dress_self1-7	Bathing Or Dressing Yourself		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No, Not Limited At All" 1="Yes, Limited A Little" 2="Yes, Limited A Lot"
01. Principal	hwb_full_of_pep1-7	Did You Feel Full Of Pep?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="None Of The Time" 1="A Little Of The Time" 2="Some Of The Time" 3="Good Bit Of The Time" 4="Most Of The Time" 5="All Of The Time"
01. Principal	hwb_gen_health1-7	In General, Would You Say Your Health Is:		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Fair" 1="Good" 2="Very Good" 3="Excellent"

Class	Variable	Label	Description	Format Text
01. Principal	hwb_gen_health_1yr1-7	Compared To One Year Ago, How Would You Rate Your Health In General Now?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Somewhat Worse Now Than One Year Ago" 1="About The Same As One Year Ago" 2="Somewhat Better Now Than One Year Ago" 3="Much Better Now Than One Year Ago"
01. Principal	hwb_happy_prsn1-7	Have You Been A Happy Person?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="None Of The Time" 1="A Little Of The Time" 2="Some Of The Time" 3="Good Bit Of The Time" 4="Most Of The Time" 5="All Of The Time"
01. Principal	hwb_health_excellent1-7	My Health Is Excellent		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Definitely False" 1="Mostly False" 2="Don't Know" 3="Mostly True" 4="Definitely True"
01. Principal	hwb_health_get_worse1-7	I Expect My Health To Get Worse		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="Definitely False" 1="Mostly False" 2="Don't Know" 3="Mostly True" 4="Definitely True"
01. Principal	hwb_int_social1-7	During The Past 4 Weeks, How Much Of The Times Has Your Physical Health Or Emotional Problems Interfered With Your Social Activities?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="None Of The Time" 1="A Little Of The Time" 2="Some Of The Time" 3="Good Bit Of The Time" 4="Most Of The Time" 5="All Of The Time"
01. Principal	hwb_intef_normal1-7	During The Past 4 Weeks, To What Extent Has Your Physical Health Or Emotional Problems Interfered With Your Normal Social Activities With Family, Friends, Neighbors, Or Groups?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely"

Class	Variable	Label	Description	Format Text
01. Principal	hwb_lift1-7	Lifting Or Carrying Groceries		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No, Not Limited At All" 1="Yes, Limited A Little" 2="Yes, Limited A Lot"
01. Principal	hwb_mod_act1-7	Moderate Activities Such As Moving A Table, Pushing A Vacuum Cleaner, Bowling, Or Playing Golf		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No, Not Limited At All" 1="Yes, Limited A Little" 2="Yes, Limited A Lot"
01. Principal	hwb_nervous1-7	Have You Been A Very Nervous Person?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="None Of The Time" 1="A Little Of The Time" 2="Some Of The Time" 3="Good Bit Of The Time" 4="Most Of The Time" 5="All Of The Time"
01. Principal	hwb_no_cheer1-7	Have You Felt So Down In The Dumps That Nothing Could Cheer You Up?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="None Of The Time" 1="A Little Of The Time" 2="Some Of The Time" 3="Good Bit Of The Time" 4="Most Of The Time" 5="All Of The Time"
01. Principal	hwb_pain1-7	How Much Bodily Pain Have You Had During The Past 4 Weeks?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="None" 1="Very Mild" 2="Milde" 3="Moderate" 4="Severe" 5="Very Severe"
01. Principal	hwb_pain_int_work1-7	During The Past 4 Weeks, How Much Did Pain Interfere With Your Normal Work (Including Both Work Outside The Home And Housework)?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Not At All" 1="Slightly" 2="Moderately" 3="Quite A Bit" 4="Extremely"
01. Principal	hwb_sick_easier1-7	I Seem To Get Sick A Little Easier Than Other People		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="Definitely False" 1="Mostly False" 2="Don't Know" 3="Mostly True" 4="Definitely True"

Class	Variable	Label	Description	Format Text
01. Principal	hwb_tired1-7	Did You Feel Tired?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="None Of The Time" 1="A Little Of The Time" 2="Some Of The Time" 3="Good Bit Of The Time" 4="Most Of The Time" 5="All Of The Time"
01. Principal	hwb_vig_act1-7	Vigorous Activities Such As Running, Lifting Heavy Objects, Participating In Strenuous Sports		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No, Not Limited At All" 1="Yes, Limited A Little" 2="Yes, Limited A Lot"
01. Principal	hwb_visit_dt1-7	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	hwb_walk_1_block1-7	Walking One Blocks		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No, Not Limited At All" 1="Yes, Limited A Little" 2="Yes, Limited A Lot"
01. Principal	hwb_walk_mile1-7	Walking More Than A Mile		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No, Not Limited At All" 1="Yes, Limited A Little" 2="Yes, Limited A Lot"
01. Principal	hwb_walk_sev_block1-7	Walking Several Blocks		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No, Not Limited At All" 1="Yes, Limited A Little" 2="Yes, Limited A Lot"
01. Principal	hwb_work_less_care1-7	Did Work Or Other Activities Less Carefully Than Usual		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	hwb_work_limited1-7	Were Limited In The Kind Of Work Or Other Activities		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	hwb_worn_out1-7	Did You Feel Worn Out?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="None Of The Time" 1="A Little Of The Time" 2="Some Of The Time" 3="Good Bit Of The Time" 4="Most Of The Time" 5="All Of The Time"

Section 37: Tissue History

Class	Variable	Label	Description	Format Text
01. Principal	tissue_biop_rese c_v1_1-10	Were Biopsies/Resections Taken During Today's Procedure For Clinical Purposes?		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	tissue_biop_rese c_v3_1-10	Were Biopsies/Resections Taken During Today's Procedure For Clinical Purposes?		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	tissue_biop_rese c_v7_1-10	Were Biopsies/Resections Taken During Today's Procedure For Clinical Purposes?		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	tissue_biop_rese c_v9_1-10	Were Biopsies/Resections Taken During Today's Procedure For Clinical Purposes?		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	tissue_loc1_cm_ v1_1-10	Location (cm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_loc1_cm_ v3_1-10	Location (cm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_loc1_cm_ v7_1-10	Location (cm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_loc1_cm_ v9_1-10	Location (cm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_loc2_cm_ v1_1-10	Location (cm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_loc2_cm_ v3_1-10	Location (cm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_loc2_cm_ v7_1-10	Location (cm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_loc2_cm_ v9_1-10	Location (cm)		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_loc_oth_v 1_1-10	Other		Char
01. Principal	tissue_loc_oth_v 3_1-10	Other		Char

Class	Variable	Label	Description	Format Text
01. Principal	tissue_loc_oth_v7_1-10	Other		Char
01. Principal	tissue_loc_oth_v9_1-10	Other		Char
01. Principal	tissue_loc_v1_1-10	Location (General)		.M="Missing" .R="Not Randomized" 0="Esophagus" 1="GEJ" 2="Gastric Cardia" 3="Other"
01. Principal	tissue_loc_v3_1-10	Location (General)		.M="Missing" .R="Not Randomized" 0="Esophagus" 1="GEJ" 2="Gastric Cardia" 3="Other"
01. Principal	tissue_loc_v7_1-10	Location (General)		.M="Missing" .R="Not Randomized" 0="Esophagus" 1="GEJ" 2="Gastric Cardia" 3="Other"
01. Principal	tissue_loc_v9_1-10	Location (General)		.M="Missing" .R="Not Randomized" 0="Esophagus" 1="GEJ" 2="Gastric Cardia" 3="Other"
01. Principal	tissue_oth_find_v1_1-10	If Other, Please Specify:		Char
01. Principal	tissue_oth_find_v3_1-10	If Other, Please Specify:		Char
01. Principal	tissue_oth_find_v7_1-10	If Other, Please Specify:		Char
01. Principal	tissue_oth_find_v9_1-10	If Other, Please Specify:		Char
01. Principal	tissue_path_finding_v1_1-10	Pathology Finding		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_path_finding_v3_1-10	Pathology Finding		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_path_finding_v7_1-10	Pathology Finding		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_path_finding_v9_1-10	Pathology Finding		Numeric .M="Missing" .R="Not Randomized"
01. Principal	tissue_sample_num_v1_1-10	Sample #		Char
01. Principal	tissue_sample_num_v3_1-10	Sample #		Char

Class	Variable	Label	Description	Format Text
01. Principal	tissue_sample_num_v7_1-10	Sample #		Char
01. Principal	tissue_sample_num_v9_1-10	Sample #		Char
01. Principal	tissue_type_v1_1-10	SampleType		.M="Missing" .R="Not Randomized" 1="Biopsy"
01. Principal	tissue_type_v3_1-10	SampleType		.M="Missing" .R="Not Randomized" 1="Biopsy"
01. Principal	tissue_type_v7_1-10	SampleType		.M="Missing" .R="Not Randomized" 1="Biopsy"
01. Principal	tissue_type_v9_1-10	SampleType		.M="Missing" .R="Not Randomized" 1="Biopsy"
01. Principal	tissue_visit_dt_v1_1-10	Visit Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	tissue_visit_dt_v3_1-10	Visit Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	tissue_visit_dt_v7_1-10	Visit Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	tissue_visit_dt_v9_1-10	Visit Date		SAS Date .M="Missing" .R="Not Randomized"

Section 38: Symptom Assessment

Class	Variable	Label	Description	Format Text
01. Principal	symptom_ab_pain_desc_v0-9	Abdominal Pain: Description		Char
01. Principal	symptom_ab_pain_had_v0-9	Abdominal Pain: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_ab_pain_scale_v0-9	Abdominal Pain: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_ab_pain_severity_v0-9	Abdominal Pain: Severity		Char
01. Principal	symptom_ab_pain_start_dt_v0-9	Abdominal Pain: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_ab_pain_stop_dt_v0-9	Abdominal Pain: Stop Date		SAS Date .F="No Record For This Visit" .O="Ongoing" .R="Not Randomized"
01. Principal	symptom_abnormal_bleed_desc_v0-9	Abnormal Bleeding: Description		Char
01. Principal	symptom_abnormal_bleed_had_v0-9	Abnormal Bleeding: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_abnormal_bleed_scale_v0-9	Abnormal Bleeding: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_abnormal_bleed_severity_v0-9	Abnormal Bleeding: Severity		Char
01. Principal	symptom_abnormal_bleed_start_dt_v0-9	Abnormal Bleeding: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_abnormal_bleed_stop_dt_v0-9	Abnormal Bleeding: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_breathing_desc_v0-9	Breathing Difficulties: Description		Char
01. Principal	symptom_breathing_had_v0-9	Breathing Difficulties: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	symptom_breathing_scale_v0-9	Breathing Difficulties: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_breathing_severity_v0-9	Breathing Difficulties: Severity		Char
01. Principal	symptom_breathing_start_dt_v0-9	Breathing Difficulties: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_breathing_stop_dt_v0-9	Breathing Difficulties: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_chest_pain_desc_v0-9	Chest Pain: Description		Char
01. Principal	symptom_chest_pain_had_v0-9	Chest Pain: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_chest_pain_scale_v0-9	Chest Pain: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_chest_pain_severity_v0-9	Chest Pain: Severity		Char
01. Principal	symptom_chest_pain_start_dt_v0-9	Chest Pain: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_chest_pain_stop_dt_v0-9	Chest Pain: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_const_desc_v0-9	Constipation: Description		Char
01. Principal	symptom_const_had_v0-9	Constipation: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_const_scale_v0-9	Constipation: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_const_severity_v0-9	Constipation: Severity		Char
01. Principal	symptom_const_start_dt_v0-9	Constipation: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_const_stop_dt_v0-9	Constipation: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_cough_desc_v0-9	Coughing: Description		Char

Class	Variable	Label	Description	Format Text
01. Principal	symptom_cough_had_v0-9	Coughing: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_cough_scale_v0-9	Coughing: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_cough_severity_v0-9	Coughing: Severity		Char
01. Principal	symptom_cough_start_dt_v0-9	Coughing: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_cough_stop_dt_v0-9	Coughing: Stop Date		SAS Date .F="No Record For This Visit" .O="Ongoing" .R="Not Randomized"
01. Principal	symptom_diarrhea_desc_v0-9	Diarrhea: Description		Char
01. Principal	symptom_diarrhea_had_v0-9	Diarrhea: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_diarrhea_scale_v0-9	Diarrhea: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_diarrhea_severity_v0-9	Diarrhea: Severity		Char
01. Principal	symptom_diarrhea_start_dt_v0-9	Diarrhea: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_diarrhea_stop_dt_v0-9	Diarrhea: Stop Date		SAS Date .F="No Record For This Visit" .O="Ongoing" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_dizzy_desc_v0-9	Dizziness: Description		Char
01. Principal	symptom_dizzy_had_v0-9	Dizziness: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_dizzy_scale_v0-9	Dizziness: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_dizzy_severity_v0-9	Dizziness: Severity		Char

Class	Variable	Label	Description	Format Text
01. Principal	symptom_dizzy_start_dt_v0-9	Dizziness: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_dizzy_stop_dt_v0-9	Dizziness: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_edema_desc_v0-9	Edema (Feet Or Legs): Description		Char
01. Principal	symptom_edema_had_v0-9	Edema (Feet Or Legs): Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_edema_scale_v0-9	Edema (Feet Or Legs): Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_edema_severity_v0-9	Edema (Feet Or Legs): Severity		Char
01. Principal	symptom_edema_start_dt_v0-9	Edema (Feet Or Legs): Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_edema_stop_dt_v0-9	Edema (Feet Or Legs): Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_en_lvl_chng_desc_v0-9	Change In Energy Level: Description		Char
01. Principal	symptom_en_lvl_chng_had_v0-9	Change In Energy Level: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_en_lvl_chng_scale_v0-9	Change In Energy Level: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_en_lvl_chng_severity_v0-9	Change In Energy Level: Severity		Char
01. Principal	symptom_en_lvl_chng_start_dt_v0-9	Change In Energy Level: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_en_lvl_chng_stop_dt_v0-9	Change In Energy Level: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_fatigue_desc_v0-9	Fatigue: Description		Char
01. Principal	symptom_fatigue_had_v0-9	Fatigue: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	symptom_fatigue_scale_v0-9	Fatigue: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_fatigue_severity_v0-9	Fatigue: Severity		Char
01. Principal	symptom_fatigue_start_dt_v0-9	Fatigue: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_fatigue_stop_dt_v0-9	Fatigue: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_forgetful_desc_v0-9	Forgetfulness: Description		Char
01. Principal	symptom_forgetful_had_v0-9	Forgetfulness: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_forgetful_scale_v0-9	Forgetfulness: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_forgetful_severity_v0-9	Forgetfulness: Severity		Char
01. Principal	symptom_forgetful_start_dt_v0-9	Forgetfulness: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_forgetful_stop_dt_v0-9	Forgetfulness: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_gastro_upset_desc_v0-9	Other Gastrointestinal Upset: Description		Char
01. Principal	symptom_gastro_upset_had_v0-9	Other Gastrointestinal Upset: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_gastro_upset_scale_v0-9	Other Gastrointestinal Upset: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_gastro_upset_severity_v0-9	Other Gastrointestinal Upset: Severity		Char
01. Principal	symptom_gastro_upset_start_dt_v0-9	Other Gastrointestinal Upset: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_gastro_upset_stop_dt_v0-9	Other Gastrointestinal Upset: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_headache_desc_v0-9	Headache: Description		Char

Class	Variable	Label	Description	Format Text
01. Principal	symptom_headache_had_v0-9	Headache: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_headache_scale_v0-9	Headache: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_headache_severity_v0-9	Headache: Severity		Char
01. Principal	symptom_headache_start_dt_v0-9	Headache: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_headache_stop_dt_v0-9	Headache: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_hearing_desc_v0-9	Hearing Problems: Description		Char
01. Principal	symptom_hearing_had_v0-9	Hearing Problems: Had Symptom		.F="No Record For This Visit" .M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_hearing_scale_v0-9	Hearing Problems: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_hearing_severity_v0-9	Hearing Problems: Severity		Char
01. Principal	symptom_hearing_start_dt_v0-9	Hearing Problems: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_hearing_stop_dt_v0-9	Hearing Problems: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_heartburn_desc_v0-9	Heartburn: Description		Char
01. Principal	symptom_heartburn_had_v0-9	Heartburn: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_heartburn_scale_v0-9	Heartburn: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_heartburn_severity_v0-9	Heartburn: Severity		Char

Class	Variable	Label	Description	Format Text
01. Principal	symptom_heartburn_start_dt_v0-9	Heartburn: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_heartburn_stop_dt_v0-9	Heartburn: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_impair_balance_desc_v0-9	Impaired Balance: Description		Char
01. Principal	symptom_impair_balance_had_v0-9	Impaired Balance: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_impair_balance_scale_v0-9	Impaired Balance: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_impair_balance_severity_v0-9	Impaired Balance: Severity		Char
01. Principal	symptom_impair_balance_start_dt_v0-9	Impaired Balance: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_impair_balance_stop_dt_v0-9	Impaired Balance: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_joint_pain_desc_v0-9	Joint Pain: Description		Char
01. Principal	symptom_joint_pain_had_v0-9	Joint Pain: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_joint_pain_scale_v0-9	Joint Pain: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_joint_pain_severity_v0-9	Joint Pain: Severity		Char
01. Principal	symptom_joint_pain_start_dt_v0-9	Joint Pain: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_joint_pain_stop_dt_v0-9	Joint Pain: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_joint_swelling_desc_v0-9	Joint Swelling: Description		Char
01. Principal	symptom_joint_swelling_had_v0-9	Joint Swelling: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	symptom_joint_swell_scale_v0-9	Joint Swelling: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_joint_swell_severity_v0-9	Joint Swelling: Severity		Char
01. Principal	symptom_joint_swell_start_dt_v0-9	Joint Swelling: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_joint_swell_stop_dt_v0-9	Joint Swelling: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_mouth_desc_v0-9	Mouth Sores: Description		Char
01. Principal	symptom_mouth_had_v0-9	Mouth Sores: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_mouth_scale_v0-9	Mouth Sores: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_mouth_severity_v0-9	Mouth Sores: Severity		Char
01. Principal	symptom_mouth_start_dt_v0-9	Mouth Sores: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_mouth_stop_dt_v0-9	Mouth Sores: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_muscle_pain_desc_v0-9	Muscle Pain: Description		Char
01. Principal	symptom_muscle_pain_had_v0-9	Muscle Pain: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_muscle_pain_scale_v0-9	Muscle Pain: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_muscle_pain_severity_v0-9	Muscle Pain: Severity		Char
01. Principal	symptom_muscle_pain_start_dt_v0-9	Muscle Pain: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_muscle_pain_stop_dt_v0-9	Muscle Pain: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	symptom_muscle_weak_desc_v0-9	Muscle Weakness: Description		Char
01. Principal	symptom_muscle_weak_had_v0-9	Muscle Weakness: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_muscle_weak_scale_v0-9	Muscle Weakness: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_muscle_weak_severity_v0-9	Muscle Weakness: Severity		Char
01. Principal	symptom_muscle_weak_start_dt_v0-9	Muscle Weakness: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_muscle_weak_stop_dt_v0-9	Muscle Weakness: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_nausea_desc_v0-9	Nausea: Description		Char
01. Principal	symptom_nausea_had_v0-9	Nausea: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_nausea_scale_v0-9	Nausea: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_nausea_severity_v0-9	Nausea: Severity		Char
01. Principal	symptom_nausea_start_dt_v0-9	Nausea: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_nausea_stop_dt_v0-9	Nausea: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_numbness_desc_v0-9	Numbness/Tingling: Description		Char
01. Principal	symptom_numbness_had_v0-9	Numbness/Tingling: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_numbness_scale_v0-9	Numbness/Tingling: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_numbness_severity_v0-9	Numbness/Tingling: Severity		Char

Class	Variable	Label	Description	Format Text
01. Principal	symptom_numbness_start_dt_v0-9	Numbness/Tingling: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_numbness_stop_dt_v0-9	Numbness/Tingling: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_palpitations_desc_v0-9	Palpitations: Description		Char
01. Principal	symptom_palpitations_had_v0-9	Palpitations: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_palpitations_scale_v0-9	Palpitations: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_palpitations_severity_v0-9	Palpitations: Severity		Char
01. Principal	symptom_palpitations_start_dt_v0-9	Palpitations: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_palpitations_stop_dt_v0-9	Palpitations: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_pruritis_desc_v0-9	Pruritis: Description		Char
01. Principal	symptom_pruritis_had_v0-9	Pruritis: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_pruritis_scale_v0-9	Pruritis: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_pruritis_severity_v0-9	Pruritis: Severity		Char
01. Principal	symptom_pruritis_start_dt_v0-9	Pruritis: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_pruritis_stop_dt_v0-9	Pruritis: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_rash_desc_v0-9	Rash: Description		Char
01. Principal	symptom_rash_had_v0-9	Rash: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	symptom_rash_scale_v0-9	Rash: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_rash_severity_v0-9	Rash: Severity		Char
01. Principal	symptom_rash_start_dt_v0-9	Rash: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_rash_stop_dt_v0-9	Rash: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_seizure_desc_v0-9	Seizures: Description		Char
01. Principal	symptom_seizure_had_v0-9	Seizures: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_seizure_scale_v0-9	Seizures: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_seizure_severity_v0-9	Seizures: Severity		Char
01. Principal	symptom_seizure_start_dt_v0-9	Seizures: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_seizure_stop_dt_v0-9	Seizures: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_sleep_chng_desc_v0-9	Change In Sleep Habits: Description		Char
01. Principal	symptom_sleep_chng_had_v0-9	Change In Sleep Habits: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_sleep_chng_scale_v0-9	Change In Sleep Habits: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_sleep_chng_severity_v0-9	Change In Sleep Habits: Severity		Char
01. Principal	symptom_sleep_chng_start_dt_v0-9	Change In Sleep Habits: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_sleep_chng_stop_dt_v0-9	Change In Sleep Habits: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_sob_desc_v0-9	SOB: Description		Char

Class	Variable	Label	Description	Format Text
01. Principal	symptom_sob_had_v0-9	SOB: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_sob_scale_v0-9	SOB: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_sob_severity_v0-9	SOB: Severity		Char
01. Principal	symptom_sob_start_dt_v0-9	SOB: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_sob_stop_dt_v0-9	SOB: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_swallow_desc_v0-9	Swallowing Difficulties: Description		Char
01. Principal	symptom_swallow_had_v0-9	Swallowing Difficulties: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_swallow_scale_v0-9	Swallowing Difficulties: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_swallow_severity_v0-9	Swallowing Difficulties: Severity		Char
01. Principal	symptom_swallow_start_dt_v0-9	Swallowing Difficulties: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_swallow_stop_dt_v0-9	Swallowing Difficulties: Stop Date		SAS Date .F="No Record For This Visit" .O="Ongoing" .R="Not Randomized"
01. Principal	symptom_urinating_desc_v0-9	Problem W/ Urinating: Description		Char
01. Principal	symptom_urinating_had_v0-9	Problem W/ Urinating: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_urinating_scale_v0-9	Problem W/ Urinating: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_urinating_severity_v0-9	Problem W/ Urinating: Severity		Char
01. Principal	symptom_urinating_start_dt_v0-9	Problem W/ Urinating: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	symptom_urinating_stop_dt_v0-9	Problem W/ Urinating: Stop Date		SAS Date .F="No Record For This Visit" .O="Ongoing" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_vision_desc_v0-9	Vision Problems: Description		Char
01. Principal	symptom_vision_had_v0-9	Vision Problems: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_vision_scale_v0-9	Vision Problems: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_vision_severity_v0-9	Vision Problems: Severity		Char
01. Principal	symptom_vision_start_dt_v0-9	Vision Problems: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_vision_stop_dt_v0-9	Vision Problems: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_visit_dt_v0-9	Visit Date		SAS Date .M="Missing" .R="Not Randomized"
01. Principal	symptom_weight_ch_desc_v0-9	Change In Weight: Description		Char
01. Principal	symptom_weight_ch_had_v0-9	Change In Weight: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"
01. Principal	symptom_weight_ch_scale_v0-9	Change In Weight: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_weight_ch_severity_v0-9	Change In Weight: Severity		Char
01. Principal	symptom_weight_ch_start_dt_v0-9	Change In Weight: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized" .U="Unknown"
01. Principal	symptom_weight_ch_stop_dt_v0-9	Change In Weight: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_wheezing_desc_v0-9	Wheezing: Description		Char
01. Principal	symptom_wheezing_had_v0-9	Wheezing: Had Symptom		.F="No Record For This Visit" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	symptom_wheezing_scale_v0-9	Wheezing: Symptom Scale		Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
01. Principal	symptom_wheezing_severity_v0-9	Wheezing: Severity		Char
01. Principal	symptom_wheezing_start_dt_v0-9	Wheezing: Start Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"
01. Principal	symptom_wheezing_stop_dt_v0-9	Wheezing: Stop Date		SAS Date .F="No Record For This Visit" .R="Not Randomized"

Section 39: AE and Concomitant Medication Eval

Class	Variable	Label	Description	Format Text
01. Principal	ae_conmed_ae_change_v1-7	Were Any New Or Changes In Adverse Events Reported?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="N/a"
01. Principal	ae_conmed_cmed_change_v1-7	Were Any New Or Changes In Concomitant Medications Reported?		.M="Missing" .R="Not Randomized" 0="No" 1="Yes" 2="N/a"
01. Principal	ae_conmed_no_visit_v1-7	N/A (Visit Did Not Occur)		.M="Missing" .R="Not Randomized" 0="False" 1="True"
01. Principal	ae_conmed_visit_dt_v1-7	Visit Date		SAS Date .M="Missing" .R="Not Randomized"

Section 40: Compliance

Class	Variable	Label	Description	Format Text
01. Principal	comp_agent_prev_na1-6	Agent Provided At Previous Visit N/A		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	comp_agent_provided1-6	Was Agent Provided At This Visit?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="N/A" 9="Unknown"
01. Principal	comp_amt_miss1-6	Amount Of Agent Missing/Not Accounted For This Period		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	comp_amt_prov1-6	Amount Of Agent Provided At This Visit		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	comp_amt_prov_last1-6	Amount Of Agent Provided At Last Visit		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	comp_amt_returned1-6	Amount Of Agent Returned At This Visit		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	comp_amt_taken1-6	Amount Of Agent Taken During This Period		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	comp_compliant1-6	Is The Participant Compliant With Protocol Intervention?		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="N/A" 9="Unknown"
01. Principal	comp_first_dose_dt1-6	Date Of First Dose Taken This Period		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	comp_interrupted1-6	Was Agent Interrupted During This Period?		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No" 1="Yes" 2="N/A" 9="Unknown"
01. Principal	comp_last_dose_dt1-6	Date Of Last Dose Taken This Period		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	comp_no_reasons1-6	If No, Specify Reason For Noncompliance		Char
01. Principal	comp_num	Number Of Compliance Observations		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	comp_num_interrupt1-6	If Yes, Indicate Number Of Interruptions This Period		Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	comp_visit_dt1-6	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Section 41: Compliance Drug Labels

Class	Variable	Label	Description	Format Text
01. Principal	compdrug_labels _affix1-5	Were Drug Labels Affixed?		.N="N/A" .R="Not Randomized" 1="Yes"
01. Principal	compdrug_num	Number Of Compliance Observations		Numeric .R="Not Randomized"
01. Principal	compdrug_verif_ dt1-5	Compliance Drug Labels Verification Date		SAS Date .N="N/A" .R="Not Randomized"
01. Principal	compdrug_visit_ dt1-5	Compliance Drug Labels Visit Date		SAS Date .N="N/A" .R="Not Randomized"

Section 42: Off-Study

Class	Variable	Label	Description	Format Text
01. Principal	comment_num	Number Of Comments		Numeric .F="No Record For This Visit" .R="Not Randomized"
01. Principal	off_agent_end_dt	Agent End Date		SAS Date .M="Missing" .U="Unknown"
01. Principal	off_follow_off_dt	Date Off Follow-Up:		SAS Date 2="NULL"
01. Principal	off_follow_on_dt	Date On Follow-Up:		SAS Date 2="NULL"
01. Principal	off_form_dt	Form Date		SAS Date .M="Missing"
01. Principal	off_last_cont_dt	Date Of Last Contact		SAS Date .M="Missing"
01. Principal	off_na	Not Applicable		0="False" 1="True"
01. Principal	off_no_ae	Participant Did Not Experience Any Adverse Events.		.M="Missing" 0="False" 1="True" 2="NULL"
01. Principal	off_no_agent_int	Participant Did Not Have Any Agent Interruptions. run		.M="Missing" 0="False" 1="True" 2="NULL"
01. Principal	off_no_conmed	Participant Did Not Take Any Concomitant Medications.		.M="Missing" 0="False" 1="True" 2="NULL"
01. Principal	off_study_comments	Comments		Char
01. Principal	off_study_dt	Off Study Date		SAS Date
01. Principal	off_study_na	Not Applicable		1="True" 2="NULL"
01. Principal	off_study_reason	Off Study Reason		1="Study Complete" 2="Adverse Event" 3="Ineligible" 4="Lost To Follow-Up" 5="Participant Refused Follow-Up" 6="Participant Withdrawal" 7="Other, Specify"

Section 43: Comments

Class	Variable	Label	Description	Format Text
01. Principal	comment_dt1-2	Comment Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	comment_spec1-2	Comment Verbatim, Specify		Char
01. Principal	comment_type1-2	Comment Type		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Biopsy Specimen-Research" 2="Participant Contact Form"
01. Principal	comment_type_spec1-2	Comment Type, Specify		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Biopsy Specimen Level 1 (1 cm Above GE Junction)" 2="Contact Type" 3="Vial Barcode"
01. Principal	comment_verbat1-2	Comment Verbatim		Char

Section 44: Specimen Shipping Form

Class	Variable	Label	Description	Format Text
01. Principal	specship_biop_v1_1-3	Biopsy		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Baseline" 5="12 Months" 7="18 Months"
01. Principal	specship_biop_v7_1-3	Biopsy		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Baseline" 5="12 Months" 7="18 Months"
01. Principal	specship_biop_v9_1-3	Biopsy		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Baseline" 5="12 Months" 7="18 Months"
01. Principal	specship_flash_freeze_v1_1-3	Flash Frozen		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	specship_flash_freeze_v7_1-3	Flash Frozen		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	specship_flash_freeze_v9_1-3	Flash Frozen		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	specship_formalin_fix_v1_1-3	Formalin Fixed		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	specship_formalin_fix_v7_1-3	Formalin Fixed		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	specship_formalin_fix_v9_1-3	Formalin Fixed		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	specship_num_vials_v1_1-3	Number Of Vials		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_num_vials_v7_1-3	Number Of Vials		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_num_vials_v9_1-3	Number Of Vials		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_rec_dt_v1_1-3	Date Received		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_rec_dt_v7_1-3	Date Received		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_rec_dt_v9_1-3	Date Received		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_rec_time_v1_1-3	Time Received		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_rec_time_v7_1-3	Time Received		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_rec_time_v9_1-3	Time Received		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_rnalater_v1_1-3	RNALater		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	specship_rnalater_v7_1-3	RNALater		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"
01. Principal	specship_rnalater_v9_1-3	RNALater		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	specship_ship_d t_v1_1-3	Date Shipped		SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_ship_d t_v7_1-3	Date Shipped		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_ship_d t_v9_1-3	Date Shipped		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_ship_ti me_v1_1-3	Time Shipped		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_ship_ti me_v7_1-3	Time Shipped		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_ship_ti me_v9_1-3	Time Shipped		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_state_s pec_v1_1-3	Other		Char
01. Principal	specship_state_s pec_v7_1-3	Other		Char
01. Principal	specship_state_s pec_v9_1-3	Other		Char
01. Principal	specship_state_v 1_1-3	State of Blood Samples		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Cold" 2="Frozen" 3="Other"
01. Principal	specship_state_v 7_1-3	State of Blood Samples		.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Cold" 2="Frozen" 3="Other"
01. Principal	specship_state_v 9_1-3	State of Blood Samples		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Cold" 2="Frozen" 3="Other"

Class	Variable	Label	Description	Format Text
01. Principal	specship_verif2_dt_v1_1-3	Date Verified 2		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_verif2_dt_v7_1-3	Date Verified 2		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_verif2_dt_v9_1-3	Date Verified 2		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_verif2_time_v1_1-3	Time Verified 2		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_verif2_time_v7_1-3	Time Verified 2		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_verif2_time_v9_1-3	Time Verified 2		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_verif_dt_v1_1-3	Date Verified 1		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_verif_dt_v7_1-3	Date Verified 1		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_verif_dt_v9_1-3	Date Verified 1		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_verif_time_v1_1-3	Time Verified 1		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_verif_time_v7_1-3	Time Verified 1		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_verif_time_v9_1-3	Time Verified 1		SAS Time .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_visit_dt_v1_1-3	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"

Class	Variable	Label	Description	Format Text
01. Principal	specship_visit_dt_v7_1-3	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_visit_dt_v9_1-3	Visit Date		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
01. Principal	specship_visit_time_v1_1-3	Time Date		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_visit_time_v7_1-3	Time Date		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
01. Principal	specship_visit_time_v9_1-3	Time Date		SAS Time .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"