UWI2016-07-01 - ENHANCED PERSON: DATA DICTIONARY

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UWI2016-07-01 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
SEQUENCE_NO_	Patient ID		Numeric

Section 2: Study-wide

Variable	Label	Description	Format Text
protocol_ver	Protocol Version	Indicates the version of the protocol used. Different baseline alcohol and tobacco assessment forms were used based on the protocol version.	.R="Not Randomized" 1="2.1" 2="3.2/4.1"
rnd_dt	Randomization Date		SAS Date .R="Not Randomized"
rnd_num	Randomization Number		Numeric .R="Not Randomized"
rnd_washout_end_dt	Washout End Date		SAS Date .N="N/A" .R="Not Randomized"
rnd_washout_start_dt	Washout Start Date		SAS Date .N="N/A" .R="Not Randomized"
treatment	Treatment		.R="Not Randomized" 1="ACTOplus" 2="Placebo"
visit_dt_v0	Date Of Visit 0 (Baseline)		SAS Date
visit_dt_v1	Date Of Visit 1 (End Of Study Or Early Termination)		SAS Date .F="No Record For This Visit"

Section 3: Demographics

Variable	Label	Description	Format Text
min_country_code	Country Code - [Minimum]		Char
min_enroll_dt	Date Of Enrollment - [Minimum]		SAS Date
min_pay_method	Method Of Payment - [Minimum]		1="Private Insurance" 4="Military Sponsored (including CHAMPUS & TriCare)" 7="Medicare" 8="Medicare and Private Insurance" 9="Self-Pay (No Insurance)" 10="Managed Care/Medicare" 11="State Supplemental Health Insurance"
min_tac	Treatment Assignment Code (TAC) - [Minimum]		0="TAC-0" 1="TAC-1"
reg_age	Participant Age - [Registration]	Age of the participant at registration (Derived from date of birth at registration).	Numeric
reg_consent_biobank	The Participant Agrees His/Her Samples And Related Information May Be Kept In A Biobank For Use In Future Health Research. - [Registration]		1="Yes"
reg_consent_contact	The Participant Agrees That His/Her Study Doctor, Or Their Representative, May Contact Him/Her Or His/Her Physician To See If He/She Wishes To Participate In Other Research In The Future. - [Registration]		1="Yes"
reg_consent_dt	Informed Consent Date - [Registration]		SAS Date
reg_consent_genetic	The Participant Agrees That His/Her Genetic And Health Information Can Be Released, With No Direct Identifiers, Into Scientific Databases. - [Registration]		1="Yes"
reg_consent_version	Informed Consent Version Number - [Registration]		Numeric
reg_consent_version_dt	Informed Consent Version Date - [Registration]		SAS Date
reg_dt	Registration Date - [Registration]		SAS Date
reg_eligible	Does The Participant Satisfy All Of The Eligibility Criteria? - [Registration]		0="No" 1="Yes"

Variable	Label	Description	Format Text
reg_ethnicity	Ethnicity - [Registration]		2="Not Hispanic or Latino"
reg_gender	Gender - [Registration]		1="Female" 2="Male"
reg_institution	Registering Institution - [Registration]		1="MD017" 2="MN022" 4="WI020"
reg_race	Race - [Registration]		1="White" 5="American Indian or Alaska Native"
reg_race_eth	Race + Ethnicity - [Registration]	Combination of the Race and Ethnicity variables. Participants can only be considered white or black when they are not Hispanic. If the participant is white or black and Hispanic, then they are considered Hispanic. If the participant is Asian, Pacific Islander, or American Indian then they are considered that race.	1="White, Non-Hispanic" 6="American Indian"

Section 4: Screening

Variable	Label	Description	Format Text
screen_cmnt	Comments - [Screening]		Char
screen_dt	Screening Date - [Screening]		SAS Date
screen_find_out	How Did The Participant Find Out About The Study? - [Screening]		1="Physician" 9="Other, specify"
screen_find_out_ot h	Other, Specify - [Screening]		Char
screen_met_criteria	Does The Participant Meet The Screening Criteria? - [Screening]		0="No" 1="Yes"
screen_referred	Who Referred The Participant? - [Screening]		1="Physician"

Section 5: Exclusion Criteria

Variable	Label	Description	Format Text
excl_alcoholic	An Active Alcoholic Or Consumes Excessive Amounts Of Alcohol. - [Exclusion Criteria]	Question 4.2.15. Participant is an active alcoholic or consumes excessive amounts of alcohol.	.N="N/A" 0="No"
excl_allergic	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To ACTOplus Met® XR. - [Exclusion Criteria]	Question 4.2.9. Participant has a history of allergic reactions attributed to compounds of similar chemical or biologic composition to ACTOplus Met® XR.	.N="N/A" 0="No"
excl_biguanide	Taken A Biguanide [e.g. Metformin (Glucophage, Glumetza, Fortamet, Riomet), Or Proguanil (Paludrine)] In The Past 3 Months. - [Exclusion Criteria]	Question 4.2.3.2. Participant has taken a Biguanide [e.g. Metformin (Glucophage, Glumetza, fortamet, Riomet), or Proguanil (Paludrine)] in the past 3 months.	.N="N/A" 0="No"
excl_blad_cncr	History Of Bladder Cancer (Including In Situ Bladder Cancer). - [Exclusion Criteria]	Question 4.2.17. Participant has a history of bladder cancer (including in situ bladder cancer).	.N="N/A" 0="No"
excl_cationic	Currently Taking A Cationic Drug Or Multidrug And Toxin Extrusion [MATE] Inhibitor - [Exclusion Criteria]	Question 4.2.7. Participant is currently taking a cationic drug or multidrug and toxin extrusion [MATE] inhibitor [e.g. amiloride (Midamor); cimetidine (Tagamet); digoxin (Lanoxin, Digitek, Digox); dolutegravir (Tivicay); morphine (Roxanol, Duramorph, Kadian, MS Contin); procainamide (Pronestyl, Procanbid); quinidine (Quinidex, Cardioquin,Quin-G, Quinora); quinine (Qualaquin, Quinamm, Quiphile); ranitidine (Zantac, Deprizine, Gabitidine); ranolazine (Ranexa); triamterene (Dyrenium); trimethoprim (Proloprim, Trimpex, Primsol); vancomycin (Vancocin, Vancoled); or vandetanib (Calpresa).	.N="N/A" 0="No"

Variable	Label	Description	Format Text
excl_chf_nyha	History Of Congestive Heart Failure Or New York Heart Association (NYHA) Class III Or IV Functional Status. - [Exclusion Criteria]	Question 4.2.11. Participant has a history of Congestive Heart Failure or New York Heart Association (NYHA) Class III or IV Functional Status.	.N="N/A" 0="No"
excl_combo_drug	Taken A Combination Drug Containing One Of The Agents Above - [Exclusion Criteria]	Question 4.2.3.3. Participant has taken a combination drug containing one of the agents above (brand names include: ACTOplus Met, Avandamet, Avandaryl, Duetact, Glucovance, Invokamet, Janumet, Jentadueto, Komboglyze, Metaglip, PrandiMet, Synjardy, Xigudo) in the past 3 months.	.N="N/A" 0="No"
excl_concur_diabetes	Concurrent Diagnosis Of Type I Or Type II Diabetes That Is Being Treated With Insulin Or An Antidiabetic Agent. - [Exclusion Criteria]	Question 4.2.2. Participant has a concurrent diagnosis of type I or type II diabetes that is being treated with insulin or an antidiabetic agent.	.N="N/A" 0="No"
excl_contraindication	Contraindication To Biopsy. - [Exclusion Criteria]	Question 4.2.10. Participant has a contraindication to biopsy.	.N="N/A" 0="No"
excl_ctcae1_limb_edema	> CTCAE Grade 1 Limb Edema - [Exclusion Criteria]	Question 4.2.13. Participant has > CTCAE grade 1 limb edema	.N="N/A" 0="No"
excl_cyp2c8_inhibitor	Currently Taking A Strong CYP2C8 Inhibitor [e.g. Gemfibrozil (Lopid)]. - [Exclusion Criteria]	Question 4.2.4. Participant is currently taking a strong CYP2C8 inhibitor [e.g. Gemfibrozil (Lopid)].	.N="N/A" 0="No"
excl_enzyme_inducer	Currently Taking An Enzyme Inducer Of CYP2C8 - [Exclusion Criteria]	Question 4.2.5. Participant is currently taking an enzyme inducer of CYP2C8 [carbamazepine (Carbatrol, Epitol, Equetro, Tegretol); cortisol (Hydrocortisone); dexamethasone (Decadron); phenobarbital (Luminal Sodium); phenytoin (Dilantin, Phenytek, Novaplus Phenytoin Sodium); primidone (Mysoline); rifampin (Rifadin, Rimactane); rifapentine (Priftin); secobarbitol (Seconal)].	.N="N/A" 0="No"
excl_hypoglycemia	History Of Hypoglycemia - [Exclusion Criteria]	Question 4.2.14. Participant has a history of hypoglycemia	.N="N/A" 0="No"

Variable	Label	Description	Format Text
excl_illness	Uncontrolled Intercurrent Illness - [Exclusion Criteria]	Question 4.2.19. Participant has uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements	.N="N/A" 0="No"
excl_invasive_cncr	History Of Invasive Cancer (Other Than Non-melanoma Skin Cancer Or Cervical Cancer In Situ) Active Within 18 Months Prior To Baseline - [Exclusion Criteria]	Question 4.2.18. Participant has a history of invasive cancer (other than non-melanoma skin cancer or cervical cancer in situ) active within 18 months prior to the baseline study visit.	.N="N/A" 0="No"
excl_investig_agent	Taking Another Investigational Agent. - [Exclusion Criteria]	Question 4.2.8. Participant is taking another investigational agent.	.N="N/A" 0="No"
excl_liver_disease	History Of Liver Disease. - [Exclusion Criteria]	Question 4.2.12. Participant has a history of liver disease.	.N="N/A" 0="No"
excl_macular_edema	History Of Macular Edema. - [Exclusion Criteria]	Question 4.2.16. Participant has a history of macular edema.	.N="N/A" 0="No"
excl_meets_criteria	Meets Exclusion Criteria? - [Exclusion Criteria]		.N="N/A" 1="Yes"
excl_pregnant	Pregnant, Breast Feeding Or Planning To Become Pregnant. - [Exclusion Criteria]	Question 4.2.20. Participant is pregnant, breast feeding or planning to become pregnant. (All participants of childbearing potential regardless of method of birth control must have a negative pregnancy test at baseline. a woman is considered not to be of childbearing potential if she has had a hysterectomy, bilateral oophorectomy, or if she is > 55 years of age with > 2 years of amenorrhea.)	.N="N/A" 0="No"
excl_thiazol	Taken A Thiazolidinedione [e.g. Pioglitazone (Actos) Or Rosiglitazone (Avandia)] In The Past 3 Months. - [Exclusion Criteria]	Question 4.2.3.1. Participant has taken a Thiazolidinedione [e.g. Pioglitazone (Actos) or Rosiglitazone (Avandia)] in the past 3 months.	.N="N/A" 0="No"

Variable	Label	Description	Format Text
excl_topiramate	Currently Taking Topiramate (Topamax) Commonly Used In Epilepsy Or To Prevent Migraines Or Other Carbonic Anhydrase Inhibitors - [Exclusion Criteria]	Question 4.2.6. Participant is currently taking topiramate (Topamax) commonly used in epilepsy or to prevent migraines or other carbonic anhydrase inhibitors [e.g. zonisamide (Zonegran); acetazolaminde (Diamox Sequels); or dichlorphenamide (Keveyis, Daranide)].	.N="N/A" 0="No"
excl_trt_prior	Received Or Will Receive Some Form Of Treatment For Their Cancer Prior To Completing A Minimum Of 14 Days Of Study Agent Dosing. - [Exclusion Criteria]	Question 4.2.1. Participant has received or will receive some form of treatment for their cancer prior to completing a minimum of 14 days of study agent dosing.	.N="N/A" 0="No"

Section 6: Inclusion Criteria

Variable	Label	Description	Format Text
incl_able_to_complete_14d	Able To Complete A Minimum Of 14 Days Of Study Agent Dosing Prior To Initiation Of Definitive Treatment For Their Cancer. - [Inclusion Criteria]	Question 4.1.3. Participant is able to complete a minimum of 14 days of study agent dosing prior to initiation of definitive treatment for their cancer.	.N="N/A" 1="Yes"
incl_accessible_to_biopsy	Primary Tumor Is Accessible To Biopsy In The Outpatient Clinic Setting And Participant Is Willing To Have 4 mm Punch Biopsies - [Inclusion Criteria]	Question 4.1.2. The participant's primary tumor is accessible to biopsy in the outpatient clinic setting and the participant is willing to have baseline and end of study (day 15-26) 4mm punch biopsies of tumor and adjacent visually normal appearing tissue obtained for biomarker analysis.	.N="N/A" 1="Yes"
incl_age_18plus	Age >= 18 Years - [Inclusion Criteria]	Question 4.1.5. Age >= 18 years	.N="N/A" 1="Yes"
incl_alt_sgpt	ALT (SGPT) Within Normal Institutional Limits - [Inclusion Criteria]	Question 4.1.9. ALT (SGPT) within normal institutional limits	.N="N/A" 1="Yes"
incl_ast_sgot	AST (SGOT) Within Normal Institutional Limits - [Inclusion Criteria]	Question 4.1.9. AST (SGOT) within normal institutional limits	.N="N/A" 1="Yes"
incl_bilirubin	Total Bilirubin Within Normal Institutional Limits - [Inclusion Criteria]	Question 4.1.9. Total bilirubin within normal institutional limits (or 1.5 x institutional upper limit of normal if participant is diagnosed with Gilbert's Disease)	.N="N/A" 1="Yes"
incl_bmi_gr18	Body Mass Index (BMI) Is >= 18.5. - [Inclusion Criteria]	Question 4.1.8. Body Mass Index (BMI) is >= 18.5.	.N="N/A" 1="Yes"
incl_consent	Ability To Understand And The Willingness To Sign A Written Informed Consent Document. - [Inclusion Criteria]	Question 4.1.13. Ability to understand and the willingness to sign a written informed consent document.	.N="N/A" 1="Yes"

Variable	Label	Description	Format Text
incl_contraception	Agrees To Use Adequate Contraception - [Inclusion Criteria]	Question 4.1.12. Participant of childbearing potential agrees to use adequate contraception (a hormonal method that has been in continual use for a minimum of 3 months prior to the study screening visit, a barrier method, or abstinence) for the duration of their study participation.	.N="N/A"
incl_ecog_0_or_1	ECOG Performance Status = 0 Or 1 - [Inclusion Criteria]	Question 4.1.6. ECOG Performance Status = 0 or 1	.N="N/A" 1="Yes"
incl_egfr	eGFR > 45 mL/min Per Cockcroft-Gault - [Inclusion Criteria]	Question 4.1.9. eGFR > 45 mL/min per Cockcroft-Gault	.N="N/A" 1="Yes"
incl_end_biopsy	Scheduled For An End Of Study Biopsy Within 22 Days Of Starting Study Agent And Within 52 Days Of Their Study Screening Visit. - [Inclusion Criteria]	Question 4.1.4. Participant is scheduled for an end of study biopsy within 22 days of starting study agent and within 52 days of their study screening visit.	.N="N/A" 1="Yes"
incl_full_duration	Willing And Able To Participate For The Duration Of The Study. - [Inclusion Criteria]	Question 4.1.11. Participant is willing and able to participate for the duration of the study.	.N="N/A" 1="Yes"
incl_glucose_serum	Glucose, Serum < 200 mg/dL - [Inclusion Criteria]	Question 4.1.9. Glucose, serum < 200 mg/dL	.N="N/A" 1="Yes"
incl_hemoglobin	Hemoglobin >= 10 g/dl - [Inclusion Criteria]	Question 4.1.9. Hemoglobin >= 10 g/dl	.N="N/A" 1="Yes"
incl_life_expectancy_gr6m	Life Expectancy Is > 6 Months. - [Inclusion Criteria]	Question 4.1.7. Life expectancy is > 6 months.	.N="N/A" 1="Yes"
incl_meets_criteria	Meets Inclusion Criteria? - [Inclusion Criteria]		.N="N/A" 1="Yes"
incl_new_dx	Newly Diagnosed, Histologically Confirmed, Stage I-IV Squamous Cell Carcinoma Of The Oral Cavity Or Oropharynx - [Inclusion Criteria]	Question 4.1.1. Participant has a newly diagnosed, histologically confirmed, stage I-IV squamous cell carcinoma or squamous cell carcinoma in situ of the oral cavity or oropharynx and will be undergoing definitive surgical, radiotherapy, or chemoradiation treatment. Patients who are NOT candidates for localized treatment (surgery, radiation or chemoradiation) with curative intent (i.e. patients with distant metastasis or contra-indication to localized treatment) are not eligible.	.N="N/A" 1="Yes"

Variable	Label	Description	Format Text
incl_platelets	Platelets >= 100,000/microliter - [Inclusion Criteria]	Question 4.1.9. Platelets >= 100,000/microliter	.N="N/A" 1="Yes"
incl_swallow_tablet	Able To Swallow A Tablet Whole. - [Inclusion Criteria]	Question 4.1.10. Participant is able to swallow a tablet whole.	.N="N/A" 1="Yes"
incl_wbc	White Blood Cells >= 3,000/microliter - [Inclusion Criteria]	Question 4.1.9. White Blood Cells >= 3,000/microliter	.N="N/A" 1="Yes"

Section 7: Medical History

Variable	Label	Description	Format Text
medhist_all_normal	Are All Body Systems Normal? - [Medical History Dataset 1]		.N="N/A" 0="No"
medhist_aller_spec	Allergies Participant Has (Specified) - [Medical History Dataset 1]		Char
medhist_allergies	Does Participant Have Any Allergies? - [Medical History Dataset 1]		.N="N/A" 0="No" 1="Yes"
medhist_breast_abn	Breasts - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No"
medhist_breast_cmnt	Breasts - Comments - [Medical History Dataset 2]		Char
medhist_cardio_abn	Cardiovascular System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
medhist_cardio_cmnt	Cardiovascular System - Comments - [Medical History Dataset 2]		Char
medhist_derma_abn	Dermatologic System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
medhist_derma_cmnt	Dermatologic System - Comments - [Medical History Dataset 2]		Char
medhist_endometa_abn	Endocrine/Metabolic System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
medhist_endometa_cmnt	Endocrine/Metabolic System - Comments - [Medical History Dataset 2]		Char
medhist_gastro_abn	Gastrointestinal System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 1="Yes"
medhist_gastro_cmnt	Gastrointestinal System - Comments - [Medical History Dataset 2]		Char
medhist_genit_abn	Genitourinary System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
medhist_genit_cmnt	Genitourinary System - Comments - [Medical History Dataset 2]		Char
medhist_heent_abn	H/E/E/N/T System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 1="Yes"

Variable	Label	Description	Format Text
medhist_heent_cmnt	H/E/E/N/T System - Comments - [Medical History Dataset 2]		Char
medhist_hemalymph_abn	Hematopoietic/Lymph System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
medhist_hemalymph_cmnt	Hematopoietic/Lymph System - Comments - [Medical History Dataset 2]		Char
medhist_muscskel_abn	Musculoskeletal System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
medhist_muscskel_cmnt	Musculoskeletal System - Comments - [Medical History Dataset 2]		Char
medhist_neck_abn	Neck - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
medhist_neck_cmnt	Neck - Comments - [Medical History Dataset 2]		Char
medhist_neuro_abn	Neurologic System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
medhist_neuro_cmnt	Neurologic System - Comments - [Medical History Dataset 2]		Char
medhist_oth_sys_abn	Other Body System - Abnormal? - [Medical History Dataset 3]		.F="No Record For This Visit" .R="Not Randomized" 1="Yes"
medhist_oth_sys_cmnt	Other Body System - Comments - [Medical History Dataset 3]		Char
medhist_oth_sys_name	Other Body System - Name - [Medical History Dataset 3]		Char
medhist_resp_abn	Respiratory System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
medhist_resp_cmnt	Respiratory System - Comments - [Medical History Dataset 2]		Char

Section 8: Baseline Symptoms

Variable	Label	Description	Format Text
bsymp_any	Any Baseline Symptoms? - [Baseline Symptoms]		0="No" 1="Yes"
bsymp_comments1-5	Comments - Baseline Symptom # - [Baseline Symptoms]		Char
bsymp_ctcae_term1-5	CTCAE Term - Baseline Symptom # - [Baseline Symptoms]		Char
bsymp_description1-5	Description - Baseline Symptom # - [Baseline Symptoms]		Char
bsymp_grade1-5	CTCAE Grade - Baseline Symptom # - [Baseline Symptoms]		.N="N/A" 1="1: Mild" 2="2: Moderate"
bsymp_meddra_soc 1-5	MedDRA System Organ Class - Baseline Symptom # - [Baseline Symptoms]		Char
bsymp_num	Number Of Baseline Symptoms - [Baseline Symptoms]		Numeric
bsymp_onset_dt1-5	Onset Date - Baseline Symptom # - [Baseline Symptoms]		SAS Date .N="N/A" .U="Unknown"
bsymp_stop_dt1-5	Stop Date - Baseline Symptom # - [Baseline Symptoms]		SAS Date .C="Continuous" .N="N/A"

Section 9: Concomitant Medications

Variable	Label	Description	Format Text
conmed_dose1-20	Dose - Medication # - [Concomitant Medications]		Numeric .N="N/A"
conmed_end_dt1-20	End Date - Medication # - [Concomitant Medications]		SAS Date .C="Continuous" .N="N/A"
conmed_freq1-20	Frequency - Medication # - [Concomitant Medications]		Char
conmed_medication 1-20	Medication Name - Medication # - [Concomitant Medications]		Char
conmed_num	Number Of Concomitant Medications Taken - [Concomitant Medications]		Numeric .N="N/A"
conmed_reason1-20	Reason - Medication # - [Concomitant Medications]		Char
conmed_report_dt1-20	Report Date - Medication # - [Concomitant Medications]		SAS Date .N="N/A"
conmed_start_dt1-20	Start Date - Medication # - [Concomitant Medications]		SAS Date .N="N/A" .U="Unknown"
conmed_units1-20	Units - Medication # - [Concomitant Medications]		Char

Section 10: Intervention Administration

Variable	Label	Description	Format Text
intadm_agent_prov _dt	Date Agent Was Provided - [Intervention Administration]		SAS Date .R="Not Randomized"
intadm_agent_start _dt	Date Agent Was Started - [Intervention Administration]		SAS Date .R="Not Randomized" .U="Unknown"

Section 11: Contact

Variable	Label	Description	Format Text
contact_any_ae_c1	Any Symptoms Or Adverse Events? - Contact 1 (Interim Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
contact_any_ae_c2	Any Symptoms Or Adverse Events? - Contact 2 (Final Dosing Reminder Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
contact_any_conmed_c1	Any Changes In Concomitant Medications? - Contact 1 (Interim Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
contact_any_conmed_c2	Any Changes In Concomitant Medications? - Contact 2 (Final Dosing Reminder Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
contact_compliant_c1	Compliant With Study Protocol? - Contact 1 (Interim Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
contact_compliant_c2	Compliant With Study Protocol? - Contact 2 (Final Dosing Reminder Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
contact_dt_c1	Date Of Contact - Contact 1 (Interim Phone Contact) - [Contact]		SAS Date .R="Not Randomized"
contact_dt_c2	Date Of Contact - Contact 2 (Final Dosing Reminder Phone Contact) - [Contact]		SAS Date .R="Not Randomized"
contact_time_c1	Time Of Contact - Contact 1 (Interim Phone Contact) - [Contact]		Numeric .R="Not Randomized"
contact_time_c2	Time Of Contact - Contact 2 (Final Dosing Reminder Phone Contact) - [Contact]		Numeric .R="Not Randomized"
contact_type_c1	Type Of Contact - Contact 1 (Interim Phone Contact) - [Contact]		.R="Not Randomized" 1="Home Phone" 3="Home Cell"
contact_type_c2	Type Of Contact - Contact 2 (Final Dosing Reminder Phone Contact) - [Contact]		.R="Not Randomized" 1="Home Phone" 3="Home Cell"

Section 12: Adverse Events

Variable	Label	Description	Format Text
ae_gastro_max_attrib	Gastrointestinal Disorders - Maximum Attribution - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 3="Possible" 4="Probable"
ae_gastro_max_sev	Gastrointestinal Disorders - Maximum Severity - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 1="Mild"
ae_general_max_attrib	General Disorders And Administration Site Conditions - Maximum Attribution - [Maximum AEs By Body System]		0="None" 1="Unrelated"
ae_general_max_sev	General Disorders And Administration Site Conditions - Maximum Severity - [Maximum AEs By Body System]		0="None" 1="Mild"
ae_has_any	Any Adverse Events? - [Adverse Events Summary]		.R="Not Randomized" 0="No" 1="Yes"
ae_has_multiple	Multiple Adverse Events? - [Adverse Events Summary]		.R="Not Randomized" 0="No" 1="Yes"
ae_has_sae	Any Serious Adverse Events? - [Adverse Events Summary]		.R="Not Randomized" 0="No"
ae_has_severe	Any Severe Adverse Events? - [Adverse Events Summary]		.R="Not Randomized" 0="No" 1="Yes"
ae_max_attribution	Maximum Attribution Of All Adverse Events - [Adverse Events Summary]		.R="Not Randomized" 0="None" 1="Unrelated" 3="Possible" 4="Probable"
ae_max_severity	Maximum Severity Of All Adverse Events - [Adverse Events Summary]		.R="Not Randomized" 0="None" 1="Mild" 2="Moderate" 3="Severe"
ae_nervous_max_attrib	Nervous System Disorders - Maximum Attribution - [Maximum AEs By Body System]		0="None" 1="Unrelated"
ae_nervous_max_sev	Nervous System Disorders - Maximum Severity - [Maximum AEs By Body System]		0="None" 1="Mild"

Variable	Label	Description	Format Text
ae_num	Number Of Adverse Events The Participant Experienced During The Study - [Adverse Events]		Numeric .N="N/A"
ae_num_cat	Categorized Number Of Adverse Events - [Adverse Events Summary]		Numeric .R="Not Randomized"
ae_overall_max_attrib	Overall - Maximum Attribution - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 1="Unrelated" 3="Possible" 4="Probable"
ae_overall_max_sev	Overall - Maximum Severity - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 1="Mild" 2="Moderate" 3="Severe"
ae_resp_thor_medi_max_attrib	Respiratory, Thoracic And Mediastinal Disorders - Maximum Attribution - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 1="Unrelated"
ae_resp_thor_medi_max_sev	Respiratory, Thoracic And Mediastinal Disorders - Maximum Severity - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 2="Moderate"
ae_vascular_max_attrib	Vascular Disorders - Maximum Attribution - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 1="Unrelated"
ae_vascular_max_sev	Vascular Disorders - Maximum Severity - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 2="Moderate" 3="Severe"

Section 13: Agent Interruption and Modification

Variable	Label	Description	Format Text
agent_interrupted	Was Agent Interrupted? - [Agent Interruption]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
agent_mod_dose	Modified Dosage - [Agent Modification]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
agent_mod_dt	Date Agent Was Modified - [Agent Modification]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
agent_mod_freq	Modified Frequency - [Agent Modification]		Char
agent_mod_rsn	Reason Agent Was Modified - [Agent Modification]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
agent_mod_spec	Specific Reason Agent Was Modified - [Agent Modification]		Char
agent_modified	Was Agent Modified? - [Agent Modification]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
agent_restart_dt	Date Agent Regimen Was Restarted - [Agent Interruption]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized" .U="Unknown"
agent_restart_rsn	Reason Agent Was Restarted - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Participant Decision"
agent_restarted	Was Agent Restarted? - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Yes"
agent_stop_dt	Date Agent Regimen Was Stopped - [Agent Interruption]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized" .U="Unknown"
agent_stop_rsn	Reason Agent Was Stopped - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Participant Decision"

Variable	Label	Description	Format Text
agent_stop_spec	Specific Reason Agent Was Stopped - [Agent Interruption]		Char

Section 14: Compliance

Variable	Label	Description	Format Text
comp_agent_dispense_dt	Agent Dispense Date - [Compliance]		SAS Date .R="Not Randomized"
comp_agent_missing	Amount Of Agent Missing - [Compliance]		Numeric .R="Not Randomized"
comp_agent_provided	Amount Of Agent Provided - [Compliance]		Numeric .R="Not Randomized"
comp_agent_returned	Amount Of Agent Returned - [Compliance]		Numeric .R="Not Randomized"
comp_agent_taken	Amount Of Agent Taken - [Compliance]		Numeric .R="Not Randomized" .U="Unknown"
comp_compliant	Compliant With Protocol Intervention? - [Compliance]		.R="Not Randomized" 0="No" 1="Yes"
comp_first_dose_dt	Date Of First Dose - [Compliance]		SAS Date .R="Not Randomized" .U="Unknown"
comp_first_dose_time	Time Of First Dose - [Compliance]		Numeric .M="Missing" .R="Not Randomized"
comp_last_dose_dt	Date Of Last Dose - [Compliance]		SAS Date .R="Not Randomized" .U="Unknown"
comp_last_dose_time	Time Of Last Dose - [Compliance]		Numeric .M="Missing" .R="Not Randomized"
comp_noncomp_rsn	Reason For Noncompliance - [Compliance]		Char

Section 15: Off Study

Variable	Label	Description	Format Text
off_agent_end_dt	Agent End Date - [Off Study]		SAS Date .N="N/A" .U="Unknown"
off_form_dt	Form Date - [Off Study]		SAS Date
off_fu_off_dt	Date Off Follow-Up - [Off Study]		SAS Date .N="N/A"
off_fu_on_dt	Date On Follow-Up - [Off Study]		SAS Date .N="N/A"
off_last_contact_dt	Date Of Last Contact - [Off Study]		SAS Date
off_rsn	Reason Off Study - [Off Study]		1="Study Complete" 2="Ineligible" 5="Participant Withdrawal"
off_rsn_spec	Reason Off Study Other, Specify - [Off Study]		Char
off_study_dt	Off Study Date - [Off Study]		SAS Date

Section 16: Pregnancy Specimen

Variable	Label	Description	Format Text
pregspec_col_dt	Date Specimen Collected - [Pregnancy Specimen]		SAS Date .M="Missing" .N="N/A"
pregspec_lab_test	Lab Test - [Pregnancy Specimen]		Numeric .M="Missing" .N="N/A"
pregspec_result	Result - [Pregnancy Specimen]		Numeric .M="Missing" .N="N/A"
pregspec_rsn_not_col	Reason Pregnancy Data Not Collected - [Pregnancy Specimen]		.N="N/A" 4="Surgically sterilized" 5="Participant is male"
pregspec_test_type	Pregnancy Test Type - [Pregnancy Specimen]		Numeric .M="Missing" .N="N/A"

Section 17: Anthropometry

Variable	Label	Description	Format Text
pe_bp_diastolic_v0	Diastolic Blood Pressure (mmHg) - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A"
pe_bp_diastolic_v1	Diastolic Blood Pressure (mmHg) - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
pe_bp_systolic_v0	Systolic Blood Pressure (mmHg) - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A"
pe_bp_systolic_v1	Systolic Blood Pressure (mmHg) - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
pe_ecog_v0	ECOG Performance Status - Visit 0 (Baseline) - [Physical Exam Dataset 1]		.N="N/A" 0="Normal activity. Fully active, able to carry on all pre-disease performance without restriction."
pe_ecog_v1	ECOG Performance Status - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		.N="N/A"
pe_height_v0	Height (cm) - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A"
pe_height_v1	Height (cm) - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
pe_pulse_rate_v0	Pulse Rate - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
pe_pulse_rate_v1	Pulse Rate - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
pe_resp_rate_v0	Respiration Rate - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
pe_resp_rate_v1	Respiration Rate - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"

Variable	Label	Description	Format Text
pe_temperature_v0	Temperature (C) - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
pe_temperature_v1	Temperature (C) - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
pe_weight_v0	Weight (kg) - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A"
pe_weight_v1	Weight (kg) - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
vit_bmi_v0	BMI - Visit 0 (Baseline) - [Vitals]		Numeric .R="Not Randomized"
vit_bmi_v1	BMI - Visit 1 (End Of Study Or Early Termination) - [Vitals]		Numeric .M="Missing" .R="Not Randomized"

Section 18: Physical Exam

Variable	Label	Description	Format Text
pe_abdomen_abn_v0	Abdomen - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A" 0="No"
pe_abdomen_abn_v1	Abdomen - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No"
pe_abdomen_cmnt_v0	Abdomen - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_abdomen_cmnt_v1	Abdomen - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_appearance_abn_v0	Appearance - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A" 0="No"
pe_appearance_abn_v1	Appearance - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No"
pe_appearance_cmnt_v0	Appearance - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_appearance_cmnt_v1	Appearance - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_body_sys_exam_v0	Were Body Systems Examined? - Visit 0 (Baseline) - [Physical Exam Dataset 1]		.N="N/A" 1="Yes"
pe_body_sys_exam_v1	Were Body Systems Examined? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		.N="N/A" 0="No" 1="Yes"
pe_breasts_abn_v0	Breasts - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.N="N/A" 0="No" 9="Not Assessed"
pe_breasts_abn_v1	Breasts - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No" 9="Not Assessed"
pe_breasts_cmnt_v0	Breasts - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char

Variable	Label	Description	Format Text
pe_breasts_cmnt_v1	Breasts - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_cardio_abn_v0	Cardiovascular System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A"
pe_cardio_abn_v1	Cardiovascular System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit"
pe_cardio_cmnt_v0	Cardiovascular System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_cardio_cmnt_v1	Cardiovascular System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_chest_abn_v0	Chest - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A" 0="No"
pe_chest_abn_v1	Chest - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No"
pe_chest_cmnt_v0	Chest - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_chest_cmnt_v1	Chest - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_chf_v0	Signs Of Congestive Heart Failure (CHF)? - Visit 0 (Baseline) - [Physical Exam Dataset 1]		.N="N/A" 0="No"
pe_chf_v1	Signs Of Congestive Heart Failure (CHF)? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		.M="Missing" .N="N/A" 0="No"
pe_derma_abn_v0	Dermatologic System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A"
pe_derma_abn_v1	Dermatologic System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit"

Variable	Label	Description	Format Text
pe_derma_cmnt_v0	Dermatologic System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_derma_cmnt_v1	Dermatologic System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_edema_v0	Signs Of Edema? - Visit 0 (Baseline) - [Physical Exam Dataset 1]		.N="N/A" 0="No" 1="Yes"
pe_edema_v1	Signs Of Edema? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		.M="Missing" .N="N/A" 0="No" 1="Yes"
pe_endometa_abn_v0	Endocrine/Metabolic System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A"
pe_endometa_abn_v1	Endocrine/Metabolic System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit"
pe_endometa_cmnt_v0	Endocrine/Metabolic System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_endometa_cmnt_v1	Endocrine/Metabolic System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_exam_dt_v0	Exam Date - Visit 0 (Baseline) - [Physical Exam Dataset 1]		SAS Date .N="N/A"
pe_exam_dt_v1	Exam Date - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		SAS Date .M="Missing" .N="N/A"
pe_gastro_abn_v0	Gastrointestinal System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A"
pe_gastro_abn_v1	Gastrointestinal System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit"
pe_gastro_cmnt_v0	Gastrointestinal System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char

Variable	Label	Description	Format Text
pe_gastro_cmnt_v1	Gastrointestinal System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_genitalia_abn_v0	Genitalia - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A" 9="Not Assessed"
pe_genitalia_abn_v1	Genitalia - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 9="Not Assessed"
pe_genitalia_cmnt_v0	Genitalia - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_genitalia_cmnt_v1	Genitalia - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_genitourinary_abn_v0	Genitourinary System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A"
pe_genitourinary_abn_v1	Genitourinary System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit"
pe_genitourinary_cmnt_v0	Genitourinary System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_genitourinary_cmnt_v1	Genitourinary System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_heart_abn_v0	Heart - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A" 0="No"
pe_heart_abn_v1	Heart - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No"
pe_heart_cmnt_v0	Heart - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_heart_cmnt_v1	Heart - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_heent_abn_v0	H/E/E/N/T System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.N="N/A" 1="Yes"

Variable	Label	Description	Format Text
pe_heent_abn_v1	H/E/E/N/T System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
pe_heent_cmnt_v0	H/E/E/N/T System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_heent_cmnt_v1	H/E/E/N/T System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_hemalymph_abn _v0	Hematopoietic/Lymph System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A"
pe_hemalymph_abn _v1	Hematopoietic/Lymph System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit"
pe_hemalymph_cm nt_v0	Hematopoietic/Lymph System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_hemalymph_cm nt_v1	Hematopoietic/Lymph System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_lungs_abn_v0	Lungs - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A" 0="No"
pe_lungs_abn_v1	Lungs - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No"
pe_lungs_cmnt_v0	Lungs - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_lungs_cmnt_v1	Lungs - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_lymph_abn_v0	Lymph Nodes - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A" 0="No" 9="Not Assessed"
pe_lymph_abn_v1	Lymph Nodes - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No" 9="Not Assessed"

Variable	Label	Description	Format Text
pe_lymph_cmnt_v0	Lymph Nodes - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_lymph_cmnt_v1	Lymph Nodes - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_muscskel_abn_v0	Musculoskeletal System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.N="N/A" 0="No" 9="Not Assessed"
pe_muscskel_abn_v1	Musculoskeletal System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No" 9="Not Assessed"
pe_muscskel_cmnt_v0	Musculoskeletal System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_muscskel_cmnt_v1	Musculoskeletal System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_neck_abn_v0	Neck - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A"
pe_neck_abn_v1	Neck - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit"
pe_neck_cmnt_v0	Neck - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_neck_cmnt_v1	Neck - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_neuro_abn_v0	Neurological System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.N="N/A" 0="No" 9="Not Assessed"
pe_neuro_abn_v1	Neurological System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No"
pe_neuro_cmnt_v0	Neurological System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char

Variable	Label	Description	Format Text
pe_neuro_cmnt_v1	Neurological System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_pelvis_abn_v0	Pelvis - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A" 9="Not Assessed"
pe_pelvis_abn_v1	Pelvis - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 9="Not Assessed"
pe_pelvis_cmnt_v0	Pelvis - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_pelvis_cmnt_v1	Pelvis - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_rectal_abn_v0	Rectal System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A" 9="Not Assessed"
pe_rectal_abn_v1	Rectal System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 9="Not Assessed"
pe_rectal_cmnt_v0	Rectal System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_rectal_cmnt_v1	Rectal System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_resp_abn_v0	Respiratory System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A"
pe_resp_abn_v1	Respiratory System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit"
pe_resp_cmnt_v0	Respiratory System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_resp_cmnt_v1	Respiratory System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_skin_abn_v0	Skin - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .N="N/A" 0="No" 9="Not Assessed"

Variable	Label	Description	Format Text
pe_skin_abn_v1	Skin - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No" 9="Not Assessed"
pe_skin_cmnt_v0	Skin - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_skin_cmnt_v1	Skin - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_thyroid_abn_v0	Thyroid - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.N="N/A" 0="No" 9="Not Assessed"
pe_thyroid_abn_v1	Thyroid - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No" 9="Not Assessed"
pe_thyroid_cmnt_v0	Thyroid - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_thyroid_cmnt_v1	Thyroid - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char
pe_vascular_abn_v0	Vascular System - Abnormal? - Visit 0 (Baseline) - [Physical Exam Dataset 2]		.N="N/A" 0="No" 1="Yes" 9="Not Assessed"
pe_vascular_abn_v1	Vascular System - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		.F="No Record For This Visit" .M="Missing" 0="No"
pe_vascular_cmnt_v0	Vascular System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_vascular_cmnt_v1	Vascular System - Comments - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 2]		Char

Section 19: Lab Tests

Variable	Label	Description	Format Text
bldchem_albumin_abn_ever	Albumin - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
bldchem_albumin_abn_v0	Albumin - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_albumin_abn_v1	Albumin - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
bldchem_albumin_clinsig_ever	Albumin - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_albumin_clinsig_v0	Albumin - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_albumin_clinsig_v1	Albumin - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_albumin_result_v0	Albumin - Result (g/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_albumin_result_v1	Albumin - Result (g/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_alk_phos_abn_ever	Alkaline Phosphatase - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_alk_phos_abn_v0	Alkaline Phosphatase - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_alk_phos_abn_v1	Alkaline Phosphatase - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_alk_phos_clinsig_ever	Alkaline Phosphatase - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_alk_phos_clinsig_v0	Alkaline Phosphatase - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_alk_phos_clinsig_v1	Alkaline Phosphatase - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
bldchem_alk_phos_result_v0	Alkaline Phosphatase - Result (mkat/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_alk_phos_result_v1	Alkaline Phosphatase - Result (mkat/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_anion_gap_abn_ever	Anion Gap - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_anion_gap_abn_v0	Anion Gap - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_anion_gap_abn_v1	Anion Gap - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_anion_gap_clinsig_ever	Anion Gap - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_anion_gap_clinsig_v0	Anion Gap - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_anion_gap_clinsig_v1	Anion Gap - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_anion_gap_result_v0	Anion Gap - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_anion_gap_result_v1	Anion Gap - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_bicarb_abn_ever	Bicarbonate - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bicarb_abn_v0	Bicarbonate - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_bicarb_abn_v1	Bicarbonate - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bicarb_clinsig_ever	Bicarbonate - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bicarb_clinsig_v0	Bicarbonate - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
bldchem_bicarb_clinsig_v1	Bicarbonate - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bicarb_result_v0	Bicarbonate - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_bicarb_result_v1	Bicarbonate - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_bilirubin_abn_ever	Bilirubin - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bilirubin_abn_v0	Bilirubin - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_bilirubin_abn_v1	Bilirubin - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bilirubin_clinsig_ever	Bilirubin - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bilirubin_clinsig_v0	Bilirubin - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_bilirubin_clinsig_v1	Bilirubin - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bilirubin_result_v0	Bilirubin - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_bilirubin_result_v1	Bilirubin - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_bun_abn_ever	BUN - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bun_abn_v0	BUN - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_bun_abn_v1	BUN - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bun_clinsig_ever	BUN - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bun_clinsig_v0	BUN - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
bldchem_bun_clinsig_v1	BUN - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_bun_result_v0	BUN - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_bun_result_v1	BUN - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_calcium_abn_ever	Calcium - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_calcium_abn_v0	Calcium - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_calcium_abn_v1	Calcium - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_calcium_clinsig_ever	Calcium - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_calcium_clinsig_v0	Calcium - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_calcium_clinsig_v1	Calcium - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_calcium_result_v0	Calcium - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_calcium_result_v1	Calcium - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_chloride_abn_ever	Chloride - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
bldchem_chloride_abn_v0	Chloride - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_chloride_abn_v1	Chloride - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
bldchem_chloride_clinsig_ever	Chloride - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_chloride_clinsig_v0	Chloride - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
bldchem_chloride_clinsig_v1	Chloride - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_chloride_result_v0	Chloride - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_chloride_result_v1	Chloride - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_creatinine_abn_ever	Creatinine - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_creatinine_abn_v0	Creatinine - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_creatinine_abn_v1	Creatinine - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_creatinine_clinsig_ever	Creatinine - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_creatinine_clinsig_v0	Creatinine - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_creatinine_clinsig_v1	Creatinine - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_creatinine_result_v0	Creatinine - Result (mumol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_creatinine_result_v1	Creatinine - Result (mumol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_egfr_abn_ever	eGFR - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_egfr_abn_v0	eGFR - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_egfr_abn_v1	eGFR - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_egfr_clinsig_ever	eGFR - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_egfr_clinsig_v0	eGFR - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"

UWI2016-07-01 - Enhanced Person: Data Dictionary
07/10/2020

Variable	Label	Description	Format Text
bldchem_egfr_clinsig_v1	eGFR - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_egfr_result_v0	eGFR - Result (mL/min/1.73) - Visit 0 (Baseline) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_egfr_result_v1	eGFR - Result (mL/min/1.73) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_glucose_abn_ever	Glucose - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
bldchem_glucose_abn_v0	Glucose - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
bldchem_glucose_abn_v1	Glucose - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
bldchem_glucose_clinsig_ever	Glucose - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_glucose_clinsig_v0	Glucose - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_glucose_clinsig_v1	Glucose - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_glucose_result_v0	Glucose - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_glucose_result_v1	Glucose - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_potassium_abn_ever	Potassium - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_potassium_abn_v0	Potassium - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_potassium_abn_v1	Potassium - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_potassium_clinsig_ever	Potassium - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
bldchem_potassium _clinsig_v0	Potassium - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_potassium _clinsig_v1	Potassium - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_potassium _result_v0	Potassium - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_potassium _result_v1	Potassium - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_protein_a bn_ever	Protein - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_protein_a bn_v0	Protein - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_protein_a bn_v1	Protein - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_protein_cli nsig_ever	Protein - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_protein_cli nsig_v0	Protein - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_protein_cli nsig_v1	Protein - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_protein_re sult_v0	Protein - Result (g/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_protein_re sult_v1	Protein - Result (g/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_sgot_ast_ abn_ever	SGOT/AST - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sgot_ast_ abn_v0	SGOT/AST - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_sgot_ast_ abn_v1	SGOT/AST - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sgot_ast_ clinsig_ever	SGOT/AST - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sgot_ast_ clinsig_v0	SGOT/AST - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
bldchem_sgot_ast_clinsig_v1	SGOT/AST - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sgot_ast_result_v0	SGOT/AST - Result (mukat/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_sgot_ast_result_v1	SGOT/AST - Result (mukat/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_sgpt_alt_abn_ever	SGPT/ALT - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sgpt_alt_abn_v0	SGPT/ALT - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_sgpt_alt_abn_v1	SGPT/ALT - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sgpt_alt_clinsig_ever	SGPT/ALT - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sgpt_alt_clinsig_v0	SGPT/ALT - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_sgpt_alt_clinsig_v1	SGPT/ALT - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sgpt_alt_result_v0	SGPT/ALT - Result (mukat/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_sgpt_alt_result_v1	SGPT/ALT - Result (mukat/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
bldchem_sodium_abn_ever	Sodium - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sodium_abn_v0	Sodium - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
bldchem_sodium_abn_v1	Sodium - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sodium_clinsig_ever	Sodium - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sodium_clinsig_v0	Sodium - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
bldchem_sodium_clinsig_v1	Sodium - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
bldchem_sodium_result_v0	Sodium - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
bldchem_sodium_result_v1	Sodium - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
hema_basophils_abn_ever	Basophils - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_basophils_abn_v0	Basophils - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_basophils_abn_v1	Basophils - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_basophils_clinsig_ever	Basophils - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_basophils_clinsig_v0	Basophils - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_basophils_clinsig_v1	Basophils - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_basophils_result_v0	Basophils - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
hema_basophils_result_v1	Basophils - Result (10^9/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
hema_eosinophils_abn_ever	Eosinophils - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_eosinophils_abn_v0	Eosinophils - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
hema_eosinophils_abn_v1	Eosinophils - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_eosinophils_clinsig_ever	Eosinophils - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
hema_eosinophils_clinsig_v0	Eosinophils - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_eosinophils_clinsig_v1	Eosinophils - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_eosinophils_result_v0	Eosinophils - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
hema_eosinophils_result_v1	Eosinophils - Result (10^9/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
hema_hematocrit_abn_ever	Hematocrit - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
hema_hematocrit_abn_v0	Hematocrit - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_hematocrit_abn_v1	Hematocrit - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
hema_hematocrit_clinsig_ever	Hematocrit - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_hematocrit_clinsig_v0	Hematocrit - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_hematocrit_clinsig_v1	Hematocrit - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_hematocrit_result_v0	Hematocrit - Result (Proportion) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
hema_hematocrit_result_v1	Hematocrit - Result (Proportion) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
hema_hemoglobin_abn_ever	Hemoglobin - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
hema_hemoglobin_abn_v0	Hemoglobin - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
hema_hemoglobin_abn_v1	Hemoglobin - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"

Variable	Label	Description	Format Text
hema_hemoglobin_ clinsig_ever	Hemoglobin - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_hemoglobin_ clinsig_v0	Hemoglobin - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_hemoglobin_ clinsig_v1	Hemoglobin - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_hemoglobin_ result_v0	Hemoglobin - Result (g/dL) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
hema_hemoglobin_ result_v1	Hemoglobin - Result (g/dL) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
hema_lymphocytes _abn_ever	Lymphocytes - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
hema_lymphocytes _abn_v0	Lymphocytes - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
hema_lymphocytes _abn_v1	Lymphocytes - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
hema_lymphocytes _clinsig_ever	Lymphocytes - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_lymphocytes _clinsig_v0	Lymphocytes - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_lymphocytes _clinsig_v1	Lymphocytes - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_lymphocytes _result_v0	Lymphocytes - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
hema_lymphocytes _result_v1	Lymphocytes - Result (10^9/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
hema_monocytes_a bn_ever	Monocytes - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_monocytes_a bn_v0	Monocytes - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
hema_monocytes_abn_v1	Monocytes - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_monocytes_clinsig_ever	Monocytes - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_monocytes_clinsig_v0	Monocytes - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_monocytes_clinsig_v1	Monocytes - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_monocytes_result_v0	Monocytes - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
hema_monocytes_result_v1	Monocytes - Result (10^9/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
hema_neutrophils_abn_ever	Neutrophils - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_neutrophils_abn_v0	Neutrophils - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_neutrophils_abn_v1	Neutrophils - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_neutrophils_clinsig_ever	Neutrophils - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_neutrophils_clinsig_v0	Neutrophils - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_neutrophils_clinsig_v1	Neutrophils - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_neutrophils_result_v0	Neutrophils - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
hema_neutrophils_result_v1	Neutrophils - Result (10^9/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
hema_platelets_abn_ever	Platelets - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
hema_platelets_abn_v0	Platelets - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_platelets_abn_v1	Platelets - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_platelets_clinsig_ever	Platelets - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_platelets_clinsig_v0	Platelets - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_platelets_clinsig_v1	Platelets - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_platelets_result_v0	Platelets - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
hema_platelets_result_v1	Platelets - Result (10^9/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
hema_wbc_abn_ever	WBC - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_wbc_abn_v0	WBC - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_wbc_abn_v1	WBC - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_wbc_clinsig_ever	WBC - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_wbc_clinsig_v0	WBC - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
hema_wbc_clinsig_v1	WBC - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
hema_wbc_result_v0	WBC - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
hema_wbc_result_v1	WBC - Result (10^9/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
labs_fasting_v0	Fasting? - Visit 0 (Baseline) - [Lab Tests]		.N="N/A" 0="No" 1="Yes" 9="Unknown"

Variable	Label	Description	Format Text
labs_fasting_v1	Fasting? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" 0="No" 1="Yes"
labs_spec_col_dt_v0	Specimen Collection Date - Visit 0 (Baseline) - [Lab Tests]		SAS Date .N="N/A"
labs_spec_col_dt_v1	Specimen Collection Date - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		SAS Date .F="No Record For This Visit"
labs_spec_col_time_v0	Specimen Collection Time - Visit 0 (Baseline) - [Lab Tests]		Numeric .N="N/A"
labs_spec_col_time_v1	Specimen Collection Time - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit"

Section 20: Pathologic Characteristics

Variable	Label	Description	Format Text
path_diff	Differentiation - [Pathologic Characteristics]		.R="Not Randomized" 1="In situ" 2="Grade I" 6="Unknown/Not specified"
path_hist	Histology - [Pathologic Characteristics]		.R="Not Randomized" 1="Squamous cell carcinoma NOS" 2="Keratinizing squamous cell carcinoma" 3="Non-keratinizing squamous cell carcinoma"
path_p16_neg_meta	p16-: Metastasis (V8) - [Pathologic Characteristics]		Numeric .M="Missing" .R="Not Randomized"
path_p16_neg_node	p16-: Node Stage (V8) - [Pathologic Characteristics]		Numeric .M="Missing" .R="Not Randomized"
path_p16_neg_tumor	p16-: Tumor Stage (V8) - [Pathologic Characteristics]		Numeric .M="Missing" .R="Not Randomized"
path_p16_pos_meta	p16+: Metastasis (V8) - [Pathologic Characteristics]		.M="Missing" .R="Not Randomized" .U="Unknown" 1="cM0"
path_p16_pos_node	p16+: Node Stage (V8) - [Pathologic Characteristics]		.M="Missing" .R="Not Randomized" 3="pN1" 4="pN2"
path_p16_pos_tumor	p16+:Tumor Stage (V8) - [Pathologic Characteristics]		.M="Missing" .R="Not Randomized" 1="T1"
path_p16_status	p16 Status - [Pathologic Characteristics]		.R="Not Randomized" 1="Positive" 3="Not Tested"
path_spec_col_dt	Date Specimen Collected - [Pathologic Characteristics]		SAS Date .R="Not Randomized"
path_tumor_subsite_loc	Tumor Subsite Location - [Pathologic Characteristics]		.R="Not Randomized" 1="Oral tongue (front 2/3)" 9="Tonsil" 11="Base of tongue (back 1/3)"

Section 21: Specimen Collection

Variable	Label	Description	Format Text
spec_bld_cmnt_v0	Comments - Visit 0 (Baseline) - [Specimen Collection(Blood)]		Char
spec_bld_cmnt_v1	Comments - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		Char
spec_bld_col_dt_v0	Date Specimen Collected - Visit 0 (Baseline) - [Specimen Collection(Blood)]		SAS Date .N="N/A"
spec_bld_col_dt_v1	Date Specimen Collected - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		SAS Date .N="N/A" .O="Not Obtained"
spec_bld_col_time_v0	Time Specimen Collected - Visit 0 (Baseline) - [Specimen Collection(Blood)]		Numeric .N="N/A"
spec_bld_col_time_v1	Time Specimen Collected - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		Numeric .N="N/A" .O="Not Obtained"
spec_bld_last_agent_dt_v0	Date Last Study Agent Taken - Visit 0 (Baseline) - [Specimen Collection(Blood)]		SAS Date .M="Missing" .N="N/A"
spec_bld_last_agent_dt_v1	Date Last Study Agent Taken - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		SAS Date .N="N/A" .O="Not Obtained"
spec_bld_last_agent_time_v0	Time Last Study Agent Taken - Visit 0 (Baseline) - [Specimen Collection(Blood)]		Numeric .M="Missing" .N="N/A"
spec_bld_last_agent_time_v1	Time Last Study Agent Taken - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		Numeric .N="N/A" .O="Not Obtained"
spec_bld_ship_dt_v0	Specimen Shipping Date - Visit 0 (Baseline) - [Specimen Collection(Blood)]		SAS Date .M="Missing" .N="N/A"

Variable	Label	Description	Format Text
spec_bld_ship_dt_v1	Specimen Shipping Date - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		SAS Date .M="Missing" .N="N/A" .O="Not Obtained"
spec_bld_storage_temp_v0	Storage Temperature (C) - Visit 0 (Baseline) - [Specimen Collection(Blood)]		Numeric .N="N/A"
spec_bld_storage_temp_v1	Storage Temperature (C) - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		Numeric .N="N/A" .O="Not Obtained"
spec_tis_cmnt_norm_v0	Comments - Normal Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		Char
spec_tis_cmnt_norm_v1	Comments - Normal Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		Char
spec_tis_cmnt_tmr_v0	Comments - Tumor Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		Char
spec_tis_cmnt_tmr_v1	Comments - Tumor Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		Char
spec_tis_col_dt_norm_v0	Date Specimen Collected - Normal Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		SAS Date .N="N/A"
spec_tis_col_dt_norm_v1	Date Specimen Collected - Normal Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
spec_tis_col_dt_tmr_v0	Date Specimen Collected - Tumor Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		SAS Date .N="N/A"
spec_tis_col_dt_tmr_v1	Date Specimen Collected - Tumor Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
spec_tis_col_time_norm_v0	Time Specimen Collected - Normal Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		Numeric .N="N/A"

Variable	Label	Description	Format Text
spec_tis_col_time_norm_v1	Time Specimen Collected - Normal Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"
spec_tis_col_time_tmr_v0	Time Specimen Collected - Tumor Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		Numeric .N="N/A"
spec_tis_col_time_tmr_v1	Time Specimen Collected - Tumor Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"
spec_tis_last_dt_norm_v0	Date Last Study Agent Taken - Normal Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
spec_tis_last_dt_norm_v1	Date Last Study Agent Taken - Normal Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
spec_tis_last_dt_tmr_v0	Date Last Study Agent Taken - Tumor Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
spec_tis_last_dt_tmr_v1	Date Last Study Agent Taken - Tumor Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
spec_tis_last_time_norm_v0	Time Last Study Agent Taken - Normal Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"
spec_tis_last_time_norm_v1	Time Last Study Agent Taken - Normal Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"
spec_tis_last_time_tmr_v0	Time Last Study Agent Taken - Tumor Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"

Variable	Label	Description	Format Text
spec_tis_last_time_tmr_v1	Time Last Study Agent Taken - Tumor Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"
spec_tis_obtained_norm_v0	Tissue Obtained? - Normal Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		.N="N/A" 1="Yes"
spec_tis_obtained_norm_v1	Tissue Obtained? - Normal Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		.N="N/A" 0="No" 1="Yes"
spec_tis_obtained_tmr_v0	Tissue Obtained? - Tumor Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		.N="N/A" 1="Yes"
spec_tis_obtained_tmr_v1	Tissue Obtained? - Tumor Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		.N="N/A" 0="No" 1="Yes"
spec_tis_ship_dt_norm_v0	Specimen Shipping Date - Normal Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
spec_tis_ship_dt_norm_v1	Specimen Shipping Date - Normal Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
spec_tis_ship_dt_tmr_v0	Specimen Shipping Date - Tumor Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
spec_tis_ship_dt_tmr_v1	Specimen Shipping Date - Tumor Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
spec_tis_storage_temp_norm_v0	Storage Temperature (C) - Normal Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		Numeric .N="N/A"
spec_tis_storage_temp_norm_v1	Storage Temperature (C) - Normal Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"
spec_tis_storage_temp_tmr_v0	Storage Temperature (C) - Tumor Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		Numeric .N="N/A"

Variable	Label	Description	Format Text
spec_tis_storage_temp_tmr_v1	Storage Temperature (C) - Tumor Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"

Section 22: Alcohol Assessment

Variable	Label	Description	Format Text
alc_base_12_drinks_in_life	In Your Entire Life, Have You Had At Least 12 Drinks Of Any Kind Of Alcoholic Beverage? - [Alcohol Assessment (Baseline)]	Question 1. In your entire life, have you had at least 12 drinks of any kind of alcoholic beverage?	.N="N/A" .R="Not Randomized" 1="Yes"
alc_base_age_drink_reg	At What Age Did You Begin Drinking Regularly? - [Alcohol Assessment (Baseline)]	Question 7. (ver. 2.1) / 9. (ver. 3.2, 4.1) At what age did you begin drinking regularly?	Numeric .D="Don't Know/Not Sure" .N="N/A" .R="Not Randomized"
alc_base_consume_now	Do You NOW Consume Alcohol? - [Alcohol Assessment (Baseline)]	Question 2. (ver. 2.1) Do you NOW consume alcohol?	.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 3="Not at All"
alc_base_drink_beer	What Type(s) Of Alcohol Do You Drink? - Beer? - [Alcohol Assessment (Baseline)]	Question 8. (ver. 2.1) / 10. (ver. 3.2, 4.1) What type (s) of alcohol do you drink? - beer was selected.	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
alc_base_drink_liquor	What Type(s) Of Alcohol Do You Drink? - Liquor? - [Alcohol Assessment (Baseline)]	Question 8. (ver. 2.1) / 10. (ver. 3.2, 4.1) What type (s) of alcohol do you drink? - liquor was selected.	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
alc_base_drinks_per_day	In The Past 12 Months, On Those Days That You Drank Alcoholic Beverages, On Average, How Many Drinks Did You Have Per Day? - [Alcohol Assessment (Baseline)]	Question 3. (ver. 3.2, 4.1) In the past 12 months, on those days that you drank alcoholic beverages, on average, how many drinks did you have per day?	Numeric .D="Don't Know/Not Sure" .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
alc_base_five_or_more_ever	Was There Ever A Time Or Times In Your Life When You Drank 5 Or More Drinks Of Any Kind Of Alcoholic Beverage Almost Every Day? - [Alcohol Assessment (Baseline)]	Question 5. (ver. 3.2, 4.1) Was there ever a time or times in your life when you drank 5 or more drinks of any kind of alcoholic beverage almost every day?	.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 0="No"
alc_base_five_or_more_past12m	In The Past 12 Months, On How Many Days Did You Have 5 Or More Drinks Of Any Alcoholic Beverage? - [Alcohol Assessment (Baseline)]	Question 4a. (ver. 3.2, 4.1) In the past 12 months, on how many days did you have 5 or more drinks of any alcoholic beverage?	Numeric .D="Don't Know/Not Sure" .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
alc_base_heaviest_drink_num	At The Heaviest Point, Either Now Or In The Past, On The Days When You Drank, About How Many Drinks Did You Drink On The Average? - [Alcohol Assessment (Baseline)]	Question 4a. (ver. 2.1) / 7a. (ver. 3.2, 4.1) At the heaviest point, either now or in the past, on the days when you drank, about how many drinks did you drink on the average?	Numeric .D="Don't Know/Not Sure" .N="N/A" .R="Not Randomized"

Variable	Label	Description	Format Text
alc_base_past12m_freq	In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcoholic Beverage? (Frequency) - [Alcohol Assessment (Baseline)]	Question 5b. (ver. 2.1) / 2b. (ver. 3.2, 4.1) Frequency	Char
alc_base_past12m_num	In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcoholic Beverage? (Number) - [Alcohol Assessment (Baseline)]	Question 5a. (ver. 2.1) / 2a. (ver. 3.2, 4.1) In the past 12 months, on average, how often did you drink any type of alcoholic beverage?	Numeric .N="N/A" .R="Not Randomized"
alc_base_time_since_drank_reg	If You Do Not Currently Drink Alcoholic Beverages, But Did In The Past, How Long Has It Been Since You Last Drank Regularly - [Alcohol Assessment (Baseline)]	Question 3. (ver. 2.1) / 6. (ver. 3.2, 4.1) If you do not currently drink alcoholic beverages, but did in the past, how long has it been since you last drank regularly?	.N="N/A" .R="Not Randomized" 0="Never Drank Regularly" 6="Between 5 And 15 Years (5 To 15 Years Ago)"
alc_base_years_drink_reg	How Many Years Have You Been Drinking (Or Did You Drink) Regularly? - [Alcohol Assessment (Baseline)]	Question 6a. (ver. 2.1) / 8a. (ver. 3.2, 4.1) How many years have you been drinking (or did you drink) regularly?	Numeric .D="Don't Know/Not Sure" .N="N/A" .R="Not Randomized"
alc_fu_drink_any	During The Past 30 Days, Did You Drink Any Alcoholic Beverages? - [Alcohol Assessment (Follow-up)]	Question 1. During the past 30 days, did you drink any alcoholic beverages?	.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
alc_fu_drink_freq	During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages, On The Average? (Frequency) - [Alcohol Assessment (Follow-up)]	Question 2b. Frequency	Char
alc_fu_drink_num	During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages, On The Average? (Number) - [Alcohol Assessment (Follow-up)]	Question 2a. During the past 30 days, how many days per week or per month did you drink any alcoholic beverages, on the average?	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
alc_fu_drinks_per_day	On The Days When You Drank, On Average, About How Many Drinks Did You Have? - [Alcohol Assessment (Follow-up)]	Question 3a. On the days when you drank, on average, about how many drinks did you have?	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
alc_fu_five_or_more	In The Past 30 Days, On How Many Days Did You Have 5 Or More Drinks Per Day? - [Alcohol Assessment (Follow-up)]	Question 4a. In the past 30 days, on how many days did you have 5 or more drinks per day?	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 23: Tobacco Assessment

Variable	Label	Description	Format Text
tob_base_after_dx_cncr	After Diagnosis, And Before Treatment Started - [Tobacco Assessment (Baseline)]	Question b. (ver. 2.1) After diagnosis, and before treatment started	.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 3="Didn't smoke at all"
tob_base_age_first_smoked	How Old Were You When You First Smoked A Cigarette (Even One Or Two Puffs)? - [Tobacco Assessment (Baseline)]	Question 2. How old were you when you first smoked a cigarette (even one or two puffs)?	Numeric .M="Missing" .N="N/A" .R="Not Randomized"
tob_base_age_smoked_reg	How Old Were You When You First Began Smoking Cigarettes Regularly? - [Tobacco Assessment (Baseline)]	Question 3. How old were you when you first began smoking cigarettes regularly?	Numeric .M="Missing" .N="N/A" .R="Not Randomized"
tob_base_amt_smoked_2d	How Frequently Did You Smoke From 2 Days Before Your Last Cancer Surgery To 2 Days After - [Tobacco Assessment (Baseline)]	Question c. (ver. 2.1) How frequently did you smoke from 2 days before your last cancer surgery to 2 days after	Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
tob_base_amt_smoked_after	How Frequently Did You Smoke After Treatment Ended - [Tobacco Assessment (Baseline)]	Question e. (ver. 2.1) How frequently did you smoke after treatment ended	Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
tob_base_amt_smoked_during	How Frequently Did You Smoke During The Course Of Treatment - [Tobacco Assessment (Baseline)]	Question d. (ver. 2.1) How frequently did you smoke during the course of treatment	Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
tob_base_any_cig_past30d	In The Past 30 Days, Have You Smoked Any Cigarettes, Even One Or Two Puffs? - [Tobacco Assessment (Baseline)]	Question 10a. (ver. 2.1) In the past 30 days, have you smoked any cigarettes, even one or two puffs?	.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No"
tob_base_avg_cigs_smoked	On Average When You Have Smoked, About How Many Cigarettes Do You (Or Did You) Smoke A Day? - [Tobacco Assessment (Baseline)]	Question 5. On average when you have smoked, about how many cigarettes do you (or did you) smoke a day?	Numeric .M="Missing" .N="N/A" .R="Not Randomized"
tob_base_cancer_assist	Since You Were First Told You Had Cancer, What Assistance Have You Used To Quit (Or To Stay Off) Smoking Cigarettes? - [Tobacco Assessment (Baseline)]	Question 12. (ver. 2.1) Since you were first told you had cancer, what assistance have you used to quit (or to stay off) smoking cigarettes?	.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 9="None"

Variable	Label	Description	Format Text
tob_base_cancer_quit	Since You Were First Told You Had Cancer, Which Of The Following Products Have You Used To Quit (Or To Stay Off) Smoking Cigarettes? - [Tobacco Assessment (Baseline)]	Question 11. (ver. 2.1) Since you were first told you had cancer, which of the following products have you used to quit (or to stay off) smoking cigarettes?	.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 9="None"
tob_base_doctor_advised	Have Your Cancer Doctors Advised You To Quit Smoking Cigarettes? - [Tobacco Assessment (Baseline)]	Question 13. (ver. 2.1) Have your cancer doctors advised you to quit smoking cigarettes?	Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
tob_base_how_often_other	How Often Do You/Did You Use Other Forms Of Tobacco? - [Tobacco Assessment (Baseline)]	Question 10a. (ver. 3.2, 4.1) How often do you/did you use other forms of tobacco?	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 1="Every day"
tob_base_live_smoke_ever	Thinking Of All Your Childhood And Adult Years, Have You Ever Lived In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Assessment (Baseline)]	Question 21. (ver. 2.1) / 16a. (ver. 3.2, 4.1) Thinking of all your childhood and adult years, have you ever lived in a place where other people smoked cigarettes indoors?	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
tob_base_live_smoke_ever_yrs	How Many Years Total Have You Lived In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Assessment (Baseline)]	Question 16b. (ver. 3.2, 4.1) In total, for about how many years?	Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
tob_base_live_smoke_past30d	In The Past 30 Days, Have You Lived In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Assessment (Baseline)]	Question 19a. (ver. 2.1) / 14. (ver. 3.2, 4.1) Lived in a place where other people smoked cigarettes indoors?	.N="N/A" .R="Not Randomized" 0="No"
tob_base_live_with_smoker	Are You Currently Living With A Smoker? - [Tobacco Assessment (Baseline)]	Question 19. (ver. 2.1) / 13. (ver. 3.2, 4.1) Are you currently living with a smoker?	.N="N/A" .R="Not Randomized" 0="No"
tob_base_longest_time_off_cncr	Since You Were First Told You Had Cancer, What Was The Longest Time You Stayed (Or Have Stayed) Off Cigarettes? - [Tobacco Assessment (Baseline)]	Question 9. (ver. 2.1) Since you were first told you had cancer, what was the longest time you stayed (or have stayed) off cigarettes?	.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Stayed off cigarettes entire time since diagnosis OR"
tob_base_now_smoke_cigs	Do You Now Smoke Cigarettes? - [Tobacco Assessment (Baseline)]	Question 6. (ver. 3.2, 4.1) Do you now smoke cigarettes?	.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 3="Not at all"

Variable	Label	Description	Format Text
tob_base_other_freq	Daily Frequency Of Use Of Other Forms Of Tobacco - [Tobacco Assessment (Baseline)]	Question 10c. (ver. 3.2, 4.1) Daily frequency of use of other forms of tobacco	Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
tob_base_products_used_past30d	In The Past 30 Days, Which Of The Following Products Have You Used? - [Tobacco Assessment (Baseline)]	Question 18. (ver. 2.1) In the past 30 days, which of the following products have you used?	.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 11="None"
tob_base_products_used_reg	Which Of The Following Products Have You Ever Used Regularly? - [Tobacco Assessment (Baseline)]	Question 17. (ver. 2.1) / 11a. (ver. 3.2, 4.1) Which of the following products have you ever used regularly?	.M="Missing" .N="N/A" .R="Not Randomized" 8="Smokeless tobacco, like dip, chew or snuff" 11="None"
tob_base_products_used_reg_cncr	Since You Were First Told You Had Cancer, Which Of The Following Products Have You Used Regularly? - [Tobacco Assessment (Baseline)]	Question 8. (ver. 2.1) Since you were first told you had cancer, which of the following products have you used regularly?	.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 11="None"
tob_base_quit_assist_past30d	In The Past 30 Days, What Assistance Have You Used To Quit (Or To Stay Off) Smoking Cigarettes? - [Tobacco Assessment (Baseline)]	Question 16. (ver. 2.1) In the past 30 days, what assistance have you used to quit (or to stay off) smoking cigarettes?	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
tob_base_quit_products_past30d	In The Past 30 Days, What, If Any, Products Have You Used To Quit (Or To Stay Off) Smoking Cigarettes? - [Tobacco Assessment (Baseline)]	Question 15. (ver. 2.1) In the past 30 days, what, if any, products have you used to quit (or to stay off) smoking cigarettes?	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
tob_base_smoked_100	Have You Smoked At Least 100 Cigarettes (5 Packs = 100 Cigarettes) In Your Entire Life? - [Tobacco Assessment (Baseline)]	Question 1. Have you smoked at least 100 cigarettes (5 packs = 100 cigarettes) in your entire life?	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
tob_base_time_after_wake	How Soon After You Wake Up Do You Smoke Your First Cigarette? - [Tobacco Assessment (Baseline)]	Question 7. (ver. 3.2, 4.1) How soon after you wake up do you smoke your first cigarette?	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized"
tob_base_time_since_last_cig	How Long Has It Been Since You Last Smoked A Cigarette (Even One Or Two Puffs)? - [Tobacco Assessment (Baseline)]	Question 6. (ver. 2.1) / 8a. (ver. 3.2, 4.1) How long has it been since you last smoked a cigarette (even one or two puffs)?	.M="Missing" .N="N/A" .R="Not Randomized" 5="More than 1 year" 6="Don't know/Don't remember"
tob_base_time_since_reg_use	If You Do Not Currently Use Other Forms Of Tobacco, But Did In The Past, How Long Has It Been Since You Last Used Other Forms Of Tobacco Regularly? - [Tobacco Assessment (Baseline)]	Question 12. (ver. 3.2, 4.1) If you do not currently use other forms of tobacco, but did in the past, how long has it been since you last used other forms of tobacco regularly?	.F="No Record For This Visit" .M="Missing" .N="N/A" .R="Not Randomized" 6="Between 5 and 15 years (5-15 years ago)"

Variable	Label	Description	Format Text
tob_base_trying_to_quit	In The Past 30 Days, Have You Been Trying To Quit (Or Trying To Stay Off) Smoking Cigarettes? - [Tobacco Assessment (Baseline)]	Question 14. (ver. 2.1) In the past 30 days, have you been trying to quit (or trying to stay off) smoking cigarettes?	.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No"
tob_base_used_other	Have You Ever Used Other Forms Of Tobacco, Not Including Cigarettes? - [Tobacco Assessment (Baseline)]	Question 9. (ver. 3.2, 4.1) Have you ever used other forms of tobacco, not including cigarettes?	.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 0="No" 1="Yes"
tob_base_work_smoke_ever	Thinking Of All The Years You Have Worked, Have You Ever Worked In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Assessment (Baseline)]	Question 22a. (ver. 2.1) / 17a. (ver. 3.2, 4.1) Thinking of all the years you have worked, have you ever worked in a place where other people smoked cigarettes indoors?	.N="N/A" .R="Not Randomized" 0="No" 1="Yes"
tob_base_work_smoke_ever_yrs	How Many Years Total Have You Worked In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Assessment (Baseline)]	Question 22b. (ver. 2.1) / 17b. (ver. 3.2, 4.1) How many years total have you worked in a place where other people smoked cigarettes indoors?	Numeric .M="Missing" .N="N/A" .R="Not Randomized"
tob_base_work_smoke_past30d	In The Past 30 Days, Have You Worked In A Place Where Other People Smoked Cigarettes Indoors? - [Tobacco Assessment (Baseline)]	Question 19b. (ver. 2.1) / 15. (ver. 3.2, 4.1) Worked in a place where other people smoked cigarettes indoors?	.N="N/A" .R="Not Randomized" 0="No"
tob_base_year_b4_cncr	The Year Before You Were First Told You Had Cancer - [Tobacco Assessment (Baseline)]	Question a. (ver. 2.1) The year before you were first told you had cancer	.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 3="Didn't smoke at all"
tob_base_years_since_last_cig	Years Since You Last Smoked A Cigarette - [Tobacco Assessment (Baseline)]	Question 8c. (ver. 3.2, 4.1) Years since you last smoked a cigarette	Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
tob_base_years_smoked	How Many Total Years Have You Smoked (Or Did You Smoke) Cigarettes? Do Not Count Any Time You May Have Stayed Off Cigarettes. - [Tobacco Assessment (Baseline)]	Question 4. How many total years have you smoked (or did you smoke) cigarettes? Do not count any time you may have stayed off cigarettes.	Numeric .M="Missing" .N="N/A" .R="Not Randomized"
tob_fu_avg_cig_day	On Average When You Smoked, About How Many Cigarettes Do You (Or Did You) Smoke A Day? - [Tobacco Assessment (Follow-up)]	Question 2. On average when you smoked, about how many cigarettes do you (or did you) smoke a day?	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
tob_fu_cig_freq_after	After The End Of Study Treatment, How Often Did You Smoke Cigarettes? - [Tobacco Assessment (Follow-up)]	Question 9. After the end of study treatment, how often did you smoke cigarettes?	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

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Variable	Label	Description	Format Text
tob_fu_cig_freq_clinic	Since Your Last Visit To This Clinic, How Often Did You Smoke Cigarettes? - [Tobacco Assessment (Follow-up)]	Question 10. Since your last visit to this clinic, how often did you smoke cigarettes?	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
tob_fu_cig_freq_during	During Study Treatment, How Often Did You Smoke Cigarettes? - [Tobacco Assessment (Follow-up)]	Question 8. During study treatment, how often did you smoke cigarettes?	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
tob_fu_how_often_other	How Often Do You/Did You Use Other Forms Of Tobacco? - [Tobacco Assessment (Follow-up)]	Question 5a. How often do you/did you use other forms of tobacco?	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
tob_fu_now_smoke_cigs	Do You Now Smoke Cigarettes? - [Tobacco Assessment (Follow-up)]	Question 1. Do you now smoke cigarettes?	.F="No Record For This Visit" .R="Not Randomized" 3="Not at all"
tob_fu_other_freq	Daily Frequency Of Use Of Other Forms Of Tobacco - [Tobacco Assessment (Follow-up)]	Question 5c. Daily frequency of use of other forms of tobacco	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
tob_fu_other_since_last_vis	Since Your Last Visit, Have You Used Other Forms Of Tobacco, Not Including Cigarettes? - [Tobacco Assessment (Follow-up)]	Question 4. Since your last visit, have you used other forms of tobacco, not including cigarettes?	.F="No Record For This Visit" .R="Not Randomized" 0="No"
tob_fu_products_used	Since Your Last Visit, Which Of The Following Products Have You Used? - [Tobacco Assessment (Follow-up)]	Question 6. Since your last visit, which of the following products have you used?	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
tob_fu_time_since_last_cig	How Long Has It Been Since You Last Smoked A Cigarette (Even One Or Two Puffs)? - [Tobacco Assessment (Follow-up)]	Question 3a. How long has it been since you last smoked a cigarette (even one or two puffs)?	.F="No Record For This Visit" .R="Not Randomized" 5="More than 1 year" 6="Don't know/Don't remember"
tob_fu_time_since_reg_use	If You Do Not Currently Use Other Forms Of Tobacco, But Did In The Past, How Long Has It Been Since You Last Used Other Forms Of Tobacco Regularly? - [Tobacco Assessment (Follow-up)]	Question 7. If you do not currently use other forms of tobacco, but did in the past, how long has it been since you last used other forms of tobacco regularly?	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"
tob_fu_years_since_last_cig	Years Since You Last Smoked A Cigarette - [Tobacco Assessment (Follow-up)]	Question 3c. Years since you last smoked a cigarette	Numeric .F="No Record For This Visit" .M="Missing" .R="Not Randomized"

Section 24: Verification

Variable	Label	Description	Format Text
verif_dt	Form Date - [Verification]		SAS Date
verif_has_sig	Investigator's Signature - [Verification]		1="Yes"
verif_sig_dt	Investigator's Signature Date - [Verification]		SAS Date