

# UWI2016-07-01 - ENHANCED PERSON: DATA DICTIONARY

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## Document Summary

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## UWI2016-07-01 - Enhanced Person: Data Dictionary

### Section 1: Identifiers

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Variable	Label	Description	Format Text
<b>SEQUENCE_NO_</b>	Patient ID		Numeric

## Section 2: Study-wide

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Variable	Label	Description	Format Text
<b>protocol_ver</b>	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"
<b>rnd_dt</b>	Randomization Date		SAS Date .R="Not Randomized"
<b>rnd_num</b>	Randomization Number		Numeric .R="Not Randomized"
<b>rnd_washout_end_dt</b>	Washout End Date		SAS Date .N="N/A" .R="Not Randomized"
<b>rnd_washout_start_dt</b>	Washout Start Date		SAS Date .N="N/A" .R="Not Randomized"
<b>treatment</b>	Treatment		.R="Not Randomized" 1="ACTOplus" 2="Placebo"
<b>visit_dt_v0</b>	Date Of Visit 0 (Baseline)		SAS Date
<b>visit_dt_v1</b>	Date Of Visit 1 (End Of Study Or Early Termination)		SAS Date .F="No Record For This Visit"

## Section 3: Demographics

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Variable	Label	Description	Format Text
<b>min_country_code</b>	Country Code - [Minimum]		Char
<b>min_enroll_dt</b>	Date Of Enrollment - [Minimum]		SAS Date
<b>min_pay_method</b>	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"
<b>min_tac</b>	Treatment Assignment Code (TAC) - [Minimum]		0="TAC-0" 1="TAC-1"
<b>reg_age</b>	Participant Age - [Registration]	Age of the participant at registration (Derived from date of birth at registration).	Numeric
<b>reg_consent_biobank</b>	The Participant Agrees His/Her Samples And Related Information May Be Kept In A Biobank For Use In Future Health Research. - [Registration]		1="Yes"
<b>reg_consent_contact</b>	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"
<b>reg_consent_dt</b>	Informed Consent Date - [Registration]		SAS Date
<b>reg_consent_genetic</b>	The Participant Agrees That His/Her Genetic And Health Information Can Be Released, With No Direct Identifiers, Into Scientific Databases. - [Registration]		1="Yes"
<b>reg_consent_version</b>	Informed Consent Version Number - [Registration]		Numeric
<b>reg_consent_version_dt</b>	Informed Consent Version Date - [Registration]		SAS Date
<b>reg_dt</b>	Registration Date - [Registration]		SAS Date
<b>reg_eligible</b>	Does The Participant Satisfy All Of The Eligibility Criteria? - [Registration]		0="No" 1="Yes"

Variable	Label	Description	Format Text
<b>reg_ethnicity</b>	Ethnicity - [Registration]		2="Not Hispanic or Latino"
<b>reg_gender</b>	Gender - [Registration]		1="Female" 2="Male"
<b>reg_institution</b>	Registering Institution - [Registration]		1="MD017" 2="MN022" 4="WI020"
<b>reg_race</b>	Race - [Registration]		1="White" 5="American Indian or Alaska Native"
<b>reg_race_eth</b>	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

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Variable	Label	Description	Format Text
<b>screen_cmnt</b>	Comments - [Screening]		Char
<b>screen_dt</b>	Screening Date - [Screening]		SAS Date
<b>screen_find_out</b>	How Did The Participant Find Out About The Study? - [Screening]		1="Physician" 6="Nurse; Physician" 9="Other, specify"
<b>screen_find_out_ot_h</b>	Other, Specify - [Screening]		Char
<b>screen_met_criteria</b>	Does The Participant Meet The Screening Criteria? - [Screening]		0="No" 1="Yes"
<b>screen_referred</b>	Who Referred The Participant? - [Screening]		1="Physician"

## Section 5: Exclusion Criteria

Variable	Label	Description	Format Text
<b>excl_alcoholic</b>	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"
<b>excl_allergic</b>	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"
<b>excl_biguanide</b>	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"
<b>excl_blad_cncr</b>	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"
<b>excl_cationic</b>	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
<b>excl_chf_nyha</b>	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"
<b>excl_combo_drug</b>	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, Xigduo) in the past 3 months.	.N="N/A" 0="No"
<b>excl_concur_diabetes</b>	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"
<b>excl_contraindication</b>	Contraindication To Biopsy. - [Exclusion Criteria]	Question 4.2.10. Participant has a contraindication to biopsy.	.N="N/A" 0="No"
<b>excl_ctcae1_limb_edema</b>	> CTCAE Grade 1 Limb Edema - [Exclusion Criteria]	Question 4.2.13. Participant has > CTCAE grade 1 limb edema	.N="N/A" 0="No"
<b>excl_cyp2c8_inhibitor</b>	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"
<b>excl_enzyme_inducer</b>	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); secobarbital (Seconal)].	.N="N/A" 0="No"
<b>excl_hypoglycemia</b>	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
<b>excl_illness</b>	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"
<b>excl_invasive_cncr</b>	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"
<b>excl_investig_agent</b>	Taking Another Investigational Agent. - [Exclusion Criteria]	Question 4.2.8. Participant is taking another investigational agent.	.N="N/A" 0="No"
<b>excl_liver_disease</b>	History Of Liver Disease. - [Exclusion Criteria]	Question 4.2.12. Participant has a history of liver disease.	.N="N/A" 0="No"
<b>excl_macular_edema</b>	History Of Macular Edema. - [Exclusion Criteria]	Question 4.2.16. Participant has a history of macular edema.	.N="N/A" 0="No"
<b>excl_meets_criteria</b>	Meets Exclusion Criteria? - [Exclusion Criteria]		.N="N/A" 1="Yes"
<b>excl_pregnant</b>	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"
<b>excl_thiazol</b>	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
<b>excl_topiramate</b>	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); acetazolamide (Diamox Sequels); or dichlorphenamide (Keveyis, Daranide)].	.N="N/A" 0="No"
<b>excl_trt_prior</b>	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
<b>medhist_all_normal</b>	Are All Body Systems Normal? - [Medical History Dataset 1]		.N="N/A" 0="No"
<b>medhist_aller_spec</b>	Allergies Participant Has (Specified) - [Medical History Dataset 1]		Char
<b>medhist_allergies</b>	Does Participant Have Any Allergies? - [Medical History Dataset 1]		.N="N/A" 0="No" 1="Yes"
<b>medhist_breast_abn</b>	Breasts - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No"
<b>medhist_breast_cm nt</b>	Breasts - Comments - [Medical History Dataset 2]		Char
<b>medhist_cardio_abn</b>	Cardiovascular System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
<b>medhist_cardio_cm nt</b>	Cardiovascular System - Comments - [Medical History Dataset 2]		Char
<b>medhist_derma_abn</b>	Dermatologic System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
<b>medhist_derma_cm nt</b>	Dermatologic System - Comments - [Medical History Dataset 2]		Char
<b>medhist_endometa_abn</b>	Endocrine/Metabolic System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
<b>medhist_endometa_cmnt</b>	Endocrine/Metabolic System - Comments - [Medical History Dataset 2]		Char
<b>medhist_gastro_abn</b>	Gastrointestinal System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 1="Yes"
<b>medhist_gastro_cm nt</b>	Gastrointestinal System - Comments - [Medical History Dataset 2]		Char
<b>medhist_genit_abn</b>	Genitourinary System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 0="No" 1="Yes"
<b>medhist_genit_cmnt</b>	Genitourinary System - Comments - [Medical History Dataset 2]		Char
<b>medhist_heent_abn</b>	H/E/E/N/T System - Abnormal? - [Medical History Dataset 2]		.R="Not Randomized" 1="Yes"

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

## Section 8: Baseline Symptoms

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Variable	Label	Description	Format Text
<b>bsymp_any</b>	Any Baseline Symptoms? - [Baseline Symptoms]		0="No" 1="Yes"
<b>bsymp_comments1-5</b>	Comments - Baseline Symptom # - [Baseline Symptoms]		Char
<b>bsymp_ctcae_term1-5</b>	CTCAE Term - Baseline Symptom # - [Baseline Symptoms]		Char
<b>bsymp_description1-5</b>	Description - Baseline Symptom # - [Baseline Symptoms]		Char
<b>bsymp_grade1-5</b>	CTCAE Grade - Baseline Symptom # - [Baseline Symptoms]		.N="N/A" 1="1: Mild" 2="2: Moderate"
<b>bsymp_meddra_soc1-5</b>	MedDRA System Organ Class - Baseline Symptom # - [Baseline Symptoms]		Char
<b>bsymp_num</b>	Number Of Baseline Symptoms - [Baseline Symptoms]		Numeric
<b>bsymp_onset_dt1-5</b>	Onset Date - Baseline Symptom # - [Baseline Symptoms]		SAS Date .N="N/A" .U="Unknown"
<b>bsymp_stop_dt1-5</b>	Stop Date - Baseline Symptom # - [Baseline Symptoms]		SAS Date .C="Continuous" .N="N/A"

## Section 9: Concomitant Medications

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Variable	Label	Description	Format Text
<b>conmed_dose1-20</b>	Dose - Medication # - [Concomitant Medications]		Numeric .N="N/A"
<b>conmed_end_dt1-20</b>	End Date - Medication # - [Concomitant Medications]		SAS Date .C="Continuous" .N="N/A"
<b>conmed_freq1-20</b>	Frequency - Medication # - [Concomitant Medications]		Char
<b>conmed_medication1-20</b>	Medication Name - Medication # - [Concomitant Medications]		Char
<b>conmed_num</b>	Number Of Concomitant Medications Taken - [Concomitant Medications]		Numeric .N="N/A"
<b>conmed_reason1-20</b>	Reason - Medication # - [Concomitant Medications]		Char
<b>conmed_report_dt1-20</b>	Report Date - Medication # - [Concomitant Medications]		SAS Date .N="N/A"
<b>conmed_start_dt1-20</b>	Start Date - Medication # - [Concomitant Medications]		SAS Date .N="N/A" .U="Unknown"
<b>conmed_units1-20</b>	Units - Medication # - [Concomitant Medications]		Char

## Section 10: Intervention Administration

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Variable	Label	Description	Format Text
<b>intadm_agent_prov_dt</b>	Date Agent Was Provided - [Intervention Administration]		SAS Date .R="Not Randomized"
<b>intadm_agent_start_dt</b>	Date Agent Was Started - [Intervention Administration]		SAS Date .R="Not Randomized" .U="Unknown"

## Section 11: Contact

Variable	Label	Description	Format Text
<b>contact_any_ae_c1</b>	Any Symptoms Or Adverse Events? - Contact 1 (Interim Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
<b>contact_any_ae_c2</b>	Any Symptoms Or Adverse Events? - Contact 2 (Final Dosing Reminder Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
<b>contact_any_commed_c1</b>	Any Changes In Concomitant Medications? - Contact 1 (Interim Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
<b>contact_any_commed_c2</b>	Any Changes In Concomitant Medications? - Contact 2 (Final Dosing Reminder Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
<b>contact_compliant_c1</b>	Compliant With Study Protocol? - Contact 1 (Interim Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
<b>contact_compliant_c2</b>	Compliant With Study Protocol? - Contact 2 (Final Dosing Reminder Phone Contact) - [Contact]		.R="Not Randomized" 0="No" 1="Yes"
<b>contact_dt_c1</b>	Date Of Contact - Contact 1 (Interim Phone Contact) - [Contact]		SAS Date .R="Not Randomized"
<b>contact_dt_c2</b>	Date Of Contact - Contact 2 (Final Dosing Reminder Phone Contact) - [Contact]		SAS Date .R="Not Randomized"
<b>contact_time_c1</b>	Time Of Contact - Contact 1 (Interim Phone Contact) - [Contact]		Numeric .R="Not Randomized"
<b>contact_time_c2</b>	Time Of Contact - Contact 2 (Final Dosing Reminder Phone Contact) - [Contact]		Numeric .R="Not Randomized"
<b>contact_type_c1</b>	Type Of Contact - Contact 1 (Interim Phone Contact) - [Contact]		.R="Not Randomized" 1="Home Phone" 3="Home Cell"
<b>contact_type_c2</b>	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
<b>ae_gastro_max_attri b</b>	Gastrointestinal Disorders - Maximum Attribution - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 3="Possible" 4="Probable"
<b>ae_gastro_max_sev</b>	Gastrointestinal Disorders - Maximum Severity - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 1="Mild"
<b>ae_general_max_att rib</b>	General Disorders And Administration Site Conditions - Maximum Attribution - [Maximum AEs By Body System]		0="None" 1="Unrelated"
<b>ae_general_max_se v</b>	General Disorders And Administration Site Conditions - Maximum Severity - [Maximum AEs By Body System]		0="None" 1="Mild"
<b>ae_has_any</b>	Any Adverse Events? - [Adverse Events Summary]		.R="Not Randomized" 0="No" 1="Yes"
<b>ae_has_multiple</b>	Multiple Adverse Events? - [Adverse Events Summary]		.R="Not Randomized" 0="No" 1="Yes"
<b>ae_has_sae</b>	Any Serious Adverse Events? - [Adverse Events Summary]		.R="Not Randomized" 0="No"
<b>ae_has_severe</b>	Any Severe Adverse Events? - [Adverse Events Summary]		.R="Not Randomized" 0="No" 1="Yes"
<b>ae_max_attribution</b>	Maximum Attribution Of All Adverse Events - [Adverse Events Summary]		.R="Not Randomized" 0="None" 1="Unrelated" 3="Possible" 4="Probable"
<b>ae_max_severity</b>	Maximum Severity Of All Adverse Events - [Adverse Events Summary]		.R="Not Randomized" 0="None" 1="Mild" 2="Moderate" 3="Severe"
<b>ae_nervous_max_at rib</b>	Nervous System Disorders - Maximum Attribution - [Maximum AEs By Body System]		0="None" 1="Unrelated"
<b>ae_nervous_max_sev</b>	Nervous System Disorders - Maximum Severity - [Maximum AEs By Body System]		0="None" 1="Mild"

Variable	Label	Description	Format Text
<b>ae_num</b>	Number Of Adverse Events The Participant Experienced During The Study - [Adverse Events]		Numeric .N="N/A"
<b>ae_num_cat</b>	Categorized Number Of Adverse Events - [Adverse Events Summary]		Numeric .R="Not Randomized"
<b>ae_overall_max_attrib</b>	Overall - Maximum Attribution - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 1="Unrelated" 3="Possible" 4="Probable"
<b>ae_overall_max_sev</b>	Overall - Maximum Severity - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 1="Mild" 2="Moderate" 3="Severe"
<b>ae_resp_thor_medi_max_attrib</b>	Respiratory, Thoracic And Mediastinal Disorders - Maximum Attribution - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 1="Unrelated"
<b>ae_resp_thor_medi_max_sev</b>	Respiratory, Thoracic And Mediastinal Disorders - Maximum Severity - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 2="Moderate"
<b>ae_vascular_max_attrib</b>	Vascular Disorders - Maximum Attribution - [Maximum AEs By Body System]		.R="Not Randomized" 0="None" 1="Unrelated"
<b>ae_vascular_max_sev</b>	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
<b>agent_interrupted</b>	Was Agent Interrupted? - [Agent Interruption]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
<b>agent_mod_dose</b>	Modified Dosage - [Agent Modification]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
<b>agent_mod_dt</b>	Date Agent Was Modified - [Agent Modification]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
<b>agent_mod_freq</b>	Modified Frequency - [Agent Modification]		Char
<b>agent_mod_rsn</b>	Reason Agent Was Modified - [Agent Modification]		Numeric .F="No Record For This Visit" .N="N/A" .R="Not Randomized"
<b>agent_mod_spec</b>	Specific Reason Agent Was Modified - [Agent Modification]		Char
<b>agent_modified</b>	Was Agent Modified? - [Agent Modification]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>agent_restart_dt</b>	Date Agent Regimen Was Restarted - [Agent Interruption]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized" .U="Unknown"
<b>agent_restart_rsn</b>	Reason Agent Was Restarted - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Participant Decision"
<b>agent_restarted</b>	Was Agent Restarted? - [Agent Interruption]		.F="No Record For This Visit" .N="N/A" .R="Not Randomized" 1="Yes"
<b>agent_stop_dt</b>	Date Agent Regimen Was Stopped - [Agent Interruption]		SAS Date .F="No Record For This Visit" .N="N/A" .R="Not Randomized" .U="Unknown"
<b>agent_stop_rsn</b>	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
<b>agent_stop_spec</b>	Specific Reason Agent Was Stopped - [Agent Interruption]		Char

## Section 14: Compliance

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

## Section 15: Off Study

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

## Section 16: Pregnancy Specimen

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

## Section 17: Anthropometry

Variable	Label	Description	Format Text
<b>pe_bp_diastolic_v0</b>	Diastolic Blood Pressure (mmHg) - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A"
<b>pe_bp_diastolic_v1</b>	Diastolic Blood Pressure (mmHg) - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
<b>pe_bp_systolic_v0</b>	Systolic Blood Pressure (mmHg) - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A"
<b>pe_bp_systolic_v1</b>	Systolic Blood Pressure (mmHg) - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
<b>pe_ecog_v0</b>	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."
<b>pe_ecog_v1</b>	ECOG Performance Status - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		.N="N/A"
<b>pe_height_v0</b>	Height (cm) - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A"
<b>pe_height_v1</b>	Height (cm) - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
<b>pe_pulse_rate_v0</b>	Pulse Rate - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
<b>pe_pulse_rate_v1</b>	Pulse Rate - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
<b>pe_resp_rate_v0</b>	Respiration Rate - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
<b>pe_resp_rate_v1</b>	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
<b>pe_temperature_v0</b>	Temperature (C) - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
<b>pe_temperature_v1</b>	Temperature (C) - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
<b>pe_weight_v0</b>	Weight (kg) - Visit 0 (Baseline) - [Physical Exam Dataset 1]		Numeric .N="N/A"
<b>pe_weight_v1</b>	Weight (kg) - Visit 1 (End Of Study Or Early Termination) - [Physical Exam Dataset 1]		Numeric .N="N/A" .O="Not Obtained"
<b>vit_bmi_v0</b>	BMI - Visit 0 (Baseline) - [Vitals]		Numeric .R="Not Randomized"
<b>vit_bmi_v1</b>	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_cmnt_v0	Hematopoietic/Lymph System - Comments - Visit 0 (Baseline) - [Physical Exam Dataset 2]		Char
pe_hemalymph_cmnt_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
<b>bldchem_albumin_a bn_ever</b>	Albumin - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
<b>bldchem_albumin_a bn_v0</b>	Albumin - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_albumin_a bn_v1</b>	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"
<b>bldchem_albumin_c linsig_ever</b>	Albumin - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_albumin_c linsig_v0</b>	Albumin - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_albumin_c linsig_v1</b>	Albumin - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_albumin_r esult_v0</b>	Albumin - Result (g/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_albumin_r esult_v1</b>	Albumin - Result (g/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>bldchem_alk_phos_ abn_ever</b>	Alkaline Phosphatase - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_alk_phos_ abn_v0</b>	Alkaline Phosphatase - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_alk_phos_ abn_v1</b>	Alkaline Phosphatase - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_alk_phos_ clinsig_ever</b>	Alkaline Phosphatase - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_alk_phos_ clinsig_v0</b>	Alkaline Phosphatase - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_alk_phos_ clinsig_v1</b>	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
<b>bldchem_alk_phos_result_v0</b>	Alkaline Phosphatase - Result (mkat/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_alk_phos_result_v1</b>	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"
<b>bldchem_anion_gap_abn_ever</b>	Anion Gap - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_anion_gap_abn_v0</b>	Anion Gap - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_anion_gap_abn_v1</b>	Anion Gap - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_anion_gap_clinsig_ever</b>	Anion Gap - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_anion_gap_clinsig_v0</b>	Anion Gap - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_anion_gap_clinsig_v1</b>	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"
<b>bldchem_anion_gap_result_v0</b>	Anion Gap - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_anion_gap_result_v1</b>	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"
<b>bldchem_bicarb_abn_ever</b>	Bicarbonate - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bicarb_abn_v0</b>	Bicarbonate - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_bicarb_abn_v1</b>	Bicarbonate - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bicarb_clinsig_ever</b>	Bicarbonate - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bicarb_clinsig_v0</b>	Bicarbonate - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
<b>bldchem_bicarb_clinsig_v1</b>	Bicarbonate - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bicarb_result_v0</b>	Bicarbonate - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_bicarb_result_v1</b>	Bicarbonate - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>bldchem_bilirubin_abn_ever</b>	Bilirubin - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bilirubin_abn_v0</b>	Bilirubin - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_bilirubin_abn_v1</b>	Bilirubin - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bilirubin_cclinisig_ever</b>	Bilirubin - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bilirubin_cclinisig_v0</b>	Bilirubin - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_bilirubin_cclinisig_v1</b>	Bilirubin - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bilirubin_result_v0</b>	Bilirubin - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_bilirubin_result_v1</b>	Bilirubin - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>bldchem_bun_abn_ever</b>	BUN - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bun_abn_v0</b>	BUN - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_bun_abn_v1</b>	BUN - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bun_clinsig_ever</b>	BUN - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bun_clinsig_v0</b>	BUN - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
<b>bldchem_bun_clinsi_g_v1</b>	BUN - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_bun_resul_t_v0</b>	BUN - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_bun_resul_t_v1</b>	BUN - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>bldchem_calcium_abn_ever</b>	Calcium - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_calcium_abn_v0</b>	Calcium - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_calcium_abn_v1</b>	Calcium - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_calcium_c linsig_ever</b>	Calcium - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_calcium_c linsig_v0</b>	Calcium - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_calcium_c linsig_v1</b>	Calcium - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_calcium_resul_t_v0</b>	Calcium - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_calcium_resul_t_v1</b>	Calcium - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>bldchem_chloride_abn_ever</b>	Chloride - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
<b>bldchem_chloride_abn_v0</b>	Chloride - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_chloride_abn_v1</b>	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"
<b>bldchem_chloride_c linsig_ever</b>	Chloride - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_chloride_c linsig_v0</b>	Chloride - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
<b>bldchem_chloride_c_linsig_v1</b>	Chloride - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_chloride_result_v0</b>	Chloride - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_chloride_result_v1</b>	Chloride - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>bldchem_creatinine_abn_ever</b>	Creatinine - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_creatinine_abn_v0</b>	Creatinine - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_creatinine_abn_v1</b>	Creatinine - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_creatinine_clinsig_ever</b>	Creatinine - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_creatinine_clinsig_v0</b>	Creatinine - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_creatinine_clinsig_v1</b>	Creatinine - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_creatinine_result_v0</b>	Creatinine - Result (umol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_creatinine_result_v1</b>	Creatinine - Result (umol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>bldchem_egfr_abn_ever</b>	eGFR - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_egfr_abn_v0</b>	eGFR - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_egfr_abn_v1</b>	eGFR - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_egfr_clinsig_ever</b>	eGFR - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_egfr_clinsig_v0</b>	eGFR - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
<b>bldchem_egfr_clinsi_g_v1</b>	eGFR - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_egfr_resul_t_v0</b>	eGFR - Result (mL/min/1.73) - Visit 0 (Baseline) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>bldchem_egfr_resul_t_v1</b>	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"
<b>bldchem_glucose_abn_ever</b>	Glucose - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
<b>bldchem_glucose_abn_v0</b>	Glucose - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
<b>bldchem_glucose_abn_v1</b>	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"
<b>bldchem_glucose_c_linsig_ever</b>	Glucose - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_glucose_c_linsig_v0</b>	Glucose - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_glucose_c_linsig_v1</b>	Glucose - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_glucose_r esult_v0</b>	Glucose - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_glucose_r esult_v1</b>	Glucose - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>bldchem_potassium_abn_ever</b>	Potassium - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_potassium_abn_v0</b>	Potassium - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_potassium_abn_v1</b>	Potassium - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_potassium_clinsig_ever</b>	Potassium - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
<b>bldchem_potassium_clinsig_v0</b>	Potassium - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_potassium_clinsig_v1</b>	Potassium - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_potassium_result_v0</b>	Potassium - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_potassium_result_v1</b>	Potassium - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>bldchem_protein_a.bn_ever</b>	Protein - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_protein_a.bn_v0</b>	Protein - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_protein_a.bn_v1</b>	Protein - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_protein_clinsig_ever</b>	Protein - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_protein_clinsig_v0</b>	Protein - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_protein_clinsig_v1</b>	Protein - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_protein_result_v0</b>	Protein - Result (g/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_protein_result_v1</b>	Protein - Result (g/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>bldchem_sgott_ast_abn_ever</b>	SGOT/AST - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_sgott_ast_abn_v0</b>	SGOT/AST - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>bldchem_sgott_ast_abn_v1</b>	SGOT/AST - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_sgott_ast_clinsig_ever</b>	SGOT/AST - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_sgott_ast_clinsig_v0</b>	SGOT/AST - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"

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

Variable	Label	Description	Format Text
<b>bldchem_sodium_cl insig_v1</b>	Sodium - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>bldchem_sodium_re sult_v0</b>	Sodium - Result (mmol/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>bldchem_sodium_re sult_v1</b>	Sodium - Result (mmol/L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>hema_basophils_ab n_ever</b>	Basophils - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_basophils_ab n_v0</b>	Basophils - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_basophils_ab n_v1</b>	Basophils - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_basophils_cli nsig_ever</b>	Basophils - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_basophils_cli nsig_v0</b>	Basophils - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_basophils_cli nsig_v1</b>	Basophils - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_basophils_re sult_v0</b>	Basophils - Result (10 <sup>9</sup> /L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>hema_basophils_re sult_v1</b>	Basophils - Result (10 <sup>9</sup> /L) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>hema_eosinophils_ abn_ever</b>	Eosinophils - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_eosinophils_ abn_v0</b>	Eosinophils - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
<b>hema_eosinophils_ abn_v1</b>	Eosinophils - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_eosinophils_ clinsig_ever</b>	Eosinophils - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
<b>hema_eosinophils_clinsig_v0</b>	Eosinophils - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_eosinophils_clinsig_v1</b>	Eosinophils - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_eosinophils_result_v0</b>	Eosinophils - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>hema_eosinophils_result_v1</b>	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"
<b>hema_hematocrit_abn_ever</b>	Hematocrit - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
<b>hema_hematocrit_abn_v0</b>	Hematocrit - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_hematocrit_abn_v1</b>	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"
<b>hema_hematocrit_clinsig_ever</b>	Hematocrit - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_hematocrit_clinsig_v0</b>	Hematocrit - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_hematocrit_clinsig_v1</b>	Hematocrit - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_hematocrit_result_v0</b>	Hematocrit - Result (Proportion) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>hema_hematocrit_result_v1</b>	Hematocrit - Result (Proportion) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>hema_hemoglobin_abn_ever</b>	Hemoglobin - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
<b>hema_hemoglobin_abn_v0</b>	Hemoglobin - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
<b>hema_hemoglobin_abn_v1</b>	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
<b>hema_hemoglobin_clinsig_ever</b>	Hemoglobin - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_hemoglobin_clinsig_v0</b>	Hemoglobin - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_hemoglobin_clinsig_v1</b>	Hemoglobin - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_hemoglobin_result_v0</b>	Hemoglobin - Result (g/dL) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>hema_hemoglobin_result_v1</b>	Hemoglobin - Result (g/dL) - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		Numeric .F="No Record For This Visit" .R="Not Randomized"
<b>hema_lymphocytes_abn_ever</b>	Lymphocytes - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No" 1="Yes"
<b>hema_lymphocytes_abn_v0</b>	Lymphocytes - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No" 1="Yes"
<b>hema_lymphocytes_abn_v1</b>	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"
<b>hema_lymphocytes_clinsig_ever</b>	Lymphocytes - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_lymphocytes_clinsig_v0</b>	Lymphocytes - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_lymphocytes_clinsig_v1</b>	Lymphocytes - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_lymphocytes_result_v0</b>	Lymphocytes - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>hema_lymphocytes_result_v1</b>	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"
<b>hema_monocytes_abn_ever</b>	Monocytes - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_monocytes_abn_v0</b>	Monocytes - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
<b>hema_monocytes_a.bn_v1</b>	Monocytes - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_monocytes_c.linsig_ever</b>	Monocytes - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_monocytes_c.linsig_v0</b>	Monocytes - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_monocytes_c.linsig_v1</b>	Monocytes - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_monocytes_result_v0</b>	Monocytes - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>hema_monocytes_result_v1</b>	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"
<b>hema_neutrophils_a.bn_ever</b>	Neutrophils - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_neutrophils_a.bn_v0</b>	Neutrophils - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_neutrophils_a.bn_v1</b>	Neutrophils - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_neutrophils_c.linsig_ever</b>	Neutrophils - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_neutrophils_c.linsig_v0</b>	Neutrophils - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_neutrophils_c.linsig_v1</b>	Neutrophils - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_neutrophils_result_v0</b>	Neutrophils - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>hema_neutrophils_result_v1</b>	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"
<b>hema_platelets_abn_ever</b>	Platelets - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"

Variable	Label	Description	Format Text
<b>hema_platelets_abn_v0</b>	Platelets - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_platelets_abn_v1</b>	Platelets - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_platelets_clin_sig_ever</b>	Platelets - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_platelets_clin_sig_v0</b>	Platelets - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_platelets_clin_sig_v1</b>	Platelets - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_platelets_res_ult_v0</b>	Platelets - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>hema_platelets_res_ult_v1</b>	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"
<b>hema_wbc_abn_ever</b>	WBC - Ever Abnormal? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_wbc_abn_v0</b>	WBC - Abnormal? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_wbc_abn_v1</b>	WBC - Abnormal? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_wbc_clinsig_ever</b>	WBC - Ever Clinically Significant? - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_wbc_clinsig_v0</b>	WBC - Clinically Significant? - Visit 0 (Baseline) - [Lab Tests]		.R="Not Randomized" 0="No"
<b>hema_wbc_clinsig_v1</b>	WBC - Clinically Significant? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" .R="Not Randomized" 0="No"
<b>hema_wbc_result_v0</b>	WBC - Result (10^9/L) - Visit 0 (Baseline) - [Lab Tests]		Numeric .R="Not Randomized"
<b>hema_wbc_result_v1</b>	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"
<b>labs_fasting_v0</b>	Fasting? - Visit 0 (Baseline) - [Lab Tests]		.N="N/A" 0="No" 1="Yes" 9="Unknown"

Variable	Label	Description	Format Text
<b>labs_fasting_v1</b>	Fasting? - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		.F="No Record For This Visit" 0="No" 1="Yes"
<b>labs_spec_col_dt_v0</b>	Specimen Collection Date - Visit 0 (Baseline) - [Lab Tests]		SAS Date .N="N/A"
<b>labs_spec_col_dt_v1</b>	Specimen Collection Date - Visit 1 (End Of Study Or Early Termination) - [Lab Tests]		SAS Date .F="No Record For This Visit"
<b>labs_spec_col_time_v0</b>	Specimen Collection Time - Visit 0 (Baseline) - [Lab Tests]		Numeric .N="N/A"
<b>labs_spec_col_time_v1</b>	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
<b>path_diff</b>	Differentiation - [Pathologic Characteristics]		.R="Not Randomized" 1="In situ" 2="Grade I" 6="Unknown/Not specified"
<b>path_hist</b>	Histology - [Pathologic Characteristics]		.R="Not Randomized" 1="Squamous cell carcinoma NOS" 2="Keratinizing squamous cell carcinoma" 3="Non-keratinizing squamous cell carcinoma"
<b>path_p16_neg_meta</b>	p16-: Metastasis (V8) - [Pathologic Characteristics]		Numeric .M="Missing" .R="Not Randomized"
<b>path_p16_neg_node</b>	p16-: Node Stage (V8) - [Pathologic Characteristics]		Numeric .M="Missing" .R="Not Randomized"
<b>path_p16_neg_tumor</b>	p16-: Tumor Stage (V8) - [Pathologic Characteristics]		Numeric .M="Missing" .R="Not Randomized"
<b>path_p16_pos_meta</b>	p16+: Metastasis (V8) - [Pathologic Characteristics]		.M="Missing" .R="Not Randomized" .U="Unknown" 1="cM0"
<b>path_p16_pos_node</b>	p16+: Node Stage (V8) - [Pathologic Characteristics]		.M="Missing" .R="Not Randomized" 3="pN1" 4="pN2"
<b>path_p16_pos_tumor</b>	p16+: Tumor Stage (V8) - [Pathologic Characteristics]		.M="Missing" .R="Not Randomized" 1="T1"
<b>path_p16_status</b>	p16 Status - [Pathologic Characteristics]		.R="Not Randomized" 1="Positive" 3="Not Tested"
<b>path_spec_col_dt</b>	Date Specimen Collected - [Pathologic Characteristics]		SAS Date .R="Not Randomized"
<b>path_tumor_subsite_loc</b>	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
<b>spec_bld_cmnt_v0</b>	Comments - Visit 0 (Baseline) - [Specimen Collection(Blood)]		Char
<b>spec_bld_cmnt_v1</b>	Comments - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		Char
<b>spec_bld_col_dt_v0</b>	Date Specimen Collected - Visit 0 (Baseline) - [Specimen Collection(Blood)]		SAS Date .N="N/A"
<b>spec_bld_col_dt_v1</b>	Date Specimen Collected - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		SAS Date .N="N/A" .O="Not Obtained"
<b>spec_bld_col_time_v0</b>	Time Specimen Collected - Visit 0 (Baseline) - [Specimen Collection(Blood)]		Numeric .N="N/A"
<b>spec_bld_col_time_v1</b>	Time Specimen Collected - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		Numeric .N="N/A" .O="Not Obtained"
<b>spec_bld_last_agent_dt_v0</b>	Date Last Study Agent Taken - Visit 0 (Baseline) - [Specimen Collection(Blood)]		SAS Date .M="Missing" .N="N/A"
<b>spec_bld_last_agent_dt_v1</b>	Date Last Study Agent Taken - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		SAS Date .N="N/A" .O="Not Obtained"
<b>spec_bld_last_agent_time_v0</b>	Time Last Study Agent Taken - Visit 0 (Baseline) - [Specimen Collection(Blood)]		Numeric .M="Missing" .N="N/A"
<b>spec_bld_last_agent_time_v1</b>	Time Last Study Agent Taken - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Blood)]		Numeric .N="N/A" .O="Not Obtained"
<b>spec_bld_ship_dt_v0</b>	Specimen Shipping Date - Visit 0 (Baseline) - [Specimen Collection(Blood)]		SAS Date .M="Missing" .N="N/A"

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

Variable	Label	Description	Format Text
<b>spec_tis_col_time_norm_v1</b>	Time Specimen Collected - Normal Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"
<b>spec_tis_col_time_tmr_v0</b>	Time Specimen Collected - Tumor Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		Numeric .N="N/A"
<b>spec_tis_col_time_tmr_v1</b>	Time Specimen Collected - Tumor Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"
<b>spec_tis_last_dt_norm_v0</b>	Date Last Study Agent Taken - Normal Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
<b>spec_tis_last_dt_norm_v1</b>	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"
<b>spec_tis_last_dt_tmrv0</b>	Date Last Study Agent Taken - Tumor Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		SAS Date .M="Missing" .N="N/A"
<b>spec_tis_last_dt_tmrv1</b>	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"
<b>spec_tis_last_time_norm_v0</b>	Time Last Study Agent Taken - Normal Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"
<b>spec_tis_last_time_norm_v1</b>	Time Last Study Agent Taken - Normal Tissue - Visit 1 (End Of Study Or Early Termination) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"
<b>spec_tis_last_time_tmr_v0</b>	Time Last Study Agent Taken - Tumor Tissue - Visit 0 (Baseline) - [Specimen Collection(Tissue)]		Numeric .M="Missing" .N="N/A"

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

Variable	Label	Description	Format Text
<b>spec_tis_storage_temp_tmr_v1</b>	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_liqor	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_f req	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
<b>tob_base_after_dx_cncr</b>	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"
<b>tob_base_age_first_smoked</b>	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"
<b>tob_base_age_smoked_reg</b>	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"
<b>tob_base_amt_smoked_2d</b>	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"
<b>tob_base_amt_smoked_after</b>	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"
<b>tob_base_amt_smoked_during</b>	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"
<b>tob_base_any_cig_past30d</b>	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"
<b>tob_base_avg_cigs_smoked</b>	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"
<b>tob_base_cancer_assist</b>	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
<b>tob_base_cancer_quit</b>	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"
<b>tob_base_doctor ADVISED</b>	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"
<b>tob_base_how_often_other</b>	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"
<b>tob_base_live_smoke_ever</b>	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"
<b>tob_base_live_smoke_ever_yrs</b>	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"
<b>tob_base_live_smoke_past30d</b>	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"
<b>tob_base_live_with_smoker</b>	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"
<b>tob_base_longest_time_off_cncr</b>	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"
<b>tob_base_now_smoke_cigs</b>	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
<b>tob_base_other_freq</b>	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"
<b>tob_base_products_used_past30d</b>	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"
<b>tob_base_products_used_reg</b>	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"
<b>tob_base_products_used_reg_cncr</b>	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"
<b>tob_base_quit_assist_past30d</b>	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"
<b>tob_base_quit_products_past30d</b>	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"
<b>tob_base_smoked_100</b>	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"
<b>tob_base_time_after_wake</b>	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"
<b>tob_base_time_since_last_cig</b>	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"
<b>tob_base_time_since_reg_use</b>	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
<b>tob_base_trying_to_quit</b>	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"
<b>tob_base_used_other</b>	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"
<b>tob_base_work_smoke_ever</b>	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"
<b>tob_base_work_smoke_ever_yrs</b>	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"
<b>tob_base_work_smoke_past30d</b>	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"
<b>tob_base_year_b4_cncr</b>	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"
<b>tob_base_years_since_last_cig</b>	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"
<b>tob_base_years_smoked</b>	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"
<b>tob_fu_avg_cig_day</b>	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"
<b>tob_fu_cig_freq_aft</b>	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"

Variable	Label	Description	Format Text
<b>tob_fu_cig_freq_clinic</b>	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"
<b>tob_fu_cig_freq_during</b>	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"
<b>tob_fu_how_often_other</b>	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"
<b>tob_fu_now_smoke_cigs</b>	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"
<b>tob_fu_other_freq</b>	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"
<b>tob_fu_other_since_last_vis</b>	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"
<b>tob_fu_products_used</b>	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"
<b>tob_fu_time_since_last_cig</b>	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"
<b>tob_fu_time_since_recent_use</b>	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"
<b>tob_fu_years_since_last_cig</b>	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

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