

UAZ2017-09-02 - Enhanced Person Data Dictionary

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Document Summary

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UAZ2017-09-02 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	ParticipantID	Participant ID		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	arm	Study Arm	The High-Low Arm starts with 8 tablets of Avmacol® per day during Intervention Period 1 and changes to 4 tablets of Avmacol® per day during Intervention Period. The Low-High Arm starts with 4 tablets of Avmacol® per day during Intervention Period 1 and changes to 8 tablets of Avmacol® per day during Intervention Period.	.E="Not Eligible For Study" .F="No Record For This Visit" 1="High-Low" 2="Low-High"
01. Principal	build_dt	Build Date		SAS Date
01. Principal	rnd_dt	Randomization Date		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	rnd_num	Randomization Number		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	visit_dt_v1	Date of Visit 1 (Screening)		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	visit_dt_v2	Date of Visit 2 (Baseline 1)		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	visit_dt_v3	Date of Visit 3 (Intervention Period 1 Day 4 Or 5)		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	visit_dt_v4	Date of Visit 4 (End Of Intervention 1)		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	visit_dt_v5	Date of Visit 5 (Baseline 2)		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	visit_dt_v6	Date of Visit 6 (Intervention Period 2 Day 4 Or 5)		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	visit_dt_v7	Date of Visit 7 (End Of Intervention 2)		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Section 3: Registration

Class	Variable	Label	Description	Format Text
01. Principal	reg_biobank	Has Participant Given Permission To Keep The Remaining Samples And Related Information In A Biobank For The Future Health Research? - [Registration]		1="Yes"
01. Principal	reg_consent_dt	Date Of Informed Consent - [Registration]		SAS Date
01. Principal	reg_consent_sig_dt	Date Informed Consent Signed - [Registration]		SAS Date
01. Principal	reg_consent_ver	Informed Consent Version - [Registration]		SAS Date
01. Principal	reg_contact	Has Participant Given Permission That His/Her Study Doctor Or Representative May Contact Him/Her Or His/Her Physician To See If He/She Wishes To Participate In Future Research? - [Registration]		1="Yes"
01. Principal	reg_dt	Date of Registration - [Registration]		SAS Date
01. Principal	reg_eligible	Participant Satisfies All Eligibility Criteria? - [Registration]		0="No" 1="Yes"
01. Principal	reg_ethnicity	Ethnicity - [Registration]		1="Hispanic or Latino" 2="Not Hispanic or Latino" 4="Not Reported"
01. Principal	reg_gender	Gender - [Registration]		1="Male" 2="Female"
01. Principal	reg_genetic	Has Participant Given Permission For Release Of Genetic Data And Health Information, With No Direct Identifiers, Into Scientific Databases? - [Registration]		0="No" 1="Yes"
01. Principal	reg_oth_pay_method	Other Method of Payment - [Registration]		Char
01. Principal	reg_pay_method	Method of Payment - [Registration]		Char

Class	Variable	Label	Description	Format Text
01. Principal	reg_race1-2	Race # - [Registration]		.N="N/A" 1="White" 2="Black or African American" 5="American Indian or Alaska Native" 7="Not Reported"
01. Principal	reg_race_eth	Race + Ethnicity - [Registration]		1="White, Non-Hispanic" 2="Black, Non-Hispanic" 3="Hispanic" 6="American Indian or Alaska Native" 8="Not Reported"
01. Principal	reg_screen_dt	Screen Date - [Registration]		SAS Date
01. Principal	reg_tobacco	Has Participant Given Permission That The Information From His/Her Tobacco And Alcohol Questionnaires May Be Used In Future Health Research? - [Registration]		1="Yes"

Section 4: Medical/Surgical History

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_all_normal	All Body Systems Normal - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	medsurg_allergies	Participant Has Allergies - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	medsurg_breasts_cmnt	Comments - Breasts - [Medical/Surgical History]		Char
01. Principal	medsurg_breasts_finding	Finding - Breasts - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"
01. Principal	medsurg_cardio_cmnt	Comments - Cardiovascular - [Medical/Surgical History]		Char
01. Principal	medsurg_cardio_finding	Finding - Cardiovascular - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"
01. Principal	medsurg_derma_cmnt	Comments - Dermatologic - [Medical/Surgical History]		Char
01. Principal	medsurg_derma_finding	Finding - Dermatologic - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"
01. Principal	medsurg_endometa_cmnt	Comments - Endocrine/Metabolic - [Medical/Surgical History]		Char
01. Principal	medsurg_endometa_finding	Finding - Endocrine/Metabolic - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"
01. Principal	medsurg_gastro_cmnt	Comments - Gastrointestinal - [Medical/Surgical History]		Char
01. Principal	medsurg_gastro_finding	Finding - Gastrointestinal - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_genit_cmnt	Comments - Genitourinary - [Medical/Surgical History]		Char
01. Principal	medsurg_genit_finding	Finding - Genitourinary - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"
01. Principal	medsurg_heent_cmnt	Comments - H/E/E/N/T - [Medical/Surgical History]		Char
01. Principal	medsurg_heent_finding	Finding - H/E/E/N/T - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"
01. Principal	medsurg_hemalymp_cmnt	Comments - Hematopoietic/Lymph - [Medical/Surgical History]		Char
01. Principal	medsurg_hemalymp_finding	Finding - Hematopoietic/Lymph - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"
01. Principal	medsurg_musculoskel_cmnt	Comments - Musculoskeletal - [Medical/Surgical History]		Char
01. Principal	medsurg_musculoskel_finding	Finding - Musculoskeletal - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"
01. Principal	medsurg_neck_cmnt	Comments - Neck - [Medical/Surgical History]		Char
01. Principal	medsurg_neck_finding	Finding - Neck - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"
01. Principal	medsurg_neuro_cmnt	Comments - Neurologic - [Medical/Surgical History]		Char
01. Principal	medsurg_neuro_finding	Finding - Neurologic - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"
01. Principal	medsurg_oth_cmnt1-3	Comments - Other System # - [Medical/Surgical History]		Char
01. Principal	medsurg_oth_finding1-3	Finding - Other System # - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 2="Abnormal"

Class	Variable	Label	Description	Format Text
01. Principal	medsurg_oth_num	Number Of Other Body Systems Tested - [Medical/Surgical History]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	medsurg_oth_system1-3	System - Other System # - [Medical/Surgical History]		Char
01. Principal	medsurg_resp_comment	Comments - Respiratory - [Medical/Surgical History]		Char
01. Principal	medsurg_resp_finding	Finding - Respiratory - [Medical/Surgical History]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal" 2="Abnormal"
01. Principal	medsurg_spec_allergies	Specify Allergies - [Medical/Surgical History]		Char

Section 5: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	conmed_dose1-20	Dose - Medication # - [Concomitant Medications]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	conmed_freq1-20	Frequency - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_name1-20	Medication - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_num	Number Of Concomitant Medications - [Concomitant Medications]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	conmed_reason1-20	Reason - Medication # - [Concomitant Medications]		Char
01. Principal	conmed_rpt_dt1-20	Medication Report Date - Medication # - [Concomitant Medications]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	conmed_start_dt1-20	Start Date - Medication # - [Concomitant Medications]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	conmed_stop_dt1-20	Stop Date - Medication # - [Concomitant Medications]		SAS Date .C="Continuing" .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	conmed_units1-20	Units - Medication # - [Concomitant Medications]		Char

Section 6: Pregnancy Specimen Data

Class	Variable	Label	Description	Format Text
01. Principal	preg_result_v1	Test Result - Urine Test - Visit 1 (Screening) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .N="N/A" 3="Negative"
01. Principal	preg_result_v2	Test Result - Urine Test - Visit 2 (Baseline 1) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 3="Negative"
01. Principal	preg_result_v5	Test Result - Urine Test - Visit 5 (Baseline 2) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 3="Negative"
01. Principal	preg_rsn_not_col_v1	Reason Test Was Not Collected - Urine Test - Visit 1 (Screening) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .N="N/A" 1="Participant Is Male" 2="Participant Is Female And Not Of Childbearing Potential"
01. Principal	preg_rsn_not_col_v2	Reason Test Was Not Collected - Urine Test - Visit 2 (Baseline 1) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 1="Participant Is Male" 2="Participant Is Female And Not Of Childbearing Potential"
01. Principal	preg_rsn_not_col_v5	Reason Test Was Not Collected - Urine Test - Visit 5 (Baseline 2) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 1="Participant Is Male" 2="Participant Is Female And Not Of Childbearing Potential"
01. Principal	preg_spec_dt_v1	Specimen Collection Date - Urine Test - Visit 1 (Screening) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .N="N/A"
01. Principal	preg_spec_dt_v2	Specimen Collection Date - Urine Test - Visit 2 (Baseline 1) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	preg_spec_dt_v5	Specimen Collection Date - Urine Test - Visit 5 (Baseline 2) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Section 7: Baseline Alcohol

Class	Variable	Label	Description	Format Text
01. Principal	alc_bl_inv_sig	Investigator Signature Present - [Baseline Alcohol]		.E="Not Eligible For Study" 1="Yes"
01. Principal	alc_bl_inv_sig_dt	Investigator Signature Date - [Baseline Alcohol]		SAS Date .E="Not Eligible For Study"
01. Principal	alc_bl_q10_beer	10. What Type(s) Of Alcohol Do You Drink? - Beer? - [Baseline Alcohol]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	alc_bl_q10_liquor	10. What Type(s) Of Alcohol Do You Drink? - Liquor? - [Baseline Alcohol]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	alc_bl_q10_wine	10. What Type(s) Of Alcohol Do You Drink? - Wine? - [Baseline Alcohol]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	alc_bl_q10_wine_cooler	10. What Type(s) Of Alcohol Do You Drink? - Wine Coolers? - [Baseline Alcohol]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	alc_bl_q1_12_lifetime	1. At Least 12 Alcoholic Drinks In Lifetime - [Baseline Alcohol]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	alc_bl_q2_p12_freq	2. In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcohol - Frequency - [Baseline Alcohol]		.E="Not Eligible For Study" .M="Missing" .N="N/A" .U="Unknown" 2="Week" 3="Month" 4="Year"
01. Principal	alc_bl_q2_p12_num	2. In The Past 12 Months, On Average, How Often Did You Drink Any Type Of Alcohol - Number - [Baseline Alcohol]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	alc_bl_q3_p12_num	3. In The Past 12 Months, On Those Days That You Drank Alcoholic Beverages, On Average, How Many Drinks Did You Have Per Day? - [Baseline Alcohol]		Numeric .E="Not Eligible For Study" .M="Missing" .U="Unknown"

Class	Variable	Label	Description	Format Text
01. Principal	alc_bl_q4_p12_5gr	4. In The Past 12 Months, On How Many Days Did You Have 5 Or More Drinks Of Any Alcoholic Beverage? - [Baseline Alcohol]		Numeric .E="Not Eligible For Study" .M="Missing" .U="Unknown"
01. Principal	alc_bl_q5_life_more_5	5. 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? - [Baseline Alcohol]		.E="Not Eligible For Study" .M="Missing" .R="Refused" .U="Unknown" 0="No" 1="Yes"
01. Principal	alc_bl_q6_time_since_reg	6. If You Do Not Currently Drink Alcoholic Beverages, But Did In The Past, How Long Has It Been Since You Last Drank Regularly? - [Baseline Alcohol]		.E="Not Eligible For Study" .M="Missing" .N="Never Drank Regularly" .U="Don't Know/Not Sure" 1="Within The Past Month (0 To 1 Month Ago)" 2="Between 1 And 3 Months (1 To 3 Months Ago)" 3="Between 3 And 6 Months (3 To 6 Months Ago)" 4="Between 6 And 12 Months (6 To 12 Months Ago)" 5="Between 1 And 5 Years (1 To 5 Years Ago)" 7="More Than 15 Years Ago"
01. Principal	alc_bl_q7_heaviest	7. At The Heaviest Point, Either Now Or In The Past, On The Days When You Drank, About How Many Drinks Did You Drink A Day On The Average? - [Baseline Alcohol]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	alc_bl_q8_years_reg	8. How Many Years Have You Been Drinking (Or Did Drink) Regularly? - [Baseline Alcohol]		Numeric .E="Not Eligible For Study" .M="Missing"
01. Principal	alc_bl_q9_age_reg	9. At What Age Did You Begin Drinking Regularly? - [Baseline Alcohol]		Numeric .E="Not Eligible For Study" .M="Missing" .U="Unknown"

Section 8: Baseline Tobacco

Class	Variable	Label	Description	Format Text
01. Principal	tob_bl_inv_sig	Investigator Signature Present - [Baseline Tobacco]		.E="Not Eligible For Study" 1="Yes"
01. Principal	tob_bl_inv_sig_dt	Investigator Signature Date - [Baseline Tobacco]		SAS Date .E="Not Eligible For Study"
01. Principal	tob_bl_q10_oth_cat	10. How Often Do You/Did You Use Other Forms Of Tobacco? - [Baseline Tobacco]		.E="Not Eligible For Study" .N="N/A" 1="Every Day" 2="Some Days"
01. Principal	tob_bl_q10_oth_freq	10. How Often Do You/Did You Use Other Forms Of Tobacco? - Frequency - [Baseline Tobacco]		.E="Not Eligible For Study" .N="N/A" 2="Week" 3="Month" 4="Year"
01. Principal	tob_bl_q10_oth_num	10. How Often Do You/Did You Use Other Forms Of Tobacco? - Number - [Baseline Tobacco]		Numeric .E="Not Eligible For Study" .N="N/A"
01. Principal	tob_bl_q11_bidis	11. Which Of The Following Products Have You Ever Used Regularly? - Bidis - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q11_cig	11. Which Of The Following Products Have You Ever Used Regularly? - Cigarettes - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q11_cigar	11. Which Of The Following Products Have You Ever Used Regularly? - Traditional Cigars, Cigarillos Or Filtered Cigars - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q11_clove	11. Which Of The Following Products Have You Ever Used Regularly? - Clove Cigarettes Or Kreteks - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	tob_bl_q11_elec	11. Which Of The Following Products Have You Ever Used Regularly? - E-Cigarettes Or Other Electronic Nicotine Delivery System - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q11_hookah	11. Which Of The Following Products Have You Ever Used Regularly? - Hookah - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No"
01. Principal	tob_bl_q11_oth	11. Which Of The Following Products Have You Ever Used Regularly? - Other, Please Specify - [Baseline Tobacco]		Char
01. Principal	tob_bl_q11_paan	11. Which Of The Following Products Have You Ever Used Regularly? - Paan With Tobacco, Gutka, Zarda, Khaini - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No"
01. Principal	tob_bl_q11_pipe	11. Which Of The Following Products Have You Ever Used Regularly? - Pipes - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q11_smokeless	11. Which Of The Following Products Have You Ever Used Regularly? - Smokeless Tobacco, Like Dip, Chew, Or Snuff - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q11_snus	11. Which Of The Following Products Have You Ever Used Regularly? - Snus - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q11_waterpipe	11. Which Of The Following Products Have You Ever Used Regularly? - Waterpipe - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	tob_bl_q12_time_since	12. 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? - [Baseline Tobacco]		.E="Not Eligible For Study" .M="Missing" .N="N/A" .U="Unknown" 1="Within The Past Month (0 To 1 Month Ago)" 4="Between 6 And 12 Months (6 To 12 Months Ago)" 5="Between 1 And 5 Years (1 To 5 Years Ago)" 6="Between 5 And 15 Years (5 To 15 Years Ago)"
01. Principal	tob_bl_q13_curr_live	13. Are You Currently Living With A Smoker? - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q14_p30_live	14. In The Past 30 Days, Have You Lived In A Place Where Other People Smoked Cigarettes Indoors? - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q15_p30_work	15. In The Past 30 Days, Have You Worked In A Place Where Other People Smoked Cigarettes Indoors? - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q16_ever_live	16. Thinking Of All Your Childhood And Adult Years, Have You Ever Lived In A Place Where Other People Smoked Cigarettes Indoors? - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q16_yrs	16. In Total, For About How Many Years? - [Baseline Tobacco]		Numeric .E="Not Eligible For Study" .N="N/A"
01. Principal	tob_bl_q17_ever_work	17. Thinking Of All The Years You Have Worked, Have You Ever Worked In A Place Where Other People Smoked Cigarettes Indoors? - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"
01. Principal	tob_bl_q17_yrs	17. In Total, For About How Many Years? - [Baseline Tobacco]		Numeric .E="Not Eligible For Study" .N="N/A"
01. Principal	tob_bl_q1_smoked100	1. Have You Smoked At Least 100 Cigarettes (5 Packs = 100 Cigarettes) In Your Entire Life? - [Baseline Tobacco]		.E="Not Eligible For Study" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	tob_bl_q2_age_1stcig	2. How Old Were You When You First Smoked A Cigarette (Even One Or Two Puffs)? - [Baseline Tobacco]		Numeric .E="Not Eligible For Study"
01. Principal	tob_bl_q3_age_began	3. How Old Were You When You First Began Smoking Cigarettes Regularly? - [Baseline Tobacco]		Numeric .E="Not Eligible For Study"
01. Principal	tob_bl_q4_years_smoked	4. How Many Total Years Have You Smoked (Or Did You Smoke) Cigarettes? - [Baseline Tobacco]		Numeric .E="Not Eligible For Study"
01. Principal	tob_bl_q5_avg_num	5. On Average When You Have Smoked, About How Many Cigarettes Do You (Or Did You) Smoke A Day? (A Pack Usually Has 20 Cigarettes In It) - [Baseline Tobacco]		Numeric .E="Not Eligible For Study"
01. Principal	tob_bl_q6_now_smoke	6. Do You NOW Smoke Cigarettes? - [Baseline Tobacco]		.E="Not Eligible For Study" 1="Every Day" 2="Some Days"
01. Principal	tob_bl_q7_wake	7. How Soon After You Wake Up Do You Smoke Your First Cigarette? - [Baseline Tobacco]		.E="Not Eligible For Study" 1="Within 30 Minutes" 2="After 30 Minutes"
01. Principal	tob_bl_q8_last_smoke_cat	8. How Long Has It Been Since You Last Smoked A Cigarette (Even One Or Two Puffs)? - [Baseline Tobacco]		.E="Not Eligible For Study" 1="I Smoked A Cigarette Today (At Least One Puff)" 2="1-7 Days"
01. Principal	tob_bl_q8_last_smoke_days	8. How Many Days It Has Been Since Your Last Cigarette? - [Baseline Tobacco]		Numeric .E="Not Eligible For Study"
01. Principal	tob_bl_q9_oth_forms	9. Have You Ever Used Other Forms Of Tobacco, Not Including Cigarettes? - [Baseline Tobacco]		.E="Not Eligible For Study" 0="No" 1="Yes"

Section 9: Intervention Administration

Class	Variable	Label	Description	Format Text
01. Principal	intadm_end_dt_v2	Agent End Date - Visit 2 (Baseline 1) - [Intervention Administration]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	intadm_end_dt_v5	Agent End Date - Visit 5 (Baseline 2) - [Intervention Administration]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	intadm_start_dt_v2	Agent Start Date - Visit 2 (Baseline 1) - [Intervention Administration]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	intadm_start_dt_v5	Agent Start Date - Visit 5 (Baseline 2) - [Intervention Administration]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Section 10: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_num	Number Of Adverse Events The Participant Experienced During The Study - [Adverse Events]		Numeric

Section 11: Agent Interruption

Class	Variable	Label	Description	Format Text
01. Principal	agent_restart_dt	Date Restarted - [Agent Interruption]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	agent_restart_rsn	Reason Restarted - [Agent Interruption]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Investigator Decision"
01. Principal	agent_restarted	Was Agent Restarted? - [Agent Interruption]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	agent_stop_dt	Date Stopped - [Agent Interruption]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	agent_stop_rsn	Reason Stopped - [Agent Interruption]		.E="Not Eligible For Study" .F="No Record For This Visit" 3="AE SAE"
01. Principal	agent_stop_rsn_spec	Specific Reason Stopped - [Agent Interruption]		Char

Section 12: Compliance

Class	Variable	Label	Description	Format Text
01. Principal	comp_agent_expected_v4	Amount Of Agent Expected To Be Returned For This Period - Visit 4 (End Of Intervention 1) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_expected_v7	Amount Of Agent Expected To Be Returned For This Period - Visit 7 (End Of Intervention 2) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_last_v4	Amount Of Agent Provided At Last Visit - Visit 4 (End Of Intervention 1) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_last_v7	Amount Of Agent Provided At Last Visit - Visit 7 (End Of Intervention 2) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_missing_v4	Amount Of Agent Missing - Visit 4 (End Of Intervention 1) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_missing_v7	Amount Of Agent Missing - Visit 7 (End Of Intervention 2) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_modified_v4	Agent Modified - Visit 4 (End Of Intervention 1) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	comp_agent_modified_v7	Agent Modified - Visit 7 (End Of Intervention 2) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	comp_agent_prescribed_v4	Amount Of Agent Prescribed For This Period - Visit 4 (End Of Intervention 1) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_prescribed_v7	Amount Of Agent Prescribed For This Period - Visit 7 (End Of Intervention 2) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_provided_v4	Agent Provided At This Visit - Visit 4 (End Of Intervention 1) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	comp_agent_provided_v7	Agent Provided At This Visit - Visit 7 (End Of Intervention 2) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	comp_agent_returned_v4	Amount Of Agent Returned This Visit - Visit 4 (End Of Intervention 1) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_returned_v7	Amount Of Agent Returned This Visit - Visit 7 (End Of Intervention 2) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_taken_v4	Amount Of Agent Taken During This Period - Visit 4 (End Of Intervention 1) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_taken_v7	Amount Of Agent Taken During This Period - Visit 7 (End Of Intervention 2) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_this_v4	Amount Of Agent Provided At This Visit - Visit 4 (End Of Intervention 1) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_agent_this_v7	Amount Of Agent Provided At This Visit - Visit 7 (End Of Intervention 2) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_compliant_v4	Participant Compliant - Visit 4 (End Of Intervention 1) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	comp_compliant_v7	Participant Compliant - Visit 7 (End Of Intervention 2) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	comp_first_dose_dt_v4	First Dose Date - Visit 4 (End Of Intervention 1) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_first_dose_dt_v7	First Dose Date - Visit 7 (End Of Intervention 2) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_interrupted_v4	Agent Interrupted - Visit 4 (End Of Intervention 1) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	comp_interrupted_v7	Agent Interrupted - Visit 7 (End Of Intervention 2) - [Compliance]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	comp_last_dose_dt_v4	Last Dose Date - Visit 4 (End Of Intervention 1) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_last_dose_dt_v7	Last Dose Date - Visit 7 (End Of Intervention 2) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_last_dose_time_v4	Last Dose Time - Visit 4 (End Of Intervention 1) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_last_dose_time_v7	Last Dose Time - Visit 7 (End Of Intervention 2) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	comp_noncomp_rsn_v4	Specify Reason For Noncompliance - Visit 4 (End Of Intervention 1) - [Compliance]		Char
01. Principal	comp_noncomp_rsn_v7	Specify Reason For Noncompliance - Visit 7 (End Of Intervention 2) - [Compliance]		Char
01. Principal	comp_num_interruptions_v4	Number Of Interruptions This Period - Visit 4 (End Of Intervention 1) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	comp_num_interruptions_v7	Number Of Interruptions This Period - Visit 7 (End Of Intervention 2) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Section 13: Off Study

Class	Variable	Label	Description	Format Text
01. Principal	offstudy_dt	Date Off Study - [Off Study]		SAS Date
01. Principal	offstudy_last_agent_dt	Date Last Agent Taken - [Off Study]		SAS Date .N="N/A"
01. Principal	offstudy_last_contact_dt	Date Of Last Contact - [Off Study]		SAS Date
01. Principal	offstudy_off_fup_dt	Date Off Follow-up - [Off Study]		SAS Date .N="N/A"
01. Principal	offstudy_on_fup_dt	Date On Follow-up - [Off Study]		SAS Date .N="N/A"
01. Principal	offstudy_oth_expl	Other Reason Explanation - [Off Study]		Char
01. Principal	offstudy_reason	Reason Off Study - [Off Study]		1="Study Complete" 2="Ineligible" 3="Adverse Event"

Section 14: Follow-up Alcohol

Class	Variable	Label	Description	Format Text
01. Principal	alc_fu_inv_sig	Investigator Signature Present - [Follow-up Alcohol]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	alc_fu_inv_sig_dt	Investigator Signature Date - [Follow-up Alcohol]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	alc_fu_q1_past30_any	1. During The Past 30 Days, Did You Drink Any Alcoholic Beverages? - [Follow-up Alcohol]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	alc_fu_q2_past30_freq	2. During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages, On The Average? - Frequency - [Follow-up Alcohol]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A" .U="Don't Know/Not Sure" 2="Week" 3="Month"
01. Principal	alc_fu_q2_past30_num	2. During The Past 30 Days, How Many Days Per Week Or Per Month Did You Drink Any Alcoholic Beverages, On The Average? - Number - [Follow-up Alcohol]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	alc_fu_q3_past30_amt	3. On The Days When You Drank, On Average, About How Many Drinks Did You Have? - [Follow-up Alcohol]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .U="Unknown"
01. Principal	alc_fu_q4_past30_5more	4. In The Past 30 Days, On How Many Days Did You Have 5 Or More Drinks Per Day? - [Follow-up Alcohol]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" .R="Refused" .U="Unknown"

Section 15: Follow-Up Tobacco

Class	Variable	Label	Description	Format Text
01. Principal	tob_fu_inv_sig	Investigator Signature Present - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	tob_fu_inv_sig_dt	Investigator Signature Date - [Follow-Up Tobacco]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	tob_fu_q10_last_vis	10. How Often Did You Smoke Since Your Last Visit To This Clinic? - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 1="Smoked Every Day"
01. Principal	tob_fu_q1_now_smoke	1. Do You Now Smoke Cigarettes? - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Every Day" 2="Some Days"
01. Principal	tob_fu_q2_cig_avg	2. On Average, When You Smoked, About How Many Cigarettes Do You (Or Did You) Smoke A Day? (A Pack Usually Has 20 Cigarettes In It). - [Follow-Up Tobacco]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	tob_fu_q3_last_smoke_cat	3. How Long Has It Been Since You Last Smoked A Cigarette (Even One Or Two Puffs)? - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="I Smoked A Cigarette Today (At Least One Puff)"
01. Principal	tob_fu_q3_last_smoke_days	3. How Many Days It Has Been Since Your Last Cigarette? - [Follow-Up Tobacco]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	tob_fu_q4_used_oth	4. Since Your Last Visit, Have You Used Other Forms Of Tobacco, Not Including Cigarettes? - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	tob_fu_q5_other_cat	5. How Often Do You/Did You Use Other Forms Of Tobacco? - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 1="Every Day" 2="Some Days"
01. Principal	tob_fu_q5_other_freq	5. How Often Do You/Did You Use Other Forms Of Tobacco? - Frequency - [Follow-Up Tobacco]		Char

Class	Variable	Label	Description	Format Text
01. Principal	tob_fu_q5_other_num	5. How Often Do You/Did You Use Other Forms Of Tobacco? - Number - [Follow-Up Tobacco]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	tob_fu_q6_bidis	6. Since Your Last Visit, Which Of The Following Products Have You Used? - Bidis - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	tob_fu_q6_cig	6. Since Your Last Visit, Which Of The Following Products Have You Used? - Cigarettes - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	tob_fu_q6_cigar	6. Since Your Last Visit, Which Of The Following Products Have You Used? - Traditional Cigars, Cigarillos Or Filtered Cigars - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	tob_fu_q6_clove	6. Since Your Last Visit, Which Of The Following Products Have You Used? - Clove Cigarettes Or Kreteks - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	tob_fu_q6_elec	6. Since Your Last Visit, Which Of The Following Products Have You Used? - E-Cigarettes Or Other Electronic Nicotine Delivery System - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	tob_fu_q6_hookah	6. Since Your Last Visit, Which Of The Following Products Have You Used? - Hookah - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	tob_fu_q6_paan	6. Since Your Last Visit, Which Of The Following Products Have You Used? - Paan With Tobacco, Gutka, Zarda, Khaini - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	tob_fu_q6_pipe	6. Since Your Last Visit, Which Of The Following Products Have You Used? - Pipes - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	tob_fu_q6_smokeless	6. Since Your Last Visit, Which Of The Following Products Have You Used? - Smokeless Tobacco, Like Dip, Chew, Or Snuff - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	tob_fu_q6_snus	6. Since Your Last Visit, Which Of The Following Products Have You Used? - Snus - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	tob_fu_q6_waterpipe	6. Since Your Last Visit, Which Of The Following Products Have You Used? - Waterpipe - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	tob_fu_q7_time_since	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? - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .U="Unknown" 1="Within The Past Month (0 To 1 Month Ago)"
01. Principal	tob_fu_q8_during_trt	8. How Often Did You Smoke During Study Treatment? - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 1="Smoked Every Day" 2="Smoked Some Days"
01. Principal	tob_fu_q9_after_trt	9. How Often Did You Smoke After The End Of Study Treatment? - [Follow-Up Tobacco]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .U="Unknown" 1="Smoked Every Day" 2="Smoked Some Days"

Section 16: Physical Examination

Class	Variable	Label	Description	Format Text
01. Principal	phys_abdomen_cmnt_v1	Abdomen - Comments - Visit 1 (Screening) - [Physical Examination]		Char
01. Principal	phys_abdomen_finding_v1	Abdomen - Finding - Visit 1 (Screening) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal"
01. Principal	phys_avg_10cigs_v1	Smoked An Average Of 10 Cigarettes Per Day Since Last Visit - Visit 1 (Screening) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	phys_avg_10cigs_v2	Smoked An Average Of 10 Cigarettes Per Day Since Last Visit - Visit 2 (Baseline 1) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	phys_avg_10cigs_v3	Smoked An Average Of 10 Cigarettes Per Day Since Last Visit - Visit 3 (Intervention Period 1 Day 4 Or 5) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	phys_avg_10cigs_v4	Smoked An Average Of 10 Cigarettes Per Day Since Last Visit - Visit 4 (End Of Intervention 1) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	phys_avg_10cigs_v5	Smoked An Average Of 10 Cigarettes Per Day Since Last Visit - Visit 5 (Baseline 2) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	phys_avg_10cigs_v6	Smoked An Average Of 10 Cigarettes Per Day Since Last Visit - Visit 6 (Intervention Period 2 Day 4 Or 5) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	phys_avg_10cigs_v7	Smoked An Average Of 10 Cigarettes Per Day Since Last Visit - Visit 7 (End Of Intervention 2) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Yes"
01. Principal	phys_bp_diastolic_v1	Diastolic Blood Pressure (mm Hg) - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	phys_bp_diastolic_v2	Diastolic Blood Pressure (mm Hg) - Visit 2 (Baseline 1) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_bp_diastolic_v4	Diastolic Blood Pressure (mm Hg) - Visit 4 (End Of Intervention 1) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_bp_diastolic_v5	Diastolic Blood Pressure (mm Hg) - Visit 5 (Baseline 2) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_bp_diastolic_v7	Diastolic Blood Pressure (mm Hg) - Visit 7 (End Of Intervention 2) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_bp_systolic_v1	Systolic Blood Pressure (mm Hg) - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_bp_systolic_v2	Systolic Blood Pressure (mm Hg) - Visit 2 (Baseline 1) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_bp_systolic_v4	Systolic Blood Pressure (mm Hg) - Visit 4 (End Of Intervention 1) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_bp_systolic_v5	Systolic Blood Pressure (mm Hg) - Visit 5 (Baseline 2) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_bp_systolic_v7	Systolic Blood Pressure (mm Hg) - Visit 7 (End Of Intervention 2) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_chest_comments_v1	Chest - Comments - Visit 1 (Screening) - [Physical Examination]		Char
01. Principal	phys_chest_finding_v1	Chest - Finding - Visit 1 (Screening) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal"
01. Principal	phys_exam_dt_v1	Examination Date - Visit 1 (Screening) - [Physical Examination]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_exam_dt_v2	Examination Date - Visit 2 (Baseline 1) - [Physical Examination]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_exam_dt_v4	Examination Date - Visit 4 (End Of Intervention 1) - [Physical Examination]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	phys_exam_dt_v5	Examination Date - Visit 5 (Baseline 2) - [Physical Examination]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_exam_dt_v7	Examination Date - Visit 7 (End Of Intervention 2) - [Physical Examination]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_heart_cmnt_v1	Heart - Comments - Visit 1 (Screening) - [Physical Examination]		Char
01. Principal	phys_heart_finding_v1	Heart - Finding - Visit 1 (Screening) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal"
01. Principal	phys_height_v1	Height (in) - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_karnofsky_v1	Karnofsky Performance Status - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_lung_cmnt_v1	Lungs - Comments - Visit 1 (Screening) - [Physical Examination]		Char
01. Principal	phys_lung_finding_v1	Lungs - Finding - Visit 1 (Screening) - [Physical Examination]		.E="Not Eligible For Study" .F="No Record For This Visit" 1="Normal"
01. Principal	phys_pulse_rate_v1	Pulse Rate - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_pulse_rate_v2	Pulse Rate - Visit 2 (Baseline 1) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_pulse_rate_v4	Pulse Rate - Visit 4 (End Of Intervention 1) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_pulse_rate_v5	Pulse Rate - Visit 5 (Baseline 2) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_pulse_rate_v7	Pulse Rate - Visit 7 (End Of Intervention 2) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_temperature_v1	Temperature (F) - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_temperature_v2	Temperature (F) - Visit 2 (Baseline 1) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	phys_temperature_v4	Temperature (F) - Visit 4 (End Of Intervention 1) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_temperature_v5	Temperature (F) - Visit 5 (Baseline 2) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_temperature_v7	Temperature (F) - Visit 7 (End Of Intervention 2) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_weight_v1	Weight (lb) - Visit 1 (Screening) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_weight_v2	Weight (lb) - Visit 2 (Baseline 1) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_weight_v4	Weight (lb) - Visit 4 (End Of Intervention 1) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	phys_weight_v5	Weight (lb) - Visit 5 (Baseline 2) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	phys_weight_v7	Weight (lb) - Visit 7 (End Of Intervention 2) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Section 17: Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	bld_alb_glob_clin_v1	Albumin/Globulin (Ratio) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_alb_glob_clin_v7	Albumin/Globulin (Ratio) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bld_alb_glob_oor_v1	Albumin/Globulin (Ratio) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_alb_glob_oor_v7	Albumin/Globulin (Ratio) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bld_alb_glob_rslt_v1	Albumin/Globulin (Ratio) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_alb_glob_rslt_v7	Albumin/Globulin (Ratio) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bld_albumin_clin_v1	Albumin (g/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_albumin_clin_v7	Albumin (g/dL) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_albumin_oor_v1	Albumin (g/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_albumin_oor_v7	Albumin (g/dL) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_albumin_rslt_v1	Albumin (g/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	bld_albumin_rslt_v7	Albumin (g/dL) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_alk_phos_clin_v1	Alkaline Phosphatase (IU/L) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_alk_phos_clin_v7	Alkaline Phosphatase (IU/L) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_alk_phos_or_v1	Alkaline Phosphatase (IU/L) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_alk_phos_or_v7	Alkaline Phosphatase (IU/L) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_alk_phos_rslt_v1	Alkaline Phosphatase (IU/L) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_alk_phos_rslt_v7	Alkaline Phosphatase (IU/L) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_anion_gap_clin_v1	Anion Gap - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_anion_gap_clin_v7	Anion Gap - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bld_anion_gap_or_v1	Anion Gap - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_anion_gap_or_v7	Anion Gap - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bld_anion_gap_rslt_v1	Anion Gap - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_anion_gap_rslt_v7	Anion Gap - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	bld_bicarbonate_clin_v1	Bicarbonate (mmol/l) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bld_bicarbonate_clin_v7	Bicarbonate (mmol/l) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_bicarbonate_oor_v1	Bicarbonate (mmol/l) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bld_bicarbonate_oor_v7	Bicarbonate (mmol/l) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_bicarbonate_rslt_v1	Bicarbonate (mmol/l) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bld_bicarbonate_rslt_v7	Bicarbonate (mmol/l) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_bilirubin_clin_v1	Bilirubin (mg/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_bilirubin_clin_v7	Bilirubin (mg/dL) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_bilirubin_oor_v1	Bilirubin (mg/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_bilirubin_oor_v7	Bilirubin (mg/dL) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_bilirubin_rslt_v1	Bilirubin (mg/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_bilirubin_rslt_v7	Bilirubin (mg/dL) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_bun_clin_v1	BUN (mg/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bld_bun_clin_v7	BUN (mg/dL) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_bun_creat_clin_v1	Bun/Creatinine (Ratio) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_bun_creat_clin_v7	Bun/Creatinine (Ratio) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No"
01. Principal	bld_bun_creat_oor_v1	Bun/Creatinine (Ratio) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_bun_creat_oor_v7	Bun/Creatinine (Ratio) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
01. Principal	bld_bun_creat_rslt_v1	Bun/Creatinine (Ratio) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_bun_creat_rslt_v7	Bun/Creatinine (Ratio) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	bld_bun_oor_v1	BUN (mg/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_bun_oor_v7	BUN (mg/dL) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_bun_rslt_v1	BUN (mg/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_bun_rslt_v7	BUN (mg/dL) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_calcium_clin_v1	Calcium (mg/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_calcium_clin_v7	Calcium (mg/dL) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bld_calcium_oor_v1	Calcium (mg/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_calcium_oor_v7	Calcium (mg/dL) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_calcium_rslt_v1	Calcium (mg/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_calcium_rslt_v7	Calcium (mg/dL) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_chloride_clin_v1	Chloride (mmol/l) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_chloride_clin_v7	Chloride (mmol/l) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_chloride_oor_v1	Chloride (mmol/l) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_chloride_oor_v7	Chloride (mmol/l) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_chloride_rslt_v1	Chloride (mmol/l) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_chloride_rslt_v7	Chloride (mmol/l) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_creatinine_clin_v1	Creatinine (mg/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_creatinine_clin_v7	Creatinine (mg/dL) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_creatinine_oor_v1	Creatinine (mg/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bld_creatinine_or_v7	Creatinine (mg/dL) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_creatinine_rslt_v1	Creatinine (mg/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_creatinine_rslt_v7	Creatinine (mg/dL) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_fasting_v1	Fasting - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_fasting_v7	Fasting - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .U="Unknown"
01. Principal	bld_globulin_clin_v1	Globulin (g/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_globulin_clin_v7	Globulin (g/dL) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_globulin_oor_v1	Globulin (g/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_globulin_oor_v7	Globulin (g/dL) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_globulin_rslt_v1	Globulin (g/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_globulin_rslt_v7	Globulin (g/dL) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_glucose_clin_v1	Glucose Serum (mg/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_glucose_clin_v7	Glucose Serum (mg/dL) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bld_glucose_oor_v1	Glucose Serum (mg/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_glucose_oor_v7	Glucose Serum (mg/dL) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_glucose_rslt_v1	Glucose Serum (mg/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_glucose_rslt_v7	Glucose Serum (mg/dL) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_potassium_clin_v1	Potassium (mmol/l) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_potassium_clin_v7	Potassium (mmol/l) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_potassium_oor_v1	Potassium (mmol/l) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_potassium_oor_v7	Potassium (mmol/l) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_potassium_rslt_v1	Potassium (mmol/l) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_potassium_rslt_v7	Potassium (mmol/l) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_protein_clin_v1	Total Protein (g/dL) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" 0="No"
01. Principal	bld_protein_clin_v7	Total Protein (g/dL) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_protein_oor_v1	Total Protein (g/dL) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bld_protein_oor_v7	Total Protein (g/dL) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_protein_rslt_v1	Total Protein (g/dL) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_protein_rslt_v7	Total Protein (g/dL) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_sgop_ast_clin_v1	SGOP/AST (IU/L) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_sgop_ast_clin_v7	SGOP/AST (IU/L) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_sgop_ast_oor_v1	SGOP/AST (IU/L) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_sgop_ast_oor_v7	SGOP/AST (IU/L) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_sgop_ast_rslt_v1	SGOP/AST (IU/L) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_sgop_ast_rslt_v7	SGOP/AST (IU/L) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_sgpt_alt_clin_v1	SGPT/ALT (IU/L) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_sgpt_alt_clin_v7	SGPT/ALT (IU/L) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_sgpt_alt_oor_v1	SGPT/ALT (IU/L) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_sgpt_alt_oor_v7	SGPT/ALT (IU/L) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	bld_sgpt_alt_rslt_v1	SGPT/ALT (IU/L) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_sgpt_alt_rslt_v7	SGPT/ALT (IU/L) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_sodium_clin_v1	Sodium (mmol/l) - Clinically Significant - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_sodium_clin_v7	Sodium (mmol/l) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	bld_sodium_oor_v1	Sodium (mmol/l) - Out Of Range - Visit 1 (Screening) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_sodium_oor_v7	Sodium (mmol/l) - Out Of Range - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	bld_sodium_rslt_v1	Sodium (mmol/l) - Results - Visit 1 (Screening) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_sodium_rslt_v7	Sodium (mmol/l) - Results - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_spec_dt_v1	Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	bld_spec_dt_v7	Specimen Collection Date - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_spec_dt_v1	Specimen Collection Date - Visit 1 (Screening) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing"
01. Principal	hema_spec_dt_v7	Specimen Collection Date - Visit 7 (End Of Intervention 2) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Section 18: Hematology

Class	Variable	Label	Description	Format Text
01. Principal	hema_anc_clin_v1	ANC (k/uL) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_anc_clin_v7	ANC (k/uL) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_anc_oor_v1	ANC (k/uL) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_anc_oor_v7	ANC (k/uL) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_anc_rslt_v1	ANC (k/uL) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_anc_rslt_v7	ANC (k/uL) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_bands_clin_v1	Bands (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	hema_bands_clin_v7	Bands (%) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	hema_bands_oor_v1	Bands (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	hema_bands_oor_v7	Bands (%) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	hema_bands_rslt_v1	Bands (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	hema_bands_rslt_v7	Bands (%) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	hema_basophil_c lin_v1	Basophils (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_basophil_c lin_v7	Basophils (%) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_basophil_oor_v1	Basophils (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_basophil_oor_v7	Basophils (%) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_basophil_rslt_v1	Basophils (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_basophil_rslt_v7	Basophils (%) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_eosinophil_clin_v1	Eosinophils (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_eosinophil_clin_v7	Eosinophils (%) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_eosinophil_oor_v1	Eosinophils (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_eosinophil_oor_v7	Eosinophils (%) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_eosinophil_rslt_v1	Eosinophils (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_eosinophil_rslt_v7	Eosinophils (%) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_hematocrit_clin_v1	Hematocrit (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hema_hematocrit_clin_v7	Hematocrit (%) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_hematocrit_oor_v1	Hematocrit (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_hematocrit_oor_v7	Hematocrit (%) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_hematocrit_rslt_v1	Hematocrit (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_hematocrit_rslt_v7	Hematocrit (%) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_hemoglobin_clin_v1	Hemoglobin (g/dL) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_hemoglobin_clin_v7	Hemoglobin (g/dL) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_hemoglobin_oor_v1	Hemoglobin (g/dL) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_hemoglobin_oor_v7	Hemoglobin (g/dL) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_hemoglobin_rslt_v1	Hemoglobin (g/dL) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_hemoglobin_rslt_v7	Hemoglobin (g/dL) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_lymphocyte_clin_v1	Lymphocytes (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_lymphocyte_clin_v7	Lymphocytes (%) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hema_lymphocyte_oor_v1	Lymphocytes (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_lymphocyte_oor_v7	Lymphocytes (%) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_lymphocyte_rslt_v1	Lymphocytes (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_lymphocyte_rslt_v7	Lymphocytes (%) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_monocyte_clin_v1	Monocytes (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_monocyte_clin_v7	Monocytes (%) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_monocyte_oor_v1	Monocytes (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_monocyte_oor_v7	Monocytes (%) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_monocyte_rslt_v1	Monocytes (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_monocyte_rslt_v7	Monocytes (%) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_neutrophil_clin_v1	Neutrophils (%) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_neutrophil_clin_v7	Neutrophils (%) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_neutrophil_oor_v1	Neutrophils (%) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hema_neutrophil_oor_v7	Neutrophils (%) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_neutrophil_rslt_v1	Neutrophils (%) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_neutrophil_rslt_v7	Neutrophils (%) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_platelets_clin_v1	Platelets (k/mm3) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_platelets_clin_v7	Platelets (k/mm3) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_platelets_oor_v1	Platelets (k/mm3) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_platelets_oor_v7	Platelets (k/mm3) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_platelets_rslt_v1	Platelets (k/mm3) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_platelets_rslt_v7	Platelets (k/mm3) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_rbc_clin_v1	Red Blood Cells (m/mm3) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_rbc_clin_v7	Red Blood Cells (m/mm3) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_rbc_oor_v1	Red Blood Cells (m/mm3) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	hema_rbc_oor_v7	Red Blood Cells (m/mm3) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_rbc_rslt_v1	Red Blood Cells (m/mm3) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_rbc_rslt_v7	Red Blood Cells (m/mm3) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_wbc_clin_v1	White Blood Cells (k/mm3) - Clinically Significant - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_wbc_clin_v7	White Blood Cells (k/mm3) - Clinically Significant - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No"
01. Principal	hema_wbc_oor_v1	White Blood Cells (k/mm3) - Out Of Range - Visit 1 (Screening) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_wbc_oor_v7	White Blood Cells (k/mm3) - Out Of Range - Visit 7 (End Of Intervention 2) - [Hematology]		.E="Not Eligible For Study" .F="No Record For This Visit" 0="No" 1="Yes"
01. Principal	hema_wbc_rslt_v1	White Blood Cells (k/mm3) - Results - Visit 1 (Screening) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	hema_wbc_rslt_v7	White Blood Cells (k/mm3) - Results - Visit 7 (End Of Intervention 2) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Section 19: Specimen Collection

Class	Variable	Label	Description	Format Text
01. Principal	spec_blood_cmnt_v2	Blood Specimen - Comments - Visit 2 (Baseline 1) - [Specimen Collection]		Char
01. Principal	spec_blood_cmnt_v3	Blood Specimen - Comments - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		Char
01. Principal	spec_blood_cmnt_v4	Blood Specimen - Comments - Visit 4 (End of Intervention 1) - [Specimen Collection]		Char
01. Principal	spec_blood_cmnt_v5	Blood Specimen - Comments - Visit 5 (Baseline 2) - [Specimen Collection]		Char
01. Principal	spec_blood_cmnt_v6	Blood Specimen - Comments - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		Char
01. Principal	spec_blood_cmnt_v7	Blood Specimen - Comments - Visit 7 (End of Intervention 2) - [Specimen Collection]		Char
01. Principal	spec_blood_col_dt_v2	Blood Specimen - Collection Date - Visit 2 (Baseline 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_blood_col_dt_v3	Blood Specimen - Collection Date - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_blood_col_dt_v4	Blood Specimen - Collection Date - Visit 4 (End of Intervention 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_blood_col_dt_v5	Blood Specimen - Collection Date - Visit 5 (Baseline 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_blood_col_dt_v6	Blood Specimen - Collection Date - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	spec_blood_col_dt_v7	Blood Specimen - Collection Date - Visit 7 (End of Intervention 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_blood_col_time_v2	Blood Specimen - Collection Time - Visit 2 (Baseline 1) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_blood_col_time_v3	Blood Specimen - Collection Time - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_blood_col_time_v4	Blood Specimen - Collection Time - Visit 4 (End of Intervention 1) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_blood_col_time_v5	Blood Specimen - Collection Time - Visit 5 (Baseline 2) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_blood_col_time_v6	Blood Specimen - Collection Time - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_blood_col_time_v7	Blood Specimen - Collection Time - Visit 7 (End of Intervention 2) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_buccal_comments_v2	Buccal Specimen - Comments - Visit 2 (Baseline 1) - [Specimen Collection]		Char
01. Principal	spec_buccal_comments_v3	Buccal Specimen - Comments - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		Char
01. Principal	spec_buccal_comments_v4	Buccal Specimen - Comments - Visit 4 (End of Intervention 1) - [Specimen Collection]		Char
01. Principal	spec_buccal_comments_v5	Buccal Specimen - Comments - Visit 5 (Baseline 2) - [Specimen Collection]		Char
01. Principal	spec_buccal_comments_v6	Buccal Specimen - Comments - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		Char

Class	Variable	Label	Description	Format Text
01. Principal	spec_buccal_cmnt_v7	Buccal Specimen - Comments - Visit 7 (End of Intervention 2) - [Specimen Collection]		Char
01. Principal	spec_buccal_col_dt_v2	Buccal Specimen - Collection Date - Visit 2 (Baseline 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_buccal_col_dt_v3	Buccal Specimen - Collection Date - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_buccal_col_dt_v4	Buccal Specimen - Collection Date - Visit 4 (End of Intervention 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_buccal_col_dt_v5	Buccal Specimen - Collection Date - Visit 5 (Baseline 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_buccal_col_dt_v6	Buccal Specimen - Collection Date - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_buccal_col_dt_v7	Buccal Specimen - Collection Date - Visit 7 (End of Intervention 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_buccal_col_time_v2	Buccal Specimen - Collection Time - Visit 2 (Baseline 1) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_buccal_col_time_v3	Buccal Specimen - Collection Time - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_buccal_col_time_v4	Buccal Specimen - Collection Time - Visit 4 (End of Intervention 1) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_buccal_col_time_v5	Buccal Specimen - Collection Time - Visit 5 (Baseline 2) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_buccal_col_time_v6	Buccal Specimen - Collection Time - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"

Class	Variable	Label	Description	Format Text
01. Principal	spec_buccal_col_time_v7	Buccal Specimen - Collection Time - Visit 7 (End of Intervention 2) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_nasal_cmnt_v2	Nasal Specimen - Comments - Visit 2 (Baseline 1) - [Specimen Collection]		Char
01. Principal	spec_nasal_cmnt_v3	Nasal Specimen - Comments - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		Char
01. Principal	spec_nasal_cmnt_v4	Nasal Specimen - Comments - Visit 4 (End of Intervention 1) - [Specimen Collection]		Char
01. Principal	spec_nasal_cmnt_v5	Nasal Specimen - Comments - Visit 5 (Baseline 2) - [Specimen Collection]		Char
01. Principal	spec_nasal_cmnt_v6	Nasal Specimen - Comments - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		Char
01. Principal	spec_nasal_cmnt_v7	Nasal Specimen - Comments - Visit 7 (End of Intervention 2) - [Specimen Collection]		Char
01. Principal	spec_nasal_col_dt_v2	Nasal Specimen - Collection Date - Visit 2 (Baseline 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_nasal_col_dt_v3	Nasal Specimen - Collection Date - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	spec_nasal_col_dt_v4	Nasal Specimen - Collection Date - Visit 4 (End of Intervention 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_nasal_col_dt_v5	Nasal Specimen - Collection Date - Visit 5 (Baseline 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_nasal_col_dt_v6	Nasal Specimen - Collection Date - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	spec_nasal_col_dt_v7	Nasal Specimen - Collection Date - Visit 7 (End of Intervention 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_nasal_col_time_v2	Nasal Specimen - Collection Time - Visit 2 (Baseline 1) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_nasal_col_time_v3	Nasal Specimen - Collection Time - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .M="Missing" .N="N/A"
01. Principal	spec_nasal_col_time_v4	Nasal Specimen - Collection Time - Visit 4 (End of Intervention 1) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_nasal_col_time_v5	Nasal Specimen - Collection Time - Visit 5 (Baseline 2) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_nasal_col_time_v6	Nasal Specimen - Collection Time - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_nasal_col_time_v7	Nasal Specimen - Collection Time - Visit 7 (End of Intervention 2) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_cmnt_v2	Urine Specimen - Comments - Visit 2 (Baseline 1) - [Specimen Collection]		Char
01. Principal	spec_urine_cmnt_v3	Urine Specimen - Comments - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		Char
01. Principal	spec_urine_cmnt_v4	Urine Specimen - Comments - Visit 4 (End of Intervention 1) - [Specimen Collection]		Char
01. Principal	spec_urine_cmnt_v5	Urine Specimen - Comments - Visit 5 (Baseline 2) - [Specimen Collection]		Char
01. Principal	spec_urine_cmnt_v6	Urine Specimen - Comments - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		Char

Class	Variable	Label	Description	Format Text
01. Principal	spec_urine_cmnt_v7	Urine Specimen - Comments - Visit 7 (End of Intervention 2) - [Specimen Collection]		Char
01. Principal	spec_urine_end_dt_v2	Urine Specimen - Collection End Date - Visit 2 (Baseline 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_end_dt_v3	Urine Specimen - Collection End Date - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_urine_end_dt_v4	Urine Specimen - Collection End Date - Visit 4 (End of Intervention 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_end_dt_v5	Urine Specimen - Collection End Date - Visit 5 (Baseline 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_end_dt_v6	Urine Specimen - Collection End Date - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_urine_end_dt_v7	Urine Specimen - Collection End Date - Visit 7 (End of Intervention 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_end_time_v2	Urine Specimen - Collection End Time - Visit 2 (Baseline 1) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_end_time_v3	Urine Specimen - Collection End Time - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_urine_end_time_v4	Urine Specimen - Collection End Time - Visit 4 (End of Intervention 1) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_end_time_v5	Urine Specimen - Collection End Time - Visit 5 (Baseline 2) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_end_time_v6	Urine Specimen - Collection End Time - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	spec_urine_end_time_v7	Urine Specimen - Collection End Time - Visit 7 (End of Intervention 2) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_start_dt_v2	Urine Specimen - Collection Start Date - Visit 2 (Baseline 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_start_dt_v3	Urine Specimen - Collection Start Date - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_urine_start_dt_v4	Urine Specimen - Collection Start Date - Visit 4 (End of Intervention 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_start_dt_v5	Urine Specimen - Collection Start Date - Visit 5 (Baseline 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_start_dt_v6	Urine Specimen - Collection Start Date - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_urine_start_dt_v7	Urine Specimen - Collection Start Date - Visit 7 (End of Intervention 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_start_time_v2	Urine Specimen - Collection Start Time - Visit 2 (Baseline 1) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_start_time_v3	Urine Specimen - Collection Start Time - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_urine_start_time_v4	Urine Specimen - Collection Start Time - Visit 4 (End of Intervention 1) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_start_time_v5	Urine Specimen - Collection Start Time - Visit 5 (Baseline 2) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_start_time_v6	Urine Specimen - Collection Start Time - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	spec_urine_start_time_v7	Urine Specimen - Collection Start Time - Visit 7 (End of Intervention 2) - [Specimen Collection]		Numeric .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_vol_v2	Urine Specimen - Volume (mL) - Visit 2 (Baseline 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_vol_v3	Urine Specimen - Volume (mL) - Visit 3 (Intervention Period 1 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_urine_vol_v4	Urine Specimen - Volume (mL) - Visit 4 (End of Intervention 1) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_vol_v5	Urine Specimen - Volume (mL) - Visit 5 (Baseline 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"
01. Principal	spec_urine_vol_v6	Urine Specimen - Volume (mL) - Visit 6 (Intervention Period 2 Day 4 or 5) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit" .N="N/A"
01. Principal	spec_urine_vol_v7	Urine Specimen - Volume (mL) - Visit 7 (End of Intervention 2) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Record For This Visit"

Section 20: Verification

Class	Variable	Label	Description	Format Text
01. Principal	verif_inv_sig	Investigator Signature Present - [Verification]		1="Yes"
01. Principal	verif_inv_sig_dt	Date Of Signature - [Verification]		SAS Date