

UAZ2015-05-02 - ENHANCED PERSON: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	UAZ2015-05-02 - Enhanced Person: Data Dictionary
Date Created	11/27/2019
Sections	27
Entries	724
Document Filename	dictionary_enhanced_prsn.rtf

UAZ2015-05-02 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
build_dt	Build Date		SAS Date
ParticipantID	Participant ID		Char

Section 2: Study-wide

Variable	Label	Description	Format Text
visit_dt_et	Date of Early Termination Visit		SAS Date .E="Not Eligible For Study" .N="N/A"
visit_dt_v1	Date of Visit 1 (Baseline)		SAS Date .E="Not Eligible For Study"
visit_dt_v2	Date of Visit 2 (Agent Start)		SAS Date .E="Not Eligible For Study"
visit_dt_v4	Date of Visit 4 (Week 6)		SAS Date .E="Not Eligible For Study" .F="No Form"
visit_dt_v6	Date of Visit 6 (Week 12-14)		SAS Date .E="Not Eligible For Study" .F="No Form"

Section 3: Consent

Variable	Label	Description	Format Text
reg_biop_tissue_retention	Permission for Retention - Biopsy Tissue - [Registration]	Has participant given permission for retention of biopsy tissue for future research?	0="No" 1="Yes"
reg_blood_cell_retention	Permission for Retention - Blood Cells - [Registration]	Has participant given permission for retention of blood cells for future research?	0="No" 1="Yes"
reg_consent_dt	Date Informed Consent Signed - [Registration]		SAS Date
reg_future_contact	Permission to be Contacted for Future Research - [Registration]	Has participant given permission to be contacted for future research?	.M="Missing" 0="No" 1="Yes"
reg_genetic_data	Permission for Release of Genetic Data and PHI into Scientific Databases - [Registration]	Has participant given permission for release of genetic data and health information into scientific databases?	.M="Missing" 0="No" 1="Yes"
reg_saliva_retention	Permission for Retention - Saliva - [Registration]	Has participant given permission for retention of saliva for future research?	0="No" 1="Yes"
reg_serum_retention	Permission for Retention - Serum - [Registration]	Has participant given permission for retention of serum for future research?	0="No" 1="Yes"

Section 4: Registration

Variable	Label	Description	Format Text
institution_code	Institution Code - [Registration]		1="11280 - British Columbia Cancer Agency" 2="CA067 - UCSD" 3="MN022 - University of Minnesota"
reg_age	Age at Registration - [Registration]	Age of the participant at registration. (Derived from date of birth at registration).	Numeric
reg_country	Country Code - [Registration]		1="USA" 2="Canada"
reg_dt	Date of Registration - [Registration]		SAS Date
reg_eligible	Participant Satisfies All Eligibility Criteria - [Registration]		0="No" 1="Yes"
reg_ethnicity	Ethnicity - [Registration]		1="Hispanic or Latino" 2="Not Hispanic or Latino" 3="Unknown"
reg_gender	Gender - [Registration]		1="Male" 2="Female"
reg_race	Race - [Registration]		1="White" 2="Black or African American" 4="Asian" 6="Unknown" 7="Not Reported"
reg_race_eth	Race + Ethnicity - [Registration]	Combination of the Race and Ethnicity variables. Participants can only be considered white or black when they are not Hispanic. If the participant is white or black and Hispanic, then they are considered Hispanic. If the participant is Asian, Pacific Islander, or American Indian then they are considered that race.	1="White, Non-Hispanic" 2="Black, Non-Hispanic" 3="Hispanic" 4="Asian" 6="American Indian" 7="Not Reported"
reg_screen_dt1-2	Screen Date # - [Registration]		SAS Date .N="N/A"

Section 5: Baseline Symptoms

Variable	Label	Description	Format Text
bsymp_cmnt1-12	Comments - Symptom # - [Baseline Symptoms]		Char
bsymp_desc1-12	Description - Symptom # - [Baseline Symptoms]		Char
bsymp_grade1-12	Grade - Symptom # - [Baseline Symptoms]		.E="Not Eligible For Study" .N="N/A" 1="Mild" 2="Moderate" 3="Severe"
bsymp_num	Number of Baseline Symptoms - [Baseline Symptoms]		Numeric .E="Not Eligible For Study"
bsymp_onset_dt1-12	Onset Date - Symptom # - [Baseline Symptoms]		SAS Date .E="Not Eligible For Study" .N="N/A"

Section 6: Medical History

Variable	Label	Description	Format Text
medhist_all_normal	All Body Systems Normal? - [Medical History]		.E="Not Eligible For Study" 0="No"
medhist_breast_cmnt	Breasts Comments - [Medical History]		Char
medhist_breast_finding	Breasts Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
medhist_cardio_cmnt	Cardiovascular System Comments - [Medical History]		Char
medhist_cardio_finding	Cardiovascular System Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
medhist_derma_cmnt	Dermatologic System Comments - [Medical History]		Char
medhist_derma_finding	Dermatologic System Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
medhist_endometa_cmnt	Endocrine/Metabolic System Comments - [Medical History]		Char
medhist_endometa_finding	Endocrine/Metabolic System Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
medhist_gastro_cmnt	Gastrointestinal System Comments - [Medical History]		Char
medhist_gastro_finding	Gastrointestinal System Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
medhist_genit_cmnt	Genitourinary System Comments - [Medical History]		Char
medhist_genit_finding	Genitourinary System Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
medhist_has_allergies	Any Allergies? - [Medical History]		.E="Not Eligible For Study" 0="No" 1="Yes"
medhist_heent_cmnt	H/E/E/N/T System Comments - [Medical History]		Char
medhist_heent_finding	H/E/E/N/T System Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"

Variable	Label	Description	Format Text
medhist_hemalymph_cmnt	Hematopoietic/Lymph System Comments - [Medical History]		Char
medhist_hemalymph_finding	Hematopoietic/Lymph System Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
medhist_muscskel_cmnt	Musculoskeletal System Comments - [Medical History]		Char
medhist_muscskel_finding	Musculoskeletal System Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
medhist_neck_cmnt	Neck Comments - [Medical History]		Char
medhist_neck_finding	Neck Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal"
medhist_neuro_cmnt	Neurologic System Comments - [Medical History]		Char
medhist_neuro_finding	Neurologic System Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
medhist_oth_cmnt1-2	Comments - Other Body System # - [Medical History]		Char
medhist_oth_finding1-2	Finding - Other Body System # - [Medical History]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 2="Abnormal"
medhist_oth_num	Number of Other Body Systems Reported - [Medical History]		Numeric .E="Not Eligible For Study" .F="No Form"
medhist_oth_sys1-2	Type - Other Body System # - [Medical History]		Char
medhist_resp_cmnt	Respiratory System Comments - [Medical History]		Char
medhist_resp_finding	Respiratory System Finding - [Medical History]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
medhist_spec_allergies	Specific Allergies - [Medical History]		Char

Section 7: Concomitant Medications

Variable	Label	Description	Format Text
conmed_dose1-47	Dose - Medication # - [Concomitant Medications]		Numeric .E="Not Eligible For Study" .N="N/A"
conmed_freq1-47	Frequency - Medication # - [Concomitant Medications]		Char
conmed_name1-47	Name - Medication # - [Concomitant Medications]		Char
conmed_num	Number of Concomitant Medications Taken - [Concomitant Medications]		Numeric .E="Not Eligible For Study"
conmed_reason1-47	Reason for Taking - Medication # - [Concomitant Medications]		Char
conmed_report_dt1-47	Report Date - Medication # - [Concomitant Medications]		SAS Date .E="Not Eligible For Study" .N="N/A"
conmed_resolved_dt1-47	Resolved Date - Medication # - [Concomitant Medications]		SAS Date .C="Continuous" .E="Not Eligible For Study" .N="N/A"
conmed_start_dt1-47	Start Date - Medication # - [Concomitant Medications]		SAS Date .E="Not Eligible For Study" .N="N/A"
conmed_units1-47	Units - Medication # - [Concomitant Medications]		Char

Section 8: Pregnancy Specimen Data

Variable	Label	Description	Format Text
preg_result_et	Test Result - Urine Test - Early Termination - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .N="N/A"
preg_result_v1	Test Result - Urine Test - Visit 1 (Baseline) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .N="N/A" 3="Negative"
preg_result_v2	Test Result - Urine Test - Visit 2 (Agent Start) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .N="N/A" 1="Not Obtained"
preg_result_v4	Test Result - Urine Test - Visit 4 (Week 6) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 3="Negative"
preg_result_v6	Test Result - Urine Test - Visit 6 (Week 12-14) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 3="Negative"
preg_rsn_not_collected_et	Reason Test Was Not Collected - Urine Test - Early Termination - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .N="N/A" 1="Participant is male" 2="Participant is female and not of childbearing potential"
preg_rsn_not_collected_v1	Reason Test Was Not Collected - Urine Test - Visit 1 (Baseline) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .N="N/A" 1="Participant is male" 2="Participant is female and not of childbearing potential"
preg_rsn_not_collected_v2	Reason Test Was Not Collected - Urine Test - Visit 2 (Agent Start) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .N="N/A" 1="Participant is male" 2="Participant is female and not of childbearing potential"
preg_rsn_not_collected_v4	Reason Test Was Not Collected - Urine Test - Visit 4 (Week 6) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 1="Participant is male" 2="Participant is female and not of childbearing potential"
preg_rsn_not_collected_v6	Reason Test Was Not Collected - Urine Test - Visit 6 (Week 12-14) - [Pregnancy Specimen Data]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 1="Participant is male" 2="Participant is female and not of childbearing potential"

Variable	Label	Description	Format Text
preg_spec_col_dt_e t	Specimen Collection Date - Urine Test - Early Termination - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .M="Missing" .N="N/A"
preg_spec_col_dt_v 1	Specimen Collection Date - Urine Test - Visit 1 (Baseline) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .M="Missing"
preg_spec_col_dt_v 2	Specimen Collection Date - Urine Test - Visit 2 (Agent Start) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .M="Missing"
preg_spec_col_dt_v 4	Specimen Collection Date - Urine Test - Visit 4 (Week 6) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .F="No Form" .M="Missing"
preg_spec_col_dt_v 6	Specimen Collection Date - Urine Test - Visit 6 (Week 12-14) - [Pregnancy Specimen Data]		SAS Date .E="Not Eligible For Study" .F="No Form" .M="Missing"

Section 9: Alcohol - Baseline

Variable	Label	Description	Format Text
alc_base_12_in_life	Drank at Least 12 Alcoholic Drinks in Life? - [Alcohol - Baseline]	1. During your entire life, have you had at least 12 drinks of any kind of alcoholic beverage?	.E="Not Eligible For Study" 1="Yes"
alc_base_age_drink_reg	Age PPT Started Drinking Regularly - [Alcohol - Baseline]	7. At what age did you begin drinking regularly?	Numeric .E="Not Eligible For Study" 999="Don't Know"
alc_base_beer	Drink Beer? - [Alcohol - Baseline]	8. What type(s) of alcohol do you drink? (Mark all that apply)	.E="Not Eligible For Study" 0="No" 1="Yes"
alc_base_cooler	Drink Wine Coolers? - [Alcohol - Baseline]	8. What type(s) of alcohol do you drink? (Mark all that apply)	.E="Not Eligible For Study" 0="No" 1="Yes"
alc_base_current_freq	Current Frequency of Alcohol Use - [Alcohol - Baseline]	2. Do you NOW consume alcohol?	.E="Not Eligible For Study" 1="Every Day" 2="Some Days" 3="Not At All"
alc_base_drink_freq	Average Drink Frequency in Life - [Alcohol - Baseline]	5. On average, how many days per week or month or year do or did you drink any alcoholic beverages?	Char
alc_base_heaviest_drinking	Number of Drinks Per Day at the Heaviest Drinking Point in Life - [Alcohol - Baseline]	4. At the heaviest point, either now or in the past, on the days when you drank, about how many drinks did you drink on the average? (A drink is 1 can or bottle of beer, 1 glass of wine, 1 can or bottle of wine cooler, 1 cocktail or 1 shot of liquor; please enter median if participant answers with a range, i.e. "4-5" = "4.5")	Numeric .E="Not Eligible For Study" .M="Missing"
alc_base_last_drank_reg	Time Since PPT Drank Regularly? - [Alcohol - Baseline]	3. If you do not currently drink alcoholic beverages, but did in the past, how long has it been since you last drank regularly (that is, everyday or some days)?	.E="Not Eligible For Study" .M="Missing" 2="Between 1 and 3 Months (1 to 3 Months Ago)" 5="Between 1 and 5 Years (1 to 5 Years Ago)" 7="More than 15 Years Ago"
alc_base_liquor	Drink Liquor? - [Alcohol - Baseline]	8. What type(s) of alcohol do you drink? (Mark all that apply)	.E="Not Eligible For Study" 0="No" 1="Yes"
alc_base_wine	Drink Wine? - [Alcohol - Baseline]	8. What type(s) of alcohol do you drink? (Mark all that apply)	.E="Not Eligible For Study" 0="No" 1="Yes"

Variable	Label	Description	Format Text
alc_base_years_drink_reg	Years Drinking/Drank Regularly? - [Alcohol - Baseline]	6. How many years have you been drinking (or did drink) regularly?	Numeric .E="Not Eligible For Study" .M="Missing" 999="Don't Know"

Section 10: Tobacco Assessment - Baseline

Variable	Label	Description	Format Text
tob_base_cigs_per_day	Cigarettes Per Day - [Tobacco Assessment - Baseline]	4. On the average, about how many cigarettes a day do (or did) you smoke? (1 pack = 20 cigarettes; please enter median if participant answers with a range, i.e. "4-5" = "4.5")	Numeric .E="Not Eligible For Study" .M="Missing"
tob_base_current_smoke_freq	Currently Smoke Cigarettes? - [Tobacco Assessment - Baseline]	2. Do you NOW smoke cigarettes?	.E="Not Eligible For Study" .N="N/A" 1="Every Day" 2="Some Days" 3="Not At All"
tob_base_freq_oth	Frequency of Other Forms of Tobacco - [Tobacco Assessment - Baseline]	13. Do you use other forms of tobacco every day, some days, or not at all?	.E="Not Eligible For Study" .N="N/A" 3="Not At All"
tob_base_freq_oth_num_days	Frequency of Other Forms of Tobacco - Number of Days - [Tobacco Assessment - Baseline]	13. Do you use other forms of tobacco every day, some days, or not at all?	Numeric .E="Not Eligible For Study" .M="Missing"
tob_base_last_smoked	Time Since PPT Last Smoked Regularly - [Tobacco Assessment - Baseline]	3. If you do not currently smoke cigarettes, but did in the past, how long has it been since you last smoked regularly (that is, everyday or some days)?	.E="Not Eligible For Study" .M="Missing" .N="N/A" 4="Between 6 and 12 Months" 5="Between 1 and 5 Years" 6="Between 5 and 15 Years" 7="More Than 15 Years Ago"
tob_base_oth_day_freq	Frequency of Other Tobacco Forms in a Day - [Tobacco Assessment - Baseline]	14. How often do/did you use other forms of tobacco in a day? (please be as specific as possible e.g. smoked pipe 3 times per day)	Numeric .E="Not Eligible For Study" .M="Missing"
tob_base_oth_forms	Other Forms of Tobacco Used - [Tobacco Assessment - Baseline]	12. What other forms of tobacco do (did) you use?	Char
tob_base_oth_forms_spec	Specific Other Tobacco Forms - [Tobacco Assessment - Baseline]	12. What other forms of tobacco do (did) you use?	Char
tob_base_quit_next_6_months	Seriously Thinking About Quitting Smoking in Next 6 Months? - [Tobacco Assessment - Baseline]	10. Are you seriously thinking about quitting smoking in the next 6 months?	.E="Not Eligible For Study" .M="Missing" .N="N/A" 1="Yes"
tob_base_quit_next_month	Seriously Thinking About Quitting Smoking in Next Month? - [Tobacco Assessment - Baseline]	9. Are you seriously thinking about quitting in the next month?	.E="Not Eligible For Study" .M="Missing" .N="N/A" 0="No" 1="Yes"

Variable	Label	Description	Format Text
tob_base_smoked_100	Smoked 100 Cigarettes in Lifetime? - [Tobacco Assessment - Baseline]	1. Have you smoked 100 cigarettes or more during your entire lifetime? (5 packs = 100 cigarettes)	.E="Not Eligible For Study" 0="No" 1="Yes"
tob_base_smoking_age	Age PPT Began Smoking Regularly - [Tobacco Assessment - Baseline]	6. At what age did you begin smoking regularly?	Numeric .E="Not Eligible For Study" .M="Missing"
tob_base_time_since_oth	Time Since PPT Last Used Other Forms of Tobacco Regularly - [Tobacco Assessment - Baseline]	3. If you do not currently smoke cigarettes, but did in the past, how long has it been since you last smoked regularly (that is, everyday or some days)?	.E="Not Eligible For Study" .N="N/A" 7="More Than 15 Years Ago"
tob_base_time_til_first_cig	Time After Waking Up Until First Cigarette - [Tobacco Assessment - Baseline]	7. How soon after you wake up do you smoke your first cigarette?	.E="Not Eligible For Study" .M="Missing" .N="N/A" 1="Within 30 Minutes" 2="After 30 Minutes"
tob_base_times_quit	Times PPT Quit Smoking in the Last 12 Months - [Tobacco Assessment - Baseline]	8. How many times in the last 12 months have you tried to quit smoking cigarettes and stayed off for at least 24 hours (please enter median if participant answers with a range, i.e. "4-5" = "4.5")?	Numeric .E="Not Eligible For Study" .M="Missing"
tob_base_used_oth	Used Other Forms of Tobacco? - [Tobacco Assessment - Baseline]	11. Have you ever used other forms of tobacco?	.E="Not Eligible For Study" 0="No" 1="Yes"
tob_base_years_smoking	Years Smoking - [Tobacco Assessment - Baseline]	5. How many years have you been smoking (or did smoke) regularly?	Numeric .E="Not Eligible For Study" .M="Missing"

Section 11: Intervention Administration

Variable	Label	Description	Format Text
agent_1000mg_provided_dt	Date Provided - 1000mg QD - [Intervention Administration]		SAS Date .E="Not Eligible For Study"
agent_1000mg_start_dt	Start Date - 1000mg QD - [Intervention Administration]		SAS Date .E="Not Eligible For Study" .M="Missing"
agent_2000mg_provided_dt	Date Provided - 2000mg QD - [Intervention Administration]		SAS Date .E="Not Eligible For Study"
agent_2000mg_start_dt	Start Date - 2000mg QD - [Intervention Administration]		SAS Date .E="Not Eligible For Study" .M="Missing"
agent_500mg_provided_dt	Date Provided - 500mg QD - [Intervention Administration]		SAS Date .E="Not Eligible For Study"
agent_500mg_start_dt	Start Date - 500mg QD - [Intervention Administration]		SAS Date .E="Not Eligible For Study"

Section 12: Adverse Events

Variable	Label	Description	Format Text
ae_num	Number of Adverse Events the Participant Experienced During the Study - [Adverse Events]		Numeric

Section 13: Agent Interruption

Variable	Label	Description	Format Text
agent_int_or_mod1-4	Agent Interruption or Modification? - Event # - [Agent Interruption]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 1="Interruption" 2="Modification" 3="Interruption and Modification"
agent_mod_dt1-4	Date Modified - Event # - [Agent Interruption]		SAS Date .E="Not Eligible For Study" .F="No Form" .N="N/A"
agent_mod_rsn1-4	Reason Modified - Event # - [Agent Interruption]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 1="Investigator Decision" 2="Participant Decision" 3="AE SAE"
agent_mod_rsn_spec1-4	Specific Reason Restarted - Event # - [Agent Interruption]		Char
agent_num_events	Number of Agent Events (Interruptions and/or Modifications) - [Agent Interruption]		Numeric .E="Not Eligible For Study" .F="No Form"
agent_restart_dt1-4	Date Restarted - Event # - [Agent Interruption]		SAS Date .E="Not Eligible For Study" .F="No Form" .N="N/A"
agent_restart_rsn1-4	Reason Restarted - Event # - [Agent Interruption]		.E="Not Eligible For Study" .F="No Form" .M="Missing" .N="N/A" 1="Investigator Decision"
agent_restarted1-4	Was Agent Restarted? - Event # - [Agent Interruption]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 0="No" 1="Yes"
agent_stop_dt1-4	Date Stopped - Event # - [Agent Interruption]		SAS Date .E="Not Eligible For Study" .F="No Form" .N="N/A"
agent_stop_rsn1-4	Reason Stopped - Event # - [Agent Interruption]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 2="Participant Decision" 3="AE SAE"
agent_stop_rsn_spec1-4	Specific Reason Stopped - Event # - [Agent Interruption]		Char

Section 14: Compliance

Variable	Label	Description	Format Text
comp_amt_agent_missing_et	Amount of Agent Missing - Early Termination - [Compliance]		Numeric .E="Not Eligible For Study" .N="N/A"
comp_amt_agent_missing_v4	Amount of Agent Missing - Visit 4 (Week 6) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"
comp_amt_agent_missing_v6	Amount of Agent Missing - Visit 6 (Week 12-14) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"
comp_amt_agent_provided_last_et	Amount of Agent Provided at Last Visit - Early Termination - [Compliance]		Numeric .E="Not Eligible For Study" .N="N/A"
comp_amt_agent_provided_last_v4	Amount of Agent Provided at Last Visit - Visit 4 (Week 6) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"
comp_amt_agent_provided_last_v6	Amount of Agent Provided at Last Visit - Visit 6 (Week 12-14) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"
comp_amt_agent_provided_this_et	Amount of Agent Provided at This Visit - Early Termination - [Compliance]		Numeric .E="Not Eligible For Study" .N="N/A"
comp_amt_agent_provided_this_v4	Amount of Agent Provided at This Visit - Visit 4 (Week 6) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"
comp_amt_agent_provided_this_v6	Amount of Agent Provided at This Visit - Visit 6 (Week 12-14) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"
comp_amt_agent_returned_et	Amount of Agent Returned - Early Termination - [Compliance]		Numeric .E="Not Eligible For Study" .N="N/A"
comp_amt_agent_returned_v4	Amount of Agent Returned - Visit 4 (Week 6) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"
comp_amt_agent_returned_v6	Amount of Agent Returned - Visit 6 (Week 12-14) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"
comp_amt_agent_taken_et	Amount of Agent Taken - Early Termination - [Compliance]		Numeric .E="Not Eligible For Study" .N="N/A"
comp_amt_agent_taken_v4	Amount of Agent Taken - Visit 4 (Week 6) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"

Variable	Label	Description	Format Text
comp_amt_agent_tkn_v6	Amount of Agent Taken - Visit 6 (Week 12-14) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"
comp_compliant_et	Compliant? - Early Termination - [Compliance]		.E="Not Eligible For Study" .N="N/A" 1="Yes"
comp_compliant_v4	Compliant? - Visit 4 (Week 6) - [Compliance]		.E="Not Eligible For Study" .F="No Form" 1="Yes"
comp_compliant_v6	Compliant? - Visit 6 (Week 12-14) - [Compliance]		.E="Not Eligible For Study" .F="No Form" 1="Yes"
comp_first_dose_dt_et	First Dose Date - Early Termination - [Compliance]		SAS Date .E="Not Eligible For Study" .N="N/A"
comp_first_dose_dt_v4	First Dose Date - Visit 4 (Week 6) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Form"
comp_first_dose_dt_v6	First Dose Date - Visit 6 (Week 12-14) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Form"
comp_interrupted_et	Agent Interrupted? - Early Termination - [Compliance]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
comp_interrupted_v4	Agent Interrupted? - Visit 4 (Week 6) - [Compliance]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
comp_interrupted_v6	Agent Interrupted? - Visit 6 (Week 12-14) - [Compliance]		.E="Not Eligible For Study" .F="No Form" 0="No"
comp_last_dose_dt_et	Last Dose Date - Early Termination - [Compliance]		SAS Date .E="Not Eligible For Study" .N="N/A"
comp_last_dose_dt_v4	Last Dose Date - Visit 4 (Week 6) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Form"
comp_last_dose_dt_v6	Last Dose Date - Visit 6 (Week 12-14) - [Compliance]		SAS Date .E="Not Eligible For Study" .F="No Form"
comp_modified_et	Agent Modified? - Early Termination - [Compliance]		.E="Not Eligible For Study" .N="N/A" 0="No"
comp_modified_v4	Agent Modified? - Visit 4 (Week 6) - [Compliance]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
comp_modified_v6	Agent Modified? - Visit 6 (Week 12-14) - [Compliance]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"

Variable	Label	Description	Format Text
comp_noncomp_rs_n_et	Reason For Noncompliance - Early Termination - [Compliance]		Char
comp_noncomp_rs_n_v4	Reason For Noncompliance - Visit 4 (Week 6) - [Compliance]		Char
comp_noncomp_rs_n_v6	Reason For Noncompliance - Visit 6 (Week 12-14) - [Compliance]		Char
comp_num_ints_et	Number of Interruptions - Early Termination - [Compliance]		Numeric .E="Not Eligible For Study" .N="N/A"
comp_num_ints_v4	Number of Interruptions - Visit 4 (Week 6) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"
comp_num_ints_v6	Number of Interruptions - Visit 6 (Week 12-14) - [Compliance]		Numeric .E="Not Eligible For Study" .F="No Form"
comp_provided_et	Agent Provided at This Visit? - Early Termination - [Compliance]		.E="Not Eligible For Study" .N="N/A" 0="No"
comp_provided_v4	Agent Provided at This Visit? - Visit 4 (Week 6) - [Compliance]		.E="Not Eligible For Study" .F="No Form" 1="Yes"
comp_provided_v6	Agent Provided at This Visit? - Visit 6 (Week 12-14) - [Compliance]		.E="Not Eligible For Study" .F="No Form" 0="No"

Section 15: Off Study

Variable	Label	Description	Format Text
offstudy_dt	Date Off Study - [Off Study]		SAS Date
offstudy_form_dt	Form Date - [Off Study]		SAS Date
offstudy_last_agent_dt	Date Last Agent Taken - [Off Study]		SAS Date .N="N/A"
offstudy_last_contact_dt	Date of Last Contact - [Off Study]		SAS Date
offstudy_off_followup_dt	Date Off Follow-up - [Off Study]		SAS Date .N="N/A"
offstudy_on_followup_dt	Date On Follow-up - [Off Study]		SAS Date .N="N/A"
offstudy_oth_explanation	Other Reason Explanation - [Off Study]		Char
offstudy_reason	Reason Off Study - [Off Study]		1="Study Complete" 2="Ineligible" 3="Adverse Event" 5="Participant Withdrawal"

Section 16: Comments

Variable	Label	Description	Format Text
comments_field_name1-2	Field Name - Comment # - [Comments]		Char
comments_form_code1-2	Form Code - Comment # - [Comments]		"AE - Adverse Events"="AE - Adverse Events" "INTAD - Intervention Administration"="INTAD - Intervention Administration" "LEM - Lesion Measurement"="LEM - Lesion Measurement"
comments_form_dt1-2	Form Date - Comment # - [Comments]		SAS Date .E="Not Eligible For Study" .F="No Form" .N="N/A"
comments_text1-2	Comment Text - Comment # - [Comments]		Char
comments_visit1-2	Visit Number - Comment # - [Comments]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"

Section 17: Physical Examination

Variable	Label	Description	Format Text
pe_abdomen_cmnt_et	Abdomen Comments - Early Termination - [Physical Examination]		Char
pe_abdomen_cmnt_v1	Abdomen Comments - Visit 1 (Baseline) - [Physical Examination]		Char
pe_abdomen_cmnt_v4	Abdomen Comments - Visit 4 (Week 6) - [Physical Examination]		Char
pe_abdomen_cmnt_v6	Abdomen Comments - Visit 6 (Week 12-14) - [Physical Examination]		Char
pe_abdomen_findin_g_et	Abdomen Finding - Early Termination - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal"
pe_abdomen_findin_g_v1	Abdomen Finding - Visit 1 (Baseline) - [Physical Examination]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
pe_abdomen_findin_g_v4	Abdomen Finding - Visit 4 (Week 6) - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal" 2="Abnormal"
pe_abdomen_findin_g_v6	Abdomen Finding - Visit 6 (Week 12-14) - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal" 3="Not Examined"
pe_bp_diastolic_et	Diastolic Blood Pressure (mm Hg) - Early Termination - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_bp_diastolic_v1	Diastolic Blood Pressure (mm Hg) - Visit 1 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study"
pe_bp_diastolic_v4	Diastolic Blood Pressure (mm Hg) - Visit 4 (Week 6) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_bp_diastolic_v6	Diastolic Blood Pressure (mm Hg) - Visit 6 (Week 12-14) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_bp_systolic_et	Systolic Blood Pressure (mm Hg) - Early Termination - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"

Variable	Label	Description	Format Text
pe_bp_systolic_v1	Systolic Blood Pressure (mm Hg) - Visit 1 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study"
pe_bp_systolic_v4	Systolic Blood Pressure (mm Hg) - Visit 4 (Week 6) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_bp_systolic_v6	Systolic Blood Pressure (mm Hg) - Visit 6 (Week 12-14) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_chest_cmnt_et	Chest Comments - Early Termination - [Physical Examination]		Char
pe_chest_cmnt_v1	Chest Comments - Visit 1 (Baseline) - [Physical Examination]		Char
pe_chest_cmnt_v4	Chest Comments - Visit 4 (Week 6) - [Physical Examination]		Char
pe_chest_cmnt_v6	Chest Comments - Visit 6 (Week 12-14) - [Physical Examination]		Char
pe_chest_finding_et	Chest Finding - Early Termination - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal"
pe_chest_finding_v1	Chest Finding - Visit 1 (Baseline) - [Physical Examination]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
pe_chest_finding_v4	Chest Finding - Visit 4 (Week 6) - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal" 2="Abnormal"
pe_chest_finding_v6	Chest Finding - Visit 6 (Week 12-14) - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal" 2="Abnormal" 3="Not Examined"
pe_examination_dt_et	Examination Date - Early Termination - [Physical Examination]		SAS Date .E="Not Eligible For Study" .F="No Form"
pe_examination_dt_v1	Examination Date - Visit 1 (Baseline) - [Physical Examination]		SAS Date .E="Not Eligible For Study"
pe_examination_dt_v4	Examination Date - Visit 4 (Week 6) - [Physical Examination]		SAS Date .E="Not Eligible For Study" .F="No Form"
pe_examination_dt_v6	Examination Date - Visit 6 (Week 12-14) - [Physical Examination]		SAS Date .E="Not Eligible For Study" .F="No Form"
pe_heart_cmnt_et	Heart Comments - Early Termination - [Physical Examination]		Char

Variable	Label	Description	Format Text
pe_heart_cmnt_v1	Heart Comments - Visit 1 (Baseline) - [Physical Examination]		Char
pe_heart_cmnt_v4	Heart Comments - Visit 4 (Week 6) - [Physical Examination]		Char
pe_heart_cmnt_v6	Heart Comments - Visit 6 (Week 12-14) - [Physical Examination]		Char
pe_heart_finding_et	Heart Finding - Early Termination - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal"
pe_heart_finding_v1	Heart Finding - Visit 1 (Baseline) - [Physical Examination]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
pe_heart_finding_v4	Heart Finding - Visit 4 (Week 6) - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal" 2="Abnormal"
pe_heart_finding_v6	Heart Finding - Visit 6 (Week 12-14) - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal" 2="Abnormal" 3="Not Examined"
pe_height_et	Height (in) - Early Termination - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form" .M="Missing"
pe_height_v1	Height (in) - Visit 1 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study"
pe_height_v4	Height (in) - Visit 4 (Week 6) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form" .M="Missing"
pe_height_v6	Height (in) - Visit 6 (Week 12-14) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form" .M="Missing"
pe_karnofsky_et	Karnofsky Performance Status - Early Termination - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" .M="Missing"
pe_karnofsky_v1	Karnofsky Performance Status - Visit 1 (Baseline) - [Physical Examination]		.E="Not Eligible For Study" 80="Normal activity with effort; some signs or symptoms of disease." 90="Able to carry on normal activity; minor signs or symptoms of disease." 100="Normal, no complaints, no evidence of disease."
pe_karnofsky_v4	Karnofsky Performance Status - Visit 4 (Week 6) - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" .M="Missing" .N="N/A" 100="Normal, no complaints, no evidence of disease."

Variable	Label	Description	Format Text
pe_karnofsky_v6	Karnofsky Performance Status - Visit 6 (Week 12-14) - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" .M="Missing" .N="N/A"
pe_lower_extrem_cmnt_et	Lower Extremities Comments - Early Termination - [Physical Examination]		Char
pe_lower_extrem_cmnt_v1	Lower Extremities Comments - Visit 1 (Baseline) - [Physical Examination]		Char
pe_lower_extrem_cmnt_v4	Lower Extremities Comments - Visit 4 (Week 6) - [Physical Examination]		Char
pe_lower_extrem_cmnt_v6	Lower Extremities Comments - Visit 6 (Week 12-14) - [Physical Examination]		Char
pe_lower_extrem_finding_et	Lower Extremities Finding - Early Termination - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal"
pe_lower_extrem_finding_v1	Lower Extremities Finding - Visit 1 (Baseline) - [Physical Examination]		.E="Not Eligible For Study" 1="Normal" 2="Abnormal"
pe_lower_extrem_finding_v4	Lower Extremities Finding - Visit 4 (Week 6) - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal" 2="Abnormal"
pe_lower_extrem_finding_v6	Lower Extremities Finding - Visit 6 (Week 12-14) - [Physical Examination]		.E="Not Eligible For Study" .F="No Form" 1="Normal" 2="Abnormal" 3="Not Examined"
pe_pulse_rate_et	Pulse Rate - Early Termination - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_pulse_rate_v1	Pulse Rate - Visit 1 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study"
pe_pulse_rate_v4	Pulse Rate - Visit 4 (Week 6) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_pulse_rate_v6	Pulse Rate - Visit 6 (Week 12-14) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_temperature_et	Temperature (F) - Early Termination - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_temperature_v1	Temperature (F) - Visit 1 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study" .M="Missing"

Variable	Label	Description	Format Text
pe_temperature_v4	Temperature (F) - Visit 4 (Week 6) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_temperature_v6	Temperature (F) - Visit 6 (Week 12-14) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_weight_et	Weight (lb) - Early Termination - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_weight_v1	Weight (lb) - Visit 1 (Baseline) - [Physical Examination]		Numeric .E="Not Eligible For Study"
pe_weight_v4	Weight (lb) - Visit 4 (Week 6) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"
pe_weight_v6	Weight (lb) - Visit 6 (Week 12-14) - [Physical Examination]		Numeric .E="Not Eligible For Study" .F="No Form"

Section 18: Specimen Collection

Variable	Label	Description	Format Text
spec_col_blood_cmnt_v1	Blood Collection For Research Samples Comments - Visit 1 (Baseline) - [Specimen Collection]		Char
spec_col_blood_cmnt_v6	Blood Collection For Research Samples Comments - Visit 6 (Week 12-14) - [Specimen Collection]		Char
spec_col_blood_dt_v1	Blood Collection For Research Samples Date - Visit 1 (Baseline) - [Specimen Collection]		SAS Date .E="Not Eligible For Study"
spec_col_blood_dt_v6	Blood Collection For Research Samples Date - Visit 6 (Week 12-14) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Form" .M="Missing"
spec_col_oral_les_cmnt_v1	Oral Lesion Biopsy Comments - Visit 1 (Baseline) - [Specimen Collection]		Char
spec_col_oral_les_cmnt_v6	Oral Lesion Biopsy Comments - Visit 6 (Week 12-14) - [Specimen Collection]		Char
spec_col_oral_les_dt_v1	Oral Lesion Biopsy Date - Visit 1 (Baseline) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .N="N/A"
spec_col_oral_les_dt_v6	Oral Lesion Biopsy Date - Visit 6 (Week 12-14) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Form"
spec_col_saliva_cmnt_v1	Saliva Collection Comments - Visit 1 (Baseline) - [Specimen Collection]		Char
spec_col_saliva_cmnt_v6	Saliva Collection Comments - Visit 6 (Week 12-14) - [Specimen Collection]		Char
spec_col_saliva_dt_v1	Saliva Collection Date - Visit 1 (Baseline) - [Specimen Collection]		SAS Date .E="Not Eligible For Study"
spec_col_saliva_dt_v6	Saliva Collection Date - Visit 6 (Week 12-14) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Form" .M="Missing"

Variable	Label	Description	Format Text
spec_col_vis_norm_mucosa_cmnt_v1	Visually Normal Mucosa Biopsy Comments - Visit 1 (Baseline) - [Specimen Collection]		Char
spec_col_vis_norm_mucosa_cmnt_v6	Visually Normal Mucosa Biopsy Comments - Visit 6 (Week 12-14) - [Specimen Collection]		Char
spec_col_vis_norm_mucosa_dt_v1	Visually Normal Mucosa Biopsy Date - Visit 1 (Baseline) - [Specimen Collection]		SAS Date .E="Not Eligible For Study"
spec_col_vis_norm_mucosa_dt_v6	Visually Normal Mucosa Biopsy Date - Visit 6 (Week 12-14) - [Specimen Collection]		SAS Date .E="Not Eligible For Study" .F="No Form" .M="Missing"

Section 19: Alcohol - Follow-Up

Variable	Label	Description	Format Text
alc_fu_at_least_1_drink	At Least 1 Drink in the Past Month? - [Alcohol - Follow-Up]	1. During the past month, have you had at least one drink of any alcoholic beverage such as beer, wine, wine coolers, or liquor?	.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
alc_fu_days_5_or_more	Days With 5 or More Drinks During Study - [Alcohol - Follow-Up]	4. Considering all types of alcoholic beverages, how many times during the past month did you have 5 or more drinks per day/week? (Please enter median if you answer with a range, i.e. "4 - 5" = "4.5").	Numeric .E="Not Eligible For Study" .F="No Form"
alc_fu_drink_day_freq	Frequency of Number of Days PPT Drank Alcohol - [Alcohol - Follow-Up]	2. During the past month, how many days per week or per month did you drink any alcoholic beverages, on the average?	.E="Not Eligible For Study" .F="No Form" .N="N/A" 1="Week" 2="Month"
alc_fu_drink_day_num	Number of Days Per Week/Month that the PPT Drank Alcohol - [Alcohol - Follow-Up]	2. During the past month, how many days per week or per month did you drink any alcoholic beverages, on the average?	Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
alc_fu_drinks_per_day	Number of Drinks Per Day on Drinking Days During Study - [Alcohol - Follow-Up]	3. On the days when you drank, about how many drinks did you drink on the average? (A drink is 1 can or bottle of beer, 1 glass of wine, 1 can or bottle of wine cooler, 1 cocktail, or 1 shot of liquor; please enter median if you answer with a range, i.e. "4 - 5" = "4.5").	Numeric .E="Not Eligible For Study" .F="No Form"

Section 20: Tobacco Assessment - Follow-Up

Variable	Label	Description	Format Text
tob_fu_cigs_per_day	Cigarettes Per Day - [Tobacco Assessment - Follow-Up]	2. On the average, about how many cigarettes a day do you smoke? (1 pack = 20 cigarettes; please enter median if participant answers with a range, i.e. "4-5" = "4.5")	Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
tob_fu_currently_smoking	Currently Smoking Cigarettes? - [Tobacco Assessment - Follow-Up]	1. Do you NOW smoke cigarettes?	.E="Not Eligible For Study" .F="No Form" 1="Every Day" 2="Some Days" 3="Not At All"
tob_fu_used_oth	Used Other Forms of Tobacco? - [Tobacco Assessment - Follow-Up]	3. Have you used any other types of tobacco products?	.E="Not Eligible For Study" .F="No Form" 0="No"

Section 21: Blood Chemistry

Variable	Label	Description	Format Text
bldchem_alb_glob_clin_v1	Albumin/Globulin Ratio - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
bldchem_alb_glob_clin_v6	Albumin/Globulin Ratio - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained"
bldchem_alb_glob_cmnt_v1	Albumin/Globulin Ratio - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_alb_glob_cmnt_v6	Albumin/Globulin Ratio - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_alb_glob_out_v1	Albumin/Globulin Ratio - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
bldchem_alb_glob_out_v6	Albumin/Globulin Ratio - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained"
bldchem_alb_glob_res_v1	Albumin/Globulin Ratio - Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
bldchem_alb_glob_res_v6	Albumin/Globulin Ratio - Result - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
bldchem_albumin_clin_v1	Albumin - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_albumin_clin_v6	Albumin - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_albumin_cmnt_v1	Albumin - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_albumin_cmnt_v6	Albumin - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_albumin_out_v1	Albumin - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"

Variable	Label	Description	Format Text
bldchem_albumin_out_v6	Albumin - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_albumin_res_v1	Albumin - Result (g/dL) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_albumin_res_v6	Albumin - Result (g/dL) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_alk_phos_clin_v1	Alkaline Phosphatase - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_alk_phos_clin_v6	Alkaline Phosphatase - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_alk_phos_cmnt_v1	Alkaline Phosphatase - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_alk_phos_cmnt_v6	Alkaline Phosphatase - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_alk_phos_out_v1	Alkaline Phosphatase - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_alk_phos_out_v6	Alkaline Phosphatase - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_alk_phos_res_v1	Alkaline Phosphatase - Result (IU/L) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_alk_phos_res_v6	Alkaline Phosphatase - Result (IU/L) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_anion_gap_clin_v1	Anion Gap - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_anion_gap_clin_v6	Anion Gap - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_anion_gap_cmnt_v1	Anion Gap - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_anion_gap_cmnt_v6	Anion Gap - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char

Variable	Label	Description	Format Text
bldchem_anion_gap_out_v1	Anion Gap - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_anion_gap_out_v6	Anion Gap - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_anion_gap_res_v1	Anion Gap - Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_anion_gap_res_v6	Anion Gap - Result - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_bicarbonate_clin_v1	Bicarbonate - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_bicarbonate_clin_v6	Bicarbonate - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_bicarbonate_cmnt_v1	Bicarbonate - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_bicarbonate_cmnt_v6	Bicarbonate - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_bicarbonate_out_v1	Bicarbonate - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_bicarbonate_out_v6	Bicarbonate - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_bicarbonate_res_v1	Bicarbonate - Result (mmol/l) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_bicarbonate_res_v6	Bicarbonate - Result (mmol/l) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_bilirubin_clin_v1	Bilirubin - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_bilirubin_clin_v6	Bilirubin - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_bilirubin_cmnt_v1	Bilirubin - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_bilirubin_cmnt_v6	Bilirubin - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char

Variable	Label	Description	Format Text
bldchem_bilirubin_out_v1	Bilirubin - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_bilirubin_out_v6	Bilirubin - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_bilirubin_res_v1	Bilirubin - Result (mg/dL) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_bilirubin_res_v6	Bilirubin - Result (mg/dL) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_bun_clin_v1	BUN - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_bun_clin_v6	BUN - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_bun_cmnt_v1	BUN - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_bun_cmnt_v6	BUN - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_bun_creat_clin_v1	BUN/Creatinine Ratio - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
bldchem_bun_creat_clin_v6	BUN/Creatinine Ratio - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
bldchem_bun_creat_cmnt_v1	BUN/Creatinine Ratio - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_bun_creat_cmnt_v6	BUN/Creatinine Ratio - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_bun_creat_out_v1	BUN/Creatinine Ratio - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
bldchem_bun_creat_out_v6	BUN/Creatinine Ratio - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
bldchem_bun_creat_res_v1	BUN/Creatinine Ratio - Result - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"

Variable	Label	Description	Format Text
bldchem_bun_creat_res_v6	BUN/Creatinine Ratio - Result - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
bldchem_bun_out_v1	BUN - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_bun_out_v6	BUN - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_bun_res_v1	BUN - Result (mg/dL) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_bun_res_v6	BUN - Result (mg/dL) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_c_peptide_clin_v1	C-peptide - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_c_peptide_clin_v6	C-peptide - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_c_peptide_cmnt_v1	C-peptide - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_c_peptide_cmnt_v6	C-peptide - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_c_peptide_out_v1	C-peptide - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_c_peptide_out_v6	C-peptide - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_c_peptide_res_v1	C-peptide - Result (ng/mL) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_c_peptide_res_v6	C-peptide - Result (ng/mL) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_calcium_clin_v1	Calcium - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_calcium_clin_v6	Calcium - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_calcium_cmnt_v1	Calcium - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char

Variable	Label	Description	Format Text
bldchem_calcium_cmnt_v6	Calcium - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_calcium_out_v1	Calcium - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_calcium_out_v6	Calcium - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_calcium_res_v1	Calcium - Result (mg/dL) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_calcium_res_v6	Calcium - Result (mg/dL) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_chloride_clin_v1	Chloride - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_chloride_clin_v6	Chloride - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_chloride_cmnt_v1	Chloride - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_chloride_cmnt_v6	Chloride - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_chloride_out_v1	Chloride - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_chloride_out_v6	Chloride - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_chloride_res_v1	Chloride - Result (mmol/l) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_chloride_res_v6	Chloride - Result (mmol/l) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_creatinine_clin_v1	Creatinine - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_creatinine_clin_v6	Creatinine - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_creatinine_cmnt_v1	Creatinine - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char

Variable	Label	Description	Format Text
bldchem_creatinine_cmnt_v6	Creatinine - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_creatinine_out_v1	Creatinine - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_creatinine_out_v6	Creatinine - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_creatinine_res_v1	Creatinine - Result (mg/dL) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_creatinine_res_v6	Creatinine - Result (mg/dL) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_egrf_clin_v1	eGRF - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .M="Missing" 0="No"
bldchem_egrf_clin_v6	eGRF - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
bldchem_egrf_cmnt_v1	eGRF - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_egrf_cmnt_v6	eGRF - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_egrf_out_v1	eGRF - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .M="Missing" 0="No"
bldchem_egrf_out_v6	eGRF - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
bldchem_egrf_res_v1	eGRF - Result (ml/min) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_egrf_res_v6	eGRF - Result (ml/min) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
bldchem_fasting_v1	Fasting? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 1="Yes"
bldchem_fasting_v6	Fasting? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 1="Yes"

Variable	Label	Description	Format Text
bldchem_globulin_c lin_v1	Globulin - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
bldchem_globulin_c lin_v6	Globulin - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained"
bldchem_globulin_c mnt_v1	Globulin - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_globulin_c mnt_v6	Globulin - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_globulin_o ut_v1	Globulin - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
bldchem_globulin_o ut_v6	Globulin - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained"
bldchem_globulin_r es_v1	Globulin - Result (g/dL) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
bldchem_globulin_r es_v6	Globulin - Result (g/dL) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
bldchem_glucose_c lin_v1	Glucose Serum - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_glucose_c lin_v6	Glucose Serum - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_glucose_c mnt_v1	Glucose Serum - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_glucose_c mnt_v6	Glucose Serum - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_glucose_o ut_v1	Glucose Serum - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_glucose_o ut_v6	Glucose Serum - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_glucose_r es_v1	Glucose Serum - Result (mg/dL) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"

Variable	Label	Description	Format Text
bldchem_glucose_res_v6	Glucose Serum - Result (mg/dL) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_hba1c_clin_v1	HbA1c - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_hba1c_clin_v6	HbA1c - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_hba1c_cmnt_v1	HbA1c - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_hba1c_cmnt_v6	HbA1c - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_hba1c_out_v1	HbA1c - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_hba1c_out_v6	HbA1c - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_hba1c_res_v1	HbA1c - Result (%) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_hba1c_res_v6	HbA1c - Result (%) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_potassium_clin_v1	Potassium - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_potassium_clin_v6	Potassium - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_potassium_cmnt_v1	Potassium - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_potassium_cmnt_v6	Potassium - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_potassium_out_v1	Potassium - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_potassium_out_v6	Potassium - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_potassium_res_v1	Potassium - Result (mmol/l) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"

Variable	Label	Description	Format Text
bldchem_potassium_res_v6	Potassium - Result (mmol/l) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_protein_clin_v1	Total Protein - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_protein_clin_v6	Total Protein - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_protein_cmnt_v1	Total Protein - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_protein_cmnt_v6	Total Protein - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_protein_out_v1	Total Protein - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_protein_out_v6	Total Protein - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_protein_res_v1	Total Protein - Result (g/dL) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_protein_res_v6	Total Protein - Result (g/dL) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_sgop_ast_clin_v1	SGOP/AST - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_sgop_ast_clin_v6	SGOP/AST - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_sgop_ast_cmnt_v1	SGOP/AST - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_sgop_ast_cmnt_v6	SGOP/AST - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_sgop_ast_out_v1	SGOP/AST - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_sgop_ast_out_v6	SGOP/AST - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_sgop_ast_res_v1	SGOP/AST - Result (IU/L) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"

Variable	Label	Description	Format Text
bldchem_sgop_ast_res_v6	SGOP/AST - Result (IU/L) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_sgpt_alt_c lin_v1	SGPT/ALT - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_sgpt_alt_c lin_v6	SGPT/ALT - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_sgpt_alt_c mnt_v1	SGPT/ALT - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_sgpt_alt_c mnt_v6	SGPT/ALT - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_sgpt_alt_out_v1	SGPT/ALT - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_sgpt_alt_out_v6	SGPT/ALT - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_sgpt_alt_res_v1	SGPT/ALT - Result (IU/L) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_sgpt_alt_res_v6	SGPT/ALT - Result (IU/L) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_sodium_clin_v1	Sodium - Clinically Significant? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_sodium_clin_v6	Sodium - Clinically Significant? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_sodium_cmnt_v1	Sodium - Comments - Visit 1 (Baseline) - [Blood Chemistry]		Char
bldchem_sodium_cmnt_v6	Sodium - Comments - Visit 6 (Week 12-14) - [Blood Chemistry]		Char
bldchem_sodium_out_v1	Sodium - Out of Range? - Visit 1 (Baseline) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No"
bldchem_sodium_out_v6	Sodium - Out of Range? - Visit 6 (Week 12-14) - [Blood Chemistry]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
bldchem_sodium_res_v1	Sodium - Result (mmol/l) - Visit 1 (Baseline) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"

Variable	Label	Description	Format Text
bldchem_sodium_results_v6	Sodium - Result (mmol/l) - Visit 6 (Week 12-14) - [Blood Chemistry]		Numeric .E="Not Eligible For Study" .F="No Form"
bldchem_spec_col_dt_v1	Specimen Collection Date - Visit 1 (Baseline) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Form"
bldchem_spec_col_dt_v6	Specimen Collection Date - Visit 6 (Week 12-14) - [Blood Chemistry]		SAS Date .E="Not Eligible For Study" .F="No Form"

Section 22: Hematology

Variable	Label	Description	Format Text
hema_abs_basophil_clin_et	Absolute Basophil - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_basophil_clin_v1	Absolute Basophil - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_basophil_clin_v6	Absolute Basophil - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_abs_basophil_cmnt_et	Absolute Basophil - Comments - Early Termination - [Hematology]		Char
hema_abs_basophil_cmnt_v1	Absolute Basophil - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_abs_basophil_cmnt_v6	Absolute Basophil - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_abs_basophil_out_et	Absolute Basophil - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_basophil_out_v1	Absolute Basophil - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_basophil_out_v6	Absolute Basophil - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_abs_basophil_res_et	Absolute Basophil - Result (k/uL) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_abs_basophil_res_v1	Absolute Basophil - Result (k/uL) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_abs_basophil_res_v6	Absolute Basophil - Result (k/uL) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
hema_abs_eosinophil_clin_et	Absolute Eosinophil - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_eosinophil_clin_v1	Absolute Eosinophil - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"

Variable	Label	Description	Format Text
hema_abs_eosinop hil_clin_v6	Absolute Eosinophil - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_abs_eosinop hil_cmnt_et	Absolute Eosinophil - Comments - Early Termination - [Hematology]		Char
hema_abs_eosinop hil_cmnt_v1	Absolute Eosinophil - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_abs_eosinop hil_cmnt_v6	Absolute Eosinophil - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_abs_eosinop hil_out_et	Absolute Eosinophil - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_eosinop hil_out_v1	Absolute Eosinophil - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"
hema_abs_eosinop hil_out_v6	Absolute Eosinophil - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_abs_eosinop hil_res_et	Absolute Eosinophil - Result (k/uL) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_abs_eosinop hil_res_v1	Absolute Eosinophil - Result (k/uL) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study"
hema_abs_eosinop hil_res_v6	Absolute Eosinophil - Result (k/uL) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form"
hema_abs_granuloc yte_clin_et	Absolute Granulocyte - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_abs_granuloc yte_clin_v1	Absolute Granulocyte - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_granuloc yte_clin_v6	Absolute Granulocyte - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_abs_granuloc yte_cmnt_et	Absolute Granulocyte - Comments - Early Termination - [Hematology]		Char
hema_abs_granuloc yte_cmnt_v1	Absolute Granulocyte - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_abs_granuloc yte_cmnt_v6	Absolute Granulocyte - Comments - Visit 6 (Week 12-14) - [Hematology]		Char

Variable	Label	Description	Format Text
hema_abs_granulocyte_out_et	Absolute Granulocyte - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_abs_granulocyte_out_v1	Absolute Granulocyte - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_granulocyte_out_v6	Absolute Granulocyte - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_abs_granulocyte_res_et	Absolute Granulocyte - Result (k/uL) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_abs_granulocyte_res_v1	Absolute Granulocyte - Result (k/uL) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_abs_granulocyte_res_v6	Absolute Granulocyte - Result (k/uL) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
hema_abs_lymphocyte_clin_et	Absolute Lymphocyte - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_lymphocyte_clin_v1	Absolute Lymphocyte - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"
hema_abs_lymphocyte_clin_v6	Absolute Lymphocyte - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_abs_lymphocyte_cmnt_et	Absolute Lymphocyte - Comments - Early Termination - [Hematology]		Char
hema_abs_lymphocyte_cmnt_v1	Absolute Lymphocyte - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_abs_lymphocyte_cmnt_v6	Absolute Lymphocyte - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_abs_lymphocyte_out_et	Absolute Lymphocyte - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_lymphocyte_out_v1	Absolute Lymphocyte - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No" 1="Yes"
hema_abs_lymphocyte_out_v6	Absolute Lymphocyte - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
hema_abs_lymphocyte_res_et	Absolute Lymphocyte - Result (k/uL) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"

Variable	Label	Description	Format Text
hema_abs_lymphocyte_res_v1	Absolute Lymphocyte - Result (k/uL) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study"
hema_abs_lymphocyte_res_v6	Absolute Lymphocyte - Result (k/uL) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form"
hema_abs_monocyte_clin_et	Absolute Monocyte - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_monocyte_clin_v1	Absolute Monocyte - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"
hema_abs_monocyte_clin_v6	Absolute Monocyte - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_abs_monocyte_cmnt_et	Absolute Monocyte - Comments - Early Termination - [Hematology]		Char
hema_abs_monocyte_cmnt_v1	Absolute Monocyte - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_abs_monocyte_cmnt_v6	Absolute Monocyte - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_abs_monocyte_out_et	Absolute Monocyte - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_monocyte_out_v1	Absolute Monocyte - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No" 1="Yes"
hema_abs_monocyte_out_v6	Absolute Monocyte - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_abs_monocyte_res_et	Absolute Monocyte - Result (k/uL) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_abs_monocyte_res_v1	Absolute Monocyte - Result (k/uL) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study"
hema_abs_monocyte_res_v6	Absolute Monocyte - Result (k/uL) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form"
hema_abs_neutrophil_clin_et	Absolute Neutrophil - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_neutrophil_clin_v1	Absolute Neutrophil - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"

Variable	Label	Description	Format Text
hema_abs_neutrop hil_clin_v6	Absolute Neutrophil - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_abs_neutrop hil_cmnt_et	Absolute Neutrophil - Comments - Early Termination - [Hematology]		Char
hema_abs_neutrop hil_cmnt_v1	Absolute Neutrophil - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_abs_neutrop hil_cmnt_v6	Absolute Neutrophil - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_abs_neutrop hil_out_et	Absolute Neutrophil - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_abs_neutrop hil_out_v1	Absolute Neutrophil - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No" 1="Yes"
hema_abs_neutrop hil_out_v6	Absolute Neutrophil - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_abs_neutrop hil_res_et	Absolute Neutrophil - Result (k/uL) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_abs_neutrop hil_res_v1	Absolute Neutrophil - Result (k/uL) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study"
hema_abs_neutrop hil_res_v6	Absolute Neutrophil - Result (k/uL) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form"
hema_bands_clin_e t	Bands - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_bands_clin_v 1	Bands - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_bands_clin_v 6	Bands - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_bands_cmnt_ et	Bands - Comments - Early Termination - [Hematology]		Char
hema_bands_cmnt_ v1	Bands - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_bands_cmnt_ v6	Bands - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_bands_out_et	Bands - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"

Variable	Label	Description	Format Text
hema_bands_out_v1	Bands - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_bands_out_v6	Bands - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_bands_res_et	Bands - Result (%) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_bands_res_v1	Bands - Result (%) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_bands_res_v6	Bands - Result (%) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
hema_basophil_clin_et	Basophils - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_basophil_clin_v1	Basophils - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_basophil_clin_v6	Basophils - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_basophil_cmnt_et	Basophils - Comments - Early Termination - [Hematology]		Char
hema_basophil_cmnt_v1	Basophils - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_basophil_cmnt_v6	Basophils - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_basophil_out_et	Basophils - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_basophil_out_v1	Basophils - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_basophil_out_v6	Basophils - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_basophil_res_et	Basophils - Result (%) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_basophil_res_v1	Basophils - Result (%) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"

Variable	Label	Description	Format Text
hema_basophil_res_v6	Basophils - Result (%) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
hema_eosinophil_clin_et	Eosinophils - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_eosinophil_clin_v1	Eosinophils - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_eosinophil_clin_v6	Eosinophils - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_eosinophil_comments_et	Eosinophils - Comments - Early Termination - [Hematology]		Char
hema_eosinophil_comments_v1	Eosinophils - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_eosinophil_comments_v6	Eosinophils - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_eosinophil_out_et	Eosinophils - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_eosinophil_out_v1	Eosinophils - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_eosinophil_out_v6	Eosinophils - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_eosinophil_results_et	Eosinophils - Result (%) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_eosinophil_results_v1	Eosinophils - Result (%) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_eosinophil_results_v6	Eosinophils - Result (%) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
hema_hematocrit_clin_et	Hematocrit - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_hematocrit_clin_v1	Hematocrit - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"
hema_hematocrit_clin_v6	Hematocrit - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"

Variable	Label	Description	Format Text
hema_hematocrit_cmnt_et	Hematocrit - Comments - Early Termination - [Hematology]		Char
hema_hematocrit_cmnt_v1	Hematocrit - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_hematocrit_cmnt_v6	Hematocrit - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_hematocrit_out_et	Hematocrit - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_hematocrit_out_v1	Hematocrit - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No" 1="Yes"
hema_hematocrit_out_v6	Hematocrit - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_hematocrit_results_et	Hematocrit - Result (%) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_hematocrit_results_v1	Hematocrit - Result (%) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study"
hema_hematocrit_results_v6	Hematocrit - Result (%) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form"
hema_hemoglobin_clin_et	Hemoglobin - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_hemoglobin_clin_v1	Hemoglobin - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"
hema_hemoglobin_clin_v6	Hemoglobin - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_hemoglobin_cmnt_et	Hemoglobin - Comments - Early Termination - [Hematology]		Char
hema_hemoglobin_cmnt_v1	Hemoglobin - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_hemoglobin_cmnt_v6	Hemoglobin - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_hemoglobin_out_et	Hemoglobin - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_hemoglobin_out_v1	Hemoglobin - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No" 1="Yes"

Variable	Label	Description	Format Text
hema_hemoglobin_out_v6	Hemoglobin - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
hema_hemoglobin_res_et	Hemoglobin - Result (g/dL) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_hemoglobin_res_v1	Hemoglobin - Result (g/dL) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study"
hema_hemoglobin_res_v6	Hemoglobin - Result (g/dL) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form"
hema_lymphocyte_clin_et	Lymphocytes - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_lymphocyte_clin_v1	Lymphocytes - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_lymphocyte_clin_v6	Lymphocytes - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_lymphocyte_cmnt_et	Lymphocytes - Comments - Early Termination - [Hematology]		Char
hema_lymphocyte_cmnt_v1	Lymphocytes - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_lymphocyte_cmnt_v6	Lymphocytes - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_lymphocyte_out_et	Lymphocytes - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_lymphocyte_out_v1	Lymphocytes - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_lymphocyte_out_v6	Lymphocytes - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_lymphocyte_res_et	Lymphocytes - Result (%) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_lymphocyte_res_v1	Lymphocytes - Result (%) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_lymphocyte_res_v6	Lymphocytes - Result (%) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"

Variable	Label	Description	Format Text
hema_monocyte_clin_et	Monocytes - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_monocyte_clin_v1	Monocytes - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_monocyte_clin_v6	Monocytes - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_monocyte_cmnt_et	Monocytes - Comments - Early Termination - [Hematology]		Char
hema_monocyte_cmnt_v1	Monocytes - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_monocyte_cmnt_v6	Monocytes - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_monocyte_out_et	Monocytes - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_monocyte_out_v1	Monocytes - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_monocyte_out_v6	Monocytes - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_monocyte_results_et	Monocytes - Result (%) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_monocyte_results_v1	Monocytes - Result (%) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_monocyte_results_v6	Monocytes - Result (%) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
hema_neutrophil_clin_et	Neutrophils - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_neutrophil_clin_v1	Neutrophils - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_neutrophil_clin_v6	Neutrophils - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_neutrophil_cmnt_et	Neutrophils - Comments - Early Termination - [Hematology]		Char

Variable	Label	Description	Format Text
hema_neutrophil_cmnt_v1	Neutrophils - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_neutrophil_cmnt_v6	Neutrophils - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_neutrophil_out_et	Neutrophils - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained"
hema_neutrophil_out_v1	Neutrophils - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_neutrophil_out_v6	Neutrophils - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" .N="Not Obtained" 0="No"
hema_neutrophil_results_et	Neutrophils - Result (%) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_neutrophil_results_v1	Neutrophils - Result (%) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_neutrophil_results_v6	Neutrophils - Result (%) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
hema_platelets_clin_et	Platelets - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_platelets_clin_v1	Platelets - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"
hema_platelets_clin_v6	Platelets - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_platelets_cmnt_et	Platelets - Comments - Early Termination - [Hematology]		Char
hema_platelets_cmnt_v1	Platelets - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_platelets_cmnt_v6	Platelets - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_platelets_out_et	Platelets - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_platelets_out_v1	Platelets - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"
hema_platelets_out_v6	Platelets - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"

Variable	Label	Description	Format Text
hema_platelets_res_et	Platelets - Result (k/mm3) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_platelets_res_v1	Platelets - Result (k/mm3) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study"
hema_platelets_res_v6	Platelets - Result (k/mm3) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form"
hema_rbc_clin_et	Red Blood Cells - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_rbc_clin_v1	Red Blood Cells - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"
hema_rbc_clin_v6	Red Blood Cells - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_rbc_cmnt_et	Red Blood Cells - Comments - Early Termination - [Hematology]		Char
hema_rbc_cmnt_v1	Red Blood Cells - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_rbc_cmnt_v6	Red Blood Cells - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_rbc_out_et	Red Blood Cells - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_rbc_out_v1	Red Blood Cells - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"
hema_rbc_out_v6	Red Blood Cells - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_rbc_res_et	Red Blood Cells - Result (m/mm3) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_rbc_res_v1	Red Blood Cells - Result (m/mm3) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study"
hema_rbc_res_v6	Red Blood Cells - Result (m/mm3) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form"
hema_spec_col_dt_et	Specimen Collection Date - Early Termination - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Form"
hema_spec_col_dt_v1	Specimen Collection Date - Visit 1 (Baseline) - [Hematology]		SAS Date .E="Not Eligible For Study"

Variable	Label	Description	Format Text
hema_spec_col_dt_v6	Specimen Collection Date - Visit 6 (Week 12-14) - [Hematology]		SAS Date .E="Not Eligible For Study" .F="No Form"
hema_wbc_clin_et	White Blood Cells - Clinically Significant? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_wbc_clin_v1	White Blood Cells - Clinically Significant? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No"
hema_wbc_clin_v6	White Blood Cells - Clinically Significant? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No"
hema_wbc_cmnt_et	White Blood Cells - Comments - Early Termination - [Hematology]		Char
hema_wbc_cmnt_v1	White Blood Cells - Comments - Visit 1 (Baseline) - [Hematology]		Char
hema_wbc_cmnt_v6	White Blood Cells - Comments - Visit 6 (Week 12-14) - [Hematology]		Char
hema_wbc_out_et	White Blood Cells - Out of Range? - Early Termination - [Hematology]		.E="Not Eligible For Study" .N="Not Obtained" 0="No"
hema_wbc_out_v1	White Blood Cells - Out of Range? - Visit 1 (Baseline) - [Hematology]		.E="Not Eligible For Study" 0="No" 1="Yes"
hema_wbc_out_v6	White Blood Cells - Out of Range? - Visit 6 (Week 12-14) - [Hematology]		.E="Not Eligible For Study" .F="No Form" 0="No" 1="Yes"
hema_wbc_res_et	White Blood Cells - Result (k/mm3) - Early Termination - [Hematology]		Numeric .E="Not Eligible For Study" .N="N/A"
hema_wbc_res_v1	White Blood Cells - Result (k/mm3) - Visit 1 (Baseline) - [Hematology]		Numeric .E="Not Eligible For Study"
hema_wbc_res_v6	White Blood Cells - Result (k/mm3) - Visit 6 (Week 12-14) - [Hematology]		Numeric .E="Not Eligible For Study" .F="No Form"

Section 23: Other Lab Tests

Variable	Label	Description	Format Text
othlab_clin_et_1-5	Clinically Significant? - Early Termination - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 0="No"
othlab_clin_v1_1-5	Clinically Significant? - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 0="No"
othlab_clin_v6_1-2	Clinically Significant? - Visit 6 (Week 12-14) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 0="No"
othlab_cmnt_et_1-5	Comments - Early Termination - Lab Test # - [Other Lab Tests]		Char
othlab_cmnt_v1_1-5	Comments - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		Char
othlab_cmnt_v6_1-2	Comments - Visit 6 (Week 12-14) - Lab Test # - [Other Lab Tests]		Char
othlab_fasting_et_1-5	Fasting? - Early Termination - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 1="Yes"
othlab_fasting_v1_1-5	Fasting? - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 1="Yes"
othlab_fasting_v6_1-2	Fasting? - Visit 6 (Week 12-14) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 1="Yes"
othlab_num_et	Number of Other Lab Tests - Early Termination - [Other Lab Tests]		Numeric .E="Not Eligible For Study" .F="No Form"
othlab_num_v1	Number of Other Lab Tests - Visit 1 (Baseline) - [Other Lab Tests]		Numeric .E="Not Eligible For Study" .F="No Form"
othlab_num_v6	Number of Other Lab Tests - Visit 6 (Week 12-14) - [Other Lab Tests]		Numeric .E="Not Eligible For Study" .F="No Form"
othlab_out_et_1-5	Out of Range? - Early Termination - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 0="No" 1="Yes"

Variable	Label	Description	Format Text
othlab_out_v1_1-5	Out of Range? - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 0="No" 1="Yes"
othlab_out_v6_1-2	Out of Range? - Visit 6 (Week 12-14) - Lab Test # - [Other Lab Tests]		.E="Not Eligible For Study" .F="No Form" .N="N/A" 0="No"
othlab_result_et_1-5	Result - Early Termination - Lab Test # - [Other Lab Tests]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
othlab_result_v1_1-5	Result - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
othlab_result_v6_1-2	Result - Visit 6 (Week 12-14) - Lab Test # - [Other Lab Tests]		Numeric .E="Not Eligible For Study" .F="No Form" .N="N/A"
othlab_spec_col_dt_et_1-5	Specimen Collection Date - Early Termination - Lab Test # - [Other Lab Tests]		SAS Date .E="Not Eligible For Study" .F="No Form" .N="N/A"
othlab_spec_col_dt_v1_1-5	Specimen Collection Date - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		SAS Date .E="Not Eligible For Study" .F="No Form" .N="N/A"
othlab_spec_col_dt_v6_1-2	Specimen Collection Date - Visit 6 (Week 12-14) - Lab Test # - [Other Lab Tests]		SAS Date .E="Not Eligible For Study" .F="No Form" .N="N/A"
othlab_test_et_1-5	Test Name - Early Termination - Lab Test # - [Other Lab Tests]		Char
othlab_test_v1_1-5	Test Name - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		Char
othlab_test_v6_1-2	Test Name - Visit 6 (Week 12-14) - Lab Test # - [Other Lab Tests]		Char
othlab_units_et_1-5	Units - Early Termination - Lab Test # - [Other Lab Tests]		Char
othlab_units_v1_1-5	Units - Visit 1 (Baseline) - Lab Test # - [Other Lab Tests]		Char
othlab_units_v6_1-2	Units - Visit 6 (Week 12-14) - Lab Test # - [Other Lab Tests]		Char

Section 24: Lesion Measurement

Variable	Label	Description	Format Text
les_meas_area_v1_1-3	Area (mm2) - Visit 1 (Baseline) - Lesion # - [Lesion Measurement]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
les_meas_area_v4_1-3	Area (mm2) - Visit 4 (Week 6) - Lesion # - [Lesion Measurement]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
les_meas_area_v6_1-3	Area (mm2) - Visit 6 (Week 12-14) - Lesion # - [Lesion Measurement]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
les_meas_biopsy_taken_v1_1-3	Was Biopsy Taken? - Visit 1 (Baseline) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
les_meas_biopsy_taken_v4_1-3	Was Biopsy Taken? - Visit 4 (Week 6) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
les_meas_biopsy_taken_v6_1-3	Was Biopsy Taken? - Visit 6 (Week 12-14) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
les_meas_completely_excised_v1_1-3	Lesion Completely Excised? - Visit 1 (Baseline) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 0="No"
les_meas_completely_excised_v4_1-3	Lesion Completely Excised? - Visit 4 (Week 6) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 0="No"
les_meas_completely_excised_v6_1-3	Lesion Completely Excised? - Visit 6 (Week 12-14) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 0="No"
les_meas_dt_v1_1-3	Measurement Date - Visit 1 (Baseline) - Lesion # - [Lesion Measurement]		SAS Date .E="Not Eligible For Study" .N="N/A"
les_meas_dt_v4_1-3	Measurement Date - Visit 4 (Week 6) - Lesion # - [Lesion Measurement]		SAS Date .E="Not Eligible For Study" .N="N/A"
les_meas_dt_v6_1-3	Measurement Date - Visit 6 (Week 12-14) - Lesion # - [Lesion Measurement]		SAS Date .E="Not Eligible For Study" .N="N/A"

Variable	Label	Description	Format Text
les_meas_length_v1_1-3	Length (mm) - Visit 1 (Baseline) - Lesion # - [Lesion Measurement]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
les_meas_length_v4_1-3	Length (mm) - Visit 4 (Week 6) - Lesion # - [Lesion Measurement]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
les_meas_length_v6_1-3	Length (mm) - Visit 6 (Week 12-14) - Lesion # - [Lesion Measurement]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
les_meas_mech_factors_v1_1-3	Is Lesion Associated With Mechanical Factors? - Visit 1 (Baseline) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 0="No"
les_meas_mech_factors_v4_1-3	Is Lesion Associated With Mechanical Factors? - Visit 4 (Week 6) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 0="No"
les_meas_mech_factors_v6_1-3	Is Lesion Associated With Mechanical Factors? - Visit 6 (Week 12-14) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 0="No"
les_meas_morph_type_v1_1-3	Morphological Type - Visit 1 (Baseline) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 1="Leukoplakia" 2="Erythroplakia" 3="Speckled"
les_meas_morph_type_v4_1-3	Morphological Type - Visit 4 (Week 6) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 1="Leukoplakia" 2="Erythroplakia" 3="Speckled" 4="Not Applicable"
les_meas_morph_type_v6_1-3	Morphological Type - Visit 6 (Week 12-14) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 1="Leukoplakia" 3="Speckled"
les_meas_photo_taken_v1_1-3	Were Photographs Taken? - Visit 1 (Baseline) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 1="Yes"
les_meas_photo_taken_v4_1-3	Were Photographs Taken? - Visit 4 (Week 6) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 0="No" 1="Yes"
les_meas_photo_taken_v6_1-3	Were Photographs Taken? - Visit 6 (Week 12-14) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 1="Yes"
les_meas_side_v1_1-3	Side - Visit 1 (Baseline) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 1="Left" 2="Right"

Variable	Label	Description	Format Text
les_meas_side_v4_1-3	Side - Visit 4 (Week 6) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 1="Left" 2="Right"
les_meas_side_v6_1-3	Side - Visit 6 (Week 12-14) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 1="Left" 2="Right"
les_meas_site_v1_1-3	Site - Visit 1 (Baseline) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 1="Buccal Mucosa" 2="Dorsal Tongue" 3="Floor of Mouth" 5="Lateral Tongue" 7="Mandibular Alveolus" 8="Maxillary Alveolus" 11="Ventral Tongue"
les_meas_site_v4_1-3	Site - Visit 4 (Week 6) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 1="Buccal Mucosa" 2="Dorsal Tongue" 3="Floor of Mouth" 5="Lateral Tongue" 6="Lip Mucosa" 7="Mandibular Alveolus" 8="Maxillary Alveolus" 11="Ventral Tongue"
les_meas_site_v6_1-3	Site - Visit 6 (Week 12-14) - Lesion # - [Lesion Measurement]		.E="Not Eligible For Study" .N="N/A" 1="Buccal Mucosa" 2="Dorsal Tongue" 3="Floor of Mouth" 5="Lateral Tongue" 6="Lip Mucosa" 7="Mandibular Alveolus" 8="Maxillary Alveolus" 11="Ventral Tongue"
les_meas_width_v1_1-3	Width (mm) - Visit 1 (Baseline) - Lesion # - [Lesion Measurement]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
les_meas_width_v4_1-3	Width (mm) - Visit 4 (Week 6) - Lesion # - [Lesion Measurement]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"
les_meas_width_v6_1-3	Width (mm) - Visit 6 (Week 12-14) - Lesion # - [Lesion Measurement]		Numeric .E="Not Eligible For Study" .M="Missing" .N="N/A"

Section 25: Lesion Histology

Variable	Label	Description	Format Text
les_hist_designation_v1_1-2	Lesion Designation - Visit 1 (Baseline) - Biopsy # - [Lesion Histology]		.E="Not Eligible For Study" 1="Target Lesion" 3="Normal Biopsy"
les_hist_designation_v6_1-2	Lesion Designation - Visit 6 (Week 12) - Biopsy # - [Lesion Histology]		.E="Not Eligible For Study" .F="No Form" 1="Target Lesion" 3="Normal Biopsy"
les_hist_details_v1_1-2	Histology Details - Visit 1 (Baseline) - Biopsy # - [Lesion Histology]		.E="Not Eligible For Study" 1="Hyperplasia" 2="Mild Dysplasia" 3="Moderate Dysplasia" 4="Severe Dysplasia" 5="Normal" 7="Other"
les_hist_details_v6_1-2	Histology Details - Visit 6 (Week 12) - Biopsy # - [Lesion Histology]		.E="Not Eligible For Study" .F="No Form" 1="Hyperplasia" 2="Mild Dysplasia" 3="Moderate Dysplasia" 5="Normal" 6="Carcinoma IN SITU" 7="Other"
les_hist_oth_spec_v1_1-2	Specific Other Histology - Visit 1 (Baseline) - Biopsy # - [Lesion Histology]		Char
les_hist_oth_spec_v6_1-2	Specific Other Histology - Visit 6 (Week 12) - Biopsy # - [Lesion Histology]		Char
les_hist_path_review_dt_v1_1-2	Date Pathology Reviewed - Visit 1 (Baseline) - Biopsy # - [Lesion Histology]		SAS Date .E="Not Eligible For Study"
les_hist_path_review_dt_v6_1-2	Date Pathology Reviewed - Visit 6 (Week 12) - Biopsy # - [Lesion Histology]		SAS Date .E="Not Eligible For Study" .F="No Form"

Section 26: Clinical and Lesion Histologic Response

Variable	Label	Description	Format Text
response_clin_post	Post-Intervention Clinical Response - Post-Intervention - [Clinical and Lesion Histologic Response]		.E="Not Eligible For Study" .F="No Form" 2="Partial response (PR) (50% reduction in the sum of the products of diameters of lesions measurable at baseline. Non-measurable lesion(s) may not increase greater than or equal to 25% in size and no new lesion may appear)." 3="No change (NC) (no change in the size of the lesions identified at baseline and no new lesions appearing, i.e., anything that is not CR, PR, or PD)." 4="Progressive disease (PD) (25% increase in the product of diameter(s) of any lesion(s) measurable at baseline or in the estimated size of lesion(s) non-measurable at baseline or the appearance of an unequivocal new lesion)."
response_les_hist_post	Post-Intervention Lesion Histologic Response - Post-Intervention - [Clinical and Lesion Histologic Response]		.E="Not Eligible For Study" .F="No Form" 1="Complete Response (CR) (complete reversal of dysplasia or hyperplasia to normal epithelium in the target lesion)." 2="Partial Response (PR) (improvement of the degree of dysplasia or hyperplasia in the target lesion)." 3="No Change (NC) (no change in the degree of dysplasia or hyperplasia in the target lesion, anything that is not CR, PR or PD)." 4="Progressive Disease (PD) (increase in the severity of grade of histology in the target lesion)."
response_sum_area_base	Sum of the Areas of the Lesion(s) (mm2) - Baseline - [Clinical and Lesion Histologic Response]		Numeric .E="Not Eligible For Study" .F="No Form"
response_sum_area_post	Sum of the Areas of the Lesion(s) (mm2) - Post-Intervention - [Clinical and Lesion Histologic Response]		Numeric .E="Not Eligible For Study" .F="No Form"

Section 27: Verification

Variable	Label	Description	Format Text
verif_form_dt	Form Date - [Verification]		SAS Date .E="Not Eligible For Study" .F="No Form"
verif_has_signature	Investigator Signature Present? - [Verification]		.E="Not Eligible For Study" .F="No Form" 1="Yes"
verif_signature_dt	Signature Date - [Verification]		SAS Date .E="Not Eligible For Study" .F="No Form"