

FINAL PERSON: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	Final Person: Data Dictionary
Date Created	11/19/2019
Sections	38
Entries	889
Document Filename	dictionary_final_person.111519.rtf

Final Person: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	MRNO	Participant ID (MRNO)	Participant ID (MRNO)	numeric

Section 2: Study

Class	Variable	Label	Description	Format Text
01. Principal	accession	Accession	Accession #	numeric
01. Principal	institution	Institution		1="Brigham and Women's Hospital" 2="M. D. Anderson Cancer Center" 3="University of Michigan Comprehensive Cancer Center" 4="University of Utah Health System - Huntsman Cancer Institute"
01. Principal	reg_date	Registration Date		numeric
01. Principal	treatment_arm	Treatment Arm		.M="Missing" 0="Placebo" 1="Naproxen 220mg" 2="Naproxen 440mg"
01. Principal	trial	Trial		1="MDA2013-01-02"
01. Principal	visit_dt0-7	Visit Date For Visit [x]		SAS Date .M="Missing" .N="Not Applicable"

Section 3: Registration

Class	Variable	Label	Description	Format Text
01. Principal	registration_age	Age		numeric .M="Missing"
01. Principal	registration_consortium	Registering Consortium		1="TX035 (MD Anderson Cancer Center)"
01. Principal	registration_dt	Date Of Registration		SAS Date
01. Principal	registration_dt_consent	Date Study Informed Consent Signed		SAS Date
01. Principal	registration_ethnicity	Ethnicity		1="Hispanic or Latino" 2="Not Hispanic or Latino" 4="Not Reported"
01. Principal	registration_gender	Gender		1="Female" 2="Male"
01. Principal	registration_institute	Registering Institution		1="Brigham and Women's Hospital" 2="M. D. Anderson Cancer Center" 3="University of Michigan Comprehensive Cancer Center" 4="University of Utah Health System - Huntsman Cancer Institute"
01. Principal	registration_payment_method1-2	Participant Payment Method		1="Private Insurance" 3="Medicaid and Medicare" 4="Military Sponsored (including CHAMPUS & TriCare)" 7="Medicare" 8="Medicare and Private Insurance"
01. Principal	registration_payment_selected1-2	Was Payment Selected?		0="False" 1="True"
01. Principal	registration_race1-2	Race		.M="Missing" 1="White" 2="Black or African American" 4="Asian" 6="American Indian or Alaska Native" 7="Unknown" 8="Not Reported"
01. Principal	registration_tac0	TAC-0 (Signed Informed Consent Document And Before Intervention)	Participants have a Tac-0 if the informed consent document was signed before intervention.	1="Yes"

Section 4: Exclusion Criteria

Class	Variable	Label	Description	Format Text
01. Principal	excv4a1_count	Count Of Exclusion Criteria	Form Version 4 A1	numeric .N="Not Applicable"
01. Principal	excv4a1_criteria1-10	Exclusion Criteria	Form Version 4 A1	char, 988 " "="Not Applicable"
01. Principal	excv4a1_num1-10	Exclusion Criteria Number	Form Version 4 A1	numeric .N="Not Applicable"
01. Principal	excv4a1_yn1-10	Is Exclusion Criteria Met?	Form Version 4 A1	.N="Not Applicable" 0="No"
01. Principal	excv5a2_count	Count Of Exclusion Criteria	Form Version 5 A2	numeric .N="Not Applicable"
01. Principal	excv5a2_criteria1-10	Exclusion Criteria	Form Version 5 A2	char, 988 " "="Not Applicable"
01. Principal	excv5a2_num1-10	Exclusion Criteria Number	Form Version 5 A2	numeric .N="Not Applicable"
01. Principal	excv5a2_yn1-10	Is Exclusion Criteria Met?	Form Version 5 A2	.N="Not Applicable" 0="No" 1="Yes"

Section 5: Inclusion Criteria

Class	Variable	Label	Description	Format Text
01. Principal	incv4a1_count	Count Of Inclusion Criteria	Form Version 4 A1	numeric .= "Missing"
01. Principal	incv4a1_criteria1-12	Inclusion Criteria	Form Version 4 A1	char, 988 " " = "Not Applicable"
01. Principal	incv4a1_num1-12	Inclusion Criteria Number	Form Version 4 A1	numeric .N = "Not Applicable"
01. Principal	incv4a1_yn1-12	Is Inclusion Criteria Met?	Form Version 4 A1	.N = "Not Applicable" 0 = "No" 1 = "Yes"
01. Principal	incv5a2_count	Count Of Inclusion Criteria	Form Version 5 A2	numeric .N = "Not Applicable"
01. Principal	incv5a2_criteria1-12	Inclusion Criteria	Form Version 5 A2	char, 988 " " = "Not Applicable"
01. Principal	incv5a2_num1-12	Inclusion Criteria Number	Form Version 5 A2	numeric .N = "Not Applicable"
01. Principal	incv5a2_yn1-12	Is Inclusion Criteria Met?	Form Version 5 A2	.N = "Not Applicable" 0 = "No" 1 = "Yes"

Section 6: Randomization

Class	Variable	Label	Description	Format Text
01. Principal	rand_agent_dt	Date Agent Started		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	rand_dt	Date Participant Randomized		SAS Date .M="Missing"
01. Principal	rand_enrollment_dt	Enrollment Date		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	rand_lynch_syndrome	Lynch Syndrome Mutation		.M="Missing" 0="Negative" 1="Positive"
01. Principal	rand_lynch_type_test	Lynch Syndrome If Negative, Specify Type Of Testing	Possible type of testing are Immunohistochemistry, MSI testing, or both.	.M="Missing" 3="Both"
01. Principal	rand_na	Not Applicable To Be Randomized		0="False" 1="True"
01. Principal	rand_number	Randomization Number		char, 140 " "="Not Applicable"
01. Principal	rand_screen1_dt	Screen 1 Date		SAS Date
01. Principal	rand_screen2_dt	Screen 2 Date		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	rand_screen_criteria	Does The Participant Meet All Screening Criteria	If no, complete Off Study form.	0="No" 1="Yes"
01. Principal	rand_tac1	TAC1	Participants who were randomized have a TAC1.	.M="Missing" 1="Yes"

Section 7: Baseline Medical/Surgical History

Class	Variable	Label	Description	Format Text
01. Principal	basemed_all_body_normal	All Body Systems Normal		.N="Not Applicable" 0="False" 1="True"
01. Principal	basemed_comment_breast	Comments For Breasts Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_comment_cardiovascular	Comments For Cardiovascular Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_comment_dermatologic	Comments For Dermatologic Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_comment_endocrine	Comments For Endocrine/Metabolic Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_comment_gastro	Comments For Gastrointestinal Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_comment_genitourinary	Comments For Genitourinary Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_comment_heent	Comments For H/E/E/N/T Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_comment_hematopoietic	Comments For Hematopoietic Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_comment_musculoskeletal	Comments For Musculoskeletal Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_comment_neck	Comments For Neck Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_comment_neurologic	Comments For Neurologic Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_comment_respiratory	Comments For Respiratory Abnormality		char, 290 " "="Not Applicable"
01. Principal	basemed_has_allergies	Does The Participant Have Any Allergies?		.N="Not Applicable" 0="No" 1="Yes"
01. Principal	basemed_specify_allergies	Specify Allergies		char, 47 " "="Not Applicable"
01. Principal	basemed_status_breast	Status For Breasts		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not Assessed"

Class	Variable	Label	Description	Format Text
01. Principal	basemed_status_cardiovascular	Status For Cardiovascular		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not Assessed"
01. Principal	basemed_status_dermatologic	Status For Dermatologic		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not Assessed"
01. Principal	basemed_status_endocrine	Status For Endocrine/Metabolic		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not Assessed"
01. Principal	basemed_status_gastrointestinal	Status For Gastrointestinal		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal"
01. Principal	basemed_status_genitourinary	Status For Genitourinary		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not Assessed"
01. Principal	basemed_status_heent	Status For H/E/E/N/T		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not Assessed"
01. Principal	basemed_status_hematopoietic	Status For Hematopoietic		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not Assessed"
01. Principal	basemed_status_musculoskeletal	Status For Musculoskeletal		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not Assessed"
01. Principal	basemed_status_neck	Status For Neck		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not Assessed"
01. Principal	basemed_status_neurologic	Status For Neurologic		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal"
01. Principal	basemed_status_respiratory	Status For Respiratory		.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal"
01. Principal	basemedother_body_system1-3	Specify Other Body System/Site		char, 15 " "="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	basemedother_comment1-3	Comments For Other Body Systems		char, 196 " " = "Not Applicable"
01. Principal	basemedother_count	Count Of Baseline Medical/Surgical History		numeric .N = "Not Applicable"
01. Principal	basemedother_status1-3	Status For Other Body Systems		.N = "Not Applicable" 1 = "Abnormal"

Section 8: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	basesymptoms_comment1-11	Comments	Required if Abnormal; provide condition/diagnosis	char, 82 " " = "Not Applicable"
01. Principal	basesymptoms_count	Count Of Baseline Symptoms		numeric .N = "Not Applicable"
01. Principal	basesymptoms_grade1-11	Grade		.M = "Missing" .N = "Not Applicable" 1 = "1 (Mild)" 2 = "2 (Moderate)" 3 = "3 (Severe)"
01. Principal	basesymptoms_onset_dt1-11	Onset Date		SAS Date .M = "Missing" .N = "Not Applicable"
01. Principal	basesymptoms_symptom_desc1-11	Symptom Description		char, 72 " " = "Not Applicable"

Section 9: Intervention Administration (Blinded Study)

Class	Variable	Label	Description	Format Text
01. Principal	intervention_agent_num	Agent Number		numeric .M="Missing" .N="Not Applicable"
01. Principal	intervention_agent_placebo	Agent/Placebo		.M="Missing" .N="Not Applicable" 1="Naproxen 440mg/220mg/ Placebo"
01. Principal	intervention_dose	Dose		numeric .M="Missing" .N="Not Applicable"
01. Principal	intervention_dose_units	Dose Units		.M="Missing" .N="Not Applicable" 1="Capsule"
01. Principal	intervention_dt_provided	Date Agent Provided (To Participant)		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	intervention_dt_started	Date Agent Started		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	intervention_frequency	Frequency		.M="Missing" .N="Not Applicable" 1="QD"

Section 10: Unblinding Form

Class	Variable	Label	Description	Format Text
01. Principal	unblind_dt	Prevention Study Unblinded	The unblinding form occurred during the study.	SAS Date .N="Not Applicable"
01. Principal	unblind_form_dt	Form Date	The unblinding form occurred during the study.	SAS Date .N="Not Applicable"
01. Principal	unblind_personnel	Personnel Unblinding Participant	The unblinding form occurred during the study.	.N="Not Applicable" 2="Pharmacist"
01. Principal	unblind_reason	Reason For Unblinding	The unblinding form occurred during the study.	char, 61 " "="Not Applicable"
01. Principal	unblind_treatment_arm	Treatment Arm	The unblinding form occurred during the study.	.N="Not Applicable" 2="Naproxen 440mg"

Section 11: Physical Exam

Class	Variable	Label	Description	Format Text
01. Principal	physexam_abdomen_comment_v0	Abdomen Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 ""="Not Applicable"
01. Principal	physexam_abdomen_comment_v6	Abdomen Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 ""="Not Applicable"
01. Principal	physexam_abdomen_status_v0	Abdomen Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_abdomen_status_v6	Abdomen Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 2="Abnormal"
01. Principal	physexam_appearance_comment_v0	Appearance Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 ""="Not Applicable"
01. Principal	physexam_appearance_comment_v6	Appearance Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 ""="Not Applicable"
01. Principal	physexam_appearance_status_v0	Appearance Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_appearance_status_v6	Appearance Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal"
01. Principal	physexam_blood_pressure_NO_v0	Blood Pressure Not Obtained At Randomization		.N="Not Applicable" 0="False"
01. Principal	physexam_blood_pressure_NO_v6	Blood Pressure Not Obtained At Visit 6		.N="Not Applicable" 0="False"
01. Principal	physexam_bmi_v0	BMI At Randomization		numeric .="Missing" .N="Not Applicable"
01. Principal	physexam_bmi_v6	BMI At Visit 6		numeric .="Missing" .N="Not Applicable"
01. Principal	physexam_breast_comment_v0	Breast Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 ""="Not Applicable"
01. Principal	physexam_breast_comment_v6	Breast Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 ""="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	physexam_breast_status_v0	Breast Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_breast_status_v6	Breast Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_chest_comment_v0	Chest Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_chest_comment_v6	Chest Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_chest_status_v0	Chest Status At Randomization		.N="Not Applicable" 1="Normal" 3="Not Examined"
01. Principal	physexam_chest_status_v6	Chest Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 3="Not Examined"
01. Principal	physexam_diastolic_v0	Diastolic (mm Hg) At Randomization		numeric .N="Not Applicable"
01. Principal	physexam_diastolic_v6	Diastolic (mm Hg) At Visit 6		numeric .N="Not Applicable"
01. Principal	physexam_dt_v0	Date At Randomization		SAS Date .N="Not Applicable"
01. Principal	physexam_dt_v6	Date At Visit 6		SAS Date .N="Not Applicable"
01. Principal	physexam_ECOG_stat_v0	ECOG Performance Status At Randomization		numeric .N="Not Applicable"
01. Principal	physexam_ECOG_stat_v6	ECOG Performance Status At Visit 6		numeric .N="Not Applicable"
01. Principal	physexam_genital_comment_v0	Genitalia Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_genital_comment_v6	Genitalia Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_genital_status_v0	Genitalia Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_genital_status_v6	Genitalia Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_heart_comment_v0	Heart Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	physexam_heart_comment_v6	Heart Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_heart_status_v0	Heart Status At Randomization		.N="Not Applicable" 1="Normal" 3="Not Examined"
01. Principal	physexam_heart_status_v6	Heart Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 2="Abnormal"
01. Principal	physexam_heent_comment_v0	H/E/E/N/T Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_heent_comment_v6	H/E/E/N/T Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_heent_status_v0	H/E/E/N/T Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_heent_status_v6	H/E/E/N/T Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 3="Not Examined"
01. Principal	physexam_height_cm_v0	Height Units At Randomization		numeric .M="Missing" .N="Not Applicable"
01. Principal	physexam_height_cm_v6	Height Units At Visit 6		numeric .="Missing" .M="Missing" .N="Not Applicable"
01. Principal	physexam_height_in_v0	Height Not Obtained At Randomization		numeric .M="Missing" .N="Not Applicable"
01. Principal	physexam_height_in_v6	Height Not Obtained At Visit 6		numeric .="Missing" .M="Missing" .N="Not Applicable"
01. Principal	physexam_height_NO_v0	Height (in) At Randomization		.N="Not Applicable" 0="False" 1="True"
01. Principal	physexam_height_NO_v6	Height (in) At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	physexam_height_unit_v0	Height (cm) At Randomization		.M="Missing" .N="Not Applicable" 1="cm" 2="in"
01. Principal	physexam_height_unit_v6	Height (cm) At Visit 6		.M="Missing" .N="Not Applicable" 1="cm" 2="in"

Class	Variable	Label	Description	Format Text
01. Principal	physexam_height_v0	Height At Randomization		numeric .="Missing" .N="Not Applicable"
01. Principal	physexam_height_v6	Height At Visit 6		numeric .="Missing" .N="Not Applicable"
01. Principal	physexam_lung_comment_v0	Lungs Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_lung_comment_v6	Lungs Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_lung_status_v0	Lungs Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_lung_status_v6	Lungs Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal"
01. Principal	physexam_lymph_comment_v0	Lymph Nodes Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_lymph_comment_v6	Lymph Nodes Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_lymph_status_v0	Lymph Nodes Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_lymph_status_v6	Lymph Nodes Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 3="Not Examined"
01. Principal	physexam_neuro_comment_v0	Neurological Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_neuro_comment_v6	Neurological Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_neuro_status_v0	Neurological Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_neuro_status_v6	Neurological Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 3="Not Examined"
01. Principal	physexam_not_done_v0	Not Done At Randomization		char, 5 .N="Not Applicable"
01. Principal	physexam_not_done_v6	Not Done At Visit 6		char, 5 .N="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	physexam_pelvis_comment_v0	Pelvis Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_pelvis_comment_v6	Pelvis Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_pelvis_status_v0	Pelvis Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_pelvis_status_v6	Pelvis Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 3="Not Examined"
01. Principal	physexam_pulse_rate_NO_v0	Pulse Rate At Randomization		.N="Not Applicable" 0="False"
01. Principal	physexam_pulse_rate_NO_v6	Pulse Rate At Visit 6		.N="Not Applicable" 0="False"
01. Principal	physexam_pulse_rate_v0	Pulse Rate At Randomization		numeric .N="Not Applicable"
01. Principal	physexam_pulse_rate_v6	Pulse Rate At Visit 6		numeric .N="Not Applicable"
01. Principal	physexam_rectal_comment_v0	Rectal Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_rectal_comment_v6	RectalComment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_rectal_status_v0	Rectal Status At Randomization		.M="Missing" .N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_rectal_status_v6	RectalStatus At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 3="Not Examined"
01. Principal	physexam_resp_rate_NO_v0	Respiration Rate At Randomization		.N="Not Applicable" 0="False" 1="True"
01. Principal	physexam_resp_rate_NO_v6	Respiration Rate At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	physexam_resp_rate_v0	Respiration Rate At Randomization		numeric .="Missing" .N="Not Applicable"
01. Principal	physexam_resp_rate_v6	Respiration Rate At Visit 6		numeric .="Missing" .N="Not Applicable"
01. Principal	physexam_skeletal_comment_v0	Musculoskeletal Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	physexam_skeletal_comment_v6	Musculoskeletal Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_skeletal_status_v0	Musculoskeletal Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_skeletal_status_v6	Musculoskeletal Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 3="Not Examined"
01. Principal	physexam_skin_comment_v0	Skin Comment At Randomization		char, 153 " "="Not Applicable"
01. Principal	physexam_skin_comment_v6	Skin Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_skin_status_v0	Skin Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_skin_status_v6	Skin Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_systolic_v0	Systolic (mm Hg) At Randomization		numeric .N="Not Applicable"
01. Principal	physexam_systolic_v6	Systolic (mm Hg) At Visit 6		numeric .N="Not Applicable"
01. Principal	physexam_temperature_celc_v0	Temperature (Celcius) At Randomization		numeric .M="Missing" .N="Not Applicable"
01. Principal	physexam_temperature_celc_v6	Temperature (Celcius) At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	physexam_temperature_fahr_v0	Temperature (Fahrenheit) At Randomization		numeric .M="Missing" .N="Not Applicable"
01. Principal	physexam_temperature_fahr_v6	Temperature (Fahrenheit) At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	physexam_temperature_NO_v0	Temperature Not Obtained At Randomization		.N="Not Applicable" 0="False" 1="True"
01. Principal	physexam_temperature_NO_v6	Temperature Not Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	physexam_temperature_unit_v0	Temperature Units At Randomization		.M="Missing" .N="Not Applicable" 1="°C" 2="°F"

Class	Variable	Label	Description	Format Text
01. Principal	physexam_tempe rature_unit_v6	Temperature Units At Visit 6		.M="Missing" .N="Not Applicable" 1="°C" 2="°F"
01. Principal	physexam_tempe rature_v0	Temperature At Randomization		numeric .M="Missing" .N="Not Applicable"
01. Principal	physexam_tempe rature_v6	Temperature At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	physexam_thyd_ comment_v0	Thyroid Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_thyd_ comment_v6	Thyroid Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_thyd_ status_v0	Thyroid Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_thyd_ status_v6	Thyroid Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_vascu l_comment_v0	Vascular Comment At Randomization	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_vascu l_comment_v6	Vascular Comment At Visit 6	(Required if Abnormal; provide condition/diagnosis)	char, 153 " "="Not Applicable"
01. Principal	physexam_vascu l_status_v0	Vascular Status At Randomization		.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_vascu l_status_v6	Vascular Status At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not Examined"
01. Principal	physexam_weigh t_kg_v0	Weight (kg) At Randomization		numeric .M="Missing" .N="Not Applicable"
01. Principal	physexam_weigh t_kg_v6	Weight (kg) At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	physexam_weigh t_lb_v0	Weight (lb) At Randomization		numeric .M="Missing" .N="Not Applicable"
01. Principal	physexam_weigh t_lb_v6	Weight (lb) At Visit 6		numeric .M="Missing" .N="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	physexam_weight_NO_v0	Weight Not Obtained At Randomization		.N="Not Applicable" 0="False" 1="True"
01. Principal	physexam_weight_NO_v6	Weight Not Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	physexam_weight_unit_v0	Weight Units At Randomization		.M="Missing" .N="Not Applicable" 1="kg" 2="lb"
01. Principal	physexam_weight_unit_v6	Weight Units At Visit 6		.M="Missing" .N="Not Applicable" 1="kg" 2="lb"
01. Principal	physexam_weight_v0	Weight At Randomization		numeric .= "Missing" .N="Not Applicable"
01. Principal	physexam_weight_v6	Weight At Visit 6		numeric .= "Missing" .N="Not Applicable"

Section 12: Pregnancy Specimen Data

Class	Variable	Label	Description	Format Text
01. Principal	pregspec_dt_collect_v0-1	Date Specimen Collected		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	pregspec_has_v0-1	Has Data At Visit0/1		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	pregspec_reason_v0-1	Reason Pregnancy Specimen Data Was Not Collected		.M="Missing" .N="Not Applicable" 1="Participant is female and not of childbearing potential" 2="Participant is male"
01. Principal	pregspec_result_v0-1	Pregnancy Result		.M="Missing" .N="Not Applicable" 2="Negative" 3="Not Obtained"
01. Principal	pregspec_test_type_v0-1	Pregnancy Test Type		.M="Missing" .N="Not Applicable" 1="Serum" 2="Urine"

Section 13: Outcome Of Pregnancy

Class	Variable	Label	Description	Format Text
01. Principal	pregoutcome_abn_discovered	Was An Abnormality Discovered When Neonate Was Assessed		.N="Not Applicable" 0="No"
01. Principal	pregoutcome_apgar_fiveminute	Five Minute Apgar Score		numeric .N="Not Applicable"
01. Principal	pregoutcome_apgar_oneminute	One Minute Apgar Score		numeric .N="Not Applicable"
01. Principal	pregoutcome_contribute_factor	Pregnancy Contributing Factors		char, 1 " "="Not Applicable"
01. Principal	pregoutcome_delivery_dt	Pregnancy Delivery Date		SAS Date .N="Not Applicable"
01. Principal	pregoutcome_delivery_type	Pregnancy Delivery Type		.N="Not Applicable" 2="Cesarean"
01. Principal	pregoutcome_gender	Neonate Gender		.N="Not Applicable" 2="Female"
01. Principal	pregoutcome_history_abortus	Obstetric History: Abortus		.N="Not Applicable" 1="True"
01. Principal	pregoutcome_history_gravida	Obstetric History: Gravida		.N="Not Applicable" 1="True"
01. Principal	pregoutcome_history_para	Obstetric History: Para		.N="Not Applicable" 1="True"
01. Principal	pregoutcome_length_cm	Neonate Length (cm)		numeric .N="Not Applicable"
01. Principal	pregoutcome_number_abortion	Total Number Of Therapeutic Abortions		numeric .N="Not Applicable"
01. Principal	pregoutcome_number_miscarriage	Total Number Of Miscarriages		numeric .N="Not Applicable"
01. Principal	pregoutcome_number_of_stillbirth	Total Number Of Stillbirths		numeric .N="Not Applicable"
01. Principal	pregoutcome_number_preg_birth	Total Number Of Pregnancies Resulting In Live Births		numeric .N="Not Applicable"
01. Principal	pregoutcome_number_preg_current	Total Number Of Pregnancies Including Current		numeric .N="Not Applicable"
01. Principal	pregoutcome_preg	Outcome Of Pregnancy		.N="Not Applicable" 1="Full Term Live Birth"
01. Principal	pregoutcome_reason_cesarean	Reason For Cesarean	Valid if Cesarean is the delivery type.	char, 49 " "="Not Applicable"
01. Principal	pregoutcome_specify_abn	Specify Abnormality		char, 1 " "="Not Applicable"
01. Principal	pregoutcome_test_dt	Pregnancy Test Date		SAS Date .N="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	pregoutcome_week_gestation	# Of Weeks In Gestation		char, 1 " " = "Not Applicable"
01. Principal	pregoutcome_weight_kg	Neonate Weight (kg)		numeric .N = "Not Applicable"

Section 14: Clinical Laboratory Data Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	bloodchem_comment_bilirubin_v0	Bilirubin, Total Test Comments At Screening/Eligibility		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_bilirubin_v6	Bilirubin, Total Test Comments At Visit 6		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_bun_v0	BUN Test Comments At Screening/Eligibility		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_bun_v6	BUN Test Comments At Visit 6		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_calcium_v0	Calcium Test Comments At Screening/Eligibility		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_calcium_v6	Calcium Test Comments At Visit 6		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_creatinine_v0	Creatinine Test Comments At Screening/Eligibility		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_creatinine_v6	Creatinine Test Comments At Visit 6		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_gfr_v0	GFR Test Comments At Screening/Eligibility		char, 12 " "="Not Applicable"
01. Principal	bloodchem_comment_gfr_v6	GFR Test Comments At Visit 6		char, 12 " "="Not Applicable"
01. Principal	bloodchem_comment_glucose_v0	Glucose Test Comments At Screening/Eligibility		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_glucose_v6	Glucose Test Comments At Visit 6		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_inr_v0	INR Test Comments At Screening/Eligibility		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_potassium_v0	Potassium Test Comments At Screening/Eligibility		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_potassium_v6	Potassium Test Comments At Visit 6		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_pt_v0	PT Test Comments At Screening/Eligibility		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_ptt_v0	PTT Test Comments At Screening/Eligibility		char, 133 " "="Not Applicable"
01. Principal	bloodchem_comment_sgot_v0	SGOT/AST Test Comments At Screening/Eligibility		char, 133 " "="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	bloodchem_comment_sgpt_v6	SGOT/ASTComments At Visit 6		char, 133 " " = "Not Applicable"
01. Principal	bloodchem_comment_sgpt_v0	SGPT/ALT Test Comments At Screening/Eligibility		char, 133 " " = "Not Applicable"
01. Principal	bloodchem_comment_sgpt_v6	SGPT/ALT Test Comments At Visit 6		char, 133 " " = "Not Applicable"
01. Principal	bloodchem_comment_sodium_v0	Sodium Test Comments At Screening/Eligibility		char, 133 " " = "Not Applicable"
01. Principal	bloodchem_comment_sodium_v6	Sodium Test Comments At Visit 6		char, 133 " " = "Not Applicable"
01. Principal	bloodchem_fasting_v0	Fasting At Screening/Eligibility		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	bloodchem_fasting_v6	Fasting At Visit 6		.N="Not Applicable" 0="No" 1="Yes"
01. Principal	bloodchem_notob_bilirubin_v0	Bilirubin, Total Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"
01. Principal	bloodchem_notob_bilirubin_v6	Bilirubin, Total Test Not Obtained At Visit 6		.N="Not Applicable" 0="False"
01. Principal	bloodchem_notob_bun_v0	BUN Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_notob_bun_v6	BUN Test Not Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_notob_calcium_v0	Calcium Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_notob_calcium_v6	Calcium Test Not Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_notob_creatinine_v0	Creatinine Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"
01. Principal	bloodchem_notob_creatinine_v6	Creatinine Test Not Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_notob_glucose_v0	Glucose Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_notob_glucose_v6	Glucose Test Not Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_notob_inr_v0	INR Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	bloodchem_noto b_potassium_v0	Potassium Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"
01. Principal	bloodchem_noto b_potassium_v6	Potassium Test Not Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_noto b_pt_v0	PT Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_noto b_ptt_v0	PTT Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_noto b_sgot_v0	SGOT/AST Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"
01. Principal	bloodchem_noto b_sgot_v6	SGOT/ASTNot Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_noto b_sgpt_v0	SGPT/ALT Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"
01. Principal	bloodchem_noto b_sgpt_v6	SGPT/ALT Test Not Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_noto b_sodium_v0	Sodium Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"
01. Principal	bloodchem_noto b_sodium_v6	Sodium Test Not Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_ bilirubin_v0	Bilirubin, Total Test Out Of Range At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_ bilirubin_v6	Bilirubin, Total Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_ bun_v0	BUN Test Out Of Range At Screening/Eligibility		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_ bun_v6	BUN Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_ calcium_v0	Calcium Test Out Of Range At Screening/Eligibility		.M="Missing" .N="Not Applicable" 0="False"
01. Principal	bloodchem_oor_ calcium_v6	Calcium Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False"

Class	Variable	Label	Description	Format Text
01. Principal	bloodchem_oor_creatinine_v0	Creatinine Test Out Of Range At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_creatinine_v6	Creatinine Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_gfr_v0	GFR Test Out Of Range At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_gfr_v6	GFR Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_glucose_v0	Glucose Test Out Of Range At Screening/Eligibility		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_glucose_v6	Glucose Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_inr_v0	INR Test Out Of Range At Screening/Eligibility		.M="Missing" .N="Not Applicable" 0="False"
01. Principal	bloodchem_oor_potassium_v0	Potassium Test Out Of Range At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_potassium_v6	Potassium Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_pt_v0	PT Test Out Of Range At Screening/Eligibility		.M="Missing" .N="Not Applicable" 0="False"
01. Principal	bloodchem_oor_ptt_v0	PTT Test Out Of Range At Screening/Eligibility		.M="Missing" .N="Not Applicable" 0="False"
01. Principal	bloodchem_oor_sgot_v0	SGOT/AST Test Out Of Range At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_sgot_v6	SGOT/AST Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_sgpt_v0	SGPT/ALT Test Out Of Range At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_sgpt_v6	SGPT/ALT Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	bloodchem_oor_sodium_v0	Sodium Test Out Of Range At Screening/Eligibility		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_oor_sodium_v6	Sodium Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	bloodchem_result_bilirubin_v0	Bilirubin, Total Test Result At Screening/Eligibility		numeric .N="Not Applicable"
01. Principal	bloodchem_result_bilirubin_v6	Bilirubin, Total Test Result At Visit 6		numeric .N="Not Applicable"
01. Principal	bloodchem_result_bun_v0	BUN Test Result At Screening/Eligibility		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_bun_v6	BUN Test Result At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_calcium_v0	Calcium Test Result At Screening/Eligibility		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_calcium_v6	Calcium Test Result At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_creatinine_v0	Creatinine Test Result At Screening/Eligibility		numeric .N="Not Applicable"
01. Principal	bloodchem_result_creatinine_v6	Creatinine Test Result At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_gfr_v0	GFR Test Result At Screening/Eligibility		char, 4 .N="Not Applicable"
01. Principal	bloodchem_result_gfr_v6	GFR Test Result At Visit 6		char, 4 .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_glucose_v0	Glucose Test Result At Screening/Eligibility		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_glucose_v6	Glucose Test Result At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_inr_v0	INR Test Result At Screening/Eligibility		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_potassium_v0	Potassium Test Result At Screening/Eligibility		numeric .N="Not Applicable"
01. Principal	bloodchem_result_potassium_v6	Potassium Test Result At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_pt_v0	PT Test Result At Screening/Eligibility		numeric .M="Missing" .N="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	bloodchem_result_ptt_v0	PTT Test Result At Screening/Eligibility		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_sgot_v0	SGOT/AST Test Result At Screening/Eligibility		numeric .N="Not Applicable"
01. Principal	bloodchem_result_sgot_v6	SGOT/AST Result At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_sgpt_v0	PT Test SGPT Test Result At Screening/Eligibility		numeric .N="Not Applicable"
01. Principal	bloodchem_result_sgpt_v6	SGPT/ALT Test Result At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_result_sodium_v0	Sodium Test Result At Screening/Eligibility		numeric .N="Not Applicable"
01. Principal	bloodchem_result_sodium_v6	Sodium Test Result At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	bloodchem_sig_bilirubin_v0	Bilirubin, Total Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	bloodchem_sig_bilirubin_v6	Bilirubin, Total Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	bloodchem_sig_bun_v0	BUN Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_bun_v6	BUN Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_calcium_v0	Calcium Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_calcium_v6	Calcium Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_creatinine_v0	Creatinine Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bloodchem_sig_creatinine_v6	Creatinine Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	bloodchem_sig_gfr_v0	GFR Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_gfr_v6	GFR Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_glucose_v0	Glucose Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_glucose_v6	Glucose Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_inr_v0	INR Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_potassium_v0	Potassium Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_potassium_v6	Potassium Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_pt_v0	PT Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_ptt_v0	PTT Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_sgot_v0	SGOT/AST Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	bloodchem_sig_sgpt_v6	SGOT/ASTClinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	bloodchem_sig_sgpt_v0	SGPT/ALT Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	bloodchem_sig_sgpt_v6	SGPT/ALT Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	bloodchem_sig_sodium_v0	Sodium Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_sig_sodium_v6	Sodium Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	bloodchem_units_gfr_v0	GFR Test Units At Screening/Eligibility		char, 7 " "="Not Applicable"
01. Principal	bloodchem_units_gfr_v6	GFR Test Units At Visit 6		char, 7 " "="Not Applicable"

Section 15: Clinical Laboratory Data Hematology

Class	Variable	Label	Description	Format Text
01. Principal	hematology_comment_anc_v0	Absolute Neutrophil Count (ANC) Test Comments At Screening/Eligibility		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_anc_v6	Absolute Neutrophil Count (ANC) Test Comments At Visit 6		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_bands_v0	Bands Test Comments At Screening/Eligibility (%)		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_bands_v6	Bands Test Comments At Visit 6 (%)		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_baso_v0	Basophilis Test Comments At Screening/Eligibility (%)		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_baso_v6	Basophilis Test Comments At Visit 6 (%)		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_eosi_v0	Eosinophilis Test Comments At Screening/Eligibility (%)		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_eosi_v6	Eosinophilis Test Comments At Visit 6 (%)		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_hematocrit_v0	Hematocrit Test Comments At Screening/Eligibility		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_hematocrit_v6	Hematocrit Test Comments At Visit 6		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_hemoglobin_v0	Hemoglobin Test Comments At Screening/Eligibility		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_hemoglobin_v6	Hemoglobin Test Comments At Visit 6		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_lymph_v0	Lymphocytes Test Comments At Screening/Eligibility (%)		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_lymph_v6	Lymphocytes Test Comments At Visit 6 (%)		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_mono_v0	Monocytes Test Comments At Screening/Eligibility (%)		char, 57 " "="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	hematology_comment_mono_v6	Monocytes Test Comments At Visit 6 (%)		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_neut_v0	Neutrophils Test Comments At Screening/Eligibility (%)		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_neut_v6	Neutrophils Test Comments At Visit 6 (%)		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_platelets_v0	Platelets Test Comments At Screening/Eligibility		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_platelets_v6	Platelets Test Comments At Visit 6		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_rbc_v0	RBC Test Comments At Screening/Eligibility		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_rbc_v6	RBC Test Comments At Visit 6		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_wbc_v0	WBC Test Comments At Screening/Eligibility		char, 57 " "="Not Applicable"
01. Principal	hematology_comment_wbc_v6	WBC Test Comments At Visit 6		char, 57 " "="Not Applicable"
01. Principal	hematology_fasting_v0	Fasting At Screening/Eligibility		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	hematology_fasting_v6	Fasting At Visit 6		.N="Not Applicable" 0="No" 1="Yes"
01. Principal	hematology_notob_anc_v0	Absolute Neutrophil Count (ANC) Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"
01. Principal	hematology_notob_anc_v6	Absolute Neutrophil Count (ANC) Test Not Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_bands_v0	Bands Test Not Obtained At Screening/Eligibility (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_bands_v6	Bands Test Not Obtained At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_baso_v0	Basophil Test Not Obtained At Screening/Eligibility (%)		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_baso_v6	Basophil Test Not Obtained At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	hematology_notob_eosi_v0	Eosinophilis Test Not Obtained At Screening/Eligibility (%)		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_eosi_v6	Eosinophilis Test Not Obtained At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_hematocrit_v0	Hematocrit Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"
01. Principal	hematology_notob_hematocrit_v6	Hematocrit Test Not Obtained At Visit 6		.N="Not Applicable" 0="False"
01. Principal	hematology_notob_hemoglobin_v0	Hemoglobin Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"
01. Principal	hematology_notob_hemoglobin_v6	Hemoglobin Test Not Obtained At Visit 6		.N="Not Applicable" 0="False"
01. Principal	hematology_notob_lymph_v0	Lymphocytes Test Not Obtained At Screening/Eligibility (%)		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_lymph_v6	Lymphocytes Test Not Obtained At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_mono_v0	Monocytes Test Not Obtained At Screening/Eligibility (%)		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_mono_v6	Monocytes Test Not Obtained At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_neut_v0	Neutrophilis Test Not Obtained At Screening/Eligibility (%)		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_neut_v6	Neutrophilis Test Not Obtained At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_platelets_v0	Platelets Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"
01. Principal	hematology_notob_platelets_v6	Platelets Test Not Obtained At Visit 6		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_notob_rbc_v0	RBC Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"
01. Principal	hematology_notob_rbc_v6	RBC Test Not Obtained At Visit 6		.N="Not Applicable" 0="False"
01. Principal	hematology_notob_wbc_v0	WBC Test Not Obtained At Screening/Eligibility		.N="Not Applicable" 0="False"

Class	Variable	Label	Description	Format Text
01. Principal	hematology_notob_wbc_v6	WBC Test Not Obtained At Visit 6		.N="Not Applicable" 0="False"
01. Principal	hematology_oor_anc_v0	Absolute Neutrophil Count (ANC) Test Out Of Range At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_anc_v6	Absolute Neutrophil Count (ANC) Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_bands_v0	Bands Test Out Of Range At Screening/Eligibility (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_bands_v6	Bands Test Out Of Range At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False"
01. Principal	hematology_oor_baso_v0	Basophilis Test Out Of Range At Screening/Eligibility (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_baso_v6	Basophilis Test Out Of Range At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_eosi_v0	Eosinophilis Test Out Of Range At Screening/Eligibility (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_eosi_v6	Eosinophilis Test Out Of Range At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_hematocrit_v0	Hematocrit Test Out Of Range At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_hematocrit_v6	Hematocrit Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_hemoglobin_v0	Hemoglobin Test Out Of Range At Screening/Eligibility		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_hemoglobin_v6	Hemoglobin Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_lymph_v0	Lymphocytes Test Out Of Range At Screening/Eligibility (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"

Class	Variable	Label	Description	Format Text
01. Principal	hematology_oor_lymph_v6	Lymphocytes Test Out Of Range At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_mono_v0	Monocytes Test Out Of Range At Screening/Eligibility (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_mono_v6	Monocytes Test Out Of Range At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_neut_v0	Neutrophils Test Out Of Range At Screening/Eligibility (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_neut_v6	Neutrophils Test Out Of Range At Visit 6 (%)		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_platelets_v0	Platelets Test Out Of Range At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_platelets_v6	Platelets Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_rbc_v0	RBC Test Out Of Range At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_rbc_v6	RBC Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_wbc_v0	WBC Test Out Of Range At Screening/Eligibility		.N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_oor_wbc_v6	WBC Test Out Of Range At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	hematology_result_anc_v0	Absolute Neutrophil Count (ANC) Test Result At Screening/Eligibility		numeric .N="Not Applicable"
01. Principal	hematology_result_anc_v6	Absolute Neutrophil Count (ANC) Test Result At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_bands_v0	Bands Test Result At Screening/Eligibility (%)		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_bands_v6	Bands Test Result At Visit 6 (%)		numeric .M="Missing" .N="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	hematology_result_baso_v0	Basophilis Test Result At Screening/Eligibility (%)		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_baso_v6	Basophilis Test Result At Visit 6 (%)		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_eosi_v0	Eosinophilis Test Result At Screening/Eligibility (%)		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_eosi_v6	Eosinophilis Test Result At Visit 6 (%)		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_hematocrit_v0	Hematocrit Test Result At Screening/Eligibility		numeric .N="Not Applicable"
01. Principal	hematology_result_hematocrit_v6	Hematocrit Test Result At Visit 6		numeric .N="Not Applicable"
01. Principal	hematology_result_hemoglobin_v0	Hemoglobin Test Result At Screening/Eligibility		numeric .N="Not Applicable"
01. Principal	hematology_result_hemoglobin_v6	Hemoglobin Test Result At Visit 6		numeric .N="Not Applicable"
01. Principal	hematology_result_lymph_v0	Lymphocytes Test Result At Screening/Eligibility (%)		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_lymph_v6	Lymphocytes Test Result At Visit 6 (%)		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_mono_v0	Monocytes Test Result At Screening/Eligibility (%)		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_mono_v6	Monocytes Test Result At Visit 6 (%)		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_neut_v0	Neutrophilis Test Result At Screening/Eligibility (%)		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_neut_v6	Neutrophilis Test Result At Visit 6 (%)		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_platelets_v0	Platelets Test Result At Screening/Eligibility		numeric .N="Not Applicable"
01. Principal	hematology_result_platelets_v6	Platelets Test Result At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	hematology_result_rbc_v0	RBC Test Result At Screening/Eligibility		numeric .N="Not Applicable"
01. Principal	hematology_result_rbc_v6	RBC Test Result At Visit 6		numeric .N="Not Applicable"
01. Principal	hematology_result_wbc_v0	WBC Test Result At Screening/Eligibility		numeric .N="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	hematology_result_wbc_v6	WBC Test Result At Visit 6		numeric .N="Not Applicable"
01. Principal	hematology_sig_anc_v0	Absolute Neutrophil Count (ANC) Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	hematology_sig_anc_v6	Absolute Neutrophil Count (ANC) Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_bands_v0	Bands Test Clinically Significant At Screening/Eligibility (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_bands_v6	Bands Test Clinically Significant At Visit 6 (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_baso_v0	Basophilis Test Clinically Significant At Screening/Eligibility (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_baso_v6	Basophilis Test Clinically Significant At Visit 6 (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	hematology_sig_eosi_v0	Eosinophilis Test Clinically Significant At Screening/Eligibility (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_eosi_v6	Eosinophilis Test Clinically Significant At Visit 6 (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_hematocrit_v0	Hematocrit Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_hematocrit_v6	Hematocrit Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hematology_sig_hemoglobin_v0	Hemoglobin Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_hemoglobin_v6	Hemoglobin Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_lymph_v0	Lymphocytes Test Clinically Significant At Screening/Eligibility (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_lymph_v6	Lymphocytes Test Clinically Significant At Visit 6 (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_mono_v0	Monocytes Test Clinically Significant At Screening/Eligibility (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_mono_v6	Monocytes Test Clinically Significant At Visit 6 (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	hematology_sig_neut_v0	Neutrophils Test Clinically Significant At Screening/Eligibility (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_neut_v6	Neutrophils Test Clinically Significant At Visit 6 (%)	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_platelets_v0	Platelets Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_platelets_v6	Platelets Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_rbc_v0	RBC Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"

Class	Variable	Label	Description	Format Text
01. Principal	hematology_sig_rbc_v6	RBC Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	hematology_sig_wbc_v0	WBC Test Clinically Significant At Screening/Eligibility	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	hematology_sig_wbc_v6	WBC Test Clinically Significant At Visit 6	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M="Missing" .N="Not Applicable" 0="No"

Section 16: Clinical Laboratory Data Other Lab Tests

Class	Variable	Label	Description	Format Text
01. Principal	otherlab_comment1-3	Comments		char, 60 " " = "Not Applicable"
01. Principal	otherlab_count	Count Of Other Lab Tests		numeric .N = "Not Applicable"
01. Principal	otherlab_lab_test1-3	Lab Test		char, 18 " " = "Not Applicable"
01. Principal	otherlab_oor1-3	Out Of Range		.M = "Missing" .N = "Not Applicable" 0 = "False" 1 = "True"
01. Principal	otherlab_result1-3	Results		numeric .M = "Missing" .N = "Not Applicable"
01. Principal	otherlab_sig1-3	Clinically Significant	All clinically significant abnormal laboratory results after baseline must be reported on the Adverse Events CRF.	.M = "Missing" .N = "Not Applicable" 0 = "No" 1 = "Yes"

Section 17: Agent Interruption Form

Class	Variable	Label	Description	Format Text
01. Principal	agent_dt_stoppe d1-12	Date Stopped From Interruption #1-12		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	agent_interruptio n_count	Count Of Agent Interruption		numeric .N="Not Applicable"
01. Principal	agent_reason_st opped1-12	Reason Stopped From Interruption #1-12		.M="Missing" .N="Not Applicable" 1="AE/SAE, specify" 2="Investigator decision, specify" 3="Other, specify" 4="Participant decision, specify"
01. Principal	agent_specify_dt _restarted1-12	Date Restarted From Interruption #1-12		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	agent_specify_re ason_restarted1- 12	Specify Reason Restarted From Interruption #1-12		.M="Missing" .N="Not Applicable" 1="Investigator decision" 2="Participant decision"
01. Principal	agent_specify_re ason_stopped1-1 2	Specify Reason Stopped From Interruption #1-12		Char, 108 " "="Not Applicable"
01. Principal	agent_was_agent _restarted1-12	Was Agent Restarted From Interruption #1-12		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Section 18: Telephone Contact

Class	Variable	Label	Description	Format Text
01. Principal	telephone_ae_v2	Did The Participant Report Any Symptoms or Adverse Events At Visit 2?	(If Yes, please enter information on AE CRF)	.N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_ae_v3	Did The Participant Report Any Symptoms or Adverse Events At Visit 3?	(If Yes, please enter information on AE CRF)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_ae_v4	Did The Participant Report Any Symptoms or Adverse Events At Visit 4?	(If Yes, please enter information on AE CRF)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_ae_v5	Did The Participant Report Any Symptoms or Adverse Events At Visit 5?	(If Yes, please enter information on AE CRF)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_ae_v7	Did The Participant Report Any Symptoms or Adverse Events At Visit 7?	(If Yes, please enter information on AE CRF)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_compliance_v2	Was Study Compliance Reviewed At Visit 2?	(If Yes, please enter information on Compliance Phone Interview CRF, N/A if Visit 7/Follow-up Phone Contact)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_compliance_v3	Was Study Compliance Reviewed At Visit 3?	(If Yes, please enter information on Compliance Phone Interview CRF, N/A if Visit 7/Follow-up Phone Contact)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_compliance_v4	Was Study Compliance Reviewed At Visit 4?	(If Yes, please enter information on Compliance Phone Interview CRF, N/A if Visit 7/Follow-up Phone Contact)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_compliance_v5	Was Study Compliance Reviewed At Visit 5?	(If Yes, please enter information on Compliance Phone Interview CRF, N/A if Visit 7/Follow-up Phone Contact)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_compliance_v7	Was Study Compliance Reviewed At Visit 7?	(If Yes, please enter information on Compliance Phone Interview CRF, N/A if Visit 7/Follow-up Phone Contact)	.M="Missing" .N="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	telephone_conmed_v2	Were Any Changes in Concomitant Medication Reported At Visit 2?	(If Yes, please enter information on Concomitant Medication CRF, N/A if Visit 7/Follow-up Phone Contact)	.N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_conmed_v3	Were Any Changes in Concomitant Medication Reported At Visit 2?	(If Yes, please enter information on Concomitant Medication CRF, N/A if Visit 7/Follow-up Phone Contact)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_conmed_v4	Were Any Changes in Concomitant Medication Reported At Visit 2?	(If Yes, please enter information on Concomitant Medication CRF, N/A if Visit 7/Follow-up Phone Contact)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_conmed_v5	Were Any Changes in Concomitant Medication Reported At Visit 2?	(If Yes, please enter information on Concomitant Medication CRF, N/A if Visit 7/Follow-up Phone Contact)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_conmed_v7	Were Any Changes in Concomitant Medication Reported At Visit 2?	(If Yes, please enter information on Concomitant Medication CRF, N/A if Visit 7/Follow-up Phone Contact)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	telephone_dt_contact_v2	Date Of Telephone Contact At Visit 2		SAS Date .N="Not Applicable"
01. Principal	telephone_dt_contact_v3	Date Of Telephone Contact At Visit 3		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	telephone_dt_contact_v4	Date Of Telephone Contact At Visit 4		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	telephone_dt_contact_v5	Date Of Telephone Contact At Visit 5		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	telephone_dt_contact_v7	Date Of Telephone Contact At Visit 7		SAS Date .M="Missing" .N="Not Applicable"

Section 19: Compliance

Class	Variable	Label	Description	Format Text
01. Principal	comp_agent_interrupted	Was Agent Interrupted During This Period?		.N="Not Applicable" 0="No" 1="Yes"
01. Principal	comp_agent_mod	Was Agent Regimen Modified During This Period	(If Yes Is Selected for Either Question, Complete Agent Interruption Form)	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	comp_agent_provided	Was Agent Provided At Visit 6?		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	comp_amount_last_visit	Amount Of Agent Provided At Visit 6		numeric .N="Not Applicable"
01. Principal	comp_amount_missing	Amount Of Agent Missing/Not Accounted For This Period		numeric .N="Not Applicable"
01. Principal	comp_amount_provided	Amount Of Agent Provided At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	comp_amount_return_visit	Amount Of Agent Returned This Visit		numeric .N="Not Applicable"
01. Principal	comp_amount_taken	Amount Of Agent Taken During This Period		numeric .N="Not Applicable"
01. Principal	comp_compliant	Is The Participant Compliant With Protocol Intervention?		.N="Not Applicable" 0="No" 1="Yes"
01. Principal	comp_first_dose_dt	Date First Dose Taken This Period		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	comp_first_dose_time	Time First Dose Taken		numeric .M="Missing" .N="Not Applicable"
01. Principal	comp_last_dose_dt	Date Last Dose Taken This Period		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	comp_last_dose_time	Time Last Dose Taken		numeric .M="Missing" .N="Not Applicable"
01. Principal	comp_noncompliance	If No, Specify Reason For Noncompliance		char, 96 " " = "Not Applicable"
01. Principal	comp_num_interrupted	If Yes, Indicate Number Of Interruptions This Period		numeric .M="Missing" .N="Not Applicable"

Section 20: Compliance Drug Labels

Class	Variable	Label	Description	Format Text
01. Principal	compdrug_count	Count Of Compliance Drug Labels		numeric .N="Not Applicable"
01. Principal	compdrug_inv_signature1-2	Investigator's Signature		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	compdrug_sig_dt1-2	Date Of Investigator's Signature		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	compdrug_were_labels_affix1-2	Were Labels Affixed?		.M="Missing" .N="Not Applicable" 1="Yes"

Section 21: Compliance Phone Interview

Class	Variable	Label	Description	Format Text
01. Principal	compphone_agent_interrupt_v3-5	Was Agent Interrupted During This Period		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	compphone_agent_mod_v3-5	Was Agent Regimen Modified During This Period	(If Yes Is Selected for Either Question, Complete Agent Interruption Form)	.M="Missing" .N="Not Applicable" 0="No"
01. Principal	compphone_comment_v3-5	Comments		char, 140 " "="Not Applicable"
01. Principal	compphone_compliant_v3-5	Is The Participant Compliant With Protocol Intervention Per Telephone Conversation		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	compphone_date_of_contact_v3-5	Date Of Telephone Contact		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	compphone_first_dose_date_v3-5	Date First Dose Taken This Period		numeric .M="Missing" .N="Not Applicable"
01. Principal	compphone_first_dose_time_v3-5	Time First Dose Taken This Period		numeric .M="Missing" .N="Not Applicable"
01. Principal	compphone_has_v3-5	Has Data At Visit3/4/5		.N="Not Applicable" 0="No" 1="Yes"
01. Principal	compphone_last_dose_date_v3-5	Date Last Dose Taken This Period		numeric .M="Missing" .N="Not Applicable"
01. Principal	compphone_last_dose_time_v3-5	Time Last Dose Taken This Period		numeric .M="Missing" .N="Not Applicable"
01. Principal	compphone_noncompliance_v3-5	If No, Specify Reason For Noncompliance		char, 96 " "="Not Applicable"
01. Principal	compphone_number_interrupt_v3-5	If Yes, Indicate Number Of Interruptions This Period		numeric .M="Missing" .N="Not Applicable"
01. Principal	compphone_pill_reminder_v3-5	Reminded Participant To Take Pill(s) Of Study Agent Per Day		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Section 22: AE and Concomitant Evaluation Form

Class	Variable	Label	Description	Format Text
01. Principal	aeconmed_adverse_reported_v0-7	Were Any New or Changes in Adverse Events Reported At Visit 0-Visit 7		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	aeconmed_concomitant_reported_v0-7	Were Any New or Changes in Concomitant Medications Reported At Visit 0-Visit 7		.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 2="Not Evaluated"

Section 23: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	conmed_continuing1-24	Concomitant Medications Continuing		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	conmed_count	Count Of Concomitant Medications		numeric .N="Not Applicable"
01. Principal	conmed_dose1-24	Concomitant Medications Dose		char, 10 " "="Not Applicable"
01. Principal	conmed_frequency1-24	Concomitant Medications Frequency		char, 3 " "="Not Applicable"
01. Principal	conmed_med_reported_dt1-24	Concomitant Medications Reported Date		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	conmed_medication_name1-24	Concomitant Medications		char, 54 " "="Not Applicable"
01. Principal	conmed_other_frequency1-24	Concomitant Medications Other Frequency		char, 53 " "="Not Applicable"
01. Principal	conmed_other_units1-24	Concomitant Medications Other Units	Un-Common Units are classified as "Other Units"	char, 41 " "="Not Applicable"
01. Principal	conmed_reason1-24	Concomitant Medications Reason		char, 65 " "="Not Applicable"
01. Principal	conmed_start_dt1-24	Concomitant Medications Start Date		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	conmed_stop_dt1-24	Concomitant Medications Stop Date		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	conmed_units1-24	Concomitant Medications Units		char, 5 " "="Not Applicable"

Section 24: Eligibility Verification

Class	Variable	Label	Description	Format Text
01. Principal	eligverif_by_dt	Date Eligibility Was Verified		SAS Date
01. Principal	eligverif_rand_dt	Randomization Date		SAS Date .M="Missing"
01. Principal	eligverif_status	Status		1="Confirmed" 2="Ineligible" 3="Override"

Section 25: Off Study

Class	Variable	Label	Description	Format Text
01. Principal	offstudy_agent_end_dt	Agent End Date		SAS Date .M="Missing"
01. Principal	offstudy_dt	Date Off Study		SAS Date
01. Principal	offstudy_dt_last_contact	Date Of Last Contact		SAS Date
01. Principal	offstudy_form_dt	Off Study Form Date		SAS Date
01. Principal	offstudy_na	Not Applicable		0="False" 1="True"
01. Principal	offstudy_reason_explanation	Reason Off Study Explanation		char, 171 " "="Not Applicable"
01. Principal	offstudy_reason_off_study	Reason Off Study		1="Adverse Event" 2="Ineligible" 3="Lost to follow-up" 4="Other, specify" 5="Participant Withdrawal" 6="Study Complete"

Section 26: Specimen Acquisition Research Blood - DNA Extraction

Class	Variable	Label	Description	Format Text
01. Principal	dnaextract_dt	Date DNA Extracted		SAS Date .N="Not Applicable"
01. Principal	dnaextract_dt_frozen	Date Extracted DNA Frozen		SAS Date .N="Not Applicable"
01. Principal	dnaextract_dt_spec_collect	Date Specimen Collected		SAS Date .N="Not Applicable"
01. Principal	dnaextract_dt_spec_receive	Date Specimen Received		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	dnaextract_dt_spec_ship	Date Specimen Shipped		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	dnaextract_flag	Was DNA Extracted		.N="Not Applicable" 1="Yes"
01. Principal	dnaextract_not_obtain	Specimen Not Obtained		.N="Not Applicable" 0="False"
01. Principal	dnaextract_receive_sig	Investigator/Designee's Signature (Received Label)		.N="Not Applicable" 1="Yes"
01. Principal	dnaextract_receive_sig_dt	Date Of Signature (Received Label)		SAS Date .N="Not Applicable"
01. Principal	dnaextract_ship_sig	Investigator/Designee's Signature (Shipping Label)		.N="Not Applicable" 1="Yes"
01. Principal	dnaextract_ship_sig_dt	Date Of Signature (Shipping Label)		SAS Date .N="Not Applicable"
01. Principal	dnaextract_spec	Specimen Type		.N="Not Applicable" 1="Whole Blood"
01. Principal	dnaextract_spec_id	Specimen ID		numeric .N="Not Applicable"
01. Principal	dnaextract_spec_ship	Will Specimen Be Shipped		.N="Not Applicable" 0="No" 1="Yes"
01. Principal	dnaextract_spec_vol	Specimen Volume (Must Be >= 2 ml)		numeric .N="Not Applicable"
01. Principal	dnaextract_storage_temp	Storage Temperature (Celsius)		numeric .M="Missing" .N="Not Applicable"

Section 27: Specimen Acquisition Research Urine - PGEM Levels

Class	Variable	Label	Description	Format Text
01. Principal	pgem_dt_spec_collect_v1	Date Specimen Collected		SAS Date .N="Not Applicable"
01. Principal	pgem_dt_spec_collect_v6	Date Specimen Collected		SAS Date .N="Not Applicable"
01. Principal	pgem_dt_spec_fridge_v1	Date Specimen Refrigerated		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	pgem_dt_spec_fridge_v6	Date Specimen Refrigerated		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	pgem_dt_spec_frozen_v1	Date Specimen Frozen		SAS Date .N="Not Applicable"
01. Principal	pgem_dt_spec_frozen_v6	Date Specimen Frozen		SAS Date .N="Not Applicable"
01. Principal	pgem_dt_spec_receive_v1	Date Specimen Received		SAS Date .N="Not Applicable"
01. Principal	pgem_dt_spec_receive_v6	Date Specimen Received		SAS Date .N="Not Applicable"
01. Principal	pgem_dt_spec_ship_v1	Date Specimen Shipped		SAS Date .N="Not Applicable"
01. Principal	pgem_dt_spec_ship_v6	Date Specimen Shipped		SAS Date .N="Not Applicable"
01. Principal	pgem_not_obtain_v1	Specimen Not Obtained		.N="Not Applicable" 0="False"
01. Principal	pgem_not_obtain_v6	Specimen Not Obtained		.N="Not Applicable" 0="False"
01. Principal	pgem_receive_sig_dt_v1	Date Of Signature (Received Label)		SAS Date .N="Not Applicable"
01. Principal	pgem_receive_sig_dt_v6	Date Of Signature (Received Label)		SAS Date .N="Not Applicable"
01. Principal	pgem_receive_sig_v1	Investigator/Designee's Signature (Received Label)		.N="Not Applicable" 1="Yes"
01. Principal	pgem_receive_sig_v6	Investigator/Designee's Signature (Received Label)		.N="Not Applicable" 1="Yes"
01. Principal	pgem_ship_sig_dt_v1	Date Of Signature (Shipping Label)		SAS Date .N="Not Applicable"
01. Principal	pgem_ship_sig_dt_v6	Date Of Signature (Shipping Label)		SAS Date .N="Not Applicable"
01. Principal	pgem_ship_sig_v1	Investigator/Designee's Signature (Shipping Label)		.N="Not Applicable" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	pgem_ship_sig_v6	Investigator/Designee's Signature (Shipping Label)		.N="Not Applicable" 1="Yes"
01. Principal	pgem_spec_fridge_v1	Date Is Specimen Refrigerated?		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	pgem_spec_fridge_v6	Date Is Specimen Refrigerated?		.N="Not Applicable" 0="No"
01. Principal	pgem_spec_id_v1	Specimen ID		numeric .N="Not Applicable"
01. Principal	pgem_spec_id_v6	Specimen ID		numeric .N="Not Applicable"
01. Principal	pgem_spec_ship_v1	Will Specimen Be Shipped?		.N="Not Applicable" 1="Yes"
01. Principal	pgem_spec_ship_v6	Will Specimen Be Shipped?		.N="Not Applicable" 1="Yes"
01. Principal	pgem_spec_vol_v1	Specimen Volume (must Be >= 2 ml)		numeric .M="Missing" .N="Not Applicable"
01. Principal	pgem_spec_vol_v6	Specimen Volume (Must Be >= 2 ml)		numeric .N="Not Applicable"
01. Principal	pgem_storage_temp_v1	Storage Temperature (Celsius)		numeric .M="Missing" .N="Not Applicable"
01. Principal	pgem_storage_temp_v6	Storage Temperature (Celsius)		numeric .N="Not Applicable"

Section 28: Specimen Acquisition Research Blood - Naproxen Levels

Class	Variable	Label	Description	Format Text
01. Principal	naproxen_dt_spec_collect	Date Specimen Collected		SAS Date .N="Not Applicable"
01. Principal	naproxen_dt_spec_receive	Date Specimen Received		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	naproxen_dt_spec_ship	Date Specimen Shipped		SAS Date .N="Not Applicable"
01. Principal	naproxen_not_obtain	Specimen Not Obtained		.N="Not Applicable" 0="False"
01. Principal	naproxen_receive_sig	Investigator/Designee's Signature (Received Label)		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	naproxen_receive_sig_dt	Date Of Signature (Received Label)		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	naproxen_ship_sig	Investigator/Designee's Signature (Shipping Label)		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	naproxen_ship_sig_dt	Date Of Signature (Shipping Label)		SAS Date .N="Not Applicable"
01. Principal	naproxen_spec	Specimen Type		.N="Not Applicable" 1="PLASMA"
01. Principal	naproxen_spec_id	Specimen ID		numeric .N="Not Applicable"
01. Principal	naproxen_spec_ship	Will Specimen Be Shipped		.N="Not Applicable" 1="Yes"
01. Principal	naproxen_spec_vol	Specimen Volume (Must Be >= 2 ml)		numeric .N="Not Applicable"
01. Principal	naproxen_storage_temp	Storage Temperature (Celsius)		numeric .N="Not Applicable"

Section 29: Biopsy Tissue Histology

Class	Variable	Label	Description	Format Text
01. Principal	biopsyhist_comment_v1	Biopsy Tissue Histology Comments At Visit 1		char, 98 " "="Not Applicable"
01. Principal	biopsyhist_comment_v6	Biopsy Tissue Histology Comments At Visit 6		char, 98 " "="Not Applicable"
01. Principal+691:691665:696665:695665:665:673	biopsyhist_dt_collect_v1	Biopsy Tissue Histology Date Specimen Collected At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsyhist_dt_collect_v6	Biopsy Tissue Histology Date Specimen Collected At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsyhist_histology_v1	Biopsy Tissue Histology At Visit 1		.N="Not Applicable" 1="Adenoma" 2="Hyperplastic Polyp" 5="Other"
01. Principal	biopsyhist_histology_v6	Biopsy Tissue Histology At Visit 6		.M="Missing" .N="Not Applicable" 1="Adenoma" 4="Invasive adenocarcinoma"
01. Principal	biopsyhist_specify_v1	Biopsy Tissue Histology Specify At Visit 1		char, 50 " "="Not Applicable"
01. Principal	biopsyhist_specify_v6	Biopsy Tissue Histology Specify At Visit 6		char, 50 " "="Not Applicable"
01. Principal	biopsyhist_type_v1	Biopsy Tissue Histology Type At Visit 1		.N="Not Applicable" 1="Normal" 2="Abnormal (indicate Histology)"
01. Principal	biopsyhist_type_v6	Biopsy Tissue Histology Type At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 2="Abnormal (indicate Histology)"

Section 30: Specimen Acquisition Tissue - Biopsy For PGE2 Levels

Class	Variable	Label	Description	Format Text
01. Principal	biopsypge2_dt_spec_collect_v1_2-4	Date Specimen Collected At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsypge2_dt_spec_collect_v6_2-4	Date Specimen Collected At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsypge2_dt_spec_receive_v1	Date Specimen Received At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsypge2_dt_spec_receive_v6	Date Specimen Received At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsypge2_dt_spec_ship_v1	Date Specimen Shipped At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsypge2_dt_spec_ship_v6	Date Specimen Shipped At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsypge2_not_obtain_v1_2-4	Specimen Not Obtained At Visit 1		.N="Not Applicable" 0="False"
01. Principal	biopsypge2_not_obtain_v6_2-4	Specimen Not Obtained At Visit 6		.M="Missing" .N="Not Applicable" 0="False"
01. Principal	biopsypge2_receive_sig_dt_v1	Date Of Signature (Received Label) At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsypge2_receive_sig_dt_v6	Date Of Signature (Received Label) At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsypge2_receive_sig_v1	Investigator/Designee's Signature (Received Label) At Visit 1		.N="Not Applicable" 1="Yes"
01. Principal	biopsypge2_receive_sig_v6	Investigator/Designee's Signature (Received Label) At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsypge2_ship_sig_dt_v1	Date Of Signature (Shipping Label) At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsypge2_ship_sig_dt_v6	Date Of Signature (Shipping Label) At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsypge2_ship_sig_v1	Investigator/Designee's Signature (Shipping Label) At Visit 1		.M="Missing" .N="Not Applicable" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	biopsypge2_ship_sig_v6	Investigator/Designee's Signature (Shipping Label) At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsypge2_spec_frozen_v1_2-4	Specimen is Flash-frozen At Visit 1		.N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsypge2_spec_frozen_v6_2-4	Specimen is Flash-frozen At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsypge2_spec_id_v1	Specimen ID At Visit 1		numeric .N="Not Applicable"
01. Principal	biopsypge2_spec_id_v6	Specimen ID At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsypge2_spec_pbs_v1_2-4	Is Specimen rinsed in sterile PBS At Visit 1		.N="Not Applicable" 1="Yes"
01. Principal	biopsypge2_spec_pbs_v6_2-4	Is Specimen rinsed in sterile PBS At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsypge2_spec_ship_v1	Will Specimen Be Shipped At Visit 1		.N="Not Applicable" 1="Yes"
01. Principal	biopsypge2_spec_ship_v6	Will Specimen Be Shipped At Visit 6		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsypge2_storage_temp_v1_2-4	Storage Temperature (Celsius) At Visit 1		numeric .N="Not Applicable"
01. Principal	biopsypge2_storage_temp_v6_2-4	Storage Temperature (Celsius) At Visit 6		numeric .N="Not Applicable"

Section 31: Specimen Acquisition Tissue - Biopsy For Naproxen Levels

Class	Variable	Label	Description	Format Text
01. Principal	biopsynap_dt_spec_co_5-6	Date Specimen Collected		SAS Date .N="Not Applicable"
01. Principal	biopsynap_dt_spec_receive	Date Specimen Received		SAS Date .N="Not Applicable"
01. Principal	biopsynap_dt_spec_ship	Date Specimen Shipped		SAS Date .N="Not Applicable"
01. Principal	biopsynap_not_obtain_5-6	Specimen Not Obtained		.N="Not Applicable" 0="False"
01. Principal	biopsynap_receive_sig	Investigator/Designee's Signature (Received Label)		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsynap_receive_sig_dt	Date Of Signature (Received Label)		SAS Date .N="Not Applicable"
01. Principal	biopsynap_ship_sig	Investigator/Designee's Signature (Shipping Label)		.N="Not Applicable" 1="Yes"
01. Principal	biopsynap_ship_sig_dt	Date Of Signature (Shipping Label)		SAS Date .N="Not Applicable"
01. Principal	biopsynap_spec_frozen_5-6	Specimen is Flash-frozen		.N="Not Applicable" 1="Yes"
01. Principal	biopsynap_spec_id	Specimen ID		numeric .N="Not Applicable"
01. Principal	biopsynap_spec_pbs_5-6	Is Specimen rinsed in sterile PBS		.N="Not Applicable" 1="Yes"
01. Principal	biopsynap_spec_ship	Will Specimen Be Shipped		.N="Not Applicable" 1="Yes"
01. Principal	biopsynap_storage_temp_5-6	Storage Temperature (Celsius)		numeric .N="Not Applicable"

Section 32: Specimen Acquisition Tissue - Biopsy For Biorepository

Class	Variable	Label	Description	Format Text
01. Principal	biopsyrepb_dt_spec_collect_v1_13-15	Date Specimen Collected At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsyrepb_dt_spec_collect_v6_13-15	Date Specimen Collected At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsyrepb_dt_spec_receive_v1	Date Specimen Received At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsyrepb_dt_spec_receive_v6	Date Specimen Received At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsyrepb_dt_spec_ship_v1	Date Specimen Shipped At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsyrepb_dt_spec_ship_v6	Date Specimen Shipped At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsyrepb_not_obtain_v1_13-15	Specimen Not Obtained At Visit 1		.N="Not Applicable" 0="False"
01. Principal	biopsyrepb_not_obtain_v6_13-15	Specimen Not Obtained At Visit 6		.M="Missing" .N="Not Applicable" 0="False"
01. Principal	biopsyrepb_receive_sig_dt_v1	Date Of Signature (Received Label) At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsyrepb_receive_sig_dt_v6	Biopsy For Biorepository - Date Of Signature (Received Label) At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsyrepb_receive_sig_v1	Investigator/Designee's Signature (Received Label) At Visit 1		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsyrepb_receive_sig_v6	Investigator/Designee's Signature (Received Label) At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsyrepb_ship_sig_dt_v1	Date Of Signature (Shipping Label) At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsyrepb_ship_sig_dt_v6	Date Of Signature (Shipping Label) At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsyrepb_ship_sig_v1	Investigator/Designee's Signature (Shipping Label) At Visit 1		.M="Missing" .N="Not Applicable" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	biopsyrepb_ship_sig_v6	Investigator/Designee's Signature (Shipping Label) At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsyrepb_spec_frozen_v1_13-15	Specimen is Flash-frozen At Visit 1		.N="Not Applicable" 1="Yes"
01. Principal	biopsyrepb_spec_frozen_v6_13-15	Specimen is Flash-frozen At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsyrepb_spec_id_v1	Specimen ID At Visit 1		numeric .N="Not Applicable"
01. Principal	biopsyrepb_spec_id_v6	Specimen ID At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsyrepb_spec_pbs_v1_13-15	Is Specimen rinsed in sterile PBS At Visit 1		.N="Not Applicable" 1="Yes"
01. Principal	biopsyrepb_spec_pbs_v6_13-15	Is Specimen rinsed in sterile PBS At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsyrepb_spec_ship_v1	Will Specimen Be Shipped At Visit 1		.N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsyrepb_spec_ship_v6	Will Specimen Be Shipped At Visit 6		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsyrepb_storage_temp_v1_13-15	Storage Temperature (Celsius) At Visit 1		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsyrepb_storage_temp_v6_13-15	Storage Temperature (Celsius) At Visit 6		numeric .N="Not Applicable"
01. Principal	biopsyrepo_count	Count Of Biopsy For Biorepository		numeric .N="Not Applicable"
01. Principal	biopsyrepo_dt_spec_collect_5-6	Date Specimen Collected		SAS Date .N="Not Applicable"
01. Principal	biopsyrepo_dt_spec_receive	Date Specimen Received		SAS Date .N="Not Applicable"
01. Principal	biopsyrepo_dt_spec_ship	Date Specimen Shipped		SAS Date .N="Not Applicable"
01. Principal	biopsyrepo_not_obtain_5-6	Specimen Not Obtained		.N="Not Applicable" 0="False"
01. Principal	biopsyrepo_receive_sig	Investigator/Designee's Signature (Received Label)		.N="Not Applicable" 1="Yes"
01. Principal	biopsyrepo_receive_sig_dt	Date Of Signature (Received Label)		SAS Date .N="Not Applicable"
01. Principal	biopsyrepo_ship_sig	Investigator/Designee's Signature (Shipping Label)		.N="Not Applicable" 1="Yes"
01. Principal	biopsyrepo_ship_sig_dt	Date Of Signature (Shipping Label)		SAS Date .N="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	biopsyrepo_spec_frozen_5-6	Specimen is Flash-frozen		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsyrepo_spec_id	Specimen ID		numeric .N="Not Applicable"
01. Principal	biopsyrepo_spec_pbs_5-6	Is Specimen rinsed in sterile PBS		.N="Not Applicable" 1="Yes"
01. Principal	biopsyrepo_spec_ship	Will Specimen Be Shipped		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsyrepo_storage_temp_5-6	Storage Temperature (Celsius)		numeric .N="Not Applicable"

Section 33: Specimen Acquisition Tissue - Biopsy (mRNA For Genomics)

Class	Variable	Label	Description	Format Text
01. Principal	biopsymrna_dt_cryovial_v1_7-8	Date Specimen is placed in RNAlater in Cryovial At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsymrna_dt_cryovial_v6_7-8	Date Specimen is placed in RNAlater in Cryovial At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_dt_freezer_v1_7-8	Date Specimen is transferred To Freezer At Visit 1		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_dt_freezer_v6_7-8	Date Specimen is transferred To Freezer At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_dt_spec_col_v1_7-8	Date Specimen Collected At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsymrna_dt_spec_col_v6_7-8	Date Specimen Collected At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_dt_spec_receive_v1	Date Specimen Received At Visit 1		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_dt_spec_receive_v6	Date Specimen Received At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_dt_spec_ship_v1	Date Specimen Shipped At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsymrna_dt_spec_ship_v6	Date Specimen Shipped At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_freezer_temp_v1_7-8	Freezer Storage Temp. (Celsius) At Visit 1		char, 7 " "="Not Applicable"
01. Principal	biopsymrna_freezer_temp_v6_7-8	Freezer Storage Temp. (Celsius) At Visit 6		char, 7 " "="Not Applicable"
01. Principal	biopsymrna_has_tube_v1_7-8	Has Tube #1 At Visit 1		.N="Not Applicable" 0="False" 1="True"
01. Principal	biopsymrna_has_tube_v6_7-8	Has Tube #1 At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	biopsymrna_not_obtain_v1_7-8	Specimen Not Obtained At Visit 1		.N="Not Applicable" 0="False"

Class	Variable	Label	Description	Format Text
01. Principal	biopsymrna_not_obtain_v6_7-8	Specimen Not Obtained At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	biopsymrna_receive_sig_dt_v1	Date Of Signature (Received Label) At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsymrna_receive_sig_dt_v6	Date Of Signature (Received Label) At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_receive_sig_v1	Investigator/Designee's Signature (Received Label) At Visit 1		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymrna_receive_sig_v6	Investigator/Designee's Signature (Received Label) At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymrna_refrig_temp_v1_7-8	RNAlater Storage Refrigerator Temp. (Celsius) At Visit 1		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_refrig_temp_v6_7-8	RNAlater Storage Refrigerator Temp. (Celsius) At Visit 6		numeric .N="Not Applicable"
01. Principal	biopsymrna_shipping_sig_dt_v1	Date Of Signature (Shipping Label) At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsymrna_shipping_sig_dt_v6	Date Of Signature (Shipping Label) At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_shipping_sig_v1	Investigator/Designee's Signature (Shipping Label) At Visit 1		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymrna_shipping_sig_v6	Investigator/Designee's Signature (Shipping Label) At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymrna_spec_id_v1	Specimen ID At Visit 1		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_spec_id_v6	Specimen ID At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsymrna_spec_pbs_v1_7-8	Is Specimen rinsed in sterile PBS At Visit 1		.N="Not Applicable" 1="Yes"
01. Principal	biopsymrna_spec_pbs_v6_7-8	Is Specimen rinsed in sterile PBS At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymrna_spec_ship_v1	Will Specimen Be Shipped At Visit 1		.N="Not Applicable" 1="Yes"
01. Principal	biopsymrna_spec_ship_v6	Will Specimen Be Shipped At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"

Section 34: Specimen Acquisition Tissue - Biopsy For microRNA

Class	Variable	Label	Description	Format Text
01. Principal	biopsymirna_dt_collect_9-10	Date Specimen Collected		SAS Date .N="Not Applicable"
01. Principal	biopsymirna_dt_spec_receive	Date Specimen Received		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymirna_dt_spec_ship	Date Specimen Shipped		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymirna_not_obtain_9-10	Specimen Not Obtained		.N="Not Applicable" 0="False"
01. Principal	biopsymirna_receive_inv_sig	Investigator/Designee's Signature (Received Label)		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymirna_receive_sig_dt	Date Of Signature (Received Label)		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymirna_shipping_sig	Investigator/Designee's Signature (Shipping Label)		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymirna_shipping_sig_dt	Date Of Signature (Shipping Label)		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymirna_spec_frozen_9-10	Specimen is Flash-frozen		.N="Not Applicable" 1="Yes"
01. Principal	biopsymirna_spec_id	Specimen ID		numeric .N="Not Applicable"
01. Principal	biopsymirna_spec_pbs_9-10	Is Specimen rinsed in sterile PBS		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymirna_spec_ship	Will Specimen Be Shipped		.N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsymirna_storage_9-10	Storage Temperature (Celsius)		numeric .N="Not Applicable"

Section 35: Specimen Acquisition Tissue - Biopsy (DNA For Genomics)

Class	Variable	Label	Description	Format Text
01. Principal	biopsydna_dt_cryovial_v1_11	Date Specimen is placed in RNAlater in Cryovial At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsydna_dt_cryovial_v1_12	Date Specimen is placed in RNAlater in Cryovial At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsydna_dt_cryovial_v6_11	Date Specimen is placed in RNAlater in Cryovial At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_dt_cryovial_v6_12	Date Specimen is placed in RNAlater in Cryovial At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_dt_freezer_v1_11	Date Specimen is transferred To Freezer At Visit 1		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_dt_freezer_v1_12	Date Specimen is transferred To Freezer At Visit 1		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_dt_freezer_v6_11	Date Specimen is transferred To Freezer At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_dt_freezer_v6_12	Date Specimen is transferred To Freezer At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_dt_spec_col_v1_11	Date Specimen Collected At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsydna_dt_spec_col_v1_12	Date Specimen Collected At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsydna_dt_spec_col_v6_11	Date Specimen Collected At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_dt_spec_col_v6_12	Date Specimen Collected At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_dt_spec_receive_v1	Date Specimen Received At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsydna_dt_spec_receive_v6	Date Specimen Received At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_dt_spec_ship_v1	Date Specimen Shipped At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsydna_dt_spec_ship_v6	Date Specimen Shipped At Visit 6		SAS Date .M="Missing" .N="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	biopsydna_freezer_temp_v1_11	Freezer Storage Temp. (Celsius) At Visit 1		char, 7 " "="Not Applicable"
01. Principal	biopsydna_freezer_temp_v1_12	Freezer Storage Temp. (Celsius) At Visit 1		char, 7 " "="Not Applicable"
01. Principal	biopsydna_freezer_temp_v6_11	Freezer Storage Temp. (Celsius) At Visit 6		char, 7 " "="Not Applicable"
01. Principal	biopsydna_freezer_temp_v6_12	Freezer Storage Temp. (Celsius) At Visit 6		char, 7 " "="Not Applicable"
01. Principal	biopsydna_has_tube_v1_11	Has Tube #1 At Visit 1		.N="Not Applicable" 0="False" 1="True"
01. Principal	biopsydna_has_tube_v1_12	Has Tube #2 At Visit 1		.N="Not Applicable" 0="False" 1="True"
01. Principal	biopsydna_has_tube_v6_11	Has Tube #1 At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	biopsydna_has_tube_v6_12	Has Tube #2 At Visit 6		.M="Missing" .N="Not Applicable" 0="False" 1="True"
01. Principal	biopsydna_not_obtain_v1_11	Specimen Not Obtained At Visit 1		.N="Not Applicable" 0="No"
01. Principal	biopsydna_not_obtain_v1_12	Specimen Not Obtained At Visit 1		.N="Not Applicable" 0="No"
01. Principal	biopsydna_not_obtain_v6_11	Specimen Not Obtained At Visit 6		.M="Missing" .N="Not Applicable" 0="No"
01. Principal	biopsydna_not_obtain_v6_12	Specimen Not Obtained At Visit 6		.M="Missing" .N="Not Applicable" 0="No"
01. Principal	biopsydna_receive_sig_dt_v1	Date Of Signature (Received Label) At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsydna_receive_sig_dt_v6	Date Of Signature (Received Label) At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_receive_sig_v1	Investigator/Designee's Signature (Received Label) At Visit 1		.N="Not Applicable" 1="Yes"
01. Principal	biopsydna_receive_sig_v6	Investigator/Designee's Signature (Received Label) At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsydna_rnaler_temp_v1_11	RNAlater Storage Refrigerator Temp. (Celsius) At Visit 1		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_rnaler_temp_v1_12	RNAlater Storage Refrigerator Temp. (Celsius) At Visit 1		numeric .M="Missing" .N="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	biopsydna_rnalater_v6_11	RNAlater Storage Refrigerator Temp. (Celsius) At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_rnalater_v6_12	RNAlater Storage Refrigerator Temp. (Celsius) At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_ship_sig_dt_v1	Date Of Signature (Shipping Label) At Visit 1		SAS Date .N="Not Applicable"
01. Principal	biopsydna_ship_sig_dt_v6	Date Of Signature (Shipping Label) At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_ship_sig_v1	Investigator/Designee's Signature (Shipping Label) At Visit 1		.N="Not Applicable" 1="Yes"
01. Principal	biopsydna_ship_sig_v6	Investigator/Designee's Signature (Shipping Label) At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsydna_spec_id_v1	Specimen ID At Visit 1		numeric .N="Not Applicable"
01. Principal	biopsydna_spec_id_v6	Specimen ID At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsydna_spec_pbs_v1_11	Is Specimen rinsed in sterile PBS At Visit 1		.N="Not Applicable" 1="Yes"
01. Principal	biopsydna_spec_pbs_v1_12	Is Specimen rinsed in sterile PBS At Visit 1		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsydna_spec_pbs_v6_11	Is Specimen rinsed in sterile PBS At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsydna_spec_pbs_v6_12	Is Specimen rinsed in sterile PBS At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsydna_spec_ship_v1	Will Specimen Be Shipped At Visit 1		.N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsydna_spec_ship_v6	Will Specimen Be Shipped At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"

Section 36: Biopsy Tissue Histology - Mucosa/Polypoid Lesions

Class	Variable	Label	Description	Format Text
01. Principal	biopsymuc_abn_lesion_collect_v1	Was Abnormal Mucosal/Polypoid Lesion(s) Collected At Visit 1		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsymuc_abn_lesion_collect_v6	Was Abnormal Mucosal/Polypoid Lesion(s) Collected At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymuc_accession_v1	If Yes, Accession #(s) At Visit 1		char, 32 " "="Not Applicable"
01. Principal	biopsymuc_accession_v6	If Yes, Accession #(s) At Visit 6		char, 32 " "="Not Applicable"
01. Principal	biopsymuc_comment_v1	Comments At Visit 1		char, 146 " "="Not Applicable"
01. Principal	biopsymuc_comment_v6	Comments At Visit 6		char, 146 " "="Not Applicable"
01. Principal	biopsymuc_dt_collect_v1	Date Specimen (s) Collected At Visit 1		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_dt_collect_v6	Date Specimen (s) Collected At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_histology_type_v1	Histologic Type At Visit 1		.M="Missing" .N="Not Applicable" 1="Normal" 2="Abnormal (indicate Histology)"
01. Principal	biopsymuc_histology_type_v6	Histologic Type At Visit 6		.M="Missing" .N="Not Applicable" 1="Normal" 2="Abnormal (indicate Histology)"
01. Principal	biopsymuc_histology_v1	Histology At Visit 1		.M="Missing" .N="Not Applicable" 1="Adenoma" 2="Hyperplastic Polyp" 5="Other"
01. Principal	biopsymuc_histology_v6	Histology At Visit 6		.M="Missing" .N="Not Applicable" 1="Adenoma" 2="Hyperplastic Polyp" 4="Invasive adenocarcinoma"
01. Principal	biopsymuc_lesion_collect_v1	Was Mucosal/Polypoid Lesion(s) Visualized At Visit 1?		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	biopsymuc_lesion_collect_v6	Was Mucosal/Polypoid Lesion(s) Visualized At Visit 6?		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsymuc_num_lesions_v1	If Yes, Number Of Polypoids Lesions Visualized At Visit 1		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_num_lesions_v6	If Yes, Number Of Polypoids Lesions Visualized At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_receive_sig_dt_v1	Date Of Signature (Received Label) At Visit 1		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_receive_sig_dt_v6	Date Of Signature (Received Label) At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_receive_sig_v1	Investigator/Designee's Signature (Received Label) At Visit 1		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymuc_receive_sig_v6	Investigator/Designee's Signature (Received Label) At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymuc_residual_spec_v1	Was Residual Specimen Paraffin-Embedded At Visit 1		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsymuc_residual_spec_v6	Was Residual Specimen Paraffin-Embedded At Visit 6		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsymuc_shipping_sig_dt_v1	Date Of Signature (Shipping Label) At Visit 1		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_shipping_sig_dt_v6	Date Of Signature (Shipping Label) At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_shipping_sig_v1	Investigator/Designee's Signature (Shipping Label) At Visit 1		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsymuc_shipping_sig_v6	Investigator/Designee's Signature (Shipping Label) At Visit 6		.M="Missing" .N="Not Applicable" 1="Yes"
01. Principal	biopsymuc_spec_id_v1	Specimen ID At Visit 1		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_spec_id_v6	Specimen ID At Visit 6		numeric .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_spec_receive_dt_v1	Date Specimen Received At Visit 1		SAS Date .M="Missing" .N="Not Applicable"

Class	Variable	Label	Description	Format Text
01. Principal	biopsymuc_spec_receive_dt_v6	Date Specimen Received At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_spec_ship_dt_v1	Date Specimen Shipped At Visit 1		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_spec_ship_dt_v6	Date Specimen Shipped At Visit 6		SAS Date .M="Missing" .N="Not Applicable"
01. Principal	biopsymuc_spec_ship_v1	Will Specimen Be Shipped At Visit 1?		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsymuc_spec_ship_v6	Will Specimen Be Shipped At Visit 6?		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
01. Principal	biopsymuc_specify_v1	Specify At Visit 1		char, 63 " "="Not Applicable"
01. Principal	biopsymuc_specify_v6	Specify At Visit 6		char, 63 " "="Not Applicable"

Section 37: Verification

Class	Variable	Label	Description	Format Text
01. Principal	verification_form_dt	Form Date		SAS Date
01. Principal	verification_sig	Investigator's Signature		1="Yes"
01. Principal	verification_sig_dt	Date Of Investigator's Signature		SAS Date

Section 38: Accounting

Class	Variable	Label	Description	Format Text
01. Principal	inaeconmed	In AE and Conmed Evaluation Dataset		0="No" 1="Yes"
01. Principal	inagent	In Agent Interruption Dataset		0="No" 1="Yes"
01. Principal	inbasemed	In Baseline Medical/Surgical History Dataset		0="No" 1="Yes"
01. Principal	inbasemedother	In Baseline Medical/Surgical History (continued) Dataset		0="No" 1="Yes"
01. Principal	inbasesymptoms	In Baseline Symptoms Dataset		0="No" 1="Yes"
01. Principal	inbiopsydna	In Specimen Acquisition Tissue - Biopsy (DNA For Genomics) Dataset		0="No" 1="Yes"
01. Principal	inbiopsyhist	In Biopsy Tissue Histology Dataset		0="No" 1="Yes"
01. Principal	inbiopsymirna	In Specimen Acquisition Tissue - Biopsy For microRNA Dataset		0="No" 1="Yes"
01. Principal	inbiopsymrna	In Specimen Acquisition Tissue - Biopsy (mRNA For Genomics) Dataset		0="No" 1="Yes"
01. Principal	inbiopsymuc	In Biopsy Tissue Histology - Mucosa/Polypoid Lesions Dataset		0="No" 1="Yes"
01. Principal	inbiopsynap	In Specimen Acquisition Tissue - Biopsy For Naproxen Levels Dataset		0="No" 1="Yes"
01. Principal	inbiopsypge2	In Specimen Acquisition Tissue - Biopsy For PGE2 Levels Dataset		0="No" 1="Yes"
01. Principal	inbiopsyrepb	In Specimen Acquisition Tissue - Biopsy For Biorepository (Visit 1 and Visit 6) Dataset		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	inbiopsyrepo	In Specimen Acquisition Tissue - Biopsy For Biorepository (Visit 1) Dataset		0="No" 1="Yes"
01. Principal	inbloodchem	In Clinical Laboratory Data Blood Chemistry Dataset		0="No" 1="Yes"
01. Principal	inbloodchemgfr	In Clinical Laboratory Data Blood Chemistry (GFR) Dataset		0="No" 1="Yes"
01. Principal	incomp	In Compliance Dataset		0="No" 1="Yes"
01. Principal	incompdrug	In Compliance Drug Labels Dataset		0="No" 1="Yes"
01. Principal	incompphone	In Compliance Phone Interview Dataset		0="No" 1="Yes"
01. Principal	inconmed	In Concomitant Medications Dataset		0="No" 1="Yes"
01. Principal	indnaextract	In Specimen Acquisition Research Blood - DNA Extraction Dataset		0="No" 1="Yes"
01. Principal	ineligverif	In Eligibility Verification Dataset		1="Yes"
01. Principal	inexc4a1	In Exclusion Criteria (v4a1) Dataset		0="No" 1="Yes"
01. Principal	inexc5a2	In Exclusion Criteria (v5a2) Dataset		0="No" 1="Yes"
01. Principal	inhematology	In Clinical Laboratory Data Hematology Dataset		0="No" 1="Yes"
01. Principal	inhematologydiff	In Clinical Laboratory Data Hematology (Differential) Dataset		0="No" 1="Yes"
01. Principal	inincv4a1	In Inclusion Criteria (v4a1) Dataset		0="No" 1="Yes"
01. Principal	inincv5a2	In Inclusion Criteria (v5a2) Dataset		0="No" 1="Yes"
01. Principal	inintervention	In Intervention Administration (Blinded Study) Dataset		0="No" 1="Yes"
01. Principal	innaproxen	In Specimen Acquisition Research Blood - Naproxen Levels Dataset		0="No" 1="Yes"
01. Principal	inoffstudy	In Off Study Dataset		1="Yes"
01. Principal	inothelab	In Clinical Laboratory Data Other Lab Tests Dataset		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	inpgemv1	In Specimen Acquisition Research Urine - PGEM Levels (Visit 1) Dataset		0="No" 1="Yes"
01. Principal	inpgemv6	In Specimen Acquisition Research Urine - PGEM Levels (Visit 6) Dataset		0="No" 1="Yes"
01. Principal	inphysexam	In Physical Exam Dataset		0="No" 1="Yes"
01. Principal	inpregoutcome	In Outcome Of Pregnancy Dataset		0="No" 1="Yes"
01. Principal	inpregspec	In Pregnancy Specimen Data Dataset		0="No" 1="Yes"
01. Principal	inrand	In Randomization Dataset		1="Yes"
01. Principal	inrandadd	In Randomization (Add) Dataset		0="No" 1="Yes"
01. Principal	inregistration	In Registration Dataset		1="Yes"
01. Principal	inregistrationrace	In Registration (Race) Dataset		1="Yes"
01. Principal	intelephone	In Telephone Contact Dataset		0="No" 1="Yes"
01. Principal	inunblind	In Unblinding Form Dataset	This unblinding occurred during the study.	0="No" 1="Yes"
01. Principal	inunblinding	In Final Unblinding Dataset	This unblinding occurred after the study.	1="Yes"
01. Principal	inverification	In Verification Dataset		1="Yes"