

MDA-2013-01-01 PERSON FILE

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Document Summary

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Document Title	MDA-2013-01-01 Person File
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Section 1: Identifiers

Variable	Label	Description	Format Text
accession	Accession	Accession	Num
arm	Arm	Arm	1="Intervention" 2="Control" 3="Not Randomized"
mrno	Subject ID	Subject ID	Num

Section 2: Demographics

Variable	Label	Description	Format Text
country	Country	Country	1="USA" 2="ITA"
ethnicity	Ethnicity	Ethnicity	2="Not Hispanic or Latino"
gender	Gender	Gender	0="Male" 1="Female"
participant_elig	Is Participant Eligible For Inclusion In The Protocol?	Is Participant Eligible For Inclusion In The Protocol?	0="No" 1="Yes" 2="Null"
race	Race	Race	1="White"
randomization_date	Randomization Date	Randomization Date	SAS Date .M="Missing"
reg_age	Age At Registration	Age At Registration	Num
reg_institution	Registering Institution	Registering Institution	1="European Institue of Oncology" 2="M. D. Anderson Cancer Center"

Section 3: Registration

Variable	Label	Description	Format Text
reg_biobank	Participant Agreed To Keep Samples And Information In Biobank	Participant Agreed To Keep Samples And Information In Biobank	.M="Missing" 1="Yes"
reg_date	Registration Date	Registration Date	SAS Date
reg_enrl_dt	Enrollment Date	Enrollment Date	SAS Date .M="Missing"
reg_future_res	Participant Agreed To Be Contacted For Other Future Research	Participant Agreed To Be Contacted For Other Future Research	.M="Missing" 1="Yes"
reg_pay_method	Payment Method	Payment Method	1="Private insurance" 2="Other"
reg_screen_dt	Screen 1 Date	Screen 1 Date	SAS Date
reg_signed_icf_dt	Date Study Informed Consent Signed	Date Study Informed Consent Signed	SAS Date
reg_tac0_sign_pre_int	TAC-0 Signed Informed Consent Document Before Intervention	TAC-0 Signed Informed Consent Document Before Intervention	1="Yes"
reg_visit_dt	Visit Date	Visit Date	SAS Date .M="Missing"

Section 4: Eligibility Verification

Variable	Label	Description	Format Text
elig_comments	Eligibility - Comments	Eligibility - Comments	Char
elig_mdacc_pid	MDACC Patient Identifier	MDACC Patient Identifier	Char
elig_meet_rand_crit	Meets Randomization Comment	Meets Randomization Comment	0="No" 1="Yes"
elig_ver_stat	Verification Status	Verification Status	0="Ineligible" 1="Confirmed"
elig_verified_dt	Verified On Date	Verified On Date	SAS Date

Section 5: Inclusion Criteria

Variable	Label	Description	Format Text
incl_age_50	Age? 50 Years	Age? 50 Years	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
incl_contraception	Women Agree To Use Contraception	Women Of Child-Bearing Potential (From First Menstruation To 1 Year After Last Menstruation) Must Agree To Use Adequate Contraception (Hormonal Or Barrier Method Of Birth Control; Abstinence) Prior To Study Entry And For The Duration Of Study Participation.	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
incl_curr_smoker	Asymptomatic Current Smoker	Asymptomatic Current Smoker	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
incl_form_version	Inclusion Form Version	Inclusion Form Version	.N="Not Applicable" 1="Inclusion Criteria Pre V8" 2="Inclusion Criteria V12" 3="Inclusion Criteria V13" 4="Inclusion Criteria V8"
incl_former_smoker	Asymptomatic Former Smoker	Asymptomatic Former Smoker (Having Stopped Within The Last 20 Years)	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
incl_normal_organ	Normal Organ And Marrow Function	Participants Must Have Normal Organ And Marrow Function As Defined Below: Leukocytes 3,000/Microliter, Absolute Neutrophil Count 1,500/Microliter, Platelets 100,000/Microliter, Total Bilirubin Within Normal Institutional Limits, Ast(Sgot)/Alt(Sgpt) 1.5 X Institutional Uln, And Creatinine Within Normal Institutional Limits	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
incl_persistent_nodule	All Nodules Should Be Persistent	All Nodules Should Be Persistent At Least After Three Months Follow Up With Id-CT	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"

Variable	Label	Description	Format Text
incl_signed_icf	Signed Informed Consent	Signed Informed Consent	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
incl_smoke_hist	SmOking History? 20 Pack/Years	Smoking History? 20 Pack/Years; Subjects Must Be Included In An Ongoing Annual Screening With Low Dose CT Scan (COSMOS 1 Or COSMOS 2)	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
incl_subsolid_4_to_10	Subsolid Nodules With Size 4-10 mm	Subjects Must Have Subsolid (Non-Solid Or Partially Solid) Nodules With Size Between 4 And 10 Mm With Any Volume Doubling Time (Vdt), Not Candidate For Surgical Excision.	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
incl_subsolid_above_10	Subsolid Nodule >10 mm, Volume Doubling Time > 400 Days	Subject Must Have Subsolid (Non-Solid Or Partially Solid) Nodule Larger Than 10 Mm With Volume Doubling Time (Vdt) Higher Than 400 Days, And Not Candidate To Surgical Excision	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
incl_understand_icf	Understand And The Willing To Sign A Informed Consent Document	Ability To Understand And The Willingness To Sign A Written Informed Consent Document.	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
incl_visit_dt	Visit Date	Visit Date	SAS Date .N="Not Applicable"
inclu_ecog_stat	ECOG Performance Status? (Karnofsky >70%)	ECOG Performance Status? 1 (Karnofsky >70%)	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
inclu_smoker_support	Current Smokers Accept Support For Quitting	All Current Smokers Should Accept To Receive Support For Smoking Cessation	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"

Section 6: Exclusion Criteria

Variable	Label	Description	Format Text
excl_absorb	Patients With Inability To Absorb Oral Medication	Patients With Known Inability To Adequately Absorb Oral Medication.	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
excl_bleed_diath	Patients With Bleeding Or Other Conditions	Patients With Bleeding Diathesis, History Of Gastric/Duodenal Ulcers, Nsaid-Precipitated Bronchospasm, Patients Unwilling Or Unable To Limit Alcohol Consumption To I.E. ? 2 Alcohol Drinks A Day.	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
excl_chronic_nsaids	Chronic Treatment With Aspirin Or Other NSAIDS	Subjects With Chronic Treatment (At Least Twice/Week For More Than 3 Months) With Aspirin Or Other Nsaids	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
excl_form_version	Exclusion Form Version	Exclusion Form Version	.N="Not Applicable" 1="Exclusion criteria pre v12" 2="Exclusion criteria v12"
excl_higher_risk	Participants Who Will Be At Higher Risk Of ASA-Related Complications	Participants Who In The Opinion Of The Pi Will Be At Higher Risk Of Asa-Related Complications.	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
excl_hist_allergic	History Of Allergic Reactions Similar To Aspirin	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Aspirin, Nsaids, Cox-2 Inhibitors.	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
excl_hist_anticoag	History Of Therapeutic Doses Of Anticoagulants	History Of Therapeutic Doses Of Anticoagulants Including Warfarin And Low Molecular Weight Heparin (E.G. Prior To Deep Venous Thrombosis And Pulmonary Embolisms In The Preceding Year)	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
excl_invasive_malign	Invasive Malignancy Diagnosed During The Last 2 Years	Invasive Malignancy (With The Exclusion Of Basal Cell Carcinoma Or Skin Squamous Cell Carcinoma) Diagnosed During The Last 2 Years Before Randomization.	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"

Variable	Label	Description	Format Text
excl_other_agent	Individual May Not Be Receiving Any Other Investigational Agents	Individual May Not Be Receiving Any Other Investigational Agents, Antiplatelet Agents (E.G. Aspirin, Clopidogrel (Plavix Or Others)), Anticoagulants (E.G. Heparin Or Heparinoids, Coumadin, Or Others), Metotrexate, Lithium.	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
excl_pregnant	Pregnant	Pregnant Women Are Excluded From This Study Because Aspirin Is An Agent With The Potential For Teratogenic Or Abortifacient Effects. Because There Is An Unknown But Potential Risk For Adverse Events In Nursing Infants Secondary To Treatment Of The Mother With Aspirin, Breastfeeding Should Be Discontinued If The Mother Is Treated With Aspirin.	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
excl_uncontr_ill	Uncontrolled Intercurrent Illness Including	Uncontrolled Intercurrent Illness Including, But Not Limited To, Ongoing Or Active Infection, Symptomatic Congestive Heart Failure, Unstable Angina Pectoris, Cardiac Arrhythmia, Or Psychiatric Illness/Social Situations That Would Limit Compliance With Study Requirements.	.N="Not Applicable" 0="No" 1="Yes" 2="N/A" 3="NULL"
excl_visit_dt	Visit Date	Visit Date	SAS Date .N="Not Applicable"

Section 7: Baseline Medical and Surgical History

Variable	Label	Description	Format Text
basemed_allergies	Does The Participant Have Any Allergies?	Does The Participant Have Any Allergies?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
basemed_allergies_spec	If Yes, (Allergies) Specify	If Yes, (Allergies) Specify	Char
basemed_breast_comment	Base Medical/Surgical History Breasts: Comments	Base Medical/Surgical History Breasts: Comments	Char
basemed_breast_stat	Base Medical/Surgical History Breasts: Status	Base Medical/Surgical History Breasts: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_cardio_comment	Base Medical/Surgical History Cardiovascular: Comments	Base Medical/Surgical History Cardiovascular: Comments	Char
basemed_cardio_stat	Base Medical/Surgical History Cardiovascular: Status	Base Medical/Surgical History Cardiovascular: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_check_all_normal	All Body Systems Are Normal	All Body Systems Are Normal	.N="Not Applicable" 0="False" 1="True"
basemed_derma_comment	Base Medical/Surgical History Dermatologic: Comments	Base Medical/Surgical History Dermatologic: Comments	Char
basemed_derma_stat	Base Medical/Surgical History Dermatologic: Status	Base Medical/Surgical History Dermatologic: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_endo_comment	Base Medical/Surgical History Endocrine/Metabolic: Comments	Base Medical/Surgical History Endocrine/Metabolic: Comments	Char
basemed_endo_stat	Base Medical/Surgical History Endocrine/Metabolic: Status	Base Medical/Surgical History Endocrine/Metabolic: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_gastro_comment	Base Medical/Surgical History Gastrointestinal: Comments	Base Medical/Surgical History Gastrointestinal: Comments	Char

Variable	Label	Description	Format Text
basemed_gastro_stat	Base Medical/Surgical History Gastrointestinal: Status	Base Medical/Surgical History Gastrointestinal: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_genit_comment	Base Medical/Surgical History Genitourinary: Comments	Base Medical/Surgical History Genitourinary: Comments	Char
basemed_genit_stat	Base Medical/Surgical History Genitourinary: Status	Base Medical/Surgical History Genitourinary: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_heent_comment	Base Medical/Surgical History H/E/E/N/T: Comments	Base Medical/Surgical History H/E/E/N/T: Comments	Char
basemed_heent_stat	Base Medical/Surgical History H/E/E/N/T: Status	Base Medical/Surgical History H/E/E/N/T: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_hema_comment	Base Medical/Surgical History Hematopoietic/Lymph: Comments	Base Medical/Surgical History Hematopoietic/Lymph: Comments	Char
basemed_hema_stat	Base Medical/Surgical History Hematopoietic/Lymph: Status	Base Medical/Surgical History Hematopoietic/Lymph: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_musculo_comment	Base Medical/Surgical History Musculoskeletal: Comments	Base Medical/Surgical History Musculoskeletal: Comments	Char
basemed_musculo_stat	Base Medical/Surgical History Musculoskeletal: Status	Base Medical/Surgical History Musculoskeletal: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_neck_comment	Base Medical/Surgical History Neck: Comments	Base Medical/Surgical History Neck: Comments	Char
basemed_neck_stat	Base Medical/Surgical History Neck: Status	Base Medical/Surgical History Neck: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_neuro_comment	Base Medical/Surgical History Neurological: Comments	Base Medical/Surgical History Neurological: Comments	Char
basemed_neuro_stat	Base Medical/Surgical History Neurological: Status	Base Medical/Surgical History Neurological: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"

Variable	Label	Description	Format Text
basemed_other_body_status	Other Body System/Site Status	Other Body System/Site Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_other_body_sys	Specify Other Body System/Site	Specify Other Body System/Site	Char .M="Missing" .N="Not Applicable"
basemed_other_comments	Other Body System/Site Comments	Other Body System/Site Comments	Char
basemed_resp_comment	Base Medical/Surgical History Respiratory: Comments	Base Medical/Surgical History Respiratory: Comments	Char
basemed_resp_stat	Base Medical/Surgical History Respiratory: Status	Base Medical/Surgical History Respiratory: Status	.M="Missing" .N="Not Applicable" 1="Abnormal" 2="Normal" 3="Not assessed"
basemed_visit_date	Base Medical And Surgical History Visit Date	Base Medical And Surgical History Visit Date	SAS Date .M="Missing" .N="Not Applicable"

Section 8: Baseline Symptoms

Variable	Label	Description	Format Text
basesym_comments1-4	Baseline Symptom Comments	Baseline Symptom Comments	Char
basesym_grade1-4	Baseline Symptom Grade	Baseline Symptom Grade	.N="Not Applicable" 1="1 (Mild)" 2="2 (Moderate)" 3="3 (Severe)"
basesym_no_reported_sym	None Reported No Baseline Symptoms	None Reported No Baseline Symptoms	.N="Not Applicable" 0="False" 1="True"
basesym_onset_date1-4	Baseline Symptom Onset Date	Baseline Symptom Onset Date	SAS Date .M="Missing" .N="Not Applicable"
basesym_symptom_desc1-4	Baseline Symptom Symptom Description	Baseline Symptom Symptom Description	Char
basesym_visit_date	Baseline Symptoms Visit Date	Baseline Symptoms Visit Date	SAS Date .N="Not Applicable"

Section 9: Physical Exam

Variable	Label	Description	Format Text
phys_ab_comments1-3	Abdomen: Comments	Abdomen: Comments	Char
phys_ab_stat1-3	Abdomen: Status	Abdomen: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_appear_comments1-3	Appearance: Comments	Appearance: Comments	Char
phys_appear_stat1-3	Appearance: Status	Appearance: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_bmi1-3	BMI	BMI	Num .N="Not Applicable"
phys_breast_comments1-3	Breasts: Comments	Breasts: Comments	Char
phys_breast_stat1-3	Breasts: Status	Breasts: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_chest_comments1-3	Chest: Comments	Chest: Comments	Char
phys_chest_stat1-3	Chest: Status	Chest: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_diastolic_bp1-3	Diastolic BP (mmhg)	Diastolic BP (mmhg)	Num .N="Not Applicable"
phys_ecog_stat1-3	Ecog Performance Status	Ecog Performance Status	Num .N="Not Applicable"
phys_exam_dt1-3	Physical Exam Date	Physical Exam Date	SAS Date .N="Not Applicable"
phys_genital_comments1-3	Genitalia: Comments	Genitalia: Comments	Char
phys_genital_stat1-3	Genitalia: Status	Genitalia: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_heart_comments1-3	Heart: Comments	Heart: Comments	Char
phys_heart_stat1-3	Heart: Status	Heart: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"

Variable	Label	Description	Format Text
phys_heent_comments1-3	H/E/E/N/T: Comments	H/E/E/N/T: Comments	Char
phys_heent_stat1-3	H/E/E/N/T: Status	H/E/E/N/T: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_height1-3	Height (cm)	Height (cm)	Num .N="Not Applicable"
phys_lung_comments1-3	Lungs: Comments	Lungs: Comments	Char
phys_lung_stat1-3	Lungs: Status	Lungs: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_lymph_comments1-3	Lymph Nodes: Comments	Lymph Nodes: Comments	Char
phys_lymph_stat1-3	Lymph Nodes: Status	Lymph Nodes: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_musculo_comments1-3	Musculoskeletal: Comments	Musculoskeletal: Comments	Char
phys_musculo_stat1-3	Musculoskeletal: Status	Musculoskeletal: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_neuro_comments1-3	Neurological: Comments	Neurological: Comments	Char
phys_neuro_stat1-3	Neurological: Status	Neurological: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_no_exam1-3	No Body Systems Were Examined	No Body Systems Were Examined	.N="Not Applicable" 0="False" 1="True"
phys_other_body_sys1-3	Other Body System	Other Body System	.N="Not Applicable" 1="Psychiatric" 2="Mouth"
phys_other_sys_comment1-3	Other Body System Comment	Other Body System Comment	Char
phys_other_sys_stat1-3	Other Body System Status	Other Body System Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_pelvis_comments1-3	Pelvis: Comments	Pelvis: Comments	Char
phys_pelvis_stat1-3	Pelvis: Status	Pelvis: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"

Variable	Label	Description	Format Text
phys_pulse1-3	Pulse	Pulse	Num .N="Not Applicable"
phys_rectal_comments1-3	Rectal: Comments	Rectal: Comments	Char
phys_rectal_stat1-3	Rectal: Status	Rectal: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_resp_rate1-3	Respiration Rate	Respiration Rate	Num .N="Not Applicable"
phys_skin_comments1-3	Skin: Comments	Skin: Comments	Char
phys_skin_stat1-3	Skin: Status	Skin: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_systolic_bp1-3	Systolic BP (mmhg)	Systolic BP (mmhg)	Num .N="Not Applicable"
phys_temp1-3	Temperature (C)	Temperature (C)	Num .N="Not Applicable"
phys_thyroid_comments1-3	Thyroid: Comments	Thyroid: Comments	Char
phys_thyroid_stat1-3	Thyroid: Status	Thyroid: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_vascular_comments1-3	Vascular: Comments	Vascular: Comments	Char
phys_vascular_stat1-3	Vascular: Status	Vascular: Status	.N="Not Applicable" 1="Normal" 2="Abnormal" 3="Not examined"
phys_visit_dt1-3	Visit Date	Visit Date	SAS Date .N="Not Applicable"
phys_weight1-3	Weight (kg)	Weight (kg)	Num .N="Not Applicable"

Section 10: Pregnancy Test

Variable	Label	Description	Format Text
preg_no_test_rsn1-4	Reason Pregnancy Data Was Not Collected	Reason Pregnancy Data Was Not Collected	.M="Missing" .N="Not Applicable" 1="Participant is female and not of childbearing potential" 2="Participant is male"
preg_result1-4	Pregnancy Test Results	Pregnancy Test Results	.M="Missing" .N="Not applicable"
preg_visit_dt1-4	Visit Date	Visit Date	SAS Date .N="Not Applicable"

Section 11: Randomization

Variable	Label	Description	Format Text
rand_base_ct_date	Date Of Baseline CT	Date Of Baseline CT	SAS Date .M="Missing"
rand_date	Randomization Date	Randomization Date	SAS Date .N="Not Applicable"
rand_followup_ct	Had Followup CT	Had Followup CT	0="False" 1="True"
rand_followup_ct_d t	Date Of Followup CT	Date Of Followup CT	SAS Date .M="Missing"
rand_meet_elig	Does The Participant Meet All Eligibility Criteria For Randomization	Does The Participant Meet All Eligibility Criteria For Randomization	0="No" 1="Yes"
rand_no	Randomization Number	Randomization Number	Num
rand_nodule_char	Nodule Characteristics	Nodule Characteristics	.M="Missing" 1="Partially solid" 2="Non solid"
rand_reg_date	Registration Date	Registration Date	SAS Date
rand_screen_prog	Screening Program	Screening Program	.M="Missing" 1="COSMOS 1" 2="COSMOS 2" 3="Screening CT"
rand_smoke_stat	Smoking Status	Smoking Status	.M="Missing" 1="Current smoker" 2="Former smoker"
rand_visit_dt	Visit Date	Visit Date	SAS Date

Section 13: Hematology 1

Variable	Label	Description	Format Text
hema_anc_clin_sig1-4	Hematology Absolute Neutrophil Count (ANC) Clinically Significant	Hematology Absolute Neutrophil Count (ANC) Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
hema_anc_comments1-4	Hematology Absolute Neutrophil Count (ANC) Comments	Hematology Absolute Neutrophil Count (ANC) Comments	Char
hema_anc_lab_test1-4	Hematology Absolute Neutrophil Count (ANC) Lab Test Number	Hematology Absolute Neutrophil Count (ANC) Lab Test Number	Num .N="Not Applicable"
hema_anc_obtain1-4	Hematology Absolute Neutrophil Count (ANC) Not Obtained?	Hematology Absolute Neutrophil Count (ANC) Not Obtained?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_anc_oor1-4	Hematology Absolute Neutrophil Count (ANC) Out Of Range	Hematology Absolute Neutrophil Count (ANC) Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_anc_result1-4	Hematology Absolute Neutrophil Count (ANC) Results (kg/uL)	Hematology Absolute Neutrophil Count (ANC) Results (kg/uL)	Num .M="Missing" .N="Not Applicable"
hema_collect_dt1-4	Hematology Date Specimen Collected	Hematology Date Specimen Collected	SAS Date .N="Not Applicable"
hema_fasting1-4	Hematology Fasting?	Hematology Fasting?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_hematocrit_clin_sig1-4	Hematology Hematocrit Clinically Significant	Hematology Hematocrit Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
hema_hematocrit_comments1-4	Hematology Hematocrit Comments	Hematology Hematocrit Comments	Char
hema_hematocrit_lab_test1-4	Hematology Hematocrit Lab Test Number	Hematology Hematocrit Lab Test Number	Num .N="Not Applicable"
hema_hematocrit_obtain1-4	Hematology Hematocrit Not Obtained?	Hematology Hematocrit Not Obtained?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_hematocrit_oor1-4	Hematology Hematocrit Out Of Range	Hematology Hematocrit Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_hematocrit_result1-4	Hematology Hematocrit Results (%)	Hematology Hematocrit Results (%)	Num .N="Not Applicable"

Variable	Label	Description	Format Text
hema_hemoglobin_clin_sig1-4	Hematology Hemoglobin Clinically Significant	Hematology Hemoglobin Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
hema_hemoglobin_comments1-4	Hematology Hemoglobin Comments	Hematology Hemoglobin Comments	Char
hema_hemoglobin_lab_test1-4	Hematology Hemoglobin Lab Test Number	Hematology Hemoglobin Lab Test Number	Num .N="Not Applicable"
hema_hemoglobin_obtain1-4	Hematology Hemoglobin Not Obtained?	Hematology Hemoglobin Not Obtained?	.N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_hemoglobin_oor1-4	Hematology Hemoglobin Out Of Range	Hematology Hemoglobin Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_hemoglobin_result1-4	Hematology Hemoglobin Results (kg/uL)	Hematology Hemoglobin Results (kg/uL)	Num .N="Not Applicable"
hema_platelet_clin_sig1-4	Hematology Platelets Clinically Significant	Hematology Platelets Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
hema_platelet_comments1-4	Hematology Platelets Comments	Hematology Platelets Comments	Char
hema_platelet_lab_test1-4	Hematology Platelets Lab Test Number	Hematology Platelets Lab Test Number	Num .N="Not Applicable"
hema_platelet_obtain1-4	Hematology Platelets Not Obtained?	Hematology Platelets Not Obtained?	.N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_platelet_oor1-4	Hematology Platelets Out Of Range	Hematology Platelets Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_platelet_result1-4	Hematology Platelets Results (kg/uL)	Hematology Platelets Results (kg/uL)	Num .N="Not Applicable"
hema_rbc_clin_sig1-4	Hematology RBC Clinically Significant	Hematology RBC Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
hema_rbc_comments1-4	Hematology RBC Comments	Hematology RBC Comments	Char
hema_rbc_lab_test1-4	Hematology RBC Lab Test Number	Hematology RBC Lab Test Number	Num .N="Not Applicable"
hema_rbc_obtain1-4	Hematology RBC Not Obtained?	Hematology RBC Not Obtained?	.N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_rbc_oor1-4	Hematology RBC Out Of Range	Hematology RBC Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_rbc_result1-4	Hematology RBC Results (kg/uL)	Hematology RBC Results (kg/uL)	Num .N="Not Applicable"

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Variable	Label	Description	Format Text
hema_visit_dt1-4	Hematology Visit Date	Hematology Visit Date	SAS Date .N="Not Applicable"
hema_wbc_clin_sig1-4	Hematology WBC Clinically Significant	Hematology WBC Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
hema_wbc_comments1-4	Hematology WBC Comments	Hematology WBC Comments	Char
hema_wbc_lab_test1-4	Hematology WBC Lab Test Number	Hematology WBC Lab Test Number	Num .N="Not Applicable"
hema_wbc_obtain1-4	Hematology WBC Not Obtained?	Hematology WBC Not Obtained?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_wbc_oor1-4	Hematology WBC Out Of Range	Hematology WBC Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_wbc_result1-4	Hematology WBC Results (kg/uL)	Hematology WBC Results (kg/uL)	Num .N="Not Applicable"

Section 14: Hematology 2

Variable	Label	Description	Format Text
hema_bands_clin_sig1-4	Hematology Bands Clinically Significant	Hematology Bands Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_bands_comments1-4	Hematology Bands Comments	Hematology Bands Comments	Char
hema_bands_lab_test1-4	Hematology Bands Lab Test Number	Hematology Bands Lab Test Number	Num .N="Not Applicable"
hema_bands_obtain1-4	Hematology Bands Not Obtained?	Hematology Bands Not Obtained?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_bands_oor1-4	Hematology Bands Out Of Range	Hematology Bands Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_bands_result1-4	Hematology Bands (%) Results	Hematology Bands (%) Results	Num .M="Missing" .N="Not Applicable"
hema_baso_clin_sig1-4	Hematology Basophils Clinically Significant	Hematology Basophils Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_baso_comments1-4	Hematology Basophils Comments	Hematology Basophils Comments	Char
hema_baso_lab_test1-4	Hematology Basophils Lab Test Number	Hematology Basophils Lab Test Number	Num .N="Not Applicable"
hema_baso_obtain1-4	Hematology Basophils Not Obtained?	Hematology Basophils Not Obtained?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_baso_oor1-4	Hematology Basophils Out Of Range	Hematology Basophils Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_baso_result1-4	Hematology Basophils (%) Results	Hematology Basophils (%) Results	Num .N="Not Applicable"
hema_eosino_clin_sig1-4	Hematology Eosinophils Clinically Significant	Hematology Eosinophils Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_eosino_comments1-4	Hematology Eosinophils Comments	Hematology Eosinophils Comments	Char

Variable	Label	Description	Format Text
hema_eosino_lab_test1-4	Hematology Eosinophils Lab Test Number	Hematology Eosinophils Lab Test Number	Num .N="Not Applicable"
hema_eosino_obtain1-4	Hematology Eosinophils Not Obtained?	Hematology Eosinophils Not Obtained?	.N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_eosino_oor1-4	Hematology Eosinophils Out Of Range	Hematology Eosinophils Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_eosino_result1-4	Hematology Eosinophils (%) Results	Hematology Eosinophils (%) Results	Num .N="Not Applicable"
hema_lympho_clin_sig1-4	Hematology Lymphocytes Clinically Significant	Hematology Lymphocytes Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_lympho_comments1-4	Hematology Lymphocytes Comments	Hematology Lymphocytes Comments	Char
hema_lympho_lab_test1-4	Hematology Lymphocytes Lab Test Number	Hematology Lymphocytes Lab Test Number	Num .N="Not Applicable"
hema_lympho_obtain1-4	Hematology Lymphocytes Not Obtained?	Hematology Lymphocytes Not Obtained?	.N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_lympho_oor1-4	Hematology Lymphocytes Out Of Range	Hematology Lymphocytes Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_lympho_result1-4	Hematology Lymphocytes (%) Results	Hematology Lymphocytes (%) Results	Num .N="Not Applicable"
hema_monocyte_clin_sig1-4	Hematology Monocytes Clinically Significant	Hematology Monocytes Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_monocyte_comments1-4	Hematology Monocytes Comments	Hematology Monocytes Comments	Char
hema_monocyte_lab_test1-4	Hematology Monocytes Lab Test Number	Hematology Monocytes Lab Test Number	Num .N="Not Applicable"
hema_monocyte_obtain1-4	Hematology Monocytes Not Obtained?	Hematology Monocytes Not Obtained?	.N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_monocyte_oor1-4	Hematology Monocytes Out Of Range	Hematology Monocytes Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_monocyte_result1-4	Hematology Monocytes (%) Results	Hematology Monocytes (%) Results	Num .N="Not Applicable"

Variable	Label	Description	Format Text
hema_neutro_clin_sig1-4	Hematology Neutrophils Clinically Significant	Hematology Neutrophils Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_neutro_comments1-4	Hematology Neutrophils Comments	Hematology Neutrophils Comments	Char
hema_neutro_lab_test1-4	Hematology Neutrophils Lab Test Number	Hematology Neutrophils Lab Test Number	Num .N="Not Applicable"
hema_neutro_obtain1-4	Hematology Neutrophils Not Obtained?	Hematology Neutrophils Not Obtained?	.N="Not Applicable" 0="No" 1="Yes" 9="Unkown"
hema_neutro_oor1-4	Hematology Neutrophils Out Of Range	Hematology Neutrophils Out Of Range	.N="Not Applicable" 0="False" 1="True"
hema_neutro_result1-4	Hematology Neutrophils (%) Results	Hematology Neutrophils (%) Results	Num .N="Not Applicable"

Section 15: Concomitant Medications

Variable	Label	Description	Format Text
conmed_continuing 1-29	Medication Still Continuing?	Medication Still Continuing?	.N="Not Applicable" 0="False" 1="True"
conmed_dose1-29	Medication Dose	Medication Dose	Char
conmed_freq1-29	Medication Frequency	Medication Frequency	Char
conmed_medication 1-29	Medication Name	Medication Name	Char
conmed_other_freq 1-29	Medication Other Frequencies	Medication Other Frequencies	Char
conmed_other_unit s1-29	Medication Other Units	Medication Other Units	Char
conmed_reason1-29	Medication Reason	Medication Reason	Char
conmed_rep_dt1-29	Date Medication Reported	Date Medication Reported	SAS Date .N="Not Applicable"
conmed_start_dt1-2 9	Medication Start Date	Medication Start Date	SAS Date .M="Missing" .N="Not Applicable"
conmed_stop_dt1-2 9	Medication Stop Date	Medication Stop Date	SAS Date .N="Not Applicable"
conmed_units1-29	Medication Dose Units	Medication Dose Units	Char

Section 16: CT Scan New Lesions

Variable	Label	Description	Format Text
ct_new_infinite1-4	CT Scan New Lesions - Infinite	CT Scan New Lesions - Infinite	.N="Not Applicable" 0="False" 1="True"
ct_new_location1-4	CT Scan New Lesions - Location	CT Scan New Lesions - Location	.N="Not Applicable" 1="Lower left" 2="Lower right" 3="Upper left" 4="Upper right"
ct_new_max_diam1-4	CT Scan New Lesions - Maximum diameter (mm)	CT Scan New Lesions - Maximum diameter (mm)	Num .N="Not Applicable"
ct_new_max_hu_dens1-4	CT Scan New Lesions - Maximum density (HU)	CT Scan New Lesions - Maximum density (HU)	Num .N="Not Applicable"
ct_new_mean_hu_dens1-4	CT Scan New Lesions - Mean density (HU)	CT Scan New Lesions - Mean density (HU)	Num .N="Not Applicable"
ct_new_min_hu_dens1-4	CT Scan New Lesions - Minimum density (HU)	CT Scan New Lesions - Minimum density (HU)	Num .N="Not Applicable"
ct_new_new_lesion1-4	Is any new lesions present?	Is any new lesions present?	.N="Not Applicable" 0="No" 1="Yes"
ct_new_nodule_num1-4	CT Scan New Lesions - Nodule number	CT Scan New Lesions - Nodule number	Num .N="Not Applicable"
ct_new_num_lesion1-4	If yes, number of new lesions	If yes, number of new lesions	Num .M="Missing" .N="Not Applicable"
ct_new_scan1-4	CT Scan New Lesions - Scan	CT Scan New Lesions - Scan	Num .N="Not Applicable"
ct_new_scan_type1-4	CT scan type	CT scan type	.N="Not Applicable" 1="Non-screening CT" 2="Screening CT"
ct_new_sum_diam1-4	Sum maximum diameters (mm)	Sum maximum diameters (mm)	Num .N="Not Applicable"
ct_new_type1-4	CT Scan New Lesions - Type	CT Scan New Lesions - Type	.N="Not Applicable" 1="Non-solid" 2="Partially solid" 3="Solid"
ct_new_undetectable1-4	CT Scan New Lesions - Undetectable	CT Scan New Lesions - Undetectable	.N="Not Applicable" 0="False"
ct_new_visit_dt1-4	Visit date	Visit date	SAS Date .N="Not Applicable"
ct_new_volume1-4	CT Scan New Lesions - Volume (mm^3)	CT Scan New Lesions - Volume (mm^3)	Num .N="Not Applicable"
num_ct_new	Number Of CT Scans For New Lesions	Number Of CT Scans For New Lesions	Num

Section 17: CT Scan Non-Target Lesions

Variable	Label	Description	Format Text
ct_new_progressive1-4	Progressive disease?	Progressive disease?	.N="Not Applicable" 0="No" 1="Yes"
ct_nont_location1-4	CT Scan Non-Target Lesions - Location	CT Scan Non-Target Lesions - Location	.N="Not Applicable" 1="Lower left" 2="Lower right" 3="Upper left" 4="Upper right" 5="Medial right"
ct_nont_max_diam1-4	CT Scan Non-Target Lesions - Maximum diameter (mm)	CT Scan Non-Target Lesions - Maximum diameter (mm)	Num .N="Not Applicable"
ct_nont_new_lesion1-4	Is any new lesions present?	Is any new lesions present?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
ct_nont_nodule_num1-4	CT Scan Non-Target Lesions - Nodule number	CT Scan Non-Target Lesions - Nodule number	Num .N="Not Applicable"
ct_nont_num_lesion1-4	If yes, number of new lesions	If yes, number of new lesions	Num .N="Not Applicable"
ct_nont_scan1-4	CT Scan Non-Target Lesions -Scan	CT Scan Non-Target Lesions -Scan	Num .N="Not Applicable"
ct_nont_scan_type1-4	CT Scan Non-Target Lesions - CT scan type	CT Scan Non-Target Lesions - CT scan type	.M="Missing" .N="Not Applicable" 1="COSMOS1 screening" 2="COSMOS2 screening"
ct_nont_sum_diam1-4	Sum maximum diameters (mm)	Sum maximum diameters (mm)	Num .N="Not Applicable"
ct_nont_type1-4	CT Scan Non-Target Lesions - Type	CT Scan Non-Target Lesions - Type	.N="Not Applicable" 1="Non-solid" 2="Partially solid" 3="Solid"
ct_nont_undetectable1-4	CT Scan Non-Target Lesions - Undetectable	CT Scan Non-Target Lesions - Undetectable	.N="Not Applicable" 0="False"
ct_nont_visit_dt1-4	Visit date	Visit date	SAS Date .N="Not Applicable"
num_ct_nont	Number Of CT Scans For New Lesions	Number Of CT Scans For New Lesions	Num

Section 18: CT Scan Non-Target Lesions v12

Variable	Label	Description	Format Text
ct_nontv12_location1-2	CT Scan Non-Target Lesions v12 - Location	CT Scan Non-Target Lesions v12 - Location	.N="Not Applicable" 1="Lower left" 2="Lower right" 3="Upper left" 4="Upper right" 5="Medial right"
ct_nontv12_max_diam1-2	CT Scan Non-Target Lesions v12 - Maximum diameter (mm)	CT Scan Non-Target Lesions v12 - Maximum diameter (mm)	Num .N="Not Applicable"
ct_nontv12_new_lesion1-2	Is any new lesions present?	Is any new lesions present?	.N="Not Applicable" 0="No" 1="Yes"
ct_nontv12_nodule_num1-2	CT Scan Non-Target Lesions v12 - Nodule number	CT Scan Non-Target Lesions v12 - Nodule number	Num .N="Not Applicable"
ct_nontv12_num_lesion1-2	If yes, number of new lesions	If yes, number of new lesions	Num .N="Not Applicable"
ct_nontv12_scan1-2	CT Scan Non-Target Lesions v12 - Scan	CT Scan Non-Target Lesions v12 - Scan	Num .N="Not Applicable"
ct_nontv12_scan_type1-2	CT scan type	CT scan type	.N="Not Applicable" 1="Non-screening CT" 2="Screening CT"
ct_nontv12_sum_diam1-2	Sum maximum diameters (mm)	Sum maximum diameters (mm)	Num .N="Not Applicable"
ct_nontv12_type1-2	CT Scan Non-Target Lesions v12 - Type	CT Scan Non-Target Lesions v12 - Type	.N="Not Applicable" 1="Non-solid" 2="Partially solid" 3="Solid"
ct_nontv12_undetected1-2	CT Scan Non-Target Lesions v12 - Undetectable	CT Scan Non-Target Lesions v12 - Undetectable	.N="Not Applicable" 0="False"
ct_nontv12_visit_date1-2	Visit date	Visit date	SAS Date .N="Not Applicable"
num_ct_nontv12	Number Of CT Scans For New Lesions	Number Of CT Scans For New Lesions	Num

Section 19: CT Scan Non-Target Lesions v12 Month 3, 6, and 12

Variable	Label	Description	Format Text
ct_nontv12_3612_location1-4	CT Scan Non-Target Lesions Month 3/6/12 v12 - Location	CT Scan Non-Target Lesions Month 3/6/12 v12 - Location	.N="Not Applicable" 1="Lower left" 2="Lower right" 3="Upper left" 4="Upper right" 5="Medial right"
ct_nontv12_3612_max_diam1-4	CT Scan Non-Target Lesions Month 3/6/12 v12 - Maximum diameter (mm)	CT Scan Non-Target Lesions Month 3/6/12 v12 - Maximum diameter (mm)	Num .N="Not Applicable"
ct_nontv12_3612_new_lesion1-4	Is any new lesions present?	Is any new lesions present?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
ct_nontv12_3612_nodule_num1-4	CT Scan Non-Target Lesions Month 3/6/12 v12 - Nodule number	CT Scan Non-Target Lesions Month 3/6/12 v12 - Nodule number	Num .N="Not Applicable"
ct_nontv12_3612_num_lesion1-4	If yes, number of new lesions	If yes, number of new lesions	Num .M="Missing" .N="Not Applicable"
ct_nontv12_3612_scan1-4	CT Scan Non-Target Lesions Month 3/6/12 v12 - Scan	CT Scan Non-Target Lesions Month 3/6/12 v12 - Scan	Num .N="Not Applicable"
ct_nontv12_3612_scan_type1-4	CT scan type	CT scan type	.M="Missing" .N="Not Applicable" 1="Non-screening CT" 2="Screening CT"
ct_nontv12_3612_sum_diam1-4	Sum maximum diameters (mm)	Sum maximum diameters (mm)	Num .N="Not Applicable"
ct_nontv12_3612_type1-4	CT Scan Non-Target Lesions Month 3/6/12 v12 - Type	CT Scan Non-Target Lesions Month 3/6/12 v12 - Type	.N="Not Applicable" 1="Non-solid" 2="Partially solid" 3="Solid"
ct_nontv12_3612_undetetectable1-4	CT Scan Non-Target Lesions Month 3/6/12 v12 - Undetectable	CT Scan Non-Target Lesions Month 3/6/12 v12 - Undetectable	.N="Not Applicable" 0="False" 1="True"
ct_nontv12_3612_visit_dt1-4	Visit date	Visit date	SAS Date .N="Not Applicable"
num_ct_nontv12_3612	Number Of CT Scans For New Lesions	Number Of CT Scans For New Lesions	Num

Section 20: CT Scan Non-Target Month 3, 6, and 12

Variable	Label	Description	Format Text
ct_nont_3612_location1-6	CT Scan Non-Target Lesions Month 3/6/12 - Location	CT Scan Non-Target Lesions Month 3/6/12 - Location	.N="Not Applicable" 1="Lower left" 2="Lower right" 3="Upper left" 4="Upper right" 5="Medial right"
ct_nont_3612_max_diam1-6	CT Scan Non-Target Lesions Month 3/6/12 - Maximum diameter (mm)	CT Scan Non-Target Lesions Month 3/6/12 - Maximum diameter (mm)	Num .N="Not Applicable"
ct_nont_3612_new_lesion1-6	Is any new lesions present?	Is any new lesions present?	.N="Not Applicable" 0="No" 1="Yes"
ct_nont_3612_nodule_num1-6	CT Scan Non-Target Lesions Month 3/6/12 - Nodule number	CT Scan Non-Target Lesions Month 3/6/12 - Nodule number	Num .N="Not Applicable"
ct_nont_3612_num_lesion1-6	If yes, number of new lesions	If yes, number of new lesions	Num .N="Not Applicable"
ct_nont_3612_scan1-6	CT Scan Non-Target Lesions Month 3/6/12 - Scan	CT Scan Non-Target Lesions Month 3/6/12 - Scan	Num .N="Not Applicable"
ct_nont_3612_scan_type1-6	CT scan type	CT scan type	.M="Missing" .N="Not Applicable" 1="COSMOS1 screening" 2="COSMOS2 screening"
ct_nont_3612_sum_diam1-6	Sum maximum diameters (mm)	Sum maximum diameters (mm)	Num .N="Not Applicable"
ct_nont_3612_type1-6	CT Scan Non-Target Lesions Month 3/6/12 - Type	CT Scan Non-Target Lesions Month 3/6/12 - Type	.N="Not Applicable" 1="Non-solid" 2="Partially solid" 3="Solid"
ct_nont_3612_undetected1-6	CT Scan Non-Target Lesions Month 3/6/12 - Undetectable	CT Scan Non-Target Lesions Month 3/6/12 - Undetectable	.N="Not Applicable" 0="False"
ct_nont_3612_visit_dt1-6	Visit date	Visit date	SAS Date .N="Not Applicable"
num_ct_nont_3612	Number of CT scans for new lesions	Number of CT scans for new lesions	Num

Section 21: CT Scan Target Lesions

Variable	Label	Description	Format Text
ct_targ_infinite1-7	CT Scan Target Lesions - Infinite	CT Scan Target Lesions - Infinite	.N="Not Applicable" 0="False" 1="True"
ct_targ_location1-7	CT Scan Target Lesions - Location	CT Scan Target Lesions - Location	.N="Not Applicable" 1="Lower left" 2="Lower right" 3="Upper left" 4="Upper right" 5="Medial right"
ct_targ_max_diam1-7	CT Scan Target Lesions - Maximum diameter (mm)	CT Scan Target Lesions - Maximum diameter (mm)	Num .N="Not Applicable"
ct_targ_max_hu_dens1-7	CT Scan Target Lesions - Maximum density (HU)	CT Scan Target Lesions - Maximum density (HU)	Num .N="Not Applicable"
ct_targ_mean_hu_dens1-7	CT Scan Target Lesions - Mean density (HU)	CT Scan Target Lesions - Mean density (HU)	Num .N="Not Applicable"
ct_targ_min_hu_dens1-7	CT Scan Target Lesions - Minimum density (HU)	CT Scan Target Lesions - Minimum density (HU)	Num .N="Not Applicable"
ct_targ_nodule_num1-7	CT Scan Target Lesions - Nodule number	CT Scan Target Lesions - Nodule number	Num .N="Not Applicable"
ct_targ_scan1-7	CT Scan Target Lesions - Scan	CT Scan Target Lesions - Scan	Num .N="Not Applicable"
ct_targ_scan_type1-7	CT scan type	CT scan type	.N="Not Applicable" 1="COSMOS1 screening" 2="COSMOS2 screening"
ct_targ_sum_diam1-7	Sum maximum diameters (mm)	Sum maximum diameters (mm)	Num .N="Not Applicable"
ct_targ_type1-7	CT Scan Target Lesions - Type	CT Scan Target Lesions - Type	.N="Not Applicable" 1="Non-solid" 2="Partially solid" 3="Solid"
ct_targ_undetectable1-7	CT Scan Target Lesions - Undetectable	CT Scan Target Lesions - Undetectable	.N="Not Applicable" 0="False"
ct_targ_visit_dt1-7	Visit date	Visit date	SAS Date .N="Not Applicable"
ct_targ_vol_double1-7	CT Scan Target Lesions - Volume doubling time (days)	CT Scan Target Lesions - Volume doubling time (days)	Num .N="Not Applicable"
ct_targ_volume1-7	CT Scan Target Lesions - Volume (mm ³)	CT Scan Target Lesions - Volume (mm ³)	Num .N="Not Applicable"
num_ct_targ	Number Of CT Scans For New Lesions	Number Of CT Scans For New Lesions	Num

Section 22: CT Scan Target Lesions v14

Variable	Label	Description	Format Text
ct_targv14_ct_scan_v14_1-3	CT Scan Target Lesions v14 - CT V14 scan type	CT Scan Target Lesions v14 - CT V14 scan type	.N="Not Applicable" 1="Low dose"
ct_targv14_infinite1-3	CT Scan Target Lesions v14 - Infinite	CT Scan Target Lesions v14 - Infinite	.N="Not Applicable" 0="False" 1="True"
ct_targv14_location1-3	CT Scan Target Lesions v14 - Location	CT Scan Target Lesions v14 - Location	.N="Not Applicable" 1="Lower left" 2="Lower right" 3="Upper left" 4="Upper right" 5="Medial right"
ct_targv14_max_diam1-3	CT Scan Target Lesions v14 - Maximum diameter (mm)	CT Scan Target Lesions v14 - Maximum diameter (mm)	Num .N="Not Applicable"
ct_targv14_max_hu_dens1-3	CT Scan Target Lesions v14 - Maximum density (HU)	CT Scan Target Lesions v14 - Maximum density (HU)	Num .N="Not Applicable"
ct_targv14_mean_hu_dens1-3	CT Scan Target Lesions v14 - Mean density (HU)	CT Scan Target Lesions v14 - Mean density (HU)	Num .N="Not Applicable"
ct_targv14_min_hu_dens1-3	CT Scan Target Lesions v14 - Minimum density (HU)	CT Scan Target Lesions v14 - Minimum density (HU)	Num .N="Not Applicable"
ct_targv14_nodule_num1-3	CT Scan Target Lesions v14 - Nodule number	CT Scan Target Lesions v14 - Nodule number	Num .N="Not Applicable"
ct_targv14_scan1-3	CT Scan Target Lesions v14 - Scan	CT Scan Target Lesions v14 - Scan	Num .N="Not Applicable"
ct_targv14_scan_type1-3	CT scan type	CT scan type	.N="Not Applicable" 1="Screening CT"
ct_targv14_sum_diam1-3	Sum maximum diameters (mm)	Sum maximum diameters (mm)	Num .N="Not Applicable"
ct_targv14_type1-3	CT Scan Target Lesions v14 - Type	CT Scan Target Lesions v14 - Type	.N="Not Applicable" 1="Non-solid" 2="Partially solid" 3="Solid"
ct_targv14_undetectable1-3	CT Scan Target Lesions v14 - Undetectable	CT Scan Target Lesions v14 - Undetectable	.N="Not Applicable" 0="False"
ct_targv14_visit_dt1-3	Visit date	Visit date	SAS Date .N="Not Applicable"
ct_targv14_vol_double1-3	CT Scan Target Lesions v14 - Volume doubling time (days)	CT Scan Target Lesions v14 - Volume doubling time (days)	Num .N="Not Applicable"
ct_targv14_volume1-3	CT Scan Target Lesions v14 - Volume (mm ³)	CT Scan Target Lesions v14 - Volume (mm ³)	Num .N="Not Applicable"

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Variable	Label	Description	Format Text
num_ct_targv14	Number Of CT Scans For New Lesions	Number Of CT Scans For New Lesions	Num

Section 23: CT Scan Target Lesions Month 3, 6, and 12

Variable	Label	Description	Format Text
ct_targ_3612_infinite1-7	CT Scan Target Lesions Month 3/6/12 - Infinite	CT Scan Target Lesions Month 3/6/12 - Infinite	.N="Not Applicable" 0="False" 1="True"
ct_targ_3612_location1-7	CT Scan Target Lesions Month 3/6/12 - Location	CT Scan Target Lesions Month 3/6/12 - Location	.N="Not Applicable" 1="Lower left" 2="Lower right" 3="Upper left" 4="Upper right" 5="Medial right"
ct_targ_3612_max_diam1-7	CT Scan Target Lesions Month 3/6/12 - Maximum diameter (mm)	CT Scan Target Lesions Month 3/6/12 - Maximum diameter (mm)	Num .N="Not Applicable"
ct_targ_3612_max_hu_dens1-7	CT Scan Target Lesions Month 3/6/12 - Maximum density (HU)	CT Scan Target Lesions Month 3/6/12 - Maximum density (HU)	Num .N="Not Applicable"
ct_targ_3612_mean_hu_dens1-7	CT Scan Target Lesions Month 3/6/12 - Mean density (HU)	CT Scan Target Lesions Month 3/6/12 - Mean density (HU)	Num .N="Not Applicable"
ct_targ_3612_min_hu_dens1-7	CT Scan Target Lesions Month 3/6/12 - Minimum density (HU)	CT Scan Target Lesions Month 3/6/12 - Minimum density (HU)	Num .N="Not Applicable"
ct_targ_3612_nodule_num1-7	CT Scan Target Lesions Month 3/6/12 - Nodule number	CT Scan Target Lesions Month 3/6/12 - Nodule number	Num .N="Not Applicable"
ct_targ_3612_scan1-7	CT Scan Target Lesions Month 3/6/12 - Scan	CT Scan Target Lesions Month 3/6/12 - Scan	Num .N="Not Applicable"
ct_targ_3612_scan_type1-7	CT scan type	CT scan type	.N="Not Applicable" 1="COSMOS1 screening" 2="COSMOS2 screening"
ct_targ_3612_sum_diam1-7	Sum maximum diameters (mm)	Sum maximum diameters (mm)	Num .N="Not Applicable"
ct_targ_3612_type1-7	CT Scan Target Lesions Month 3/6/12 - Type	CT Scan Target Lesions Month 3/6/12 - Type	.N="Not Applicable" 1="Non-solid" 2="Partially solid" 3="Solid"
ct_targ_3612_undetectable1-7	CT Scan Target Lesions Month 3/6/12 - Undetectable	CT Scan Target Lesions Month 3/6/12 - Undetectable	.N="Not Applicable" 0="False"
ct_targ_3612_visit_dt1-7	Visit date	Visit date	SAS Date .N="Not Applicable"
ct_targ_3612_volume_double1-7	CT Scan Target Lesions Month 3/6/12 - Volume doubling time (days)	CT Scan Target Lesions Month 3/6/12 - Volume doubling time (days)	Num .N="Not Applicable"
ct_targ_3612_volume1-7	CT Scan Target Lesions Month 3/6/12 - Volume (mm ³)	CT Scan Target Lesions Month 3/6/12 - Volume (mm ³)	Num .N="Not Applicable"

Variable	Label	Description	Format Text
num_ct_targ_3612	Number Of CT Scans For New Lesions	Number Of CT Scans For New Lesions	Num

Section 24: CT Scan Target Lesions v14 Month 3, 6, and 12

Variable	Label	Description	Format Text
ct_targv14_3612_ct_scan_v14_1-6	CT Scan Target Lesions Month 3/6/12 v14 - Scan type	CT Scan Target Lesions Month 3/6/12 v14 - Scan type	Num .N="Not Applicable"
ct_targv14_3612_infinite1-6	CT Scan Target Lesions Month 3/6/12 v14 - Infinite	CT Scan Target Lesions Month 3/6/12 v14 - Infinite	.N="Not Applicable" 0="False" 1="True"
ct_targv14_3612_location1-6	CT Scan Target Lesions Month 3/6/12 v14 - Location	CT Scan Target Lesions Month 3/6/12 v14 - Location	.N="Not Applicable" 1="Lower left" 2="Lower right" 3="Upper left" 4="Upper right" 5="Medial right"
ct_targv14_3612_max_diam1-6	CT Scan Target Lesions Month 3/6/12 v14 - Maximum diameter (mm)	CT Scan Target Lesions Month 3/6/12 v14 - Maximum diameter (mm)	Num .N="Not Applicable"
ct_targv14_3612_max_hu_dens1-6	CT Scan Target Lesions Month 3/6/12 v14 - Maximum density (HU)	CT Scan Target Lesions Month 3/6/12 v14 - Maximum density (HU)	Num .N="Not Applicable"
ct_targv14_3612_mean_hu_dens1-6	CT Scan Target Lesions Month 3/6/12 v14 - Mean density (HU)	CT Scan Target Lesions Month 3/6/12 v14 - Mean density (HU)	Num .N="Not Applicable"
ct_targv14_3612_min_hu_dens1-6	CT Scan Target Lesions Month 3/6/12 v14 - Minimum density (HU)	CT Scan Target Lesions Month 3/6/12 v14 - Minimum density (HU)	Num .N="Not Applicable"
ct_targv14_3612_nodule_num1-6	CT Scan Target Lesions Month 3/6/12 v14 - Nodule number	CT Scan Target Lesions Month 3/6/12 v14 - Nodule number	Num .N="Not Applicable"
ct_targv14_3612_scan1-6	CT Scan Target Lesions Month 3/6/12 v14 - Scan	CT Scan Target Lesions Month 3/6/12 v14 - Scan	Num .N="Not Applicable"
ct_targv14_3612_scan_type1-6	CT scan type	CT scan type	.N="Not Applicable" 1="Screening CT" 2="Non-Screening CT"
ct_targv14_3612_sum_diam1-6	Sum maximum diameters (mm)	Sum maximum diameters (mm)	Num .N="Not Applicable"
ct_targv14_3612_type1-6	CT Scan Target Lesions Month 3/6/12 v14 - Type	CT Scan Target Lesions Month 3/6/12 v14 - Type	.N="Not Applicable" 1="Non-solid" 2="Partially solid" 3="Solid"
ct_targv14_3612_undetectable1-6	CT Scan Target Lesions Month 3/6/12 v14 - Undetectable	CT Scan Target Lesions Month 3/6/12 v14 - Undetectable	.N="Not Applicable" 0="False" 1="True"
ct_targv14_3612_visit_dt1-6	Visit date	Visit date	SAS Date .N="Not Applicable"

Variable	Label	Description	Format Text
ct_targv14_3612_vo l_double1-6	CT Scan Target Lesions Month 3/6/12 v14 - Volume doubling time (days)	CT Scan Target Lesions Month 3/6/12 v14 - Volume doubling time (days)	Num .N="Not Applicable"
ct_targv14_3612_vo lume1-6	CT Scan Target Lesions Month 3/6/12 v14 - Volume (mm ³)	CT Scan Target Lesions Month 3/6/12 v14 - Volume (mm ³)	Num .N="Not Applicable"
num_ct_targv14_36 12	Number Of CT Scans For New Lesions	Number Of CT Scans For New Lesions	Num

Section 25: Final CT Scan Summary v12 06212016

Variable	Label	Description	Format Text
f_ct_summ_comments	Comments	Comments	Char
f_ct_summ_longest_nodule	Longest Nodule Response	Longest Nodule Response	.N="Not Applicable" 1="Stable/No change" 2="Progression" 3="Regressed/Disappeared" 4="Other"
f_ct_summ_other_spec	Other Specify	Other Specify	.N="Not Applicable" 1="Surgically Removed"
f_ct_summ_overall_response	Overall Response Multiple Nodules	Overall Response Multiple Nodules	.N="Not Applicable" 1="Stable disease (SD)" 2="Progressive disease (PD)" 3="Partial response (PR)" 4="Complete Response (CR)"
f_ct_summ_vist_dt	Visit Date	Visit Date	SAS Date .N="Not Applicable"

Section 26: Research Blood

Variable	Label	Description	Format Text
bld_date_collected1-12	Date Blood Specimen Collected	Date Blood Specimen Collected	SAS Date .M="Missing" .N="Not Applicable"
bld_lab_test_num1-12	Lab Test Number	Lab Test Number	Num .M="Missing" .N="Not Applicable"
bld_sample_not_obt1-12	Blood Sample Not Obtained	Blood Sample Not Obtained	.M="Missing" .N="Not Applicable" 0="False" 1="True"
bld_sample_type1-12	Blood Sample Type	Blood Sample Type	.M="Missing" .N="Not Applicable" 1="Biorepository" 2="MicroRNA" 3="Thromboxane B2" 4="hs-CRP"
bld_spec_not_obt1-12	Blood Specimen Not Obtained	Blood Specimen Not Obtained	.N="Not Applicable" 0="False" 1="True"
bld_specimen_rec_dt1-12	Date Blood Specimen Received	Date Blood Specimen Received	SAS Date .M="Missing" .N="Not Applicable"
bld_specimen_ship_dt1-12	Date Blood Specimen Shipped	Date Blood Specimen Shipped	SAS Date .M="Missing" .N="Not Applicable"
bld_storage_temp1-12	Blood Specimen Storage Temperature (C)	Blood Specimen Storage Temperature (C)	Num .M="Missing" .N="Not Applicable"
bld_visit_dt1-12	Visit Date	Visit Date	SAS Date .N="Not Applicable"
bld_will_specimen_ship1-12	Will Blood Specimen Be Shipped?	Will Blood Specimen Be Shipped?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Section 27: Research Blood Month 6

Variable	Label	Description	Format Text
bldm6_date_collected1-2	Date Blood Specimen Collected	Date Blood Specimen Collected	SAS Date .N="Not Applicable"
bldm6_lab_test_number1-2	Lab Test Number	Lab Test Number	Num .N="Not Applicable"
bldm6_sample_not_obt1-2	Blood Sample Not Obtained	Blood Sample Not Obtained	.N="Not Applicable" 0="False" 1="True"
bldm6_sample_type1-2	Blood Sample Type	Blood Sample Type	.N="Not Applicable" 1="Biorepository" 2="MicroRNA" 3="Thromboxane B2" 4="hs-CRP"
bldm6_spec_not_obt1-2	Blood Specimen Not Obtained	Blood Specimen Not Obtained	.N="Not Applicable" 0="False" 1="True"
bldm6_specimen_received_dt1-2	Date Blood Specimen Received	Date Blood Specimen Received	SAS Date .M="Missing" .N="Not Applicable"
bldm6_specimen_shipped_dt1-2	Date Blood Specimen Shipped	Date Blood Specimen Shipped	SAS Date .M="Missing" .N="Not Applicable"
bldm6_storage_temperature1-2	Blood Specimen Storage Temperature (C)	Blood Specimen Storage Temperature (C)	Num .N="Not Applicable"
bldm6_visit_dt1-2	Visit Date	Visit Date	SAS Date .N="Not Applicable"
bldm6_will_specimen_ship1-2	Will Blood Specimen Be Shipped?	Will Blood Specimen Be Shipped?	.N="Not Applicable" 0="No" 1="Yes"

Section 28: Research Urine

Variable	Label	Description	Format Text
urine_date_collected1-12	Date Urine Specimen Collected	Date Urine Specimen Collected	SAS Date .M="Missing" .N="Not Applicable"
urine_lab_test_num1-12	Lab Test Number	Lab Test Number	Num .M="Missing" .N="Not Applicable"
urine_sample_not_obtained1-12	Urine Sample Not Obtained	Urine Sample Not Obtained	.M="Missing" .N="Not Applicable" 0="False" 1="True"
urine_sample_type1-12	Urine Sample Type	Urine Sample Type	.M="Missing" .N="Not Applicable" 1="Cotinine" 2="Creatinine" 3="LTE4" 4="PGE-M"
urine_spec_not_obtained1-12	Urine Specimen Not Obtained	Urine Specimen Not Obtained	.N="Not Applicable" 0="False" 1="True"
urine_specimen_received_dt1-12	Date Urine Specimen Received	Date Urine Specimen Received	SAS Date .M="Missing" .N="Not Applicable"
urine_specimen_shipped_dt1-12	Date Urine Specimen Shipped	Date Urine Specimen Shipped	SAS Date .M="Missing" .N="Not Applicable"
urine_storage_temp1-12	Urine Specimen Storage Temperature (C)	Urine Specimen Storage Temperature (C)	Num .M="Missing" .N="Not Applicable"
urine_visit_dt1-12	Visit Date	Visit Date	SAS Date .N="Not Applicable"
urine_will_specimen_shipped1-12	Will Urine Specimen Be Shipped?	Will Urine Specimen Be Shipped?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Section 29: Research Urine Month 6

Variable	Label	Description	Format Text
urinem6_date_collected1-2	Date Urine Specimen Collected	Date Urine Specimen Collected	SAS Date .N="Not Applicable"
urinem6_lab_test_num1-2	Lab Test Number	Lab Test Number	Num .N="Not Applicable"
urinem6_sample_not_obt1-2	Urine Sample Not Obtained	Urine Sample Not Obtained	.N="Not Applicable" 0="False" 1="True"
urinem6_sample_type1-2	Urine Sample Type	Urine Sample Type	.N="Not Applicable" 1="Cotinine" 2="Creatinine" 3="LTE4" 4="PGE-M"
urinem6_spec_not_obt1-2	Urine Specimen Not Obtained	Urine Specimen Not Obtained	.N="Not Applicable" 0="False" 1="True"
urinem6_specimen_rec_dt1-2	Date Urine Specimen Received	Date Urine Specimen Received	SAS Date .M="Missing" .N="Not Applicable"
urinem6_specimen_ship_dt1-2	Date Urine Specimen Shipped	Date Urine Specimen Shipped	SAS Date .M="Missing" .N="Not Applicable"
urinem6_storage_temp1-2	Urine Specimen Storage Temperature (C)	Urine Specimen Storage Temperature (C)	Num .N="Not Applicable"
urinem6_visit_dt1-2	Visit Date	Visit Date	SAS Date .N="Not Applicable"
urinem6_will_specimen_ship1-2	Will Urine Specimen Be Shipped?	Will Urine Specimen Be Shipped?	.N="Not Applicable" 0="No" 1="Yes"

Section 30: Other Lab Tests

Variable	Label	Description	Format Text
other_lab_clin_sig1-3	Other Lab Tests - Clinically Significant	Other Lab Tests - Clinically Significant	.N="Not Applicable" 0="No" 1="Yes"
other_lab_collect_dt1-3	Other Lab Tests - Collection Date	Other Lab Tests - Collection Date	SAS Date .N="Not Applicable"
other_lab_comments1-3	Other Lab Tests - Comments	Other Lab Tests - Comments	Char
other_lab_fasting1-3	Other Lab Tests - Fasting?	Other Lab Tests - Fasting?	.N="Not Applicable" 1="Yes"
other_lab_oor1-3	Other Lab Tests - Out Of Range	Other Lab Tests - Out Of Range	.N="Not Applicable" 0="False" 1="True"
other_lab_result1-3	Other Lab Tests - Result	Other Lab Tests - Result	Num
other_lab_test1-3	Other Lab Tests - Lab Test	Other Lab Tests - Lab Test	.N="Not Applicable" 1="Urine analysis" 2="Urine creatinine"
other_lab_visit_dt1-3	Other Lab Tests - Visit Date	Other Lab Tests - Visit Date	SAS Date .N="Not Applicable"

Section 31: Urine Specimen

Variable	Label	Description	Format Text
urinespec_collect_dt1-4	Date Urine Specimen Collected	Date Urine Specimen Collected	SAS Date .M="Missing" .N="Not Applicable"
urinespec_cotinine1-4	Cotinine Level Urine	Cotinine Level Urine	Num .M="Missing" .N="Not Applicable"
urinespec_creat1-4	Creatinine Urine (g/L Su Urine 24H)	Creatinine Urine (g/L Su Urine 24H)	Num .N="Not Applicable"
urinespec_days1-4	Day Specimen Drawn In Study	Day Specimen Drawn In Study	Num .M="Missing" .N="Not Applicable"
urinespec_draw_code1-4	Urine Specimen - Blood Draw Code	Urine Specimen - Blood Draw Code	Char
urinespec_leukotriene1-4	Leukotriene E4 Urine (pg/mL)	Leukotriene E4 Urine (pg/mL)	Num .N="Not Applicable"
urinespec_months1-4	Month Specimen Drawn In Study (0/6/12)	Month Specimen Drawn In Study (0/6/12)	Num .M="Missing" .N="Not Applicable"
urinespec_not_obt1-4	Urine Specimen - Not Obtained	Urine Specimen - Not Obtained	.N="Not Applicable" 0="False" 1="True"
urinespec_off_dt1-4	Off Study Date	Off Study Date	SAS Date .M="Missing" .N="Not Applicable"
urinespec_pgem1-4	Pgem Urine (pg/mL)	Pgem Urine (pg/mL)	Num .N="Not Applicable"
urinespec_reason_off1-4	Reason Off Study	Reason Off Study	.M="Missing" .N="Not Applicable" 1="Study Complete" 2="Ineligible" 3="Protocol Violation" 4="Other, specify"
urinespec_visit_dt1-4	Visit Date	Visit Date	SAS Date .M="Missing" .N="Not Applicable"

Section 32: Intervention Admin

Variable	Label	Description	Format Text
intervention_agent_prov_dt	Date Agent Provided	Date Agent Provided	SAS Date .N="Not Applicable"
intervention_agent_start_dt	Date Agent Started	Date Agent Started	SAS Date .N="Not Applicable"
intervention_visit_dt	Visit Date	Visit Date	SAS Date .M="Missing" .N="Not Applicable"

Section 33: Off Study

Variable	Label	Description	Format Text
off_study_agent_end_dt	Agent End Date	Agent End Date	SAS Date .M="Missing"
off_study_dt	Off Study Date	Off Study Date	SAS Date
off_study_form_dt	Form Date	Form Date	SAS Date
off_study_last_contact_dt	Date Of Last Contact	Date Of Last Contact	SAS Date
off_study_na	Reason Off Study Not Applicable	Reason Off Study Not Applicable	0="False" 1="True"
off_study_no_ae	This Participant Did Not Have Any Adverse Events	This Participant Did Not Have Any Adverse Events	.M="Missing" 0="False" 1="True"
off_study_no_conmed	This Participant Did Not Take Any Concomitant Medications	This Participant Did Not Take Any Concomitant Medications	.M="Missing" 0="False" 1="True"
off_study_no_interrupt	This Participant Did Not Have Any Agent Interrupts	This Participant Did Not Have Any Agent Interrupts	.M="Missing" 0="False" 1="True"
off_study_no_mod	This Participant Did Not Have Any Agent Modifications	This Participant Did Not Have Any Agent Modifications	.M="Missing" 0="False" 1="True"
off_study_oth_spec	Other Specify	Other Specify	Char
off_study_reason	Reason Off Study	Reason Off Study	1="Study Complete" 2="Ineligible" 3="Protocol Violation" 4="Other, specify"
off_study_reason_spec	Reason Explanation	Reason Explanation	Char

Section 34: Blood Chemistry

Variable	Label	Description	Format Text
bldchm_alk_c_sig1-3	Alkaline Phosphate: Clinically Significant	Alkaline Phosphate: Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
bldchm_alk_com1-3	Alkaline Phosphate: Comments	Alkaline Phosphate: Comments	Char
bldchm_alk_not_o1-3	Alkaline Phosphate: Not Obtained	Alkaline Phosphate: Not Obtained	.N="Not Applicable" 0="False"
bldchm_alk_oor1-3	Alkaline Phosphate: Out Of Range	Alkaline Phosphate: Out Of Range	.N="Not Applicable" 0="False" 1="True"
bldchm_alk_result1-3	Alkaline Phosphate: Results (IU/L)	Alkaline Phosphate: Results (IU/L)	Num .N="Not Applicable"
bldchm_bili_c_sig1-3	Bilirubin, Total: Clinically Significant	Bilirubin, Total: Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
bldchm_bili_com1-3	Bilirubin, Total: Comments	Bilirubin, Total: Comments	Char
bldchm_bili_not_o1-3	Bilirubin, Total: Not Obtained	Bilirubin, Total: Not Obtained	.N="Not Applicable" 0="False"
bldchm_bili_oor1-3	Bilirubin, Total: Out Of Range	Bilirubin, Total: Out Of Range	.M="Missing" .N="Not Applicable" 0="False" 1="True"
bldchm_bili_result1-3	Bilirubin, Total: Results (mg/dL)	Bilirubin, Total: Results (mg/dL)	Num .N="Not Applicable"
bldchm_bun_c_sig1-3	Bun: Clinically Significant	Bun: Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
bldchm_bun_com1-3	Bun: Comments	Bun: Comments	Char
bldchm_bun_not_o1-3	Bun: Not Obtained	Bun: Not Obtained	.N="Not Applicable" 0="False"
bldchm_bun_oor1-3	Bun: Out Of Range	Bun: Out Of Range	.M="Missing" .N="Not Applicable" 0="False" 1="True"
bldchm_bun_result1-3	Bun: Results (mg/dL)	Bun: Results (mg/dL)	Num .N="Not Applicable"
bldchm_calc_c_sig1-3	Calcium: Clinically Significant	Calcium: Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Variable	Label	Description	Format Text
bldchm_calc_com1-3	Calcium: Comments	Calcium: Comments	Char
bldchm_calc_not_o1-3	Calcium: Not Obtained	Calcium: Not Obtained	.N="Not Applicable" 0="False"
bldchm_calc_oor1-3	Calcium: Out Of Range	Calcium: Out Of Range	.M="Missing" .N="Not Applicable" 0="False" 1="True"
bldchm_calc_result1-3	Calcium: Results (mg/dL)	Calcium: Results (mg/dL)	Num .N="Not Applicable"
bldchm_chlo_c_sig1-3	Chloride: Clinically Significant	Chloride: Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
bldchm_chlo_com1-3	Chloride: Comments	Chloride: Comments	Char
bldchm_chlo_not_o1-3	Chloride: Not Obtained	Chloride: Not Obtained	.N="Not Applicable" 0="False"
bldchm_chlo_oor1-3	Chloride: Out Of Range	Chloride: Out Of Range	.N="Not Applicable" 0="False" 1="True"
bldchm_chlo_result1-3	Chloride: Results (mEq/L)	Chloride: Results (mEq/L)	Num .N="Not Applicable"
bldchm_crea_c_sig1-3	Cratinine: Clinically Significant	Cratinine: Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
bldchm_crea_com1-3	Cratinine: Comments	Cratinine: Comments	Char
bldchm_crea_not_o1-3	Cratinine: Not Obtained	Cratinine: Not Obtained	.N="Not Applicable" 0="False"
bldchm_crea_oor1-3	Cratinine: Out Of Range	Cratinine: Out Of Range	.M="Missing" .N="Not Applicable" 0="False" 1="True"
bldchm_crea_result1-3	Cratinine: Results (mg/dL)	Cratinine: Results (mg/dL)	Num .N="Not Applicable"
bldchm_fasting1-3	Blood Chemistry - Fasting?	Blood Chemistry - Fasting?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
bldchm_gluc_c_sig1-3	Glucose, Serum: Clinically Significant	Glucose, Serum: Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
bldchm_gluc_com1-3	Glucose, Serum: Comments	Glucose, Serum: Comments	Char
bldchm_gluc_not_o1-3	Glucose, Serum: Not Obtained	Glucose, Serum: Not Obtained	.N="Not Applicable" 0="False"

Variable	Label	Description	Format Text
bldchm_gluc_oor1-3	Glucose, Serum: Out Of Range	Glucose, Serum: Out Of Range	.M="Missing" .N="Not Applicable" 0="False" 1="True"
bldchm_gluc_result1-3	Glucose, Serum: Results (mg/dL)	Glucose, Serum: Results (mg/dL)	Num .N="Not Applicable"
bldchm_pot_c_sig1-3	Potassium: Clinically Significant	Potassium: Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
bldchm_pot_com1-3	Potassium: Comments	Potassium: Comments	Char
bldchm_pot_not_o1-3	Potassium: Not Obtained	Potassium: Not Obtained	.N="Not Applicable" 0="False"
bldchm_pot_oor1-3	Potassium: Out Of Range	Potassium: Out Of Range	.N="Not Applicable" 0="False" 1="True"
bldchm_pot_result1-3	Potassium: Results (mEq/L)	Potassium: Results (mEq/L)	Num .N="Not Applicable"
bldchm_sgot_c_sig1-3	SGOT/AST: Clinically Significant	SGOT/AST: Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
bldchm_sgot_com1-3	SGOT/AST: Comments	SGOT/AST: Comments	Char
bldchm_sgot_not_o1-3	SGOT/AST: Not Obtained	SGOT/AST: Not Obtained	.N="Not Applicable" 0="False"
bldchm_sgot_oor1-3	SGOT/AST: Out Of Range	SGOT/AST: Out Of Range	.N="Not Applicable" 0="False" 1="True"
bldchm_sgot_result1-3	SGOT/AST: Results (IU/L)	SGOT/AST: Results (IU/L)	Num .N="Not Applicable"
bldchm_sgpt_c_sig1-3	SGPT/ALT: Clinically Significant	SGPT/ALT: Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
bldchm_sgpt_com1-3	SGPT/ALT: Comments	SGPT/ALT: Comments	Char
bldchm_sgpt_not_o1-3	SGPT/ALT: Not Obtained	SGPT/ALT: Not Obtained	.N="Not Applicable" 0="False"
bldchm_sgpt_oor1-3	SGPT/ALT: Out Of Range	SGPT/ALT: Out Of Range	.M="Missing" .N="Not Applicable" 0="False" 1="True"
bldchm_sgpt_result1-3	SGPT/ALT: Results (IU/L)	SGPT/ALT: Results (IU/L)	Num .N="Not Applicable"
bldchm_sodi_c_sig1-3	Sodium: Clinically Significant	Sodium: Clinically Significant	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Variable	Label	Description	Format Text
bldchm_sodi_com1-3	Sodium: Comments	Sodium: Comments	Char
bldchm_sodi_not_o1-3	Sodium: Not Obtained	Sodium: Not Obtained	.N="Not Applicable" 0="False"
bldchm_sodi_oor1-3	Sodium: Out Of Range	Sodium: Out Of Range	.N="Not Applicable" 0="False" 1="True"
bldchm_sodi_result1-3	Sodium: Results (mEq/L)	Sodium: Results (mEq/L)	Num .N="Not Applicable"
bldchm_spec_dt1-3	Blood Chemistry Specimen Collected Date	Blood Chemistry Specimen Collected Date	SAS Date .N="Not Applicable"
bldchm_visit_dt1-3	Visit Date	Visit Date	SAS Date .N="Not Applicable"

Section 35: Agent Modification

Variable	Label	Description	Format Text
agentmod_agent_restarted1-2	Was Agent Restarted	Was Agent Restarted	.N="Not Applicable" 0="No" 1="Yes"
agentmod_date_modified1-2	Agent Modified Date	Agent Modified Date	SAS Date .N="Not Applicable"
agentmod_date_restarted1-2	If Yes, (Agent Restarted) Specify Date Restarted At Full Dose	If Yes, (Agent Restarted) Specify Date Restarted At Full Dose	SAS Date .N="Not Applicable"
agentmod_mod_number1-2	Modification Number	Modification Number	Num .N="Not Applicable"
agentmod_modified_frequency1-2	Modified Frequency	Modified Frequency	.N="Not Applicable" 1="Every day (QD)" 2="Every other day (QOD)"
agentmod_reason_mod1-2	Reason Agent Modified	Reason Agent Modified	.N="Not Applicable" 1="AE/SAE" 2="Other"
agentmod_reason_not_restarted1-2	If No, Reason Full Dose Was Not Restarted	If No, Reason Full Dose Was Not Restarted	.N="Not Applicable" 1="AE/SAE"
agentmod_reason_restarted1-2	Specify Reason Full Dose Restarted	Specify Reason Full Dose Restarted	.N="Not Applicable" 1="Event not resolved" 2="Gastric pain"
agentmod_specify_reason_mod1-2	Specify Reason Modified	Specify Reason Modified	.N="Not Applicable" 1="Endoscopist's suggestion for colonoscopy" 2="Hypertension" 3="Restart after withdrawn for side effects"

Section 36: Agent Interrupt

Variable	Label	Description	Format Text
agint_date_restarted1-6	Agent Restarted Date	Agent Restarted Date	SAS Date .M="Missing" .N="Not Applicable"
agint_date_stopped1-6	Agent Stopped Date	Agent Stopped Date	SAS Date .M="Missing" .N="Not Applicable"
agint_interruption_number1-6	Agent Interruption Number	Agent Interruption Number	Num .N="Not Applicable"
agint_reason_restarted1-6	Reason Agent Restarted	Reason Agent Restarted	.M="Missing" .N="Not Applicable" 1="Investigator decision" 2="Participant decision"
agint_reason_stopped1-6	Reason Agent Stopped	Reason Agent Stopped	Char
agint_reason_stopped_desc1-6	Reason Agent Stopped Description	Reason Agent Stopped Description	.M="Missing" .N="Not Applicable" 1="AE/SAE, specify" 2="Investigator decision, specify" 3="Other, specify" 4="Participant decision, specify"
agint_was_agent_restarted1-6	Was Agent Restarted?	Was Agent Restarted?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"

Section 37: Biopsy Tissue Histology

Variable	Label	Description	Format Text
bioptissue_adenocarcinoma	Biopsied Tissue - Adenocarcinoma Type	Biopsied Tissue - Adenocarcinoma Type	.N="Not Applicable" 1="AI (invasive)"
bioptissue_ai	Biopsied Tissue - AI	Biopsied Tissue - AI	.N="Not Applicable" 1="Acinar" 2="Papillary"
bioptissue_comments	Biopsied Tissue - Comments	Biopsied Tissue - Comments	Char
bioptissue_dimension	Biopsied Tissue - Dimension	Biopsied Tissue - Dimension	Num .N="Not Applicable"
bioptissue_grade	Biopsied Tissue - Grade	Biopsied Tissue - Grade	Num .N="Not Applicable"
bioptissue_histologic_type	Biopsied Tissue - Histologic Type	Biopsied Tissue - Histologic Type	.N="Not Applicable" 1="Abnormal (If abnormal, indicate histology)"
bioptissue_histology	Biopsied Tissue - Histology Type	Biopsied Tissue - Histology Type	.N="Not Applicable" 1="Adenocarcinoma"
bioptissue_histology_id	Biopsied Tissue - Histology ID	Biopsied Tissue - Histology ID	Num .N="Not Applicable"
bioptissue_histology_selected	Biopsied Tissue - Histology Selected	Biopsied Tissue - Histology Selected	.N="Not Applicable" 1="True"
bioptissue_m	Biopsied Tissue - M Cancer Stage Component	Biopsied Tissue - M Cancer Stage Component	Num .M="Missing" .N="Not Applicable"
bioptissue_n	Biopsied Tissue - N Cancer Stage Component	Biopsied Tissue - N Cancer Stage Component	Num .M="Missing" .N="Not Applicable"
bioptissue_stage	Biopsied Tissue - Stage	Biopsied Tissue - Stage	.N="Not Applicable" 1="I"
bioptissue_stage_letter	Biopsied Tissue - Stage Letter	Biopsied Tissue - Stage Letter	.N="Not Applicable" 1="A"
bioptissue_surg_date	Date Of Surgery	Date Of Surgery	SAS Date .N="Not Applicable"
bioptissue_t	Biopsied Tissue - T Cancer Stage Component	Biopsied Tissue - T Cancer Stage Component	Num .N="Not Applicable"
bioptissue_visit_date	Visit Date	Visit Date	SAS Date .N="Not Applicable"

Section 38: Adverse Events and Concomitant Medication Evaluation

Variable	Label	Description	Format Text
aeconeval_ae_reported1-8	Were Any New Or Changes In Adverse Events Reported?	Were Any New Or Changes In Adverse Events Reported?	.F="No Form" .M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="N/A"
aeconeval_con_reported1-8	Were Any New Or Changes In Concomitant Medications Reported?	Were Any New Or Changes In Concomitant Medications Reported?	.F="No Form" .M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="N/A"
aeconeval_date1-8	Adverse Event And Concomitant Medication Evaluation Visit Date	Adverse Event And Concomitant Medication Evaluation Visit Date	SAS Date .F="No Form" .M="Missing" .N="Not Applicable"
aeconeval_type1-8	Adverse Event And Concomitant Medication Evaluation Visit Type	Adverse Event And Concomitant Medication Evaluation Visit Type	.F="No Form" .N="Not Applicable" 1="Baseline/Registration" 2="Randomization" 3="Month 1" 4="Month 3" 5="Month 6" 6="Month 9" 7="Month 12" 8="Month 13 (Follow up)"

Section 39: Comments

Variable	Label	Description	Format Text
comments_comments	Comments	Comments	Char
comments_field_name	Field Name	Field Name	Char
comments_form_date	Form Date	Form Date	SAS Date .N="Not Applicable"
comments_form_name	Form Code	Form Code	Char

Section 40: Compliance

Variable	Label	Description	Format Text
comp_agent_compliant1-3	Is The Participant Compliant?	Is The Participant Compliant?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="N/A"
comp_agent_compliant_specify1-3	If No Specify Reason	If No Specify Reason	Char
comp_agent_dose1-3	Agent Dose (mg)	Agent Dose (mg)	Num .N="Not Applicable"
comp_agent_freq1-3	Agent Frequency	Agent Frequency	.M="Missing" .N="Not Applicable" 1="Every day (QD)"
comp_agent_interrupt1-3	Was Agent Interrupted?	Was Agent Interrupted?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="N/A"
comp_agent_missing1-3	Amount Of Agent Missing For This Period	Amount Of Agent Missing For This Period	Num .M="Missing" .N="Not Applicable"
comp_agent_name1-3	Agent Name	Agent Name	.N="Not Applicable" 1="Aspirin/Placebo"
comp_agent_provided1-3	Amount Of Agent Provided At This Visit	Amount Of Agent Provided At This Visit	Num .M="Missing" .N="Not Applicable"
comp_agent_provided_last1-3	Amount Of Agent Provided At Last Visit	Amount Of Agent Provided At Last Visit	Num .M="Missing" .N="Not Applicable"
comp_agent_provided_na1-3	Amount Of Agent Provided At Last Visit (Not Applicable)	Amount Of Agent Provided At Last Visit (Not Applicable)	.N="Not Applicable" 0="False" 1="True"
comp_agent_provided1-3	Was Agent Provided At This Visit?	Was Agent Provided At This Visit?	.N="Not Applicable" 0="No" 1="Yes" 9="N/A"
comp_agent_return1-3	Amount Of Agent Returned At This Visit	Amount Of Agent Returned At This Visit	Num .M="Missing" .N="Not Applicable"
comp_agent_taken1-3	Amount Of Agent Taken	Amount Of Agent Taken	Num .M="Missing" .N="Not Applicable"
comp_first_dose_date1-3	First Dose Taken This Period	First Dose Taken This Period	SAS Date .M="Missing" .N="Not Applicable"

Variable	Label	Description	Format Text
comp_first_dose_time1-3	First Dose Taken This Period (Time)	First Dose Taken This Period (Time)	Num .M="Missing" .N="Not Applicable"
comp_last_dose_date1-3	Last Dose Taken This Period	Last Dose Taken This Period	SAS Date .M="Missing" .N="Not Applicable"
comp_last_dose_time1-3	Last Dose Taken This Period (Time)	Last Dose Taken This Period (Time)	Num .M="Missing" .N="Not Applicable"
comp_num_interruptions1-3	If Yes, (Agent Interrupted) Indicate Number Of Interruptions This Period	If Yes, (Agent Interrupted) Indicate Number Of Interruptions This Period	Num .M="Missing" .N="Not Applicable"
comp_regimen_modified1-3	Was Agent Regimen Modified During This Period?	Was Agent Regimen Modified During This Period?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="N/A"
comp_visit_date1-3	Visit Date	Visit Date	SAS Date .N="Not Applicable"

Section 41: Compliance: Drug Labels

Variable	Label	Description	Format Text
druglabel_affixed1-2	Were Labels Affixed?	Were Labels Affixed?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
druglabel_date_of_s ign1-2	Date Of Investigators Signature	Date Of Investigators Signature	SAS Date .N="Not Applicable"
druglabel_inv_signe d1-2	Investigator's Signature?	Investigator's Signature?	.N="Not Applicable" 0="No" 1="Yes"
druglabel_visit_date 1-2	Drug Label Visit Date	Drug Label Visit Date	SAS Date .N="Not Applicable"

Section 42: Compliance: Phone Interview

Variable	Label	Description	Format Text
comp_ph_agent_compliant1-4	Is The Participant Compliant?	Is The Participant Compliant?	.N="Not Applicable" 0="No" 1="Yes" 9="N/A"
comp_ph_agent_compliant_specify1-4	If No Specify Reason	If No Specify Reason	Char
comp_ph_agent_dose1-4	Agent Dose (mg)	Agent Dose (mg)	Num .N="Not Applicable"
comp_ph_agent_freq1-4	Agent Frequency	Agent Frequency	.M="Missing" .N="Not Applicable" 1="Every day (QD)" 2="Four times daily (QID)" 3="Other"
comp_ph_agent_interrupt1-4	Was Agent Interrupted?	Was Agent Interrupted?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="N/A"
comp_ph_agent_name1-4	Agent Name	Agent Name	.N="Not Applicable" 1="Aspirin/Placebo"
comp_ph_comments1-4	Phone Interview Comments	Phone Interview Comments	Char
comp_ph_first_dose_date1-4	First Dose Taken This Period	First Dose Taken This Period	SAS Date .M="Missing" .N="Not Applicable"
comp_ph_first_dose_time1-4	First Dose Taken This Period (Time)	First Dose Taken This Period (Time)	Num .M="Missing" .N="Not Applicable"
comp_ph_last_dose_date1-4	Last Dose Taken This Period	Last Dose Taken This Period	SAS Date .M="Missing" .N="Not Applicable"
comp_ph_last_dose_time1-4	Last Dose Taken This Period (Time)	Last Dose Taken This Period (Time)	Num .M="Missing" .N="Not Applicable"
comp_ph_num_interruptions1-4	If Yes, (Agent Interrupted) Indicate Number Of Interruptions This Period	If Yes, (Agent Interrupted) Indicate Number Of Interruptions This Period	Num .M="Missing" .N="Not Applicable"
comp_ph_visit_date1-4	Visit Date	Visit Date	SAS Date .N="Not Applicable"
comp_ph_regimen_modified1-4	Was Agent Regimen Modified?	Was Agent Regimen Modified?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="N/A"

Variable	Label	Description	Format Text
comp_ph_reminded 1-4	Reminded Participant To Take One Table Of Study Agent Per Day	Reminded Participant To Take One Table Of Study Agent Per Day	.M="Missing" .N="Not Applicable" 0="No" 1="Yes" 9="N/A"

Section 43: Tobacco Assessment

Variable	Label	Description	Format Text
smoke_100_1-4	Have You Smoked 100 Cigarettes Or More?	Have You Smoked 100 Cigarettes Or More?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
smoke_avg_num1-4	Average Number Of Cigarettes Smoked Daily	Average Number Of Cigarettes Smoked Daily	Num .M="Missing" .N="Not Applicable"
smoke_avg_yrs1-4	Years Smoking Regularly	Years Smoking Regularly	Num .M="Missing" .N="Not Applicable"
smoke_how_soon_wake1-4	How Soon After You Wake Up Do You Smoke Your First Cigarette?	How Soon After You Wake Up Do You Smoke Your First Cigarette?	.M="Missing" .N="Not Applicable" 1="After 30 minutes" 2="Within 30 minutes"
smoke_investig_sig_n_dt1-4	Date Of Investigator's Signature	Date Of Investigator's Signature	SAS Date .M="Missing" .N="Not Applicable"
smoke_investig_sig_ned1-4	Investigator Signed?	Investigator Signed?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
smoke_last_oth_us_e1-4	How Long Since You Last Used Other Forms Of Tobacco Regularly?	How Long Since You Last Used Other Forms Of Tobacco Regularly?	.M="Missing" .N="Not Applicable" 1="(0 to 1 month ago) Within the past month" 2="(1 to 3 months ago) Between 1 and 3 months" 3="(1 to 5 years ago) Between 1 and 5 years" 4="(3 to 6 months ago) Between 3 and 6 months" 5="(5 to 15 years ago) Between 5 and 15 years" 6="(6 to 12 months ago) Between 6 and 12 months" 7="More than 15 years ago"
smoke_last_reg_us_e1-4	How Long Since You Last Smoked Regularly?	How Long Since You Last Smoked Regularly?	.M="Missing" .N="Not Applicable" 1="(0 to 1 month ago) Within the past month" 2="(1 to 3 months ago) Between 1 and 3 months" 3="(1 to 5 years ago) Between 1 and 5 years" 4="(3 to 6 months ago) Between 3 and 6 months" 5="(5 to 15 years ago) Between 5 and 15 years" 6="(6 to 12 months ago) Between 6 and 12 months" 7="More than 15 years ago"
smoke_now1-4	Do You Now Smoke Cigarettes?	Do You Now Smoke Cigarettes?	.M="Missing" .N="Not Applicable" 1="Everyday" 2="Not at all" 3="Some days"
smoke_oth_form_day_period1-4	Have You Ever Used Other Forms Of Tobacco: Days Per Period	Have You Ever Used Other Forms Of Tobacco: Days Per Period	Num .M="Missing" .N="Not Applicable"

Variable	Label	Description	Format Text
smoke_oth_form_p eriod1-4	Have You Ever Used Other Forms Of Tobacco: Period	Have You Ever Used Other Forms Of Tobacco: Period	.M="Missing" .N="Not Applicable" 1="Month" 2="Week"
smoke_oth_form_to bac1-4	Have You Ever Used Other Forms Of Tobacco	Have You Ever Used Other Forms Of Tobacco	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
smoke_oth_form_to bac_type1-4	Have You Ever Used Other Forms Of Tobacco: Type	Have You Ever Used Other Forms Of Tobacco: Type	.M="Missing" .N="Not Applicable" 1="Cigar" 2="Pipe"
smoke_oth_tobac_d aily1-4	Do You Use Other Forms Of Tobacco Everyday, Some Days, Or Not At All?	Do You Use Other Forms Of Tobacco Everyday, Some Days, Or Not At All?	.M="Missing" .N="Not Applicable" 1="Everyday" 2="Not at all" 3="Some days"
smoke_oth_tobac_f req1-4	Other Tobacco Used Days In	Other Tobacco Used Days In	Num .M="Missing" .N="Not Applicable"
smoke_oth_tobac_t ype1-4	Other Type Of Tobacco Smoked Daily	Other Type Of Tobacco Smoked Daily	.M="Missing" .N="Not Applicable" 1="Cigar" 2="Pipe"
smoke_quit_6mo1-4	Are You Seriously Thinking About Quitting Smoking In The Next 6 Months?	Are You Seriously Thinking About Quitting Smoking In The Next 6 Months?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
smoke_quit_mo1-4	Are You Seriously Thinking About Quitting In The Next Month?	Are You Seriously Thinking About Quitting In The Next Month?	.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
smoke_quit_times1- 4	Number Of Times In The Last 12 Months You Tried To Quit Smoking	Number Of Times In The Last 12 Months You Tried To Quit Smoking	Num .M="Missing" .N="Not Applicable"
smoke_start_age1-4	Age Started Smoking	Age Started Smoking	Num .M="Missing" .N="Not Applicable"
smoke_unkown_ag e1-4	Don't Know Age Started Smoking	Don't Know Age Started Smoking	.N="Not Applicable" 0="False"
smoke_unkown_ysr 1-4	Don't Know Years Smoked Regularly	Don't Know Years Smoked Regularly	.N="Not Applicable" 0="False"
smoke_value1-4	Smoking Assessment - Value	Smoking Assessment - Value	.M="Missing" .N="Not Applicable" 1="True"
smoke_visit_dt1-4	Visit Date	Visit Date	SAS Date .N="Not Applicable"

Section 44: Telephone Contact

Variable	Label	Description	Format Text
telephone_con_change1-5	Were Any Changes In Concomitant Medications Reported?	Were Any Changes In Concomitant Medications Reported?	.M="Missing" .N="N/A" 0="No" 1="Yes (Complete concomitant medication CRF"
telephone_con_dt1-5	Date Of Telephone Contact	Date Of Telephone Contact	SAS Date .N="Not Applicable"
telephone_part_rep1-5	Did The Participant Report Any Symptoms Or Adverse Events?	Did The Participant Report Any Symptoms Or Adverse Events?	.M="Missing" .N="N/A" 0="No" 1="Yes"
telephone_study_comp1-5	Was Study Compliance Reviewed?	Was Study Compliance Reviewed?	.M="Missing" .N="N/A" 0="No" 1="Yes"

Section 45: miRNA

Variable	Label	Description	Format Text
mirna_cc	miRNA - CC	miRNA - CC	Char
mirna_cosmos_2_id	miRNA - Cosmos-2 ID	miRNA - Cosmos-2 ID	Num
mirna_extract_dt	miRNA - Date Of Extraction	miRNA - Date Of Extraction	SAS Date .N="Not Applicable"
mirna_extract_rd	miRNA - Round Extraction	miRNA - Round Extraction	Num .N="Not Applicable"
mirna_post_bb_id	miRNA - Post-Biobank ID	miRNA - Post-Biobank ID	Num
mirna_post_hemo_index	miRNA - Post-Hemolysis Index	miRNA - Post-Hemolysis Index	Num .N="Not Applicable"
mirna_post_pcr_id	miRNA - Post-PcrID	miRNA - Post-PcrID	Num .M="Missing" .N="Not Applicable"
mirna_post_pred	miRNA - Post-Prediction	miRNA - Post-Prediction	.N="Not Applicable" 0="Negative" 1="Positive"
mirna_post_risk_index	miRNA - Post-Risk Index	miRNA - Post-Risk Index	Num .N="Not Applicable"
mirna_pre_bb_id	miRNA - Pre-Biobank ID	miRNA - Pre-Biobank ID	Char
mirna_pre_hemo_index	miRNA - Pre-Hemolysis Index	miRNA - Pre-Hemolysis Index	Char .N="Not Applicable"
mirna_pre_pcr_id	miRNA - Pre-PcrID	miRNA - Pre-PcrID	Num .M="Missing" .N="Not Applicable"
mirna_pre_pred	miRNA - Pre-Prediction	miRNA - Pre-Prediction	.N="Not Applicable" 0="Negative" 1="Positive"
mirna_pre_risk_index	miRNA - Pre-Risk Index	miRNA - Pre-Risk Index	Num .N="Not Applicable"

Section 46: Blood Collections

Variable	Label	Description	Format Text
bldspec_collect_dt1-3	Date blood specimen collected	Date blood specimen collected	SAS Date .M="Missing" .N="Not Applicable"
bldspec_days1-3	Day specimen drawn in study	Day specimen drawn in study	Num .M="Missing" .N="Not Applicable"
bldspec_draw_code1-3	Blood Specimen - Blood draw code	Blood Specimen - Blood draw code	Char
bldspec_hscrp1-3	hs-CRP serum (mg/dL)	hs-CRP serum (mg/dL)	Num .M="Missing" .N="Not Applicable"
bldspec_mirna_hemo1-3	miRNA hemolysis	miRNA hemolysis	Num .M="Missing" .N="Not Applicable"
bldspec_mirna_index1-3	miRNA risk index	miRNA risk index	Num .M="Missing" .N="Not Applicable"
bldspec_mirna_prediction1-3	miRNA prediction	miRNA prediction	.M="Missing" .N="Not Applicable" 0="Negative" 1="Positive"
bldspec_months1-3	Month specimen drawn in study (0/6/12)	Month specimen drawn in study (0/6/12)	Num .M="Missing" .N="Not Applicable"
bldspec_not_obt1-3	Blood Specimen - Not obtained	Blood Specimen - Not obtained	.N="Not Applicable" 0="No" 1="Yes"
bldspec_off_dt1-3	Off study date	Off study date	SAS Date .M="Missing" .N="Not Applicable"
bldspec_reason_off1-3	Reason off study	Reason off study	.M="Missing" .N="Not Applicable" 1="Study Complete" 2="Ineligible" 3="Protocol Violation" 4="Other, specify"
bldspec_thrombox1-3	Thromboxane (ng/mL) serum	Thromboxane (ng/mL) serum	Num .M="Missing" .N="Not Applicable"
bldspec_visit_dt1-3	Visit date	Visit date	SAS Date .M="Missing" .N="Not Applicable"

Section 47: Verification

Variable	Label	Description	Format Text
verif_form_dt	Form Date	Form Date	SAS Date
verif_inv_sign	Investigator Signed	Investigator Signed	1="Yes"
verif_sign_dt	Date Of Investigator's Signature	Date Of Investigator's Signature	SAS Date

Section 48: Dataset Accounting

Variable	Label	Description	Format Text
in_aeandconmedeval	In Adverse Events And Concomitant Medication Evaluation Dataset	In Adverse Events And Concomitant Medication Evaluation Dataset	0="No" 1="Yes"
in_agentinterrupt	In Agent Interrupt Dataset	In Agent Interrupt Dataset	0="No" 1="Yes"
in_agentmodification	In Agent Modification Dataset	In Agent Modification Dataset	0="No" 1="Yes"
in_basemedsurghist	In Base Medical And Surgical History Dataset	In Base Medical And Surgical History Dataset	0="No" 1="Yes"
in_basesymptoms	In Base Symptoms Dataset	In Base Symptoms Dataset	0="No" 1="Yes"
in_bioptissuehist	In Biopsy Tissue History Dataset	In Biopsy Tissue History Dataset	0="No" 1="Yes"
in_bloodchemistry	In Blood Chemistry Dataset	In Blood Chemistry Dataset	0="No" 1="Yes"
in_bloodspecimen	In Blood Specimen Dataset	In Blood Specimen Dataset	0="No" 1="Yes"
in_comments	In Comments Dataset	In Comments Dataset	0="No" 1="Yes"
in_compliance	In Compliance Dataset	In Compliance Dataset	0="No" 1="Yes"
in_compliancedruglabels	In Compliance And Drug Labels Dataset	In Compliance And Drug Labels Dataset	0="No" 1="Yes"
in_compliancephoneinterview	In Compliance And Phone Interview Dataset	In Compliance And Phone Interview Dataset	0="No" 1="Yes"
in_conmed	In Concomitant Medication Dataset	In Concomitant Medication Dataset	0="No" 1="Yes"
in_ctscannewlesions	In CT Scan New Lesions Dataset	In CT Scan New Lesions Dataset	0="No" 1="Yes"
in_ctscannontargetlesions	In CT Scan Non-Target Lesions Dataset	In CT Scan Non-Target Lesions Dataset	0="No" 1="Yes"
in_ctscannontargetlesionsv12	In CT Scan Non-Target Lesions v12 Dataset	In CT Scan Non-Target Lesions v12 Dataset	0="No" 1="Yes"
in_ctscannontargetmth3_6_12	In CT Scan Non-Target Month 3, 6, and 12 Dataset	In CT Scan Non-Target Month 3, 6, and 12 Dataset	0="No" 1="Yes"
in_ctscannontargetv12mth3_6_12	In CT Scan Non-Target v12 Month 3, 6, and 12 Dataset	In CT Scan Non-Target v12 Month 3, 6, and 12 Dataset	0="No" 1="Yes"
in_ctscantargetlesions	In CT Scan Target Lesions Dataset	In CT Scan Target Lesions Dataset	0="No" 1="Yes"
in_ctscantargetlesionsv14	In CT Scan Target Lesions v14 Dataset	In CT Scan Target Lesions v14 Dataset	0="No" 1="Yes"

Variable	Label	Description	Format Text
in_ctscantargetmth3_6_12	In CT Scan Target Month 3, 6, and 12 Dataset	In CT Scan Target Month 3, 6, and 12 Dataset	0="No" 1="Yes"
in_ctscantargetv14mth3_6_12	In CT Scan Target v14 Month 3, 6, and 12 Dataset	In CT Scan Target v14 Month 3, 6, and 12 Dataset	0="No" 1="Yes"
in_demographics	In Demographics Dataset	In Demographics Dataset	0="No" 1="Yes"
in_eligibilityverification	In Eligibility Verification Dataset	In Eligibility Verification Dataset	0="No" 1="Yes"
in_exclusioncriteriaprev12	In Exclusion Criteria Prev 12 Dataset	In Exclusion Criteria Prev 12 Dataset	0="No" 1="Yes"
in_exclusioncriteria v12	In Exclusion Criteria v12 Dataset	In Exclusion Criteria v12 Dataset	0="No" 1="Yes"
in_finalctscansummary	In Final CT Scan Summary v12 06212016 Dataset	In Final CT Scan Summary v12 06212016 Dataset	0="No" 1="Yes"
in_hematology1	In Hematology 1 Dataset	In Hematology 1 Dataset	0="No" 1="Yes"
in_hematology2	In Hematology 2 Dataset	In Hematology 2 Dataset	0="No" 1="Yes"
in_inclusioncriteria prev8	In Inclusion Criteria Pre v8 Dataset	In Inclusion Criteria Pre v8 Dataset	0="No" 1="Yes"
in_inclusioncriteria v12	In Inclusion Criteria v12 Dataset	In Inclusion Criteria v12 Dataset	0="No" 1="Yes"
in_inclusioncriteria v13	In Inclusion Criteria v13 Dataset	In Inclusion Criteria v13 Dataset	0="No" 1="Yes"
in_inclusioncriteria v8	In Inclusion Criteria v8 Dataset	In Inclusion Criteria v8 Dataset	0="No" 1="Yes"
in_interventionadmin	In Intervention Admin Dataset	In Intervention Admin Dataset	0="No" 1="Yes"
in_mirna	In miRNA Dataset	In miRNA Dataset	0="No" 1="Yes"
in_offstudy	In Offstudy Dataset	In Offstudy Dataset	0="No" 1="Yes"
in_otherlabtests	In Other Lab Tests Dataset	In Other Lab Tests Dataset	0="No" 1="Yes"
in_physicalexam	In Physical Exam Dataset	In Physical Exam Dataset	0="No" 1="Yes"
in_pregnancyspecimensdata	In Pregnancy Specimen Data Dataset	In Pregnancy Specimen Data Dataset	0="No" 1="Yes"
in_randomization	In Randomization Dataset	In Randomization Dataset	0="No" 1="Yes"
in_registration	In Registration Dataset	In Registration Dataset	0="No" 1="Yes"
in_researchblood	In Research Blood Dataset	In Research Blood Dataset	0="No" 1="Yes"
in_researchbloodmonth6	In Research Blood Month 6 Dataset	In Research Blood Month 6 Dataset	0="No" 1="Yes"

Variable	Label	Description	Format Text
in_researchurine	In Research Urine Dataset	In Research Urine Dataset	0="No" 1="Yes"
in_researchurinemo nth6	In Research Urine Month 6 Dataset	In Research Urine Month 6 Dataset	0="No" 1="Yes"
in_telephonecontact	In Telephone Contact Dataset	In Telephone Contact Dataset	0="No" 1="Yes"
in_tobaccoassessm ent	In Tobacco Assessment Dataset	In Tobacco Assessment Dataset	0="No" 1="Yes"
in_urinespecimen	In Urines Pecimen Dataset	In Urines Pecimen Dataset	0="No" 1="Yes"
in_verification	In Verification Dataset	In Verification Dataset	0="No" 1="Yes"