MDA10-16-01 - ENHANCED PERSON - 3.1: DATA DICTIONARY

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Document Title	mda10-16-01 - Enhanced Person - 3.1: Data Dictionary
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mda10-16-01 - Enhanced Person - 3.1: Data Dictionary
Section 1: Identifiers

Variable	Label	Description	Format Text
build_dt	Build Date	Build Date	SAS Date
MRNO	Participant ID (MRNO)	Participant ID (MRNO)	Char

Section 2: Study-wide

Variable	Label	Description	Format Text
ag_prov_dt	Date Study Agent was Provided - [Intervention Administration]	Date study agent was provided to the participant.	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
ag_start_dt	Date Study Agent was Started - [Intervention Administration]	Date study agent was started by the participant.	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
arm	Arm	Treatment given to the Participant: Either Placebo or DHA	0="Participant not Randomized" 1="Placebo" 2="DHA"
evaluable	Participant is Evaluable for Analysis?	Participant is Evaluable for Analysis?	0="No" 1="Yes"
randomized	Participant was Randomized? - [Randomization]	Indicates if the participant randomized into the study.	0="No" 1="Yes"
rnd_dt	Date of Randomization - [Randomization]	Date of the participant's randomization (if randomized).	SAS Date .N="N/A"
screen_dt	Date of Screening/Eligibility	Date that the participant completed study screening.	SAS Date .M="Missing"
visit_dt_v1	Date of Visit 1	Date that the participant completed study visit 1.	SAS Date .M="Missing" .R="Participant not Randomized"
visit_dt_v2	Date of Visit 2	Date that the participant completed study visit 2.	SAS Date .M="Missing" .R="Participant not Randomized"

Section 3: Demographics

Variable	Label	Description	Format Text
reg_age	Age of Participant at Registration	Age of the participant at registration. Determined by subtracting their birth year from the study registration date.	Numeric .M="Missing"
reg_ethnicity	Ethnicity - [Registration Race]	Ethnicity of the participant.	.U="Unknown" 1="Hispanic or Latino" 2="Not Hispanic or Latino"
reg_gender	Gender - [Registration Race]	Gender of the participant.	1="Female"
reg_race	Race - [Registration Race]	Race of the participant.	.M="Missing" 1="White" 2="Black or African American" 3="Asian"
reg_race_eth	Race + Ethnicity - [Registration Race]	Combination of the Race and Ethnicity variables. Participants can only be considered white or black when they are not Hispanic. If the participant is white or black and Hispanic, then they are considered Hispanic. If the participant is Asian, Pacific Islander, or American Indian then they are considered that race.	.M="Missing" 1="White, Non-Hispanic" 2="Black, Non-Hispanic" 3="Hispanic" 4="Asian"

Section 4: Registration

Variable	Label	Description	Format Text
consent_dt	Date of Consent - [Registration Race]	Date the participant consented to the study (if consented)	SAS Date
enroll_dt	Date of Enrollment - [Registration Race]	Date the participant was enrolled in the study.	SAS Date .M="Missing" .N="N/A"
reg_consent	Participant Consented to Study? - [Registration Race]	Indicates if the participant consented to the study.	1="Yes"
reg_dt	Date of Registration	Date the participant registered for the study.	SAS Date
reg_eligible	Participant Satisfies all Elligibility Criteria? - [Registration Race]	Indicates if the participant satisfied all study elligibility criteria.	0="No" 1="Yes"
reg_institution	Institution - [Registration Race]	Indicates the institution at which the participant took the study.	.M="Missing" 1="Baylor University Medical Center" 2="Columbia University Medical Center" 3="Dana Farber Cancer Institute" 4="M. D. Anderson Cancer Center"

Section 5: Screening

Variable	Label	Description	Format Text
excl_active	Any Type of Active Invasive Cancer (Excluding Breast and Non-Melanoma Skin Cancer) within the Preceding 18 Months? - [Exclusion Criteria]	Exclusion criteria: Any type of active invasive cancer (excluding breast and non-melanoma skin cancer) within the preceding 18 months?	.M="Missing" 0="No"
excl_aller	History of Allergic Reaction Attributed to of Composition to DHA or Corn/Soy Oil? - [Exclusion Criteria]	Exclusion criteria: History of allergic reaction attributed to of composition to DHA or corn/soy oil?	.M="Missing" 0="No"
excl_anticoag	History of Therapeutic Doses of Anticoagulants? - [Exclusion Criteria]	Exclusion criteria: History of therapeutic doses of anticoagulants?	.M="Missing" 0="No"
excl_aspirin	History of Daily Use of Aspirin or NSAIDs? - [Exclusion Criteria]	Exclusion criteria: History of daily use of aspirin or NSAIDs?	.M="Missing" 0="No"
excl_augmentation	History of Contralateral Breast Augmentation With Breast Implant Placement? - [Exclusion Criteria]	Exclusion criteria: History of contralateral breast augmentation with breast implant placement?	.M="Missing" 0="No"
excl_autoimmune	History of Autoimmune Disorder? - [Exclusion Criteria]	Exclusion criteria: History of autoimmune disorder?	.M="Missing" 0="No"
excl_brca_mutation	BRCA Mutation Carrier? - [Exclusion Criteria (Pre-2015)]	Exclusion criteria: BRCA mutation carrier? - Pre-2015	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
excl_chronic_illnes s	Severe Underlying Chronic Illness? - [Exclusion Criteria]	Exclusion criteria: Severe underlying chronic illness?	.M="Missing" 0="No" 1="Yes"
excl_chronic_statin	History of Chronic Statin? - [Exclusion Criteria (Pre-2015)]	Exclusion criteria: History of chronic statin? - Pre-2015	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
excl_dha	History of DHA Supplementation In the Month Preceding Study? - [Exclusion Criteria]	Exclusion criteria: History of DHA supplementation in the month preceding study?	.M="Missing" 0="No" 1="Yes"
excl_endocrine	Receiving Endocrine Therapy? - [Exclusion Criteria]	Exclusion criteria: Receiving endocrine therapy?	.M="Missing" 0="No"
excl_histologically	History of Histologically-Confirmed Bilateral Invasive Breast Cancer? - [Exclusion Criteria]	Exclusion criteria: History of histologically-confirmed bilateral invasive breast cancer?	.M="Missing" 0="No"
excl_mastectomy	Has Had Bilateral Mastectomy? - [Exclusion Criteria]	Exclusion criteria: Has had bilateral mastectomy?	.M="Missing" 0="No"

Variable	Label	Description	Format Text
excl_metastatic	History or Evidence of Metastatic Breast Cancer? - [Exclusion Criteria]	Exclusion criteria: History or evidence of metastatic breast cancer?	.M="Missing" 0="No"
excl_oth_agents	Receiving Any Other Investigational Agents? - [Exclusion Criteria]	Exclusion criteria: Receiving any other investigational agents?	.M="Missing" 0="No"
excl_pregnant	Pregnant, Breastfeeding, or of Childbearing Potential Unwilling to Use a Reliable Contraceptive? - [Exclusion Criteria]	Exclusion criteria: Pregnant, breastfeeding, or of childbearing potential unwilling to use a reliable contraceptive?	.M="Missing" 0="No"
excl_radiation	Prior Radiation Therapy or Contralateral Breast? - [Exclusion Criteria]	Exclusion criteria: Prior radiation therapy or contralateral breast?	.M="Missing" 0="No"
excl_treatment	Received Treatment of Any Cancer within 6 Months of Study? - [Exclusion Criteria]	Exclusion criteria: Received treatment of any cancer within 6 months of study?	.M="Missing" 0="No"
incl_bc_treatment	Greater than or Equal to 6 Months From All Previous Breast Cancer Treatment? - [Inclusion Criteria]	Inclusion criteria: Greater than or equal to 6 months from all previous breast cancer treatment?	.M="Missing" 0="No" 1="Yes"
incl_bmi	Body Mass Index (BMI) of 25? - [Inclusion Criteria]	Inclusion criteria: Body mass index (BMI) of 25 or more?	.M="Missing" 0="No" 1="Yes"
incl_breast_tissue	Adequate Accessible Breast Tissue as Determined by the Treating Physician, Consisting of One Breast Unaffected by Invasive Cancer, Which Has Not Been Radiated	Inclusion criteria: Adequate accessible breast tissue as determined by the treating physician, consisting of one breast unaffected by invasive cancer, which has not been radiated?	.M="Missing" 0="No" 1="Yes"
incl_comply	Willingness to Comply with All Study Interventions and Follow-Up Procedures Including the Ability to Swallow the Study Drug? - [Inclusion Criteria]	Inclusion criteria: Willingness to comply with all study interventions and follow-up procedures including the ability to swallow the study drug? - Inclusion Criteria	.M="Missing" 0="No" 1="Yes"
incl_consent	Ability to Understand and the Willingness to Sign Informed Consent Document? - [Inclusion Criteria]	Inclusion criteria: Ability to understand and the willingness to sign informed consent document?	.M="Missing" 0="No" 1="Yes"
incl_dha	Daily DHA Consumption 200 mg/Day in the Month Prior to Screening Estimated by an Abbreviated DHA Food Frequency Questionnaire? - [Inclusion Criteria]	Inclusion criteria: Daily DHA consumption 200 mg/day in the month prior to screening estimated by an abbreviated DHA food frequency questionnaire?	.M="Missing" 0="No" 1="Yes"
incl_disease	No Evidence of Disease at Trial Entry as Determined by the Investigator? - [Inclusion Criteria]	Inclusion criteria: No evidence of disease at trial entry as determined by the investigator?	.M="Missing" 0="No" 1="Yes"

Variable	Label	Description	Format Text
incl_ecog	ECOG Performance Status of 2? - [Inclusion Criteria]	Inclusion criteria: ECOG performance status of 2?	.M="Missing" 0="No" 1="Yes"
incl_gender_age	Female and Age of at Least 18? - [Inclusion Criteria]	Inclusion criteria: Female and age of at least 18?	.M="Missing" 0="No" 1="Yes"
incl_history	History of Histologically-Confirmed Stage I-III Invasive Breast Cancer, or Ductal Carcinoma in Situ (DCIS), Paget's Disease, Lobular Carcinoma in Situ (LCIS), or Pr	Inclusion criteria: History of histologically-confirmed stage I-III invasive breast cancer, or ductal carcinoma in situ (DCIS), Paget's disease, lobular carcinoma in situ (LCIS), or proliferative benign breast disease?	.M="Missing" 0="No" 1="Yes"
incl_mammogram	Mammogram within No More than 6 Months Prior to the Date of Informed Concent and No Further Routine Breast Imaging Planned during the Course of the Study? - [Incl	Inclusion criteria: Mammogram within no more than 6 months prior to the date of informed concent and no further routine breast imaging planned during the course of the study?	.M="Missing" 0="No" 1="Yes"
incl_normal	Normal Organ and Marrow Function? - [Inclusion Criteria]	Inclusion criteria: Normal organ and marrow function?	.M="Missing" 0="No" 1="Yes"
incl_pregnancy	Not Pregnant? - [Inclusion Criteria]	Inclusion criteria: Not pregnant?	.M="Missing" 0="No" 1="Yes"
screen_failure	Participant Failed Screening? - [Screening]	Indicates if the participant failed the screening process.	.F="Participant Missing from Dataset" 0="No" 1="Yes"
screen_failure_rsn	Reason for Screen Failure (if Failed) - [Screening]	Indicates the reason for screen failure (if the participant failed)	.F="Participant Missing from Dataset" .N="N/A" 1="Did not Meet Eligibility Criteria" 2="Participant Decision" 3="Other"
screen_influence	Source that Most-Influenced the Participant to Register for the Study - [Screening]	Indicates the source that most-influenced the participant to register for the study.	.F="Participant Missing from Dataset" 1="Advertisement" 2="Nurse" 3="Oncologist" 4="Clinical PR" 5="Recruitment"

Section 6: Baseline Symptoms

Variable	Label	Description	Format Text
base_grade_1-16	Grade of Severity - Symptom - [Baseline Symptoms]	Grade of severity of the specified baseline symptom (Baseline symptoms are conditions that the participant has at the start of the study)	.F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized" 1="Mild" 2="Moderate" 3="Severe" 4="Life-Threatening"
base_num	Number of Baseline Symptoms - [Baseline Symptoms]	Number of baseline symptoms the participant has (Baseline symptoms are conditions that the participant has at the start of the study)	Numeric .F="Participant Missing from Dataset" .R="Participant not Randomized"
base_onset_dt_1-16	Onset Date - Symptom - [Baseline Symptoms]	Onset date of the baseline symptom (Baseline symptoms are conditions that the participant has at the start of the study)	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"
base_symp_1-16	Type of Symptom - Symptom - [Baseline Symptoms]	Type of baseline symptom (Baseline symptoms are conditions that the participant has at the start of the study)	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 1="Allergic Rhinitis" 2="Anxiety" 3="Joint Pain/Disorders" 4="Asthma" 5="Breast and Reproductive Disorders" 6="Bruising" 7="Urinary Incontinence" 8="Fatigue" 9="Bowel Disorders" 10="Skin Disorders" 11="Sleep Disorders" 12="Throat and Mouth Disorders" 13="Digestive Disorders" 14="Depression" 15="Diabetes" 16="Eye Disorders" 17="Edema" 18="Fracture" 19="Headache/Migraine" 20="Hot Flashes" 21="Hypertension" 22="Ear/Balance Disorders" 23="Hypercholesterolemia" 24="Hypothyroidism" 25="Infection" 26="Localized Body Pain" 27="Nasal/Sinus Disorders" 28="Extremity Pain/Weakness/Tingling" 29="Obesity" 30="Palpitations" 31="Paronychia"

Variable	Label	Description	Format Text
base_symp_desc_1-16	Description of Symptom - Symptom - [Baseline Symptoms]	Description of baseline symptom type (Baseline symptoms are conditions that the participant has at the start of the study)	Char " "="Missing"

Section 7: Breast Cancer History

Variable	Label	Description	Format Text
bchist_1st_symp_dt	Date of First Symptom - [Breast Cancer History]	Date the the participant first experienced symptoms of breast cancer.	SAS Date .M="Missing" .R="Participant not Randomized"
bchist_assess_dt	Date of Assessment - [Breast Cancer History]	Date of assessment of breast cancer	SAS Date .M="Missing" .R="Participant not Randomized"
bchist_assess_method	Method of Assessment - [Breast Cancer History]	Method of assessment of breast cancer	.M="Missing" .R="Participant not Randomized" 1="Clinical" 2="Radiographic Imaging" 3="Core Biopsy" 4="Ultrasound"
bchist_con_type	Type of Histologic Confirmation - [Breast Cancer History]	Type of histologic confirmation of breast cancer	.M="Missing" .R="Participant not Randomized" 1="Benign Breast Disease" 2="Invasive Breast Cancer" 3="Premalignant Lesions"
bchist_est	Result of Test - Estrogen Receptors - [Breast Cancer History]	Result of test - Estrogen Receptors - Breast Cancer History	Numeric .M="Missing" .R="Participant not Randomized"
bchist_est_dt	Date of Hormone Receptor Testing - Estrogen Receptors - [Breast Cancer History]	Date of hormone receptor testing - Estrogen Receptors - Breast Cancer History	SAS Date .M="Missing" .R="Participant not Randomized"
bchist_est_method	Method of Testing - Estrogen Receptors - [Breast Cancer History]	Method of testing - Estrogen Receptors - Breast Cancer History	.M="Missing" .R="Participant not Randomized" 2="Radiographic Imaging" 3="Core Biopsy"
bchist_est_pct_pos	Percentage of Cells That Stained Positive for Hormone Receptors - Estrogen Receptors - [Breast Cancer History]	Percentage of cells that stained positive for hormone receptors - Estrogen Receptors - Breast Cancer History	.M="Missing" .R="Participant not Randomized" 0="0%" 2="10 - <20%" 4="30 - <40%" 5="40 - <50%" 6="50 - <60%" 8="70 - <80%" 9="80 - <90%" 10="90 - <100%" 11="100%"
bchist_grade	Grade of Cancer Severity - [Breast Cancer History]	Grade of severity of previous breast cancer	.M="Missing" .R="Participant not Randomized" 1="1" 2="1 - 2" 3="2" 4="2 - 3" 5="3"
bchist_her2	Result of Test - HER2 - [Breast Cancer History]	Result of test - HER2 - Breast Cancer History	Numeric .M="Missing" .R="Participant not Randomized"

Variable	Label	Description	Format Text
bchist_her2_allred	Allred Score - HER2 - [Breast Cancer History]	Allred Score - HER2 - Breast Cancer History	Numeric .M="Missing" .R="Participant not Randomized"
bchist_her2_dt	Date of Hormone Receptor Testing - HER2 - [Breast Cancer History]	Date of hormone receptor testing - HER2 - Breast Cancer History	SAS Date .M="Missing" .R="Participant not Randomized"
bchist_her2_method	Method of Testing - HER2 - [Breast Cancer History]	Method of testing - HER2 - Breast Cancer History	.M="Missing" .R="Participant not Randomized" 1="Clinical" 2="Radiographic Imaging" 3="Core Biopsy"
bchist_her2_pct_pos	Percentage of Cells That Stained Positive for Hormone Receptors - HER2 - [Breast Cancer History]	Percentage of cells that stained positive for hormone receptors - HER2 - Breast Cancer History	.M="Missing" .R="Participant not Randomized" 0="0%" 9="80 - <90%" 11="100%"
bchist_init_diag_dt	Date of Initial Diagnosis - [Breast Cancer History]	Date of initial diagnosis date of breast cancer	SAS Date .M="Missing" .R="Participant not Randomized"
bchist_invasive	Breast Cancer is Invasive? - [Breast Cancer History]	Breast cancer found invasive?	.M="Missing" .R="Participant not Randomized" 1="Invasive Ductal Carcinoma" 2="Invasive Lobular Carcinoma" 3="Mixed Invasive Ductal and Lobular" 4="Micro-Invasive Ductal Carcinoma Arising in a Setting of DCIS"
bchist_location	Location of Cancer - [Breast Cancer History]	Side of body breast cancer was found on	.M="Missing" .R="Participant not Randomized" 1="Left" 2="Right"
bchist_m_stage	M Stage - [Breast Cancer History]	M Stage of previous breast cancer	.M="Missing" .R="Participant not Randomized" 0="0"
bchist_n_stage	N Stage - [Breast Cancer History]	N Stage of previous breast cancer	.M="Missing" .R="Participant not Randomized" 0="0" 1="0 - 1" 2="1" 3="1 - 2" 4="2" 6="3"
bchist_premal_lesions	Premalignant Lesions and Benign Breast Disease? - [Breast Cancer History]	Participant has had premalignant lesions and benign Breast Disease?	.M="Missing" .R="Participant not Randomized" 1="Atypical Ductal Hyperplasia" 2="Atypical Lobular Hyperplasia" 3="Ductal Carcinoma in Situ" 4="Lobular Carcinoma in Situ" 5="Fibroadenoma" 6="Fibrocystic Changes" 7="Intraductal Papilloma" 8="Sclerosing Adenosis" 9="Phyllodes"
bchist_prior_dt	Date of Prior Mammogram - [Breast Cancer History]	Date of prior mammogram	SAS Date .M="Missing" .R="Participant not Randomized"

Variable	Label	Description	Format Text
bchist_prior_mam	Completed a Prior Mammogram? - [Breast Cancer History]	Indicates if the participant completed a prior mammogram	.M="Missing" .R="Participant not Randomized" 1="Yes"
bchist_prog	Result of Test - Progesterone Receptors - [Breast Cancer History]	Result of test - Progesterone Receptors - Breast Cancer History	Numeric .M="Missing" .R="Participant not Randomized"
bchist_prog_dt	Date of Hormone Receptor Testing - Progesterone Receptors - [Breast Cancer History]	Date of hormone receptor testing - Progesterone Receptors - Breast Cancer History	SAS Date .M="Missing" .R="Participant not Randomized"
bchist_prog_method	Method of Testing - Progesterone Receptors - [Breast Cancer History]	Method of testing - Progesterone Receptors - Breast Cancer History	.M="Missing" .R="Participant not Randomized" 2="Radiographic Imaging" 3="Core Biopsy"
bchist_prog_pct_pos	Percentage of Cells That Stained Positive for Hormone Receptors - Progesterone Receptors - [Breast Cancer History]	Percentage of cells that stained positive for hormone receptors - Progesterone Receptors - Breast Cancer History	.M="Missing" .R="Participant not Randomized" 0="0%" 1="1 - <10%" 2="10 - <20%" 3="20 - <30%" 4="30 - <40%" 6="50 - <60%" 7="60 - <70%" 8="70 - <80%" 9="80 - <90%" 10="90 - <100%" 11="100%"
bchist_status	Disease Status - [Breast Cancer History]	Current status of previously diagnosed breast cancer	.M="Missing" .R="Participant not Randomized" 0="No Evidence of Disease"
bchist_status_dt	Date of Disease Status - [Breast Cancer History]	Date that the current status of previously diagnosed breast cancer was determined	SAS Date .M="Missing" .R="Participant not Randomized"
bchist_t_stage	T Stage - [Breast Cancer History]	T Stage of previous breast cancer	.M="Missing" .R="Participant not Randomized" 2="1" 4="2" 6="3" 7="In Situ"
bchist_width	Width of Cancer Site (cm) - [Breast Cancer History]	Width of cancer site (cm) for previously diagnosed breast cancer	Numeric .M="Missing" .R="Participant not Randomized"

Section 8: Medical/Surgical History

Variable	Label	Description	Format Text
medhist_all_normal	All Body Systems Normal? - [Medical/Surgical History]	Indicates if all body systems were found normal in the participant's medical and surgical history.	.R="Participant not Randomized" 0="No"
medhist_aller	Any Allergies? - [Medical/Surgical History]	Indicates if the participant has any allergies.	.M="Missing" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_aller_det	Description of Allergies (If Any) - [Medical/Surgical History]	Description of any allergies the participant has.	Char " "="Missing"
medhist_breast_abn	History of Breast Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of breast abnormality	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_breast_det	Details of Breast Abnormality - [Medical/Surgical History]	Details of any breast abnormality	Char " "="Missing"
medhist_cardio_abn	History of Cardiovascualar System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of cardiovascular abnormality	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_cardio_det	Details of Cardiovascualar System Abnormality - [Medical/Surgical History]	Details of any cardiovascular system abnormality	Char " "="Missing"
medhist_derma_abn	History of Dermatologic System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of dermatologic abnormality	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_derma_det	Details of Dermatologic System Abnormality - [Medical/Surgical History]	Details of any dermatologic system abnormality	Char " "="Missing"
medhist_dm	Participant has Diabetes Mellitus? - [Comorbidities]	Participant has diabetes mellitus?	.F="Participant Missing from Dataset" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_dyslipidemia	Participant has Dyslipidemia? - [Comorbidities]	Participant has dyslipidemia?	.F="Participant Missing from Dataset" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_endometa_abn	History of Endocrine/Metabolic System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of endocrine/metabolic abnormality	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"

Variable	Label	Description	Format Text
medhist_endometa_det	Details of Endocrine/Metabolic System Abnormality - [Medical/Surgical History]	Details of any endocrine/metabolic system abnormality	Char " "="Missing"
medhist_gastro_abn	History of Gastrointestinal System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of gastrointestinal abnormality	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_gastro_det	Details of Gastrointestinal System Abnormality - [Medical/Surgical History]	Details of any gastrointestinal system abnormality	Char " "="Missing"
medhist_genit_abn	History of Genitourinary System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of genitourinary abnormality	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_genit_det	Details of Genitourinary System Abnormality - [Medical/Surgical History]	Details of any genitourinary system abnormality	Char " "="Missing"
medhist_heent_abn	History of H/E/E/N/T System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of H/E/E/N/T abnormality	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_heent_det	Details of H/E/E/N/T System Abnormality - [Medical/Surgical History]	Details of any H/E/E/N/T system abnormality	Char " "="Missing"
medhist_hemalymph_abn	History of Hematopoietic/Lymph System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of hematopoietic/lymph abnormality	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_hemalymph_det	Details of Hematopoietic/Lymph System Abnormality - [Medical/Surgical History]	Details of any hematopoietic/lymph system abnormality	Char " "="Missing"
medhist_htn	Participant has Hypertension? - [Comorbidities]	Participant has hypertension?	.F="Participant Missing from Dataset" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_muscskel_abn	History of Musculoskeletal System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of musculoskeletal abnormality	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_muscskel_det	Details of Musculoskeletal System Abnormality - [Medical/Surgical History]	Details of any musculoskeletal system abnormality	Char " "="Missing"
medhist_neck_abn	History of Neck Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of neck abnormality	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"

Variable	Label	Description	Format Text
medhist_neck_det	Details of Neck Abnormality - [Medical/Surgical History]	Details of any neck abnormality	Char " "="Missing"
medhist_neuro_abn	History of Neurological System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of neurological abnormality	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_neuro_det	Details of Neurological System Abnormality - [Medical/Surgical History]	Details of any neurological system abnormality	Char " "="Missing"
medhist_resp_abn	History of Respiratory System Abnormality? - [Medical/Surgical History]	Indicates whether or not the participant has a history of respiritory abnormality	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
medhist_resp_det	Details of Respiratory System Abnormality - [Medical/Surgical History]	Details of any respiratory system abnormality	Char " "="Missing"
medhistoth_bodysys_1	Name of Other Body System 1 - [Medical/Surgical History (Other Body Systems)]	Name of other body system 1 - Medical/Surgical History	Char " "="Missing"
medhistoth_bodysys_2	Name of Other Body System 2 - [Medical/Surgical History (Other Body Systems)]	Name of other body system 2 - Medical/Surgical History	Char " "="Missing"
medhistoth_det_1	Details of Other Body System 1 - [Medical/Surgical History (Other Body Systems)]	Details of other body system 1 - Medical/Surgical History	Char " "="Missing"
medhistoth_det_2	Details of Other Body System 2 - [Medical/Surgical History (Other Body Systems)]	Details of other body system 2 - Medical/Surgical History	Char " "="Missing"

Section 9: Previous Therapy

Variable	Label	Description	Format Text
prevther_adjuvant_ 1-9	Adjuvant or Neo-Adjuvant? - Therapy 1 - [Previous Therapy Details]	Indicates if the participant had previous breast surgery.	.F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized" 1="Adjuvant" 2="Neo-Adjuvant"
prevther_began_dt_ 1-9	Date Therapy Began - Therapy 1 - [Previous Therapy Details]	Indicates if the participant had previous chemotherapy.	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"
prevther_breast	Previous Breast Surgery? - [Previous Therapy]	Indicates if the participant had previous hormonal therapy.	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 0="No" 1="Yes"
prevther_chemo	Previous Chemotherapy? - [Previous Therapy]	Indicates if the participant had previous radiation therapy.	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 0="No" 1="Yes"
prevther_completed _dt_1-9	Date Therapy Ended - Therapy 1 - [Previous Therapy Details]	Indicates if the previous therapy result was Adjuvant or Neo-Adjuvant?	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"
prevther_details_1-9	Therapy Details - Therapy 1 - [Previous Therapy Details]	Date that the previous therapy began.	Char " "="Missing"
prevther_hormonal	Previous Hormonal Therapy? - [Previous Therapy]	Date that the previous therapy ended.	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 0="No" 1="Yes"
prevther_num	Number of Previous Therapies - [Previous Therapy Details]	Details of previous therapy.	Numeric .F="Participant Missing from Dataset" .R="Participant not Randomized"
prevther_radiation	Previous Radiation Therapy? - [Previous Therapy]	Number of previous therapies the participant completed.	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 0="No" 1="Yes"
prevther_type_1-9	Type of Therapy - Therapy 1 - [Previous Therapy Details]	Indicates the type of therapy the participant previously completed.	.F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized" 1="Breast Surgery" 2="Chemotherapy" 3="Hormonal Therapy" 4="Radiation Therapy"

Section 10: DHA Food Frequency Questionnaire

Variable	Label	Description	Format Text
dhaffq_mg_dha_d_v1	mg/DHA/d - Visit 1 - [DHA Food Frequency Questionnaire]	mg/DHA/d - DHA Food Frequency Questionnaire - Visit 1	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_mg_dha_d_v2	mg/DHA/d - Visit 2 - [DHA Food Frequency Questionnaire]	mg/DHA/d - DHA Food Frequency Questionnaire - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_mg_epa_d_v1	mg/EPA/d - Visit 1 - [DHA Food Frequency Questionnaire]	mg/EPA/d - DHA Food Frequency Questionnaire - Visit 1	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_mg_epa_d_v2	mg/EPa/d - Visit 2 - [DHA Food Frequency Questionnaire]	mg/EPa/d - DHA Food Frequency Questionnaire - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q1_dha_score_v1	Question 1 - DHA Score - Visit 1 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 1 - How many 3 oz servings of the following fish do you eat monthly?: bluefish, herring, sardines, bluefin tuna, mackerel, salmon, cisco (smoked), pollock, whitefish	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q1_dha_score_v2	Question 1 - DHA Score - Visit 2 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 2 - How many 3 oz servings of the following fish do you eat monthly?: bluefish, herring, sardines, bluefin tuna, mackerel, salmon, cisco (smoked), pollock, whitefish	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q1_epa_score_v1	Question 1 - EPA Score - Visit 1 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 1 - How many 3 oz servings of the following fish do you eat monthly?: bluefish, herring, sardines, bluefin tuna, mackerel, salmon, cisco (smoked), pollock, whitefish	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q1_epa_score_v2	Question 1 - EPA Score - Visit 2 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 2 - How many 3 oz servings of the following fish do you eat monthly?: bluefish, herring, sardines, bluefin tuna, mackerel, salmon, cisco (smoked), pollock, whitefish	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q1_serving_v1	Question 1 - Serving - Visit 1 - [DHA Food Frequency Questionnaire]	Servings - Visit 1 - How many 3 oz servings of the following fish do you eat monthly?: bluefish, herring, sardines, bluefin tuna, mackerel, salmon, cisco (smoked), pollock, whitefish	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"

Variable	Label	Description	Format Text
dhaffq_q1_serving_v2	Question 1 - Serving - Visit 2 - [DHA Food Frequency Questionnaire]	Servings - Visit 2 - How many 3 oz servings of the following fish do you eat monthly?: bluefish, herring, sardines, bluefin tuna, mackerel, salmon, cisco (smoked), pollock, whitefish	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q2_dha_score_v1	Question 2 - DHA Score - Visit 1 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 1 - How many 3 oz servings of the following fish do you eat monthly?: bass, mussels, snapper, catfish, perch, sole, drumfish, redfish, swordfish, flounder, rockfish, trout, grouper, shark, tuna (canned - 6oz)	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q2_dha_score_v2	Question 2 - DHA Score - Visit 2 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 2 - How many 3 oz servings of the following fish do you eat monthly?: bass, mussels, snapper, catfish, perch, sole, drumfish, redfish, swordfish, flounder, rockfish, trout, grouper, shark, tuna (canned - 6oz)	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q2_epa_score_v1	Question 2 - EPA Score - Visit 1 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 1 - How many 3 oz servings of the following fish do you eat monthly?: bass, mussels, snapper, catfish, perch, sole, drumfish, redfish, swordfish, flounder, rockfish, trout, grouper, shark, tuna (canned - 6oz)	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q2_epa_score_v2	Question 2 - EPA Score - Visit 2 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 2 - How many 3 oz servings of the following fish do you eat monthly?: bass, mussels, snapper, catfish, perch, sole, drumfish, redfish, swordfish, flounder, rockfish, trout, grouper, shark, tuna (canned - 6oz)	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q2_serving_v1	Question 2 - Serving - Visit 1 - [DHA Food Frequency Questionnaire]	Servings - Visit 1 - How many 3 oz servings of the following fish do you eat monthly?: bass, mussels, snapper, catfish, perch, sole, drumfish, redfish, swordfish, flounder, rockfish, trout, grouper, shark, tuna (canned - 6oz)	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"

Variable	Label	Description	Format Text
dhaffq_q2_serving_v2	Question 2 - Serving - Visit 2 - [DHA Food Frequency Questionnaire]	Servings - Visit 2 - How many 3 oz servings of the following fish do you eat monthly?: bass, mussels, snapper, catfish, perch, sole, drumfish, redfish, swordfish, flounder, rockfish, trout, grouper, shark, tuna (canned - 6oz)	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q3_dha_score_v1	Question 3 - DHA Score - Visit 1 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 1 - How many 3 oz servings of the following fish/shellfish do you eat monthly?: carp, fish patties/squares, pike, clams, fish sticks, pompano, cod, haddock, scallops, crab, lobster, shrimp (14 med), crayfish, mullet, oysters	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q3_dha_score_v2	Question 3 - DHA Score - Visit 2 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 2 - How many 3 oz servings of the following fish/shellfish do you eat monthly?: carp, fish patties/squares, pike, clams, fish sticks, pompano, cod, haddock, scallops, crab, lobster, shrimp (14 med), crayfish, mullet, oysters	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q3_epa_score_v1	Question 3 - EPA Score - Visit 1 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 1 - How many 3 oz servings of the following fish/shellfish do you eat monthly?: carp, fish patties/squares, pike, clams, fish sticks, pompano, cod, haddock, scallops, crab, lobster, shrimp (14 med), crayfish, mullet, oysters	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q3_epa_score_v2	Question 3 - EPA Score - Visit 2 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 2 - How many 3 oz servings of the following fish/shellfish do you eat monthly?: carp, fish patties/squares, pike, clams, fish sticks, pompano, cod, haddock, scallops, crab, lobster, shrimp (14 med), crayfish, mullet, oysters	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q3_serving_v1	Question 3 - Serving - Visit 1 - [DHA Food Frequency Questionnaire]	Servings - Visit 1 - How many 3 oz servings of the following fish/shellfish do you eat monthly?: carp, fish patties/squares, pike, clams, fish sticks, pompano, cod, haddock, scallops, crab, lobster, shrimp (14 med), crayfish, mullet, oysters	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"

Variable	Label	Description	Format Text
dhaffq_q3_serving_v2	Question 3 - Serving - Visit 2 - [DHA Food Frequency Questionnaire]	Servings - Visit 2 - How many 3 oz servings of the following fish/shellfish do you eat monthly?: carp, fish patties/squares, pike, clams, fish sticks, pompano, cod, haddock, scallops, crab, lobster, shrimp (14 med), crayfish, mullet, oysters	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q4_dha_score_v1	Question 4 - DHA Score - Visit 1 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 1 - How many 3 oz servings of liver (chicken, turkey, or beef) do you eat monthly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q4_dha_score_v2	Question 4 - DHA Score - Visit 2 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 2 - How many 3 oz servings of liver (chicken, turkey, or beef) do you eat monthly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q4_epa_score_v1	Question 4 - EPA Score - Visit 1 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 1 - How many 3 oz servings of liver (chicken, turkey, or beef) do you eat monthly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q4_epa_score_v2	Question 4 - EPA Score - Visit 2 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 2 - How many 3 oz servings of liver (chicken, turkey, or beef) do you eat monthly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q4_serving_v1	Question 4 - Serving - Visit 1 - [DHA Food Frequency Questionnaire]	Servings - Visit 1 - How many 3 oz servings of liver (chicken, turkey, or beef) do you eat monthly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q4_serving_v2	Question 4 - Serving - Visit 2 - [DHA Food Frequency Questionnaire]	Servings - Visit 2 - How many 3 oz servings of liver (chicken, turkey, or beef) do you eat monthly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q5_dha_score_v1	Question 5 - DHA Score - Visit 1 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 1 - How many egg yolks do you eat weekly (including egg yolks used in cooking)?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q5_dha_score_v2	Question 5 - DHA Score - Visit 2 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 2 - How many egg yolks do you eat weekly (including egg yolks used in cooking)?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q5_epa_score_v1	Question 5 - EPA Score - Visit 1 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 1 - How many egg yolks do you eat weekly (including egg yolks used in cooking)?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q5_epa_score_v2	Question 5 - EPA Score - Visit 2 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 2 - How many egg yolks do you eat weekly (including egg yolks used in cooking)?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q5_serving_v1	Question 5 - Serving - Visit 1 - [DHA Food Frequency Questionnaire]	Servings - Visit 1 - How many egg yolks do you eat weekly (including egg yolks used in cooking)?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"

Variable	Label	Description	Format Text
dhaffq_q5_serving_v2	Question 5 - Serving - Visit 2 - [DHA Food Frequency Questionnaire]	Servings - Visit 2 - How many egg yolks do you eat weekly (including egg yolks used in cooking)?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q6_dha_score_v1	Question 6 - DHA Score - Visit 1 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 1 - How many 3 oz servings of chicken, turkey or other poultry (not including livers) do you eat weekly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q6_dha_score_v2	Question 6 - DHA Score - Visit 2 - [DHA Food Frequency Questionnaire]	DHA Score - Visit 2 - How many 3 oz servings of chicken, turkey or other poultry (not including livers) do you eat weekly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q6_epa_score_v1	Question 6 - EPA Score - Visit 1 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 1 - How many 3 oz servings of chicken, turkey or other poultry (not including livers) do you eat weekly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q6_epa_score_v2	Question 6 - EPS Score - Visit 2 - [DHA Food Frequency Questionnaire]	EPA Score - Visit 2 - How many 3 oz servings of chicken, turkey or other poultry (not including livers) do you eat weekly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q6_serving_v1	Question 6 - Serving - Visit 1 - [DHA Food Frequency Questionnaire]	Servings - Visit 1 - How many 3 oz servings of chicken, turkey or other poultry (not including livers) do you eat weekly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q6_serving_v2	Question 6 - Serving - Visit 2 - [DHA Food Frequency Questionnaire]	Servings - Visit 2 - How many 3 oz servings of chicken, turkey or other poultry (not including livers) do you eat weekly?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q7_frequency_v1	Question 7 - Frequency - Visit 1 - [DHA Food Frequency Questionnaire]	Frequency - Visit 1 - Any omega-3 dietary supplements (i.e., flax, fish oil, Neuromins, DHA Gold)?	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 1="Day" 2="Week" 3="Month"
dhaffq_q7_frequency_v2	Question 7 - Frequency - Visit 2 - [DHA Food Frequency Questionnaire]	Frequency - Visit 2 - Any omega-3 dietary supplements (i.e., flax, fish oil, Neuromins, DHA Gold)?	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 1="Day" 3="Month"
dhaffq_q7_serving_v1	Question 7 - Serving - Visit 1 - [DHA Food Frequency Questionnaire]	Serving - Visit 1 - Any omega-3 dietary supplements (i.e., flax, fish oil, Neuromins, DHA Gold)?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_q7_serving_v2	Question 7 - Serving - Visit 2 - [DHA Food Frequency Questionnaire]	Serving - Visit 2 - Any omega-3 dietary supplements (i.e., flax, fish oil, Neuromins, DHA Gold)?	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"

Variable	Label	Description	Format Text
dhaffq_subtotal_dha_v1	Subtotal DHA - Visit 1 - [DHA Food Frequency Questionnaire]	Subtotal DHA - DHA Food Frequency Questionnaire - Visit 1	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_subtotal_dha_v2	Subtotal DHA - Visit 2 - [DHA Food Frequency Questionnaire]	Subtotal DHA - DHA Food Frequency Questionnaire - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_subtotal_epa_v1	Subtotal EPA - Visit 1 - [DHA Food Frequency Questionnaire]	Subtotal EPA - DHA Food Frequency Questionnaire - Visit 1	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_subtotal_epa_v2	Subtotal EPA - Visit 2 - [DHA Food Frequency Questionnaire]	Subtotal EPA - DHA Food Frequency Questionnaire - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_total_dha_v1	Total DHA - Visit 1 - [DHA Food Frequency Questionnaire]	Total DHA - DHA Food Frequency Questionnaire - Visit 1	Numeric .F="Participant Missing from Dataset" .R="Participant not Randomized"
dhaffq_total_dha_v2	Total DHA - Visit 2 - [DHA Food Frequency Questionnaire]	Total DHA - DHA Food Frequency Questionnaire - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_total_epa_v1	Total EPA - Visit 1 - [DHA Food Frequency Questionnaire]	Total EPA - DHA Food Frequency Questionnaire - Visit 1	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
dhaffq_total_epa_v2	Total EPA - Visit 2 - [DHA Food Frequency Questionnaire]	Total EPA - DHA Food Frequency Questionnaire - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"

Section 11: Anthropometry

Variable	Label	Description	Format Text
pe_bmi_v1	BMI - Visit 1 - [Physical Examination]	BMI of the participant at visit 1.	Numeric .M="Missing" .R="Participant not Randomized"
pe_bmi_v2	BMI - Visit 2 - [Physical Examination]	BMI of the participant at visit 2.	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
pe_diastolic_v1	Diastolic Blood Pressure (mmhg) - Visit 1 - [Physical Examination]	Diastolic blood pressure (mmHg) of the participant at visit 1.	Numeric .M="Missing" .R="Participant not Randomized"
pe_diastolic_v2	Diastolic Blood Pressure (mmhg) - Visit 2 - [Physical Examination]	Diastolic blood pressure (mmHg) of the participant at visit 2.	Numeric .M="Missing" .R="Participant not Randomized"
pe_ecog_v1	ECOG Performance Status - Visit 1 - [Physical Examination]	ECOG performance status of the participant at visit 1.	Numeric .M="Missing" .R="Participant not Randomized"
pe_ecog_v2	ECOG Performance Status - Visit 2 - [Physical Examination]	ECOG performance status of the participant at visit 2.	Numeric .M="Missing" .R="Participant not Randomized"
pe_height_v1	Height - Visit 1 - [Physical Examination]	Height of the participant at visit 1.	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
pe_height_v2	Height - Visit 2 - [Physical Examination]	Height of the participant at visit 2.	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
pe_pulse_rate_v1	Pulse Rate - Visit 1 - [Physical Examination]	Pulse rate of the participant at visit 1.	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
pe_pulse_rate_v2	Pulse Rate - Visit 2 - [Physical Examination]	Pulse rate of the participant at visit 2.	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
pe_resp_rate_v1	Respiration Rate - Visit 1 - [Physical Examination]	Respiration rate of the participant at visit 1.	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
pe_resp_rate_v2	Respiration Rate - Visit 2 - [Physical Examination]	Respiration rate of the participant at visit 2.	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
pe_systolic_v1	Systolic Blood Pressure (mmhg) - Visit 1 - [Physical Examination]	Systolic blood pressure (mmHg) of the participant at visit 1.	Numeric .M="Missing" .R="Participant not Randomized"

Variable	Label	Description	Format Text
pe_systolic_v2	Systolic Blood Pressure (mmhg) - Visit 2 - [Physical Examination]	Systolic blood pressure (mmHg) of the participant at visit 2.	Numeric .M="Missing" .R="Participant not Randomized"
pe_temp_v1	Temperature (C) - Visit 1 - [Physical Examination]	Body temperature (C) of the participant at visit 1.	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
pe_temp_v2	Temperature (C) - Visit 2 - [Physical Examination]	Body temperature (C) of the participant at visit 2.	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
pe_weight_v1	Weight (kg) - Visit 1 - [Physical Examination]	Body weight (kg) of the participant at visit 1.	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
pe_weight_v2	Weight (kg) - Visit 2 - [Physical Examination]	Body weight (kg) of the participant at visit 2.	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"

Section 12: Adverse Events

Variable	Label	Description	Format Text
ae_num	Number of Adverse Events the Participant Experienced During the Study - [Adverse Events]	Number of adverse events experienced during the study	Numeric .R="Participant not Randomized"

Section 13: Concomitant Medications

Variable	Label	Description	Format Text
conmed_dose_1-17	Dosage - Medication 1 - [Concomitant Medications]	Dosage of the specified concomitant medication.	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" .U="Unknown"
conmed_end_dt_1-17	Date Medication was Ended - Medication 1 - [Concomitant Medications]	Date that the specified concomitant medication was ended.	SAS Date .C="Continuing" .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized" .U="Unknown"
conmed_freq_1-17	Frequency - Medication 1 - [Concomitant Medications]	Frequency of the specified concomitant medication.	.F="Participant Missing from Dataset" .N="No Concomitant Medications Taken" .R="Participant not Randomized" .U="Unknown" 1="As Needed (PRN)" 2="At Bedtime (HS)" 3="Every 3 Hours (Q3H)" 4="Every 6 Hours (Q6H)" 5="Every Day (QD)" 6="Every Evening (QPM)" 7="Every Morning (QAM)" 8="Every Other Day (QOD)" 9="Every Week (QW)" 10="Four Times Daily (QID)" 11="One Time (1X)" 12="Three Per Week (TIW)" 13="Three Times Daily (TID)" 14="Twice Daily (BID)" 15="Twice Per Week (BIW)" 16="Every 30 Days" 17="Every Four Hours"
conmed_name_1-17	Medication Name - Medication 1 - [Concomitant Medications]	Name of the concomitant medication being used by the participant.	Char " "="Missing"
conmed_num	Number of Concomitant Medications Taken - [Concomitant Medications]	Number of concomitant medications that are taken by the participant	Numeric .F="Participant Missing from Dataset" .R="Participant not Randomized"
conmed_reason_1-17	Reason Medication Taken - Medication 1 - [Concomitant Medications]	Reason the participant is taking the indicated concomitant medication	Char " "="Missing"
conmed_rpt_dt_1-17	Date Medication was Reported - Medication 1 - [Concomitant Medications]	Date that the specified concomitant medication was reported.	SAS Date .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"

Variable	Label	Description	Format Text
conmed_start_dt_1-17	Date Medication was Started - Medication 1 - [Concomitant Medications]	Date that the specified concomitant medication was started.	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized" .U="Unknown"
conmed_units_1-17	Units - Medication 1 - [Concomitant Medications]	Units of measure for the dosage of the specified concomitant medication.	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" .U="Unknown" 1="Application (App)" 2="Capsule (Cap)" 3="Gram (G)" 4="Milliliter (mL)" 5="Percent (%)" 6="Puff Dosing Unit (Puff)" 7="Tablespoon Dosing Unit (tbs)" 8="Teaspoon Dosing Unit (tsp)" 9="Tablet (Tab)" 10="Unit Dose (Units)" 11="Drop (gtt)" 12="International Unit (IU)" 13="Microgram (µg)" 14="Milligram (mg)" 15="Spray" 16="Dose/Unit" 17="Patch"

Section 14: Physical Examination

Variable	Label	Description	Format Text
pe_abdom_abn_v1	Abdomen Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's abdomen was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_abdom_abn_v2	Abdomen Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's abdomen was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_app_abn_v1	Appearance Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's appearance was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_app_abn_v2	Appearance Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's appearance was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_breast_abn_v1	Breasts Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's breasts were found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_breast_abn_v2	Breasts Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's breasts were found abnormal at visit 2.	.M="Missing" .R="Participant not Randomized" 0="No"
pe_chest_abn_v1	Chest Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's chest was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_chest_abn_v2	Chest Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's chest was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_genit_abn_v1	Genitalia Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's genitalia was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_genit_abn_v2	Genitalia Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's genitalia was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized"
pe_heart_abn_v1	Heart Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's heart was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_heart_abn_v2	Heart Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's heart was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"

Variable	Label	Description	Format Text
pe_heent_abn_v1	H/E/E/N/T Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's H/E/E/N/T system was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_heent_abn_v2	H/E/E/N/T Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's H/E/E/N/T system was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_lung_abn_v1	Lungs Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's lungs were found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_lung_abn_v2	Lungs Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's lungs were found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_lymph_abn_v1	Lymph Nodes Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's lymph nodes were found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_lymph_abn_v2	Lymph Nodes Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's lymph nodes were found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_muscskel_abn_v1	Musculoskeletal System Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's musculoskeletal system was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_muscskel_abn_v2	Musculoskeletal System Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's musculoskeletal system was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_neuro_abn_v1	Neurological System Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's neurological system was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_neuro_abn_v2	Neurological System Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's neurological system was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_pelvis_abn_v1	Pelvis Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's pelvis was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_pelvis_abn_v2	Pelvis Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's pelvis was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_rectal_abn_v1	Rectal System Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's rectal system was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_rectal_abn_v2	Rectal System Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's rectal system was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized"

Variable	Label	Description	Format Text
pe_skin_abn_v1	Skin Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's skin was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_skin_abn_v2	Skin Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's skin was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_thyroid_abn_v1	Thyroid Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's thyroid was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_thyroid_abn_v2	Thyroid Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's thyroid was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_vasc_abn_v1	Vascular System Found Abnormal? - Visit 1 - [Physical Examination]	Indicates if the participant's vascular system was found abnormal at visit 1.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
pe_vasc_abn_v2	Vascular System Found Abnormal? - Visit 2 - [Physical Examination]	Indicates if the participant's vascular system was found abnormal at visit 2.	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"

Section 15: Agent Interruption

Variable	Label	Description	Format Text
agint_restart_dt_1-4	Date Agent Restarted (If Restarted) - Interruption 1 - [Agent Interruption]	Date the study agent was restarted (if restarted) after an interruption.	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"
agint_restart_rsn_1-4	Reason Agent Restarted (If Restarted) - Interruption 1 - [Agent Interruption]	Reason the study agent was restarted (if restarted) after an interruption.	.F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized" 1="Participant Decision" 2="Investigator Decision"
agint_stop_dt_1-4	Date Agent Stopped - Interruption 1 - [Agent Interruption]	Date the study agent was stopped.	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"
agint_stop_rsn_1-4	Reason Agent Stopped - Interruption 1 - [Agent Interruption]	Reason the study agent was stopped.	.F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized" 1="Participant Decision" 3="Adverse Event" 4="Other"

Section 16: Compliance

Variable	Label	Description	Format Text
comp_amt_missing	Amount of Study Agent Missing - [Compliance]	Amount of the study agent that was missing when checking for compliance.	Numeric .F="Participant Missing from Dataset" .R="Participant not Randomized" .U="Unknown"
comp_amt_provided	Amount of Study Agent Provided - [Compliance]	Amount of the study agent that was provided when checking for compliance.	Numeric .F="Participant Missing from Dataset" .R="Participant not Randomized" .U="Unknown"
comp_amt_returned	Amount of Study Agent Returned - [Compliance]	Amount of the study agent that was returned when checking for compliance.	Numeric .F="Participant Missing from Dataset" .R="Participant not Randomized" .U="Unknown"
comp_amt_taken	Amount of Study Agent Taken - [Compliance]	Amount of the study agent that was taken when checking for compliance.	Numeric .F="Participant Missing from Dataset" .R="Participant not Randomized" .U="Unknown"
comp_compliant	Participant Compliant Throughout the Study? - [Compliance]	Indicates whether the participant was compliant throughout the study.	.F="Participant Missing from Dataset" .R="Participant not Randomized" .U="Unknown" 0="No" 1="Yes"
comp_first_dose_dt	Date First Dose was Taken - [Compliance]	Date that the first dose of the study agent was taken.	SAS Date .F="Participant Missing from Dataset" .R="Participant not Randomized"
comp_last_dose_dt	Date Last Dose was Taken - [Compliance]	Date that the last dose of the study agent was taken.	SAS Date .F="Participant Missing from Dataset" .R="Participant not Randomized"
comp_num_ints	Number of Interruptions - [Compliance]	Number of times study agent use was interrupted throughout the study.	Numeric .F="Participant Missing from Dataset" .R="Participant not Randomized"
comp_rsn	Reason for Non-Compliance - [Compliance]	Reason for Non-Compliance	Char " "="Missing"

Section 17: Off Study

Variable	Label	Description	Format Text
off_ae	No Adverse Events during Study? - [Off Study]	Indicates if the participant went through the whole study without experiencing any adverse events.	.M="Missing" 0="No" 1="Yes"
off_conmed	No Concomitant Medications during Study? - [Off Study]	Indicates if the participant went through the whole study without taking any concomitant medications.	.M="Missing" 0="No" 1="Yes"
off_last_agent_dt	Date Last Study Agent Taken - [Off Study]	Date that the last study agent was taken.	SAS Date .M="Missing"
off_last_contact_dt	Date of Last Contact - [Off Study]	Date of last contact the study had with the participant.	SAS Date .M="Missing"
off_rsn	Reason off Study - [Off Study]	General reason for why the participant left the study.	1="Study Complete" 2="Ineligible" 3="Adverse Event" 5="Participant Withdrawal" 7="Protocol Violation" 8="Other"
off_rsn_exp	Reason off Study (Explanation) - [Off Study]	Explanation for why the participant left the study.	Char " "="Missing"
off_study_dt	Date off Study - [Off Study]	Date the participant went off the study.	SAS Date

Section 18: Telephone Contact

Variable	Label	Description	Format Text
telephone_ae_resolved	Adverse Events(s) were Resolved? - [Telephone Contact]	Indicates if adverse events that were occuring at the end of study agent use resolved by last telephone contact date?	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 1="Yes"
telephone_dt	Date of Telephone Contact - [Telephone Contact]	Date of telephone contact with the participant.	SAS Date .F="Participant Missing from Dataset" .R="Participant not Randomized"
telephone_rpt_ae	Did Participant Report Adverse Events(s) Related to DHA at Visit 2? - [Telephone Contact]	Indicates if the participant reported AE(s) related to DHA at visit 2.	.F="Participant Missing from Dataset" .R="Participant not Randomized" 0="No" 1="Yes"
telephone_scheduled	Was Participant Scheduled for Follow-up Visit with Oncologist? - [Telephone Contact]	Indicates if the participant scheduled for a follow up visit with an oncologist.	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"

Section 19: QPCR

Variable	Label	Description	Format Text
qpcr_aromatase_v1	Aromatase - Visit 1 - QPCR	Result of Aromatase test at visit 1.	Numeric .I="Inevaluable" .N="N/A" .R="Participant not Randomized"
qpcr_aromatase_v2	Aromatase - Visit 2 - QPCR	Result of Aromatase test at visit 2.	Numeric .I="Inevaluable" .N="N/A" .R="Participant not Randomized"
qpcr_cox2_v1	Cox2 - Visit 1 - QPCR	Result of Cox2 test at visit 1.	Numeric .I="Inevaluable" .N="N/A" .R="Participant not Randomized"
qpcr_cox2_v2	Cox2 - Visit 2 - QPCR	Result of Cox2 test at visit 2.	Numeric .I="Inevaluable" .N="N/A" .R="Participant not Randomized"
qpcr_il1b_v1	IL1b - Visit 1 - QPCR	Result of IL 1beta test at visit 1.	Numeric .I="Inevaluable" .N="N/A" .R="Participant not Randomized"
qpcr_il1b_v2	IL1b - Visit 2 - QPCR	Result of IL 1beta test at visit 2.	Numeric .I="Inevaluable" .R="Participant not Randomized"
qpcr_plateno_v1	Plate Number - Visit 1 - QPCR	Plate Number at visit 1.	Numeric .I="Inevaluable" .R="Participant not Randomized"
qpcr_plateno_v2	Plate Number - Visit 2 - QPCR	Plate Number at visit 2.	Numeric .I="Inevaluable" .R="Participant not Randomized"
qpcr_tnfa_v1	TNFa - Visit 1 - QPCR	Result of TNF alpha test at visit 1.	Numeric .I="Inevaluable" .N="N/A" .R="Participant not Randomized"
qpcr_tnfa_v2	TNFa - Visit 2 - QPCR	Result of TNF alpha test at visit 2.	Numeric .I="Inevaluable" .R="Participant not Randomized"

Section 20: Tissue Core Biopsy 1

Variable	Label	Description	Format Text
specimen_ID_post	Specimen ID - Post	Specimen ID - Post-Treatment	Numeric .R="Participant not Randomized"
specimen_ID_pre	Specimen ID - Pre	Specimen ID - Pre-Treatment	Numeric .R="Participant not Randomized"
tcb1_histology_v1	Histologic Type - Visit 1 - [Breast Tissue Histology V1]	Histologic Type - Breast Tissue Histology - Visit 1	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 0="Benign Tissue" 1="Fibrosis/Hyperplasia"
tcb1_histology_v2	Histologic Type - Visit 2 - [Breast Tissue Histology V2]	Histologic Type - Breast Tissue Histology - Visit 2	.C="Not Assessed Due to Non-Compliance" .F="Participant Missing from Dataset" .R="Participant not Randomized" 0="Benign Tissue" 1="Fibrosis/Hyperplasia"
tcb1_lmp_dt_v1	Date of LMP - Visit 1 - [Breast Tissue Histology V1]	Date of LMP - Breast Tissue Histology - Visit 1	SAS Date .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
tcb1_lmp_dt_v2	Date of LMP - Visit 2 - [Breast Tissue Histology V2]	Date of LMP - Breast Tissue Histology - Visit 2	SAS Date .C="Not Assessed Due to Non-Compliance" .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
tcb1_location_v1	Side of Body that Breast Specimen Came from - Visit 1 - [Breast Tissue Histology V1]	Indicates the side of the body that the breast specimen came from - Breast Tissue Histology - Visit 1	.F="Participant Missing from Dataset" .R="Participant not Randomized" 1="Left" 2="Right"
tcb1_location_v2	Side of Body that Breast Specimen Came from - Visit 2 - [Breast Tissue Histology V2]	Indicates the side of the body that the breast specimen came from - Breast Tissue Histology - Visit 2	.C="Not Assessed Due to Non-Compliance" .F="Participant Missing from Dataset" .R="Participant not Randomized" 1="Left" 2="Right"

Section 21: Tissue Core Biopsy 2

Variable	Label	Description	Format Text
tcb2_formalin_v1	Specimen is Formalin-fixed? - Visit 1 - [Tissue Core Biopsy 2]	Indicates if the specimen is Formalin-fixed - Tissue Core Biopsy 2 - Visit 1	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 0="No" 1="Yes"
tcb2_formalin_v2	Specimen is Formalin-fixed? - Visit 2 - [Tissue Core Biopsy 2]	Indicates if the specimen is Formalin-fixed - Tissue Core Biopsy 2 - Visit 2	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 0="No" 1="Yes"
tcb2_location_v1	Side of Body that Tissue was Taken From - Visit 1 - [Tissue Core Biopsy 2]	Indicates the side of the body that the tissue core was taken from - Tissue Core Biopsy 2 - Visit 1	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 1="Left" 2="Right"
tcb2_location_v2	Side of Body that Tissue was Taken From - Visit 2 - [Tissue Core Biopsy 2]	Indicates the side of the body that the tissue core was taken from - Tissue Core Biopsy 2 - Visit 2	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 1="Left" 2="Right"
tcb2_rec_dt_v1	Date Received - Visit 1 - [Tissue Core Biopsy 2]	Date the tissue core was received - Tissue Core Biopsy 2 - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb2_rec_dt_v2	Date Received - Visit 2 - [Tissue Core Biopsy 2]	Date the tissue core was received - Tissue Core Biopsy 2 - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb2_ship_dt_v1	Date of Shipment - Visit 1 - [Tissue Core Biopsy 2]	Date of shipment of the tissue core - Tissue Core Biopsy 2 - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"
tcb2_ship_dt_v2	Date of Shipment - Visit 2 - [Tissue Core Biopsy 2]	Date of shipment of the tissue core - Tissue Core Biopsy 2 - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"

Section 22: Tissue Core Biopsy 3 Through 6

Variable	Label	Description	Format Text
tcb3thru6_location_v1	Side of Body that Tissue was Taken From - Visit 1 - [Tissue Core Biopsy 3-6]	Indicates the side of the body that the tissue core was taken from - Tissue Core Biopsy 3 Through 6 - Visit 1	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 1="Left" 2="Right"
tcb3thru6_location_v2	Side of Body that Tissue was Taken From - Visit 2 - [Tissue Core Biopsy 3-6]	Indicates the side of the body that the tissue core was taken from - Tissue Core Biopsy 3 Through 6 - Visit 2	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 1="Left" 2="Right"
tcb3thru6_rec_dt_v1	Date Received - Visit 1 - [Tissue Core Biopsy 3-6]	Date the tissue cores were received - Tissue Core Biopsy 3 Through 6 - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb3thru6_rec_dt_v2	Date Received - Visit 2 - [Tissue Core Biopsy 3-6]	Date the tissue cores were received - Tissue Core Biopsy 3 Through 6 - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb3thru6_rna_dt_v1	Date Specimen Placed in Conical Tube - Visit 1 - [Tissue Core Biopsy 3-6]	Date specimen placed in conical tube - Tissue Core Biopsy 3 Through 6 - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb3thru6_rna_dt_v2	Date Specimen Placed in Conical Tube - Visit 2 - [Tissue Core Biopsy 3-6]	Date specimen placed in conical tube - Tissue Core Biopsy 3 Through 6 - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb3thru6_rna_v1	RNA Storage Temperature (C) - Visit 1 - [Tissue Core Biopsy 3-6]	RNA storage temperature (C) - Tissue Core Biopsy 3 Through 6 - Visit 1	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb3thru6_rna_v2	RNA Storage Temperature (C) - Visit 2 - [Tissue Core Biopsy 3-6]	RNA storage temperature (C) - Tissue Core Biopsy 3 Through 6 - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb3thru6_rnalater_dt_v1	Date Specimen Placed in RNAlater - Visit 1 - [Tissue Core Biopsy 3-6]	Date that the tissue core specimen was placed in RNAlater - Tissue Core Biopsy 3 Through 6 - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb3thru6_rnalater_dt_v2	Date Specimen Placed in RNAlater - Visit 2 - [Tissue Core Biopsy 3-6]	Date that the tissue core specimen was placed in RNAlater - Tissue Core Biopsy 3 Through 6 - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb3thru6_rnalater_v1	RNAlater Storage Temperature (C) - Visit 1 - [Tissue Core Biopsy 3-6]	RNAlater storage temperature (C) - Tissue Core Biopsy 3 Through 6 - Visit 1	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"

Variable	Label	Description	Format Text
tcb3thru6_rnalater_v2	RNAlater Storage Temperature (C) - Visit 2 - [Tissue Core Biopsy 3-6]	RNAlater storage temperature (C) - Tissue Core Biopsy 3 Through 6 - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb3thru6_ship_dt_v1	Date of Shipment - Visit 1 - [Tissue Core Biopsy 3-6]	Date of shipment - Tissue Core Biopsy 3 Through 6 - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"
tcb3thru6_ship_dt_v2	Date of Shipment - Visit 2 - [Tissue Core Biopsy 3-6]	Date of shipment - Tissue Core Biopsy 3 Through 6 - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"

Section 23: Tissue Core Biopsy 7

Variable	Label	Description	Format Text
tcb7_location_v1	Side of Body that Tissue was Taken From - Visit 1 - [Tissue Core Biopsy 7]	Side of body that tissue core was taken from - Tissue Core Biopsy 7 - Visit 1	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 1="Left" 2="Right"
tcb7_location_v2	Side of Body that Tissue was Taken From - Visit 2 - [Tissue Core Biopsy 7]	Side of body that tissue core was taken from - Tissue Core Biopsy 7 - Visit 2	.F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized" 1="Left" 2="Right"
tcb7_rec_dt_v1	Date Received - Visit 1 - [Tissue Core Biopsy 7]	Date that the tissue core was received - Tissue Core Biopsy 7 - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb7_rec_dt_v2	Date Received - Visit 2 - [Tissue Core Biopsy 7]	Date that the tissue core was received - Tissue Core Biopsy 7 - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb7_rna_dt_v1	Date Specimen Placed in Conical Tube - Visit 1 - [Tissue Core Biopsy 7]	Date specimen placed in conical tube - Tissue Core Biopsy 7 - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb7_rna_dt_v2	Date Specimen Placed in Conical Tube - Visit 2 - [Tissue Core Biopsy 7]	Date specimen placed in conical tube - Tissue Core Biopsy 7 - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb7_rna_v1	RNA Storage Temperature (C) - Visit 1 - [Tissue Core Biopsy 7]	RNA storage temperature (C) - Tissue Core Biopsy 7 - Visit 1	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb7_rna_v2	RNA Storage Temperature (C) - Visit 2 - [Tissue Core Biopsy 7]	RNA storage temperature (C) - Tissue Core Biopsy 7 - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb7_rnalater_dt_v1	Date Specimen Placed in RNAlater - Visit 1 - [Tissue Core Biopsy 7]	Date that the tissue core specimen was placed in RNAlater - Tissue Core Biopsy 7 - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb7_rnalater_dt_v2	Date Specimen Placed in RNAlater - Visit 2 - [Tissue Core Biopsy 7]	Date that the tissue core specimen was placed in RNAlater - Tissue Core Biopsy 7 - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb7_rnalater_v1	RNAlater Storage Temperature (C) - Visit 1 - [Tissue Core Biopsy 7]	RNAlater storage temperature (C) - Tissue Core Biopsy 7 - Visit 1	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"

Variable	Label	Description	Format Text
tcb7_rnalater_v2	RNAlater Storage Temperature (C) - Visit 2 - [Tissue Core Biopsy 7]	RNAlater storage temperature (C) - Tissue Core Biopsy 7 - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
tcb7_ship_dt_v1	Date of Shipment - Visit 1 - [Tissue Core Biopsy 7]	Date of shipment - Tissue Core Biopsy 7 - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"
tcb7_ship_dt_v2	Date of Shipment - Visit 2 - [Tissue Core Biopsy 7]	Date of shipment - Tissue Core Biopsy 7 - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"

Section 24: Lipids

Variable	Label	Description	Format Text
lipids_alpha_linolenic_diff	Alpha Linolenic (%) - Differential - [Lipids]	Alpha Linolenic % from lipids tests - Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_alpha_linolenic_v1	Alpha Linolenic (%) - Visit 1 - [Lipids]	Alpha Linolenic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_alpha_linolenic_v2	Alpha Linolenic (%) - Visit 2 - [Lipids]	Alpha Linolenic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_analysis_dt	Date of Analysis - [Lipids]	Date of Lipid Analysis	SAS Date .I="Inevaluable" .R="Participant not Randomized"
lipids_arachidic_diff	Arachidic (%) - Differential - [Lipids]	Arachidic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_arachidic_v1	Arachidic (%) - Visit 1 - [Lipids]	Arachidic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_arachidic_v2	Arachidic (%) - Visit 2 - [Lipids]	Arachidic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_arachidonic_diff	Arachidonic (%) - Differential - [Lipids]	Arachidonic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_arachidonic_v1	Arachidonic (%) - Visit 1 - [Lipids]	Arachidonic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_arachidonic_v2	Arachidonic (%) - Visit 2 - [Lipids]	Arachidonic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_behenic_diff	Behenic (%) - Differential - [Lipids]	Behenic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_behenic_v1	Behenic (%) - Visit 1 - [Lipids]	Behenic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_behenic_v2	Behenic (%) - Visit 2 - [Lipids]	Behenic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_dihomo_g_linolenic_diff	Dihomo G Linolenic (%) - Differential - [Lipids]	Dihomo G Linolenic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_dihomo_g_linolenic_v1	Dihomo G Linolenic (%) - Visit 1 - [Lipids]	Dihomo G Linolenic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"

Variable	Label	Description	Format Text
lipids_dihomo_g_lin olenic_v2	Dihomo G Linolenic (%) - Visit 2 - [Lipids]	Dihomo G Linolenic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosahexae noic_diff	Docosahexaenoic (%) - Differential - [Lipids]	Docosahexaenoic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosahexae noic_v1	Docosahexaenoic (%) - Visit 1 - [Lipids]	Docosahexaenoic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosahexae noic_v2	Docosahexaenoic (%) - Visit 2 - [Lipids]	Docosahexaenoic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosapenta enoic_n3_diff	Docosatetraenoic n3 (%) - Differential - [Lipids]	Docosatetraenoic n3 from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosapenta enoic_n3_v1	Docosapentaenoic n3 (%) - Visit 1 - [Lipids]	Docosapentaenoic n3 % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosapenta enoic_n3_v2	Docosapentaenoic n3 (%) - Visit 2 - [Lipids]	Docosapentaenoic n3 % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosapenta enoic_n6_diff	Docosatetraenoic n6 (%) - Differential - [Lipids]	Docosatetraenoic n6 from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosapenta enoic_n6_v1	Docosapentaenoic n6 (%) - Visit 1 - [Lipids]	Docosapentaenoic n6 % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosapenta enoic_n6_v2	Docosapentaenoic n6 (%) - Visit 2 - [Lipids]	Docosapentaenoic n6 % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosatetrae noic_diff	Docosatetraenoic (%) - Differential - [Lipids]	Docosatetraenoic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosatetrae noic_v1	Docosatetraenoic (%) - Visit 1 - [Lipids]	Docosatetraenoic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_docosatetrae noic_v2	Docosatetraenoic (%) - Visit 2 - [Lipids]	Docosatetraenoic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_eicosadienoi c_diff	Eicosadienoic (%) - Differential - [Lipids]	Eicosadienoic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_eicosadienoi c_v1	Eicosadienoic (%) - Visit 1 - [Lipids]	Eicosadienoic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_eicosadienoi c_v2	Eicosadoenoic (%) - Visit 2 - [Lipids]	Eicosadoenoic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_eicosapentae noic_diff	Eicosapentaenoic (%) - Differential - [Lipids]	Eicosapentaenoic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"

Variable	Label	Description	Format Text
lipids_eicosapentae noic_v1	Eicosapentaenoic (%) - Visit 1 - [Lipids]	Eicosapentaenoic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_eicosapentae noic_v2	Eicosapentaenoic (%) - Visit 2 - [Lipids]	Eicosapentaenoic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_eicosenoic_d iff	Eicosenoic (%) - Differential - [Lipids]	Eicosenoic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_eicosenoic_v 1	Eicosenoic (%) - Visit 1 - [Lipids]	Eicosenoic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_eicosenoic_v 2	Eicosenoic (%) - Visit 2 - [Lipids]	Eicosenoic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_elaidic_diff	Elaidic (%) - Differential - [Lipids]	Elaidic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_elaidic_v1	Elaidic (%) - Visit 1 - [Lipids]	Elaidic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_elaidic_v2	Elaidic (%) - Visit 2 - [Lipids]	Elaidic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_gamma_linol enic_diff	Gamma Linolenic (%) - Differential - [Lipids]	Gamma Linolenic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_gamma_linol enic_v1	Gamma linolenic (%) - Visit 1 - [Lipids]	Gamma linolenic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_gamma_linol enic_v2	Gamma Linolenic (%) - Visit 2 - [Lipids]	Gamma Linolenic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_groupnum	Group Number - [Lipids]	Group Number	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_lignoceric_dif f	Lignoceric (%) - Differential - [Lipids]	Lignoceric from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_lignoceric_v1	Lignoceric (%) - Visit 1 - [Lipids]	Lignoceric % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_lignoceric_v2	Lignoceric (%) - Visit 2 - [Lipids]	Lignoceric % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_linoelaidic_di ff	Linoelaidic (%) - Differential - [Lipids]	Linoelaidic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_linoelaidic_v1	Linoelaidic (%) - Visit 1 - [Lipids]	Linoelaidic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"

Variable	Label	Description	Format Text
lipids_linoelaidic_v2	Linoelaidic (%) - Visit 2 - [Lipids]	Linoelaidic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_linoleic_diff	Linoleic (%) - Differential - [Lipids]	Linoleic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_linoleic_v1	Linoleic (%) - Visit 1 - [Lipids]	Linoleic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_linoleic_v2	Linoleic (%) - Visit 2 - [Lipids]	Linoleic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_myristic_diff	Myristic (%) - Differential - [Lipids]	Myristic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_myristic_v1	Myristic (%) - Visit 1 - [Lipids]	Myristic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_myristic_v2	Myristic (%) - Visit 2 - [Lipids]	Myristic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_nervonic_diff	Nervonic (%) - Differential - [Lipids]	Nervonic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_nervonic_v1	Nervonic (%) - Visit 1 - [Lipids]	Nervonic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_nervonic_v2	Nervonic (%) - Visit 2 - [Lipids]	Nervonic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_oleic_diff	Oleic (%) - Differential - [Lipids]	Oleic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_oleic_v1	Oleic (%) - Visit 1 - [Lipids]	Oleic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_oleic_v2	Oleic (%) - Visit 2 - [Lipids]	Oleic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_omega3_index_diff	Omega-3 (%) - Differential - [Lipids]	Omega 3 from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_omega3_index_v1	Omega 3 Index (%) - Visit 1 - [Lipids]	Omega 3 Index % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_omega3_index_v2	Omega 3 Index (%) - Visit 2 - [Lipids]	Omega 3 Index % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_palmitelaidic_diff	Palmitelaidic (%) - Differential - [Lipids]	Palmitelaidic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"

Variable	Label	Description	Format Text
lipids_palmitelaidic_v1	Palmitelaidic (%) - Visit 1 - [Lipids]	Palmitelaidic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_palmitelaidic_v2	Palmitelaidic (%) - Visit 2 - [Lipids]	Palmitelaidic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_palmitic_diff	Palmitic (%) - Differential - [Lipids]	Palmitic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_palmitic_v1	Palmitic (%) - Visit 1 - [Lipids]	Palmitic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_palmitic_v2	Palmitic (%) - Visit 2 - [Lipids]	Palmitic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_palmitoleic_diff	Palmitoleic (%) - Differential - [Lipids]	Palmitoleic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_palmitoleic_v1	Palmitoleic (%) - Visit 1 - [Lipids]	Palmitoleic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_palmitoleic_v2	Palmitoleic (%) - Visit 2 - [Lipids]	Palmitoleic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_receive_dt	Date Received - [Lipids]	Date that the specimen for lipid testing was received.	SAS Date .I="Inevaluable" .R="Participant not Randomized"
lipids_stearic_diff	Stearic (%) - Differential - [Lipids]	Stearic from lipids tests - % Differential	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_stearic_v1	Stearic (%) - Visit 1 - [Lipids]	Stearic % from lipids tests - Visit 1	Numeric .I="Inevaluable" .R="Participant not Randomized"
lipids_stearic_v2	Stearic (%) - Visit 2 - [Lipids]	Stearic % from lipids tests - Visit 2	Numeric .I="Inevaluable" .R="Participant not Randomized"

Section 25: CLS Data

Variable	Label	Description	Format Text
cls_adipose_v1	Sum Adipose Area - Visit 1 - [CLS Data]	Sum Adipose Area - Visit 1 - CLS Data	Numeric .N="N/A" .R="Participant not Randomized"
cls_adipose_v2	Sum Adipose Area - Visit 2 - [CLS Data]	Sum Adipose Area - Visit 2 - CLS Data	Numeric .N="N/A" .R="Participant not Randomized"
cls_b_cm2_v1	cm2 - Visit 1 - [CLS Data]	cm2 - Visit 1 - CLS Data	Numeric .N="N/A" .R="Participant not Randomized"
cls_b_cm2_v2	cm2 - Visit 2 - [CLS Data]	cm2 - Visit 2 - CLS Data	Numeric .N="N/A" .R="Participant not Randomized"
cls_b_index_v1	Index - Visit 1 - [CLS Data]	Index - Visit 1 - CLS Data	Numeric .N="N/A" .R="Participant not Randomized"
cls_b_index_v2	Index - Visit 2 - [CLS Data]	Index - Visit 2 - CLS Data	Numeric .N="N/A" .R="Participant not Randomized"
cls_b_score_v1	Score - Visit 1 - [CLS Data]	Score - Visit 1 - CLS Data	Char " "="Missing"
cls_b_score_v2	Score - Visit 2 - [CLS Data]	Score - Visit 2 - CLS Data	Char " "="Missing"
cls_b_yn_v1	Y/N - Visit 1 - [CLS Data]	Y/N - Visit 1 - CLS Data	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
cls_b_yn_v2	Y/N - Visit 2 - [CLS Data]	Y/N - Visit 2 - CLS Data	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
cls_fibrous_v1	Sum Fibrous Area - Visit 1 - [CLS Data]	Sum Fibrous Area - Visit 1 - CLS Data	Numeric .N="N/A" .R="Participant not Randomized"
cls_fibrous_v2	Sum Fibrous Area - Visit 2 - [CLS Data]	Sum Fibrous Area - Visit 2 - CLS Data	Numeric .N="N/A" .R="Participant not Randomized"
cls_total_v1	Sum Total Area - Visit 1 - [CLS Data]	Sum Total Area - Visit 1 - CLS Data	Numeric .N="N/A" .R="Participant not Randomized"
cls_total_v2	Sum Total Area - Visit 2 - [CLS Data]	Sum Total Area - Visit 2 - CLS Data	Numeric .N="N/A" .R="Participant not Randomized"

Section 26: Blood Collection

Variable	Label	Description	Format Text
bldcol_receieve_dt_v1	Date Specimen was Receieved - Visit 1 - [RBC Fatty Acid Levels V1]	Date specimen receieved - Blood Collection - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
bldcol_receieve_dt_v2	Date Specimen was Receieved - Visit 2 - [RBC Fatty Acid Levels V2]	Date specimen receieved - Blood Collection - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
bldcol_ship_dt_v1	Date Specimen was Shipped - Visit 1 - [RBC Fatty Acid Levels V1]	Date specimen shipped - Blood Collection - Visit 1	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"
bldcol_ship_dt_v2	Date Specimen was Shipped - Visit 2 - [RBC Fatty Acid Levels V2]	Date specimen shipped - Blood Collection - Visit 2	SAS Date .F="Participant Missing from Dataset" .M="Missing" .N="N/A" .R="Participant not Randomized"
bldcol_storage_temp_v1	Storage Temperature (C) - Visit 1 - [RBC Fatty Acid Levels V1]	Storage temperature (C) - Blood Collection - Visit 1	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
bldcol_storage_temp_v2	Storage Temperature (C) - Visit 2 - [RBC Fatty Acid Levels V2]	Storage temperature (C) - Blood Collection - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
bldcol_volume_v1	Volume of Specimen (mL) - Visit 1 - [RBC Fatty Acid Levels V1]	Volume of specimen (mL) - Blood Collection - Visit 1	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"
bldcol_volume_v2	Volume of Specimen (mL) - Visit 2 - [RBC Fatty Acid Levels V2]	Volume of specimen (mL) - Blood Colleciton - Visit 2	Numeric .F="Participant Missing from Dataset" .M="Missing" .R="Participant not Randomized"

Section 27: Blood Chemisty

Variable	Label	Description	Format Text
bldchem_albumin_clin_v1	Result of Albumin Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of Albumin test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_albumin_clin_v2	Result of Albumin Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of Albumin test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_albumin_out_v1	Result of Albumin Test out of Range? - Visit 1 - [Blood Chemistry]	Result of Albumin test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_albumin_out_v2	Result of Albumin Test out of Range? - Visit 2 - [Blood Chemistry]	Result of Albumin test out of range? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_albumin_v1	Result of Albumin Test (g/dL) - Visit 1 - [Blood Chemistry]	Result of Albumin test (g/dL) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_albumin_v2	Result of Albumin Test (g/dL) - Visit 2 - [Blood Chemistry]	Result of Albumin test (g/dL) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_bicarbonate_clin_v1	Result of Bicarbonate Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of Bicarbonate test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" .U="Unknown" 0="No"
bldchem_bicarbonate_clin_v2	Result of Bicarbonate Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of Bicarbonate test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_bicarbonate_out_v1	Result of Bicarbonate Test out of Range? - Visit 1 - [Blood Chemistry]	Result of Bicarbonate test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_bicarbonate_out_v2	Result of Bicarbonate Test out of Range? - Visit 2 - [Blood Chemistry]	Result of Bicarbonate test out of range? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_bicarbonate_v1	Result of Bicarbonate Test (mEq/L) - Visit 1 - [Blood Chemistry]	Result of Bicarbonate test (mEq/L) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_bicarbonate_v2	Result of Bicarbonate Test (mEq/L) - Visit 2 - [Blood Chemistry]	Result of Bicarbonate test (mEq/L) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"

Variable	Label	Description	Format Text
bldchem_bilirubin_c lin_v1	Result of Bilirubin Total Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of Bilirubin Total test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_bilirubin_c lin_v2	Result of Bilirubin Total Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of Bilirubin Total test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_bilirubin_ out_v1	Result of Bilirubin Total Test out of Range? - Visit 1 - [Blood Chemistry]	Result of Bilirubin Total test out of range? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_bilirubin_ out_v2	Result of Bilirubin Total Test out of Range? - Visit 2 - [Blood Chemistry]	Result of Bilirubin Total test out of range? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_bilirubin_v 1	Result of Bilirubin Total Test (mg/dL) - Visit 1 - [Blood Chemistry]	Result of Bilirubin Total test (mg/dL) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_bilirubin_v 2	Result of Bilirubin Total Test (mg/dL) - Visit 2 - [Blood Chemistry]	Result of Bilirubin Total test (mg/dL) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_bun_clin_ v1	Result of BUN Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of Bun test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_bun_clin_ v2	Result of BUN Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of Bun test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_bun_out_v 1	Result of BUN Test out of Range? - Visit 1 - [Blood Chemistry]	Result of Bun test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_bun_out_v 2	Result of BUN Test out of Range? - Visit 2 - [Blood Chemistry]	Result of Bun test out of range? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_bun_v1	Result of BUN Test (mg/dL) - Visit 1 - [Blood Chemistry]	Result of Bun test (mg/dL) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_bun_v2	Result of BUN Test (mg/dL) - Visit 2 - [Blood Chemistry]	Result of Bun test (mg/dL) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_calcium_c lin_v1	Result of Calcium Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of Calcium test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_calcium_c lin_v2	Result of Calcium Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of Calcium test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"

Variable	Label	Description	Format Text
bldchem_calcium_out_v1	Result of Calcium Test out of Range? - Visit 1 - [Blood Chemistry]	Result of Calcium test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_calcium_out_v2	Result of Calcium Test out of Range? - Visit 2 - [Blood Chemistry]	Result of Calcium test out of range? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No"
bldchem_calcium_v1	Result of Calcium Test (mg/dL) - Visit 1 - [Blood Chemistry]	Result of Calcium test (mg/dL) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_calcium_v2	Result of Calcium Test (mg/dL) - Visit 2 - [Blood Chemistry]	Result of Calcium test (mg/dL) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_chloride_clin_v1	Result of Chloride Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of Chloride test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_chloride_clin_v2	Result of Chloride Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of Chloride test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_chloride_out_v1	Result of Chloride Test out of Range? - Visit 1 - [Blood Chemistry]	Result of Chloride test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No"
bldchem_chloride_out_v2	Result of Chloride Test out of Range? - Visit 2 - [Blood Chemistry]	Result of Chloride test out of range? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_chloride_v1	Result of Chloride Test (mEq/L) - Visit 1 - [Blood Chemistry]	Result of Chloride test (mEq/L) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_chloride_v2	Result of Chloride Test (mEq/L) - Visit 2 - [Blood Chemistry]	Result of Chloride test (mEq/L) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_creatinine_clin_v1	Result of Creatinine Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of Creatinine test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_creatinine_clin_v2	Result of Creatinine Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of Creatinine test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_creatinine_out_v1	Result of Creatinine Test out of Range? - Visit 1 - [Blood Chemistry]	Result of Creatinine test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_creatinine_out_v2	Result of Creatinine Test out of Range? - Visit 2 - [Blood Chemistry]	Result of Creatinine test out of range? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_creatinine_v1	Result of Creatinine Test (mg/dL) - Visit 1 - [Blood Chemistry]	Result of Creatinine test (mg/dL) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"

Variable	Label	Description	Format Text
bldchem_creatinine _v2	Result of Creatinine Test (mg/dL) - Visit 2 - [Blood Chemistry]	Result of Creatinine test (mg/dL) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_fasting_v1	Fasting before specimen collection? - Visit 1 - [Blood Chemistry]	Fasting Before Specimen Collection? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" .U="Unknown" 0="No" 1="Yes"
bldchem_fasting_v2	Fasting before specimen collection? - Visit 2 - [Blood Chemistry]	Fasting Before Specimen Collection? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" .U="Unknown" 0="No" 1="Yes"
bldchem_glucose_c lin_v1	Result of Glucose Serum Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of Glucose Serum test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" .U="Unknown" 0="No" 1="Yes"
bldchem_glucose_c lin_v2	Result of Glucose Serum Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of Glucose Serum test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_glucose_o ut_v1	Result of Glucose Serum Test out of Range? - Visit 1 - [Blood Chemistry]	Result of Glucose Serum test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_glucose_o ut_v2	Result of Glucose Serum Test out of Range? - Visit 2 - [Blood Chemistry]	Result of Glucose Serum test out of range? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_glucose_v 1	Result of Glucose Serum Test (mg/dL) - Visit 1 - [Blood Chemistry]	Result of Glucose Serum test (mg/dL) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_glucose_v 2	Result of Glucose Serum Test (mg/dL) - Visit 2 - [Blood Chemistry]	Result of Glucose Serum test (mg/dL) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_potassium _clin_v1	Result of Potassium Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of Potassium test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_potassium _clin_v2	Result of Potassium Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of Potassium test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_potassium _out_v1	Result of Potassium Test out of Range? - Visit 1 - [Blood Chemistry]	Result of Potassium test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No"
bldchem_potassium _out_v2	Result of Potassium Test out of Range? - Visit 2 - [Blood Chemistry]	Result of Potassium test out of range? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"

Variable	Label	Description	Format Text
bldchem_potassium _v1	Result of Potassium Test (mEq/L) - Visit 1 - [Blood Chemistry]	Result of Potassium test (mEq/L) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_potassium _v2	Result of Potassium Test (mEq/L) - Visit 2 - [Blood Chemistry]	Result of Potassium test (mEq/L) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_protein_cli n_v1	Result of Total Protein Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of Total Protein test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_protein_cli n_v2	Result of Total Protein Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of Total Protein test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_protein_o ut_v1	Result of Total Protein Test out of Range? - Visit 1 - [Blood Chemistry]	Result of Total Protein test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_protein_o ut_v2	Result of Total Protein Test out of Range? - Visit 2 - [Blood Chemistry]	Result of Total Protein test out of range? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_protein_v1	Result of Total Protein Test (g/dL) - Visit 1 - [Blood Chemistry]	Result of Total Protein test (g/dL) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_protein_v2	Result of Total Protein Test (g/dL) - Visit 2 - [Blood Chemistry]	Result of Total Protein test (g/dL) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_sgot_ast_ clin_v1	Result of SGOT/AST Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of SGOT/AST test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" .U="Unknown" 0="No" 1="Yes"
bldchem_sgot_ast_ clin_v2	Result of SGOT/AST Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of SGOT/AST test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_sgot_ast_ out_v1	Result of SGOT/AST Test out of Range? - Visit 1 - [Blood Chemistry]	Result of SGOT/AST test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_sgot_ast_ out_v2	Result of SGOT/AST Test out of Range? - Visit 2 - [Blood Chemistry]	Result of SGOT/AST test out of range? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_sgot_ast_ v1	Result of SGOT/AST Test (IU/L) - Visit 1 - [Blood Chemistry]	Result of SGOT/AST test (IU/L) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_sgot_ast_ v2	Result of SGOT/AST Test (IU/L) - Visit 2 - [Blood Chemistry]	Result of SGOT/AST test (IU/L) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"

Variable	Label	Description	Format Text
bldchem_sgpt_alt_clin_v1	Result of SGPT/ALT Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of SGPT/ALT test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" .U="Unknown" 0="No" 1="Yes"
bldchem_sgpt_alt_clin_v2	Result of SGPT/ALT Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of SGPT/ALT test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_sgpt_alt_out_v1	Result of SGPT/ALT Test out of Range? - Visit 1 - [Blood Chemistry]	Result of SGPT/ALT test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_sgpt_alt_out_v2	Result of SGPT/ALT Test out of Range? - Visit 2 - [Blood Chemistry]	Result of SGPT/ALT test out of range? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_sgpt_alt_v1	Result of SGPT/ALT Test (IU/L) - Visit 1 - [Blood Chemistry]	Result of SGPT/ALT test (IU/L) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_sgpt_alt_v2	Result of SGPT/ALT Test (IU/L) - Visit 2 - [Blood Chemistry]	Result of SGPT/ALT test (IU/L) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_sodium_clin_v1	Result of Sodium Test Clinically Significant? - Visit 1 - [Blood Chemistry]	Result of Sodium test clinically significant? - Visit 1 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_sodium_clin_v2	Result of Sodium Test Clinically Significant? - Visit 2 - [Blood Chemistry]	Result of Sodium test clinically significant? - Visit 2 - Blood Chemistry	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
bldchem_sodium_out_v1	Result of Sodium Test out of Range? - Visit 1 - [Blood Chemistry]	Result of Sodium test out of range? - Visit 1 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_sodium_out_v2	Result of Sodium Test out of Range? - Visit 2 - [Blood Chemistry]	Result of Sodium test out of range? - Visit 2 - Blood Chemistry	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
bldchem_sodium_v1	Result of Sodium Test (mEq/L) - Visit 1 - [Blood Chemistry]	Result of Sodium test (mEq/L) - Visit 1 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"
bldchem_sodium_v2	Result of Sodium Test (mEq/L) - Visit 2 - [Blood Chemistry]	Result of Sodium test (mEq/L) - Visit 2 - Blood Chemistry	Numeric .N="N/A" .R="Participant not Randomized"

Section 28: Hematology

Variable	Label	Description	Format Text
hema_anc_clin_v1	Result of Absolute Neutrophil Count (ANC) Test Clinically Significant? - Visit 1 - [Hematology]	Result of Absolute Neutrophil Count (ANC) test clinically significant? - Visit 1 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hema_anc_clin_v2	Result of Absolute Neutrophil Count (ANC) Test Clinically Significant? - Visit 2 - [Hematology]	Result of Absolute Neutrophil Count (ANC) test clinically significant? - Visit 2 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hema_anc_out_v1	Result of Absolute Neutrophil Count (ANC) Test out of Range? - Visit 1 - [Hematology]	Result of Absolute Neutrophil Count (ANC) test out of range? - Visit 1 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_anc_out_v2	Result of Absolute Neutrophil Count (ANC) Test out of Range? - Visit 2 - [Hematology]	Result of Absolute Neutrophil Count (ANC) test out of range? - Visit 2 - Hematology	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_anc_v1	Result of Absolute Neutrophil Count (ANC) Test (k/uL) - Visit 1 - [Hematology]	Result of Absolute Neutrophil Count (ANC) test (k/uL) - Visit 1 - Hematology	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
hema_anc_v2	Result of Absolute Neutrophil Count (ANC) Test (k/uL) - Visit 2 - [Hematology]	Result of Absolute Neutrophil Count (ANC) test (k/uL) - Visit 2 - Hematology	Numeric .N="N/A" .R="Participant not Randomized"
hema_hematocrit_clin_v1	Result of Hematocrit Test Clinically Significant? - Visit 1 - [Hematology]	Result of Hematocrit test clinically significant? - Visit 1 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_hematocrit_clin_v2	Result of Hematocrit Test Clinically Significant? - Visit 2 - [Hematology]	Result of Hematocrit test clinically significant? - Visit 2 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_hematocrit_out_v1	Result of Hematocrit Test out of Range? - Visit 1 - [Hematology]	Result of Hematocrit test out of range? - Visit 1 - Hematology	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_hematocrit_out_v2	Result of Hematocrit Test out of Range? - Visit 2 - [Hematology]	Result of Hematocrit test out of range? - Visit 2 - Hematology	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_hematocrit_v1	Result of Hematocrit Test (%) - Visit 1 - [Hematology]	Result of Hematocrit test (%) - Visit 1 - Hematology	Numeric .N="N/A" .R="Participant not Randomized"
hema_hematocrit_v2	Result of Hematocrit Test (%) - Visit 2 - [Hematology]	Result of Hematocrit test (%) - Visit 2 - Hematology	Numeric .N="N/A" .R="Participant not Randomized"

Variable	Label	Description	Format Text
hema_hemoglobin_ clin_v1	Result of Hemoglobin Test Clinically Significant? - Visit 1 - [Hematology]	Result of Hemoglobin test clinically significant? - Visit 1 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_hemoglobin_ clin_v2	Result of Hemoglobin Test Clinically Significant? - Visit 2 - [Hematology]	Result of Hemoglobin test clinically significant? - Visit 2 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_hemoglobin_ out_v1	Result of Hemoglobin Test out of Range? - Visit 1 - [Hematology]	Result of Hemoglobin test out of range? - Visit 1 - Hematology	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_hemoglobin_ out_v2	Result of Hemoglobin Test out of Range? - Visit 2 - [Hematology]	Result of Hemoglobin test out of range? - Visit 2 - Hematology	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_hemoglobin_ v1	Result of Hemoglobin Test (g/dL) - Visit 1 - [Hematology]	Result of Hemoglobin test (g/dL) - Visit 1 - Hematology	Numeric .N="N/A" .R="Participant not Randomized"
hema_hemoglobin_ v2	Result of Hemoglobin Test (g/dL) - Visit 2 - [Hematology]	Result of Hemoglobin test (g/dL) - Visit 2 - Hematology	Numeric .N="N/A" .R="Participant not Randomized"
hema_platelets_clin _v1	Result of Platelets Test Clinically Significant? - Visit 1 - [Hematology]	Result of Platelets test clinically significant? - Visit 1 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hema_platelets_clin _v2	Result of Platelets Test Clinically Significant? - Visit 2 - [Hematology]	Result of Platelets test clinically significant? - Visit 2 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hema_platelets_out _v1	Result of Platelets Test out of Range? - Visit 1 - [Hematology]	Result of Platelets test out of range? - Visit 1 - Hematology	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_platelets_out _v2	Result of Platelets Test out of Range? - Visit 2 - [Hematology]	Result of Platelets test out of range? - Visit 2 - Hematology	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_platelets_v1	Result of Platelets Test (k/uL) - Visit 1 - [Hematology]	Result of Platelets test (k/uL) - Visit 1 - Hematology	Numeric .N="N/A" .R="Participant not Randomized"
hema_platelets_v2	Result of Platelets Test (k/uL) - Visit 2 - [Hematology]	Result of Platelets test (k/uL) - Visit 2 - Hematology	Numeric .N="N/A" .R="Participant not Randomized"
hema_rbc_clin_v1	Result of Red Blood Cell Test Clinically Significant? - Visit 1 - [Hematology]	Result of RBC test clinically significant? - Visit 1 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hema_rbc_clin_v2	Result of Red Blood Cell Test Clinically Significant? - Visit 2 - [Hematology]	Result of RBC test clinically significant? - Visit 2 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"

Variable	Label	Description	Format Text
hema_rbc_out_v1	Result of Red Blood Cell Test out of Range? - Visit 1 - [Hematology]	Result of RBC test out of range? - Visit 1 - Hematology	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_rbc_out_v2	Result of Red Blood Cell Test out of Range? - Visit 2 - [Hematology]	Result of RBC test out of range? - Visit 2 - Hematology	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_rbc_v1	Result of Red Blood Cell Test (m/uL) - Visit 1 - [Hematology]	Result of RBC test (m/uL) - Visit 1 - Hematology	Numeric .N="N/A" .R="Participant not Randomized"
hema_rbc_v2	Result of Red Blood Cell Test (m/uL) - Visit 2 - [Hematology]	Result of RBC test (m/uL) - Visit 2 - Hematology	Numeric .N="N/A" .R="Participant not Randomized"
hema_wbc_clin_v1	Result of White Blood Cell Test Clinically Significant? - Visit 1 - [Hematology]	Result of WBC test clinically significant? - Visit 1 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hema_wbc_clin_v2	Result of White Blood Cell Test Clinically Significant? - Visit 2 - [Hematology]	Result of WBC test clinically significant? - Visit 2 - Hematology	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hema_wbc_out_v1	Result of White Blood Cell Test out of Range? - Visit 1 - [Hematology]	Result of WBC test out of range? - Visit 1 - Hematology	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_wbc_out_v2	Result of White Blood Cell Test out of Range? - Visit 2 - [Hematology]	Result of WBC test out of range? - Visit 2 - Hematology	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hema_wbc_v1	Result of White Blood Cell Test (k/uL) - Visit 1 - [Hematology]	Result of WBC test (k/uL) - Visit 1 - Hematology	Numeric .N="N/A" .R="Participant not Randomized"
hema_wbc_v2	Result of White Blood Cell Test (k/uL) - Visit 2 - [Hematology]	Result of WBC test (k/uL) - Visit 2 - Hematology	Numeric .N="N/A" .R="Participant not Randomized"
hemadiff_baso_clin_v1	Result of Basophils Test Clinically Significant? - Visit 1 - [Hematology Differential]	Result of Basophils test clinically significant? - Visit 1 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hemadiff_baso_clin_v2	Result of Basophils Test Clinically Significant? - Visit 2 - [Hematology Differential]	Result of Basophils test clinically significant? - Visit 2 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hemadiff_baso_out_v1	Result of Basophils Test out of Range? - Visit 1 - [Hematology Differential]	Result of Basophils test out of range? - Visit 1 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hemadiff_baso_out_v2	Result of Basophils Test out of Range? - Visit 2 - [Hematology Differential]	Result of Basophils test out of range? - Visit 2 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"

Variable	Label	Description	Format Text
hemadiff_baso_v1	Result of Basophils Test (%) - Visit 1 - [Hematology Differential]	Result of Basophils test (%) - Visit 1 - Hematology Differential	Numeric .M="Missing" .N="N/A" .R="Participant not Randomized"
hemadiff_baso_v2	Result of Basophils Test (%) - Visit 2 - [Hematology Differential]	Result of Basophils test (%) - Visit 2 - Hematology Differential	Numeric .N="N/A" .R="Participant not Randomized"
hemadiff_eosino_clin_v1	Result of Eosinophils Test Clinically Significant? - Visit 1 - [Hematology Differential]	Result of Eosinophils test clinically significant? - Visit 1 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hemadiff_eosino_clin_v2	Result of Eosinophils Test Clinically Significant? - Visit 2 - [Hematology Differential]	Result of Eosinophils test clinically significant? - Visit 2 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hemadiff_eosino_out_v1	Result of Eosinophils Test out of Range? - Visit 1 - [Hematology Differential]	Result of Eosinophils test out of range? - Visit 1 - Hematology Differential	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hemadiff_eosino_out_v2	Result of Eosinophils Test out of Range? - Visit 2 - [Hematology Differential]	Result of Eosinophils test out of range? - Visit 2 - Hematology Differential	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hemadiff_eosino_v1	Result of Eosinophils Test (%) - Visit 1 - [Hematology Differential]	Result of Eosinophils test (%) - Visit 1 - Hematology Differential	Numeric .N="N/A" .R="Participant not Randomized"
hemadiff_eosino_v2	Result of Eosinophils Test (%) - Visit 2 - [Hematology Differential]	Result of Eosinophils test (%) - Visit 2 - Hematology Differential	Numeric .N="N/A" .R="Participant not Randomized"
hemadiff_lymph_clin_v1	Result of Lymphocytes Test Clinically Significant? - Visit 1 - [Hematology Differential]	Result of Lymphocytes test clinically significant? - Visit 1 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" .U="Unknown" 0="No"
hemadiff_lymph_clin_v2	Result of Lymphocytes Test Clinically Significant? - Visit 2 - [Hematology Differential]	Result of Lymphocytes test clinically significant? - Visit 2 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hemadiff_lymph_out_v1	Result of Lymphocytes Test out of Range? - Visit 1 - [Hematology Differential]	Result of Lymphocytes test out of range? - Visit 1 - Hematology Differential	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hemadiff_lymph_out_v2	Result of Lymphocytes Test out of Range? - Visit 2 - [Hematology Differential]	Result of Lymphocytes test out of range? - Visit 2 - Hematology Differential	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hemadiff_lymph_v1	Result of Lymphocytes Test (%) - Visit 1 - [Hematology Differential]	Result of Lymphocytes test (%) - Visit 1 - Hematology Differential	Numeric .N="N/A" .R="Participant not Randomized"
hemadiff_lymph_v2	Result of Lymphocytes Test (%) - Visit 2 - [Hematology Differential]	Result of Lymphocytes test (%) - Visit 2 - Hematology Differential	Numeric .N="N/A" .R="Participant not Randomized"

Variable	Label	Description	Format Text
hemadiff_mono_clin _v1	Result of Monocytes Test Clinically Significant? - Visit 1 - [Hematology Differential]	Result of Monocytes test clinically significant? - Visit 1 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hemadiff_mono_clin _v2	Result of Monocytes Test Clinically Significant? - Visit 2 - [Hematology Differential]	Result of Monocytes test clinically significant? - Visit 2 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hemadiff_mono_out _v1	Result of Monocytes Test out of Range? - Visit 1 - [Hematology Differential]	Result of Monocytes test out of range? - Visit 1 - Hematology Differential	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hemadiff_mono_out _v2	Result of Monocytes Test out of Range? - Visit 2 - [Hematology Differential]	Result of Monocytes test out of range? - Visit 2 - Hematology Differential	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hemadiff_mono_v1	Result of Monocytes Test (%) - Visit 1 - [Hematology Differential]	Result of Monocytes test (%) - Visit 1 - Hematology Differential	Numeric .N="N/A" .R="Participant not Randomized"
hemadiff_mono_v2	Result of Monocytes Test (%) - Visit 2 - [Hematology Differential]	Result of Monocytes test (%) - Visit 2 - Hematology Differential	Numeric .N="N/A" .R="Participant not Randomized"
hemadiff_neubands _clin_v1	Result of Neutrophils and Bands Test Clinically Significant? - Visit 1 - [Hematology Differential]	Result of Neutrophils and Bands test clinically significant? - Visit 1 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hemadiff_neubands _clin_v2	Result of Neutrophils and Bands Test Clinically Significant? - Visit 2 - [Hematology Differential]	Result of Neutrophils and Bands test clinically significant? - Visit 2 - Hematology Differential	.M="Missing" .N="N/A" .R="Participant not Randomized" 0="No"
hemadiff_neubands _out_v1	Result of Neutrophils and Bands Test out of Range? - Visit 1 - [Hematology Differential]	Result of Neutrophils and Bands test out of range? - Visit 1 - Hematology Differential	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hemadiff_neubands _out_v2	Result of Neutrophils and Bands Test out of Range? - Visit 2 - [Hematology Differential]	Result of Neutrophils and Bands test out of range? - Visit 2 - Hematology Differential	.N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
hemadiff_neubands _v1	Result of Neutrophils and Bands Test (%) - Visit 1 - [Hematology Differential]	Result of Neutrophils and Bands test (%) - Visit 1 - Hematology Differential	Numeric .N="N/A" .R="Participant not Randomized"
hemadiff_neubands _v2	Result of Neutrophils and Bands Test (%) - Visit 2 - [Hematology Differential]	Result of Neutrophils and Bands test (%) - Visit 2 - Hematology Differential	Numeric .N="N/A" .R="Participant not Randomized"

Section 29: Other Lab Tests

Variable	Label	Description	Format Text
othlab_abs_basos_clin_v1	Result of Absolute Basophils Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of Absolute Basophils test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_basos_clin_v2	Result of Absolute Basophils Test Clinically Significant? - Visit 2 - [Other Lab Tests]	Result of Absolute Basophils test clinically significant? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_basos_out_v1	Result of Absolute Basophils Test out of Range? - Visit 1 - [Other Lab Tests]	Result of Absolute Basophils test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_basos_out_v2	Result of Absolute Basophils Test out of Range? - Visit 2 - [Other Lab Tests]	Result of Absolute Basophils test out of range? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_basos_v1	Result of Absolute Basophils Test (k/uL) - Visit 1 - [Other Lab Tests]	Result of Absolute Basophils test (k/uL) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_abs_basos_v2	Result of Absolute Basophils Test (k/uL) - Visit 2 - [Other Lab Tests]	Result of Absolute Basophils test (k/uL) - Visit 2 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_abs_blasts_clin_v1	Result of Absolute Blasts Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of Absolute Blasts test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_blasts_out_v1	Result of Absolute Blasts Test out of Range? - Visit 1 - [Other Lab Tests]	Result of Absolute Blasts test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_blasts_v1	Result of Absolute Blasts Test (k/uL) - Visit 1 - [Other Lab Tests]	Result of Absolute Blasts test (k/uL) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_abs_eos_clin_v1	Result of Absolute Eosinophils Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of Absolute Eosinophils test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_eos_clin_v2	Result of Absolute Eosinophils Test Clinically Significant? - Visit 2 - [Other Lab Tests]	Result of Absolute Eosinophils test clinically significant? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_eos_out_v1	Result of Absolute Eosinophils Test out of Range? - Visit 1 - [Other Lab Tests]	Result of Absolute Eosinophils test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"

Variable	Label	Description	Format Text
othlab_abs_eos_out _v2	Result of Absolute Eosinophils Test out of Range? - Visit 2 - [Other Lab Tests]	Result of Absolute Eosinophils test out of range? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
othlab_abs_eos_v1	Result of Absolute Eosinophils Test (k/uL) - Visit 1 - [Other Lab Tests]	Result of Absolute Eosinophils test (k/uL) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_abs_eos_v2	Result of Absolute Eosinophils Test (k/uL) - Visit 2 - [Other Lab Tests]	Result of Absolute Eosinophils test (k/uL) - Visit 2 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_abs_monos_ clin_v1	Result of Absolute Monocytes Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of Absolute Monocytes test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_monos_ clin_v2	Result of Absolute Monocytes Test Clinically Significant? - Visit 2 - [Other Lab Tests]	Result of Absolute Monocytes test clinically significant? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_monos_ out_v1	Result of Absolute Monocytes Test out of Range? - Visit 1 - [Other Lab Tests]	Result of Absolute Monocytes test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_monos_ out_v2	Result of Absolute Monocytes Test out of Range? - Visit 2 - [Other Lab Tests]	Result of Absolute Monocytes test out of range? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_monos_ v1	Result of Absolute Monocytes Test (k/uL) - Visit 1 - [Other Lab Tests]	Result of Absolute Monocytes test (k/uL) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_abs_monos_ v2	Result of Absolute Monocytes Test (k/uL) - Visit 2 - [Other Lab Tests]	Result of Absolute Monocytes test (k/uL) - Visit 2 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_abs_neu_cli n_v1	Result of Absolute Neutrophils Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of Absolute Neutrophils test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_neu_cli n_v2	Result of Absolute Neutrophils Test Clinically Significant? - Visit 2 - [Other Lab Tests]	Result of Absolute Neutrophils test clinically significant? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_neu_out _v1	Result of Absolute Neutrophils Test out of Range? - Visit 1 - [Other Lab Tests]	Result of Absolute Neutrophils test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_abs_neu_out _v2	Result of Absolute Neutrophils Test out of Range? - Visit 2 - [Other Lab Tests]	Result of Absolute Neutrophils test out of range? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"

Variable	Label	Description	Format Text
othlab_abs_neu_v1	Result of Absolute Neutrophils Test (k/uL) - Visit 1 - [Other Lab Tests]	Result of Absolute Neutrophils test (k/uL) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_abs_neu_v2	Result of Absolute Neutrophils Test (k/uL) - Visit 2 - [Other Lab Tests]	Result of Absolute Neutrophils test (k/uL) - Visit 2 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_alk_phos_clin_v1	Result of Alkaline Phosphate Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of Alkaline Phosphate test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_alk_phos_clin_v2	Result of Alkaline Phosphate Test Clinically Significant? - Visit 2 - [Other Lab Tests]	Result of Alkaline Phosphate test clinically significant? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_alk_phos_out_v1	Result of Alkaline Phosphate Test out of Range? - Visit 1 - [Other Lab Tests]	Result of Alkaline Phosphate test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
othlab_alk_phos_out_v2	Result of Alkaline Phosphate Test out of Range? - Visit 2 - [Other Lab Tests]	Result of Alkaline Phosphate test out of range? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
othlab_alk_phos_v1	Result of Alkaline Phosphate Test (U/L) - Visit 1 - [Other Lab Tests]	Result of Alkaline Phosphate test (U/L) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_alk_phos_v2	Result of Alkaline Phosphate Test (U/L) - Visit 2 - [Other Lab Tests]	Result of Alkaline Phosphate test (U/L) - Visit 2 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_globulin_clin_v1	Result of Globulin Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of Globulin test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_globulin_clin_v2	Result of Globulin Test Clinically Significant? - Visit 2 - [Other Lab Tests]	Result of Globulin test clinically significant? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_globulin_out_v1	Result of Globulin Test out of Range? - Visit 1 - [Other Lab Tests]	Result of Globulin test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_globulin_out_v2	Result of Globulin Test out of Range? - Visit 2 - [Other Lab Tests]	Result of Globulin test out of range? - Visit 2 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No" 1="Yes"
othlab_globulin_v1	Result of Globulin Test (g/dL) - Visit 1 - [Other Lab Tests]	Result of Globulin test (g/dL) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"

Variable	Label	Description	Format Text
othlab_globulin_v2	Result of Globulin Test (g/dL) - Visit 2 - [Other Lab Tests]	Result of Globulin test (g/dL) - Visit 2 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_glucose_clin _v1	Result of Glucose Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of Glucose test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 1="Yes"
othlab_glucose_out _v1	Result of Glucose Test out of Range? - Visit 1 - [Other Lab Tests]	Result of Glucose test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 1="Yes"
othlab_glucose_v1	Result of Glucose Test (mg/dL) - Visit 1 - [Other Lab Tests]	Result of Glucose test (mg/dL) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_mch_clin_v1	Result of Mean Corpuscular Hemoglobin Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of MCH test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_mch_out_v1	Result of Mean Corpuscular Hemoglobin Test out of Range? - Visit 1 - [Other Lab Tests]	Result of MCH test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_mch_v1	Result of Mean Corpuscular Hemoglobin Test (PG) - Visit 1 - [Other Lab Tests]	Result of MCH test (PG) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_mchc_clin_v 1	Result of Mean Corpuscular Hemoglobin Concentration Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of MCHC test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_mchc_out_v 1	Result of Mean Corpuscular Hemoglobin Concentration Test out of Range? - Visit 1 - [Other Lab Tests]	Result of MCHC test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 1="Yes"
othlab_mchc_v1	Result of Mean Corpuscular Hemoglobin Concentration Test (%) - Visit 1 - [Other Lab Tests]	Result of MCHC test (%) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"
othlab_mcv_clin_v1	Result of Mean Corpuscular Volume Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of MCV test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_mcv_out_v1	Result of Mean Corpuscular Volume Test out of Range? - Visit 1 - [Other Lab Tests]	Result of MCV test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_mcv_v1	Result of Mean Corpuscular Volume Test (FL) - Visit 1 - [Other Lab Tests]	Result of MCV test (FL) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"

mda10-16-01 - Enhanced Person - 3.1: Data Dictionary
08/09/2019

Variable	Label	Description	Format Text
othlab_rdw_clin_v1	Result of Red Cell Distribution Width Test Clinically Significant? - Visit 1 - [Other Lab Tests]	Result of RDW test clinically significant? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_rdw_out_v1	Result of Red Cell Distribution Width Test out of Range? - Visit 1 - [Other Lab Tests]	Result of RDW test out of range? - Visit 1 - Other Lab tests	.F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized" 0="No"
othlab_rdw_v1	Result of Red Cell Distribution Width Test (%) - Visit 1 - [Other Lab Tests]	Result of RDW test (%) - Visit 1 - Other Lab tests	Numeric .F="Participant Missing from Dataset" .N="N/A" .R="Participant not Randomized"