VITAL STUDY: Variables collected on the MAIN TRIAL QUESTIONNAIRES **Revised January 2023**

	Trial Questionnaires												*Observation Questionnaires*					
VARIABLES	**V-1**	**V-2**	**V-3**	**DIET**	**6-MO**	**YR 1**	**YR 2**	**YR 3**	**YR 4**	**YR 4.5**	**YR 5**	**Final 2018**	**OBS 1 Jan 2019**	**OBS 1.5 *RC only**	**OBS 2 Jan 2020**	**OBS 3 Jan 2021**	**OBS 4 Jan 2022**	**OBS 5 Jan 2023**
CONSENT/DEMOGR. /ANTHRO.																		
Willingness to be in the study	X	consent	X															
Willingness to provide blood		X																
Willingness to do cog. interview		X																
Age in years	X																	
Date of birth (mo/day/yr)		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
First and Last Initial (REDCap only)													X	X	X	X	X	X
Who is completing the form (REDCap only)															X	X	X	X
Gender	X	X																
Race	X																	
Ethnicity	X																	
Education	X																	
Household income			X															
Weight		X				X	X	X	X		X	X	X		X	X	X	X
Height		X																
Full social security number (SSN)		X	X															
SSN – last 4 digits only					X	X	X	X	X									
Phone numbers		X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
E-mail address			X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Provide contact information			X			X	X	X	X		X		X			X		X
DIET																		
Dairy, eggs/meat, seafood, fruits & vegetables, beverages, and miscellaneous				X						X								
ALCOHOL CONSUMPTION																		
Beer, wine, liquor – average use/year				X					X	X								

VARIABLES	V-1	V-2	V-3	DIET	6-MO	YR 1	YR 2	YR 3	YR 4	YR 4.5	YR 5	Final 2018	OBS 1 Jan 2019	OBS 1.5 *RC only	OBS 2 Jan 2020	OBS 3 Jan 2021	OBS 4 Jan 2022	OBS 5 Jan 2023
LIMITED IN DAILY ACTIVITY																		
Climbing stairs, bending, kneeling, bathing, walking, lifting, moderate and vigorous activity				X				X	X		X	X						
INDEPENDENT IN DAILY LIFE																		
Feed, dress, bed, bath				X			X	X	X		X	X						
FAMILY HISTORY																		
Heart attack, diabetes, blood pressure, hip fracture, cancer				X														
DIETARY SUPPLEMENTS																		
Vitamin D	X		X		X	X	X	X	X		X		X		X	X	X	X
Fish oil (incl. krill, cod liver at YR 2) (RX FO at OBS 1) (Lovaza,,Vascepa, Eye supps w/Omega-3 at OBS 2)	X	X	X		X	X	X	X	X		X		X		X	X	X	X
Other supps containing Omega-3					X								X		X	X	X	X
Calcium		X	X		X	X	X	X	X		X		X		X	X	X	X
Multivitamins				X						X								
Vitamin A							X											
Any other supplements **(listed)**				X						X								
MEDICATION USE																		
Anti-coagulant / blood thinner		X	X			X	X	X	X		X		X		X	X	X	X
Aromatase inhibitor			X			X	X	X	X		X		X		X	X	X	X
Aspirin (and days/month)			X			X	X	X	X		X		X		X	X	X	X
Bone loss meds **(listed)**			X			X	X	X	X		X		X		X	X	X	X
Calcitriol			X			X	X	X	X		X	X	X		X	X	X	X
Clopidogrel (Plavix)/antiplatelet med							X	X	X		X		X		X	X	X	X
Corticosteroids			X			X	X	X	X		X		X		X	X	X	X
Diabetes meds **(listed)**		X				X	X	X	X		X		X		X	X	X	X
Estrogen						X	X	X	X		X		X		X	X	X	X
Hypertension meds **(listed)**		X				X	X	X	X		X		X		X	X	X	X
Lithium						X	X	X	X		X		X		X	X	X	X
Non-statin cholesterol lowering			X			X	X	X	X		X		X		X	X	X	X

VARIABLES	V-1	V-2	V-3	DIET	6-MO	YR 1	YR 2	YR 3	YR 4	YR 4.5	YR 5	Final 2018	OBS 1 Jan 2019	OBS 1.5 *RC only	OBS 2 Jan 2020	OBS 3 Jan 2021	OBS 4 Jan 2022	OBS 5 Jan 2023
NSAID											X		X		X	X	X	X
Serotonin reuptake inhibitor			X			X	X	X	X		X		X		X	X	X	X
Statins			X			X	X	X	X		X		X		X	X	X	X
Tamoxifen			X			X	X	X	X		X		X		X	X	X	X
Thyroid medications								X	X		X		X		X	X	X	X
OTHER MEDS USE																		
H2 antagonists											X		X		X	X	X	X
Loop diuretics											X		X		X	X	X	X
Proton pump inhibitors											X		X		X	X	X	X
Thiazide diuretics											X		X		X	X	X	X
DIAGNOSES / PROCEDURES																		
Allergies to soy/allergies to FO		X	X															
Atrial fib. or other irreg. rhythm			X			X	X	X	X		X	X	X		X	X	X	X
Cancer (other than skin cancer)	X		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Cancer – SKIN (type)	X		X		X	X	X	X	X		X	X	X	X	X	X	X	X
Carotid artery surgery			X			X	X	X	X		X	X	X		X	X	X	X
Carotid stenosis			X			X	X	X	X		X	X	X		X	X	X	X
Cataract			X															
Cataract surgery (extraction)			X			X	X	X	X		X		X		X	X	X	X
Celiac disease						X												
Chest Pain (angina) – hospitalized?			X			X	X	X	X		X	X	X		X	X	X	X
Cirrhosis / other severe liver dis.		X	X			X	X	X	X		X							
Colon or rectal polyps- Polyp: repeat scope 5 years			X			X	X	X	X		X	X	X		X	X	X	X
Coronary angioplasty or stent	X		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Coronary bypass surgery	X		X		X	X	X	X	X	X	X	X	X		X	X	X	X
Coronavirus (COVID-19)																		X
Deep vein thrombosis			X			X	X	X	X		X	X	X	X	X	X	X	X
Diabetes		X	X			X	X	X	X		X	X	X		X	X	X	X
Fibrocystic breast disease – how confirmed? Mammogram/ biopsy			X			X	X	X	X		X	X	X		X	X	X	*
Gallbladder disease												X						
Gallbladder removal												X						
Gastric bypass surgery			X			X	X	X	X		X							
Headaches – describe symptoms		X							X									
Headaches – recurring										X		X						

VARIABLES	V-1	V-2	V-3	DIET	6-MO	YR 1	YR 2	YR 3	YR 4	YR 4.5	YR 5	Final 2018	OBS 1 Jan 2019	OBS 1.5 *RC only	OBS 2 Jan 2020	OBS 3 Jan 2021	OBS 4 Jan 2022	OBS 5 Jan 2023
Heart attack	X		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Heart or congestive heart failure			X			X	X	X	X		X	X	X		X	X	X	X
Hypercalcemia		X	X		X	X	X	X	X		X	X						
Hypertension		X				X	X	X	X		X	X	X		X	X	X	X
Intermittent claudication			X			X	X	X	X		X	X	X		X	X	X	X
Kidney failure or dialysis		X	X			X	X	X	X		X		X		X	X	X	X
Kidney stones		X	X		X	X	X	X	X		X	X						
Leg pain										X								
Macular degeneration		X				X	X	X	X		X	X	X		X	X	X	X
Multiple sclerosis			X			X	X	X	X		X	X	X		X	X	X	*
Parathyroid/thyroid conditions		X	X		X	X	X	X	X		X							
Parkinson's disease			X			X	X	X	X		X	X	X		X	X	X	X
Peptic ulcer			X						X		X							
Periodontal disease			X			X	X	X	X		X	X	X		X	X	X	X
Peripheral artery surgery / stenting			X			X	X	X	X		X	X	X		X	X	X	X
Pneumonia – Dx / hospitalized?		X				X	X	X	X		X	X	X		X	X	X	X
Prostatic hyperplasia			X						X		X							
Prostatitis			X						X		X							
Pulmonary embolism			X			X	X	X	X		X	X	X		X	X	X	X
RLS – describe symptoms		X							X		X							
Sarcoid or Wegener's		X	X			X	X	X	X		X	X						
Stroke	X		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Mini-stroke (TIA)		X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Tuberculosis		X	X			X	X	X	X		X							
Uterine fibroids			X															
OTHER major illness		X				X	X	X	X		X		X		X	X	X	X
POTENTIAL SIDE EFFECTS																		
Stomach upset or pain			X		X	X	X	X	X		X							
Nausea			X		X	X	X	X	X		X							
Constipation			X		X	X	X	X	X		X							
Diarrhea			X		X	X	X	X	X		X							
Skin rash			X		X	X	X	X	X		X							
Colds or URI			X		X	X	X	X	X		X							
Flu-like symptoms			X		X	X	X	X	X		X							
Frequent nosebleeds			X		X	X	X	X	X		X							
Easy bruising			X		X	X	X	X	X		X							
Blood in urine			X		X	X	X	X	X		X							

VARIABLES	V-1	V-2	V-3	DIET	6-MO	YR 1	YR 2	YR 3	YR 4	YR 4.5	YR 5	Final 2018	OBS 1 Jan 2019	OBS 1.5 *RC only	OBS 2 Jan 2020	OBS 3 Jan 2021	OBS 4 Jan 2022	OBS 5 Jan 2023
GI bleeding			X		X	X	X	X	X		X							
Bad taste in mouth			X		X	X	X	X	X		X							
Increased burping					X	X	X	X	X		X							
PILL COMPLIANCE																		
Past month – days missed			X															
"Typical" month – days missed					X	X	X	X	X		X							
Reason missed			X		X	X	X	X	X		X							
Are you currently taking?					X	X	X	X	X		X							
PHYSICAL ACTIVITY																		
Time spent in weekly activities			X					X										
Flights of stairs climb daily			X					X										
Usual walking pace			X					X										
SMOKING HISTORY																		
Smoked 100 cigarettes			X															
Avg cigs/day – currently & lifetime			X															
Currently smoking (avg. Cigs/day)			X			X		X			X		X		X	X	X	X
OTHER RISK FACTORS																		
Skin color / reaction to sun exposure		X																
Lost 5 lbs. or more in past 2 years		X																
Specific blood pressure (SBP/DBP)		X																
Total cholesterol		X																
Menopausal history			X															
SCREENING																		
Rectal exam			X				X		X		X				X			X
Hemoccult or guaiac			X				X		X		X				X			X
Colonoscopy			X				X		X		X				X			X
Sigmoidoscopy			X				X		X		X				X			X
Barium enema x-ray			X				X		X		X				X			X
Eye exam		X				X	X		X		X				X			X
BP measured						X	X		X		X				X			X
PSA test			X				X		X		X				X			X
Fasting blood sugar									X		X				X			X
Mammogram																		X

VARIABLES	V-1	V-2	V-3	DIET	6-MO	YR 1	YR 2	YR 3	YR 4	YR 4.5	YR 5	Final 2018	OBS 1 Jan 2019	OBS 1.5 *RC only	OBS 2 Jan 2020	OBS 3 Jan 2021	OBS 4 Jan 2022	OBS 5 Jan 2023
ANCILLARY QUESTIONS																		
DIABETIC KIDNEY DISEASE • Dx of diabetes and treatment • Had blood glucose test • Dx of DKD		X																
KNEE PAIN • How often have pain • Pain when walking and for how long • Knee replacement surgery • Have osteoarthritis		X																
AUTOIMMUNE DISEASE • Thyroid • IBD • PMR • RA • Psoriasis • ***Sarcoidosis or granulomatosis w/ polyangiitis (Wegener's)** • ***Multiple Sclerosis** • Other		X				X	X	X	X		X	X	X		X	X	X	X
HYPERTENSION • Have hypertension • Taking hypertensive meds • Current BP (SBP/DBP)		X				X	X	Only meds: BP or other reason	Only meds: BP or other reason		Only meds: BP or other reason		Only meds		Only meds	Only meds	Only meds	Only meds
ANEMIA • Dx of anemia • Transfusion for anemia • Evaluated by hematologist		X				X	X	X	X									

VARIABLES	V-1	V-2	V-3	DIET	6-MO	YR 1	YR 2	YR 3	YR 4	YR 4.5	YR 5	Final 2018	OBS 1 Jan 2019	OBS 1.5 *RC only	OBS 2 Jan 2020	OBS 3 Jan 2021	OBS 4 Jan 2022	OBS 5 Jan 2023
RESPIRATORY DISEASE • Usually cough • Usually bring up phlegm • Chest wheezy • Asthma Dx • Any chronic lung diseases • Recent Dx of pneumonia		X				X	X	X	X		X (not all)							
FRACTURES • Broken bones (which/when)			X			X	X	X	X		X	X	X		X	X	X	X
MOOD • Depression Dx • Felt sad 2+ weeks (asked during pill phase) • Felt sad most days in 2 or more years (asked during pill phase) • Past 2 weeks have you had these feelings (asked during pill phase)			X			X	X	X	X		X	Dx only	X (A-B)		X (A-H)	X (A-B)	X (A-B)	X (A-C)
FALLS • Number of falls • Result - need to see a doctor • Evaluated at hospital				X		X	X	X	X		X	X	X		X	X	X	X

VARIABLES	V-1	V-2	V-3	DIET	6-MO	YR 1	YR 2	YR 3	YR 4	YR 4.5	YR 5	Final 2018	OBS 1 Jan 2019	OBS 1.5 *RC only	OBS 2 Jan 2020	OBS 3 Jan 2021	OBS 4 Jan 2022	OBS 5 Jan 2023
INFECTION • Number of colds • Have you had any of these infections **(listed)** or treated with antibiotics or flu vaccine?				X		X	X	X	# of colds only		# of colds only							
DRY EYE • Eyes dry often • Eyes irritated often • Dx of dry eye		X				X	X	X	X		X							
OTHER QUESTIONS																		
Urinary incontinence							X					X						
CHF hospitalization or emergency room						X	X	X	X		X	X	X		X	X	X	X
Number of pregnancies							X											
Gestational diabetes							X											
Preeclampsia/gestational hypertension							X											
In general, describe your health			X			X	X	X	X		X	X	X		X	X	X	X
Memory in past year									X		X	X	X		X	X	X	X
Avg. # of hours of sleep per night																		X
Current ability compared to 5 YRs ago:																		
Recalling info when I really try															X			
Remembering names and faces of new people I meet															X			
Remembering things that happened recently															X			
Recalling conversations 3 days later															X			
Change in hearing past year									X			X						
Current hearing									X			X						
Ringing in ears									X			X						

VARIABLES	V-1	V-2	V-3	DIET	6-MO	YR 1	YR 2	YR 3	YR 4	YR 4.5	YR 5	Final 2018	OBS 1 Jan 2019	OBS 1.5 *RC only	OBS 2 Jan 2020	OBS 3 Jan 2021	OBS 4 Jan 2022	OBS 5 Jan 2023
Marital status											X		X			X		X
Where do you live											X		X			X		X
With whom do you live											X		X			X		X
Are you a caregiver											X		X			X		X
Pain (before/during trial, current)												X						
Change in bowel movements												X						
Change in hair volume/shine												X						
Change in nail health/growth												X						
Change in skin health/smoothness												X						
Placebo or active												X						
Day-to day hassles in life that people might experience. Questions about how you are treated.													X					
Do you have Hispanic or Latino heritage?													X					
Did you get the influenza (flu) vaccine after August, current year?																X	X	X
COVID Questions:																		
Has a doctor or another healthcare professional dx you as having had or probably having had the coronavirus (COVID-19)?																X	X	Moved to dx grid
Did you get the COVID-19 vaccine																X	X	X
Did you get the COVID-19 booster shot? / Booster type																	X	X
Symptoms that may occur w/conditions such as allergies, colds and flu, COVID-19 or when taking certain medications																	X	X
Have you participated or are you currently participating in a COVID vaccine trial?																X		

***Added to autoimmune disease list at OBS 1**

***Added to autoimmune disease list at OBS 5**

***As of 1/2023, no longer asking "fibrocystic breast disease", (mammogram screening will be asked with other screening questions (every 3 years).**

REDCap (RC) electronic survey