

VITAL STUDY: Variables collected on the MAIN TRIAL QUESTIONNAIRES

Revised January 2024

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	OBS 6 Jan 2024
CONSENT/ DEMOGRAPHICS/ 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	X
First and Last Initial (REDCap only)													X	X	X	X	X	X	X
Who is completing the form (REDCap only)															X	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	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	X
E-mail address			X		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									

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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							
PHYSICAL ACTIVITY:																			
Time spent in weekly activities			X					X											X
Flights of stairs climb daily			X					X											
Usual walking pace			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	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	X
Other supps containing Omega-3					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	X
Aromatase inhibitor			X			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	X
Bone loss meds (listed)			X			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	X

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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	X
Estrogen						X	X	X	X		X		X		X	X	X	X	X
Hypertension meds (listed)		X				X	X	X	X		X		X		X	X	X	X	X ⁵
Lithium						X	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	X
NSAID											X		X		X	X	X	X	X
Serotonin reuptake inhibitor			X			X	X	X	X		X		X		X	X	X	X	X
Statins			X			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	
RX- weight loss medications																			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	X
Cancer (other than skin cancer)	X		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	X
Carotid artery surgery			X			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	X
Cataract			X																
Cataract surgery (extraction)			X			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	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	X
Coronary angioplasty or stent	X		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	X
Coronavirus (COVID-19)																			X
Deep vein thrombosis			X			X	X	X	X		X	X	X	X	X	X	X	X	X

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Diabetes		X	X			X	X	X	X		X	X	X		X	X	X	X	X	
Dry eye syndrome or dry eye dis.															X	X	X	X	X	
Fibrocystic breast disease – how confirmed? Mammogram/ biopsy			X			X	X	X	X		X	X	X		X	X	X	X ¹		
Gallbladder disease												X								
Gallbladder removal												X								
Gastric bypass surgery			X			X	X	X	X		X									
Headaches – describe symptoms		X							X											
Headaches – recurring										X		X								
Heart attack	X		X		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	X	
Hypercalcemia		X	X		X	X	X	X	X		X	X								
Hypertension		X				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	X	
Kidney failure or dialysis		X	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	X	
Multiple sclerosis			X			X	X	X	X		X	X	X		X	X	X	X ²		
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	X	
Peptic ulcer			X						X		X									
Periodontal disease			X			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	X	
Pneumonia – Dx / hospitalized?		X				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	X	
RLS – describe symptoms		X							X		X									
Sarcoid or Wegener’s		X	X			X	X	X	X		X	X	X ³							
Stroke	X		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	X	
Thyroid-underactive/overactive																			X	
Tuberculosis		X	X			X	X	X	X		X									

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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								
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								
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	
Currently smoking only																			X
OTHER RISK FACTORS:																			
Skin color/reaction to sun exposure		X																	
Lost 5 lbs. or more in past 2 years		X																	

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Specific blood pressure (SBP/DBP)		X																	
Total cholesterol		X																	
Menopausal history			X																
SCREENING Questions:																			
Rectal exam			X				X		X		X				X				X
Hemocult 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
ANCILLARY QUESTIONS:																			
DIABETIC KIDNEY DISEASE <ul style="list-style-type: none"> Dx of diabetes and treatment Had blood glucose test Dx of DKD 		X																	
KNEE PAIN <ul style="list-style-type: none"> How often have pain Pain when walking and for how long Knee replacement surgery Have osteoarthritis 		X																	
AUTOIMMUNE DISEASE <ul style="list-style-type: none"> Thyroid IBD PMR RA Psoriasis 		X				X	X	X	X		X	X	X		X	X	X	X	X

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<ul style="list-style-type: none"> Sarcoidosis or granulomatosis w/ polyangiitis (Wegener's) Multiple Sclerosis Other 																				
HYPERTENSION <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Dx of anemia Transfusion for anemia Evaluated by hematologist 		X				X	X	X	X											
RESPIRATORY DISEASE <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Broken bones (which/when) 			X			X	X	X	X		X	X	X		X	X	X	X	X	X

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MOOD <ul style="list-style-type: none"> 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	X A-B
FALLS <ul style="list-style-type: none"> Number of falls Result - need to see a doctor Evaluated at hospital 				X		X	X	X	X		X	X	X		X	X	X	X	X # of falls only
INFECTION <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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	X
Number of pregnancies							X												
Gestational diabetes							X												
Preeclampsia/gestational hypertension							X												

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In general, describe your health			X			X	X	X	X		X	X	X		X	X	X	X	X
Memory in past year									X		X	X	X		X	X	X	X	X
Avg. # of hours of sleep per night																		X	
EVER diagnosed w/sleep apnea																			X
EVER dx w/fatty liver disease, cirrhosis of liver or other severe liver dis., chronic viral hepatitis																			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							
OTHER QUESTIONS:																			
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.													X						

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Questions about how you are treated.																				
Do you have Hispanic or Latino heritage?													X							
Did you get the influenza (flu) vaccine after August, current year?																X	X	X	X	
Other Vaccines: RSV, shingles, pneumonia																				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	X ⁴		
Did you get the COVID-19 vaccine																X	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				

¹ Mammogram moved to screening question (No longer asking fibrocystic or other benign breast disease).

² MS added to Autoimmune Disease list.

³ Sarcoid/Wegener's added to Autoimmune Disease list.

⁴ COVID question moved to diagnosis grid.

⁵ No longer listing examples of medications for hypertension.