

VITAL STUDY: Variables collected on the MAIN TRIAL QUESTIONNAIRES

Revised January 2021

VARIABLES	WHICH FORM?												Final 2018	OBS 1 Jan 2019	OBS 1.5 REDCap only	OBS 2 Jan 2020	OBS 3 Jan 2021
	V-1	V-2	V-3	DIET	6- M O	YR 1	YR 2	YR 3	YR 4	YR 4.5	YR 5						
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
First and Last Initial (REDCap only)													X	X	X	X	X
Who is completing the form (REDCap only)															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
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
E-mail address			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
DIET																	
Dairy, eggs/meat, seafood, fruits & vegetables, beverages, and miscellaneous				X						X							
ALCOHOL CONSUMPTION																	
Beer, wine, liquor – average use/year				X					X	X							
LIMITED IN DAILY ACTIVITY																	
Climbing stairs, bending, kneeling, bathing, walking, lifting, moderate and vigorous activity				X				X	X		X	X					

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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
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
Other supps containing Omega-3					X								X		X	X	X
Calcium		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
Aromatase inhibitor			X			X	X	X	X		X		X		X	X	X
Aspirin (and days/month)			X			X	X	X	X		X		X		X	X	X
Bone loss meds (listed)			X			X	X	X	X		X		X		X	X	X
Calcitriol			X			X	X	X	X		X	X	X		X	X	X
Clopidogrel (Plavix)/antiplatelet med							X	X	X		X		X		X	X	X
Corticosteroids			X			X	X	X	X		X		X		X	X	X
Diabetes meds (listed)		X				X	X	X	X		X		X		X	X	X
Estrogen						X	X	X	X		X		X		X	X	X
Hypertension meds (listed)		X				X	X	X	X		X		X		X	X	X
Lithium						X	X	X	X		X		X		X	X	X
Non-statin cholesterol lowering			X			X	X	X	X		X		X		X	X	X
NSAID											X		X		X	X	X
Serotonin reuptake inhibitor			X			X	X	X	X		X		X		X	X	X
Statins			X			X	X	X	X		X		X		X	X	X
Tamoxifen			X			X	X	X	X		X		X		X	X	X
Thyroid medications								X	X		X		X		X	X	X

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OTHER MEDS USE																	
H2 antagonists											X		X		X	X	
Loop diuretics											X		X		X	X	
Proton pump inhibitors											X		X		X	X	
Thiazide diuretics													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	
Cancer (other than skin cancer)	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	
Carotid artery surgery			X			X	X	X	X		X	X	X		X	X	
Carotid stenosis			X			X	X	X	X		X	X	X		X	X	
Cataract			X														
Cataract surgery (extraction)			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	
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	
Coronary angioplasty or stent	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	
Deep vein thrombosis			X			X	X	X	X		X	X	X	X	X	X	
Diabetes		X	X			X	X	X	X		X	X	X		X	X	
Fibr. Breast disease – how confirmed?			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					
Heart attack	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	
Hypercalcemia		X	X		X	X	X	X	X		X	X					
Hypertension		X				X	X	X	X		X	X	X		X	X	
Intermittent claudication			X			X	X	X	X		X	X	X		X	X	
Kidney failure or dialysis		X	X			X	X	X	X		X		X		X	X	

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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	
Multiple sclerosis			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	
Peptic ulcer			X						X		X						
Periodontal disease			X			X	X	X	X		X	X	X		X	X	
Peripheral artery surgery / stenting			X			X	X	X	X		X	X	X		X	X	
Pneumonia – Dx / hospitalized?		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	
RLS – describe symptoms		X							X		X						
Sarcoid or Wegener's		X	X			X	X	X	X		X	X	X				
Stroke	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	
Tuberculosis		X	X			X	X	X	X		X						
Uterine fibroids			X														
OTHER major illness		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						

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	V-1	V-2	V-3	DIET	6- M O	YR 1	YR 2	YR 3	YR 4	YR 4.5	YR 5						
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														
Currently smoking (avg. cigs/day)			X			X		X			X		X		X	X	
Avg cigs./day – currently & lifetime			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	
Hemoccult or guaiac			X				X		X		X					X	
Colonoscopy			X				X		X		X					X	
Sigmoidoscopy			X				X		X		X					X	
Barium enema x-ray			X				X		X		X					X	
Eye exam		X				X	X		X		X					X	
BP measured						X	X		X		X					X	
PSA test			X				X		X		X					X	
Mammogram			X			X	X		X		X	X	X	X		X	
Breast biopsy			X			X	X		X		X	X	X	X		X	
Fasting blood sugar									X		X					X	

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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 *Sarcoidosis or granulomatosis w/ polyangiitis (Wegener's) Other 		X				X	X	X	X		X	X	X		X	X	
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	
ANEMIA <ul style="list-style-type: none"> Dx of anemia Transfusion for anemia Evaluated by hematologist 		X				X	X	X	X								

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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	
MOOD <ul style="list-style-type: none"> • Depression Dx • Felt sad 2+ weeks • Felt sad most days in 2 or more years • Past 2 weeks have you had these feelings (listed) 			X			X	X	X	Dx only		X	Dx only	X (Little interest or pleasure in doing things / Feeling down, depressed, or hopeless)		X (A-H)	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	
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						

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OTHER QUESTIONS																	
Urinary incontinence							X					X					
CHF hospitalization or emergency room						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
Memory in past year									X		X	X				X	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					
Marital status											X		X				X
Where do you live											X		X				X
With whom do you live											X		X				X
Are you a caregiver											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				

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Has a doctor or another healthcare professional dx you as having had or probably having had the coronavirus (COVID-19)?																	X
Have you participated or are you currently participating in a COVID vaccine trial?																	X
Did you get the influenza (flu) vaccine after August 2020?																	X

* Added to autoimmune disease list at OBS 1