# MOST Ancillary Study 05-03 (AS05-03) "MOST n-3 Fatty Acids and Knee OA" (Kristen Baker)

## TABLE OF CONTENTS

1.	Dataset description and Analyst Notes	2
2.	Reference:	2
3.	Flow-chart selection	3
4.	Appendix A. AS04-07 (MRI1.5T with gadolinium) study selection plan	4

## 1. Dataset description and Analyst Notes

Dataset: AS0503\_bioassay.sas7bdat Observations: 500 records (500 participants, 37 assays; 1 visit) Documentation:

- VariableGuide\_ AS0503\_bioassay.pdf
- Distributions\_ AS0503\_bioassay.pdf

AS0503\_bioassay dataset contains 500 records; one record per participant. Assays were performed at Tufts University Cardiovascular Nutrition Laboratory on 30-month plasma samples.

<u>Note</u>: the laboratory performing the assays was blinded to subject ID and any clinical characteristic.

The Multicenter Osteoarthritis Study (MOST) collected fasting blood from a random sample of roughly 50% of the study participants at the 30m study visit (participants with prior reported KR on either knee were not eligible to be selected for blood collection). This ancillary study entitled "The Association of n-3 Fatty Acids with Symptoms and Synovial Thickening in Knee Osteoarthritis (AS05-03)", under the direction of Kristin Baker, is funded to investigate the relation of plasma fatty acid content and synovitis in knee OA. The July 2008 batch for analysis at the Tufts University Cardiovascular Nutrition Laboratory includes samples from 500 study participants. The assay for analysis is plasma phospholipid fatty acid composition. The Tufts University Cardiovascular Nutrition Laboratory (Nirupa Matthan, Coordinator) has a subcontract with Boston University to perform assays for the MOST n-3 Fatty Acids and Knee OA ancillary study.

#### Analyst Notes:

- If there was insufficient volume or some other reason assay could not be performed, and all assay values were missing, the record is not included in the analytical dataset.
- Coordinating Center did not receive any documentation from laboratory about the assays performed. The QA report could not be developed due to lack of information about normal range.

#### 2. <u>Reference:</u>

Baker KR, Matthan NR, Lichtenstein AH, Niu J, Guermazi A, Roemer F, Grainger A, Nevitt MC, Clancy M, Lewis CE, Torner JC, Felson DT. Association of plasma n-6 and n-3 polyunsaturated fatty acids with synovitis in the knee: the MOST study. Osteoarthritis Cartilage. 2012 May;20(5):382-7. doi: 10.1016/j.joca.2012.01.021. Epub 2012 Feb 4. PMCID: 3471561 http://www.ncbi.nlm.nih.gov/pubmed/22353693

## 3. Flow-chart selection



#### Notes:

- 1) Only random sample of participants (approx. 50%) were eligible for blood collection at the 30-month visit due to parent study funding limitations. Participants with known knee replacement (prior to the 30-month visit) were not eligible to be selected for blood collection.
- Additional selection criteria for ancillary study eligibility: participants are required to have gadolinium enhanced 1.5T MRI collected and read for 30m synovitis status (AS04-07, PI: Dr. D Felson, dataset V2MRI15T\_gadolinium).

## 4. Appendix A. AS04-07 (MRI1.5T with gadolinium) study selection plan

David Felson's MOST ancillary study AS04-07, "Structural Correlates of Knee Pain" (aka Gadolinium Study) provides funding for 30-month enhanced with gadolinium 1.5T MRI scans in one knee per participant for up to 900 study participants (450 participants at each of the two clinical centers).

V2MRI15T\_gadolinium dataset contains 587 records; one record per knee/participant with a Gadolinium enhanced 1.5T MRI collected during 30m clinic visit for selected group of participants (one knee per person) who met study inclusion criteria.

Exclusion by participant:

- Deceased or withdrew consent
- Both knees not eligible: K/L grade 4 (end stage OA); knee replacement (KR); inflammatory arthritis

Exclusion by knee:

- No baseline MRI
- Knee MRI ineligible (contraindication prior to clinic visit)
- Excluded due to missing patella, osteonecrosis, or amputation below knee
- Knee not eligible: K/L grade 4 (end stage OA) or KR.

Inclusion criteria:

- One knee per participant with K/L grade between 0 and 3
- Had BL+30M 1.0T knee MR (Baseline MRI obtained, no contraindication for 30m MRI recorded)
- Select knee with lower K/L grade
- If K/L grade is the same in both knees, use dominant knee (right is default if leg dominance is missing)

 Table 1: Enrollment Status by race, sex/gender and age category.

Both Clinics	Age 50-59		Age 60-69		Age 70-79		Subtotal		
	Female	Male	Female	Male	Female	Male	Female	Male	Total
White or Caucasian	147	133	97	97	30	38	274	268	542
Black or African American/ Other non-white race	17	11	10	4	2	1	29	16	45
Total	164	144	107	101	32	39	303	284	587

See V2MRI15T\_gadolinium dataset and documentation for additional information.