MOST 15-MONTH FOLLOW-UP

DATASET DESCRIPTION

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This document describes the MOST 15-month clinical dataset and data issues relevant to analysts. If you are unfamiliar with the data, it may be useful to begin by reviewing the annotated data collection forms to look for variables of interest.

FORMATS

SAS Format Library

The SAS format library (FORMATS.SAS7BDAT) contains all the formats used for the dataset.

DATASET

15-Month Telephone Interview and Clinic Visit (V1ENROLL)

The 15-month dataset (V1ENROLL.SAS7BDAT) includes clinical data from the 15-month follow-up study contacts, including a telephone interview and, for a subset of participants, a self-administered questionnaire (completed in clinic) and a clinic visit.

Variables are sorted in the order of data collection ("creation order") – as if following the participant from the first telephone screening question to the last measurement at the clinic. Page numbers referenced below correspond to the bracketed page numbers located at the bottom of each page of the annotated data collection forms.

Refer to the annotated forms for the temporal context of each variable. Data for some measurement questions was collected for the time period "since the last visit" while for others the time period was fixed (e.g., past 12 months).

There are entries for 3007 participants in this dataset. Many participants have missing values for the clinic visit measures because not all participants were eligible for a clinic visit. Eligible participants were selected for a clinic visit with or without knee radiographs.

Participants were eligible for a clinic visit at 15-months if one or both knees met the following eligibility criteria:

- the participant reported "No" to frequent knee symptom questions on most days of the past 30 days in at least one knee – the "knee of interest" – at BOTH the baseline telephone screening interview and the baseline clinic visit interview, and
- the knee of interest did not have radiographic exclusions at baseline (exclusion examples include TKR, osteonecrosis, missing patella, etc.).

Among participants with at least one knee of interest, they were eligible for a clinic visit with knee radiographs if they reported "Yes" to frequent knee symptom questions (new symptoms) for that knee at the 15-month telephone interview. These participants will have the value of 1 (“case”) for the variable V1CASE in the dataset. Analysts must be aware that this indicates a **potential** case knee meeting the MOST investigators’ endpoint definition for symptomatic incidence of knee osteoarthritis, not a confirmed case knee. Confirmed symptomatic incidence of knee osteoarthritis is available as a derived variable, V1R_SX (right) or V1L_SX (left), with the values of 1 (case) and 2 (control). Participants with a knee of interest that were eligible but did not have a clinic visit will have a value of 3 (non-clinic).

Among participants with a knee of interest who did not meet the above criteria, participants were eligible for a clinic visit without radiographs if the knee of interest had readable baseline 1.0T knee MRI scans and the participant reported "No" to frequent knee symptoms (no new symptoms) for that knee at the 15-month telephone interview. A random selection was done among participants eligible for a clinic visit without radiographs to meet an approximate 1:1 ratio of participants with and without radiographs, matched by clinic. These participants will have the value of 2 (“control”) for the variable V1CASE in the dataset. Analysts must be aware that this indicates a **potential** control knee for the MOST investigators’ endpoint definition of symptomatic incidence of knee osteoarthritis, not a confirmed control knee. The clinics successfully completed 635 15-month clinic visits.

15-month Clinic Visit (Participants):

	With Knee Radiographs	Without Knee Radiographs	Total
Clinic 1	144	162	306
Clinic 2	149	180	329
Total	293	342	635

Analysts should be aware that clinic visit eligibility was subject to change, depending on a number of factors including clinic screening errors and participant willingness to come to the clinic. Due to mistakes determining eligibility by clinic staff, some participants who completed a 15-month clinic visit were not eligible for the visit; however, their clinic visit data is still included in the V1ENROLL dataset.

Telephone Interview (Variables with ‘V1’ prefix)

The 15-month telephone interview was conducted to assess eligibility for the clinic visit. The dataset includes the following components:

pp1-2	Knee symptoms (pain, aching, and stiffness)
pp3-5	Knee injury and/or surgery
p6	Hip pain
p12	Fracture history

Self-Administered Questionnaire (SAQ) – Clinic (Variables with "V1" prefix)

The SAQ-Clinic was administered during the 15-month clinic visit. The dataset includes the following components:

p16	Joint pain, aching, and stiffness (homunculus diagram)
–	Modified WOMAC™ knee pain and stiffness[1,2]
–	Modified WOMAC™ degree of difficulty performing daily activities[1,2]
pp21-22	Knee pain visual analog scale (VAS)
p23	Modified KOOS Function in sports and recreational activities subscale[3]
pp24-25	Late-Life Function and Disability Instrument (LLFDI) – Modified Disability Component[4,5]
pp26-27	Modified SF-12 U.S. version 1.0[6]

Notes:

[1] WOMAC Osteoarthritis Index™ Likert version. This measurement was modified to include a "don't do" option for participants who cannot rate severity of pain during a particular activity because they avoid or are unable to do that activity.

[2] The WOMAC™ instrument is not displayed in the annotated forms because it is trademark and copyright protected. Information can be obtained by contacting the author, Nicholas Bellamy, via the WOMAC™ 3.1 Index website (http://www.auscan.org/womac).

[3] KOOS Function in Sports and Recreational Activities Subscale, Likert version. This measurement was modified to include a "don't do" option for participants who cannot rate severity of pain during a particular activity because they avoid or are unable to do that activity.

[4] Late-Life Function and Disability Instrument (LLFDI) – Modified Disability Component. This measurement was shortened to 12 of the authors' 16 disability subscale questions and included only the extent of limitation performing activities ("To what extent do you feel limited in …?"). Frequency performing activities ("How often do you ..?") was not collected and the last of 5 options – [Not at all] [A little] [Somewhat] [A lot] [Completely, cannot do] – was modified with "cannot do" dropped.

[5] Scoring of this measurement was modified to handle missing values in a way that is consistent with how MOST analysts scored the WOMAC™ and SF-12 measures. For more information, refer to the document Calculated Variable Descriptions and SAS Code, and also see Jette AM, et al. Late life function and disability instrument: I. Development and evaluation of the disability component. J Gerontol A Biol Sci Med Sci. 2002 Apr;57(4):M209-16. PMID: 11909885.

[6] SF-12 U.S. version 1.0. This measurement was modified to include a "Don't know" option on questions concerning the extent to which physical health limited work or other regular daily activities in the past 30 days (questions #29 – 32 on annotated forms p26).

Clinic Interview (Variables with "V1" prefix)

The clinic interview is an interviewer-administered questionnaire conducted during the 15-month clinic visit. The dataset includes the following components:

pp30-31	Knee pain, aching, or stiffness
p33	Medication Inventory Form (MIF) [1,2]

Notes:

[1] There were some differences in medication collection between the baseline and 15-month visits. At the baseline visit, all medications taken in the last 30 days (prescription, non-prescription, vitamins, supplements) were recorded, but at the 15-month visit, only targeted medications (prescription, non-prescription, vitamins, supplements) – those used for pain or arthritis in the last 30 days – were recorded.

[2] Medication ingredients, coded by the UCSF MIF group using the Iowa Drug Information Service (IDIS) dictionary, are released in Yes/No format, meaning used or not used during the last 30 days. Formulation code, duration, and frequency are not released. For further information about IDIS, see Pahor M, Chrischilles EA, and Guralnik, JM. Drug data coding and analysis in epidemiologic studies. Eur J Epidemiol. 1994 Aug;10(4):405-11.

Clinic Visit (Variables with "V1" prefix)

Selected exams were conducted at the baseline clinic visit. The dataset includes the following components:

p34	Weight
pp38	OrthOne 1.0T knee MRI[1,2]
p40	Knee x-ray[2,3]

Notes:

[1] Among participants who completed the clinic visit with radiographs, MRI scans were done on both knees if the knees were eligible for MRI after safety screening. In a contrast, among participants who completed the clinic visit without radiographs, MRI scans were done only on the knee of interest if, following safety screening, it was eligible for MRI.

[2] Some participants returned to the clinic to repeat x-ray and MRI exams when image quality was not adequate for reading. Repeat data is not included in the dataset.

[3] Eligible participants only (see dataset description on pages 1 and 2 above).