#### **MOST 60-MONTH FOLLOW-UP**

#### **DATASET DESCRIPTION**

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This document describes the MOST 60-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**

60-month Telephone Interview and Clinic Visit (V3ENROLL.SAS7BDAT)

Observations: 2768 (1 record per participant)
Annotated Forms: V3AnnotatedForms.pdf
Variable Guide: VariableGuide\_V3ENROLL.pdf
Distributions: Distributions\_V3ENROLL.pdf

The 60-month dataset (V3ENROLL.SAS7BDAT) includes clinical data from the 60-month follow-up study contacts (N=2768), including a telephone interview, two self-administered questionnaires (one done at home and the other done at the clinic), a clinic interview, and clinic visit. All participants enrolled at baseline and not deceased or withdrawn from the study were eligible for the 60-month clinic visit.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).

# **Telephone Interview (Variables with 'V3' prefix)**

The telephone interview was conducted approximately 4 weeks before the clinic visit date to assess frequent knee symptoms and eligibility for MRI. The dataset includes the following components:

pp1-2 Knee symptoms (pain, aching, and stiffness)

# Self-Administered Questionnaire (SAQ) – Home (Variables with "V3" prefix)

The SAQ-Home was mailed to participants after the telephone interview. Participants were instructed to complete the questionnaire at home prior to departure for the clinic visit. The dataset includes the following components:

p9	Arthritis diagnosis <sup>1</sup>
	Charlson Comorbidity Index – Katz Questionnaire Adaptation <sup>1,2</sup> Fractures <sup>1</sup> ; Falls
pp17-18	Joint pain, aching, and stiffness (homunculus diagram)
p19	Back pain and function <sup>3</sup>
	Targeted arthritis medications for joint pain or arthritis
pp22-24	Modified SF-12 U.S. version 1.0 <sup>1</sup>
pp25-26	CES-D (Depression scale) – Long version
pp28-29	Late Life Function and Disability Instrument (LLFDI) – Modified
	Disability Component <sup>4,5</sup>
p30	Assistive Aids and Devices
p31	Current employment
p32	Household Living and Financial Difficulty

#### Notes:

<sup>&</sup>lt;sup>1</sup> Participants who refused or were unable to participate in the 60-month clinic visit were asked to participate in an extended telephone interview (the Missed Clinic Visit Telephone Interview) that covered some questions from the SAQ-Home and Clinic Interview. Therefore, there are differences in numbers of missing values between questions that include data from the extended interview versus those that do not include data from the extended interview.

<sup>&</sup>lt;sup>2</sup> Charlson Comorbidity Index – Katz Questionnaire Adaptation. This measurement was modified to include the option of "Don't know" to accommodate participants unable to answer "Yes" or "No" to any question with certainty. Responses of "Don't know" were scored with a zero value (see the document: Calculated Variable Descriptions and SAS Code).

<sup>&</sup>lt;sup>3</sup>Responses to two back pain questions, "How many days did you stay in bed because of your back?" (V3BDDAY) and "How many days did you limit your activities because of your back?" (V3BPLAD) are numbers of days designed to sum to no more than 30. Analysts should be aware that some participants misunderstood and provided responses that sum to greater than 30.

<sup>4</sup> 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.

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

# Self-Administered Questionnaire (SAQ) - Clinic (Variables with "V3" prefix)

The SAQ-Clinic was administered during the 60-month clinic visit. The dataset includes the following components:

pp33-35	Modified WOMAC™ knee pain and stiffness <sup>1,2</sup>
	Modified WOMAC <sup>™</sup> degree of difficulty performing daily activities <sup>1,2</sup>
pp36-37	Knee pain visual analog scale (VAS)
p38	Modified KOOS Function in sports and recreational activities subscale <sup>3</sup>

### Notes:

<sup>&</sup>lt;sup>1</sup> WOMAC Osteoarthritis Index<sup>™</sup> 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.

<sup>&</sup>lt;sup>2</sup> The WOMAC<sup>™</sup> 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<sup>™</sup> 3.1 Index website (http://www.auscan.org/womac).

<sup>&</sup>lt;sup>3</sup> 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.

# Clinic Interview (Variables with "V3" prefix)

The clinic interview is an interviewer-administered questionnaire conducted during the 60-month clinic visit. The dataset includes the following components:

pp40-48 Knee pain, aching, and stiffness p48 Knee buckling<sup>1</sup> p51 Knee injury<sup>1</sup> pp52-53 Knee surgery<sup>1,2</sup> pp54-55 Hip pain, aching, and stiffness<sup>1,2</sup> p59 Knee injections for arthritis<sup>1</sup> p62 Medication Inventory Form (MIF)<sup>3,4</sup>

# Notes:

<sup>&</sup>lt;sup>1</sup> Participants who refused or were unable to participate in the 60-month clinic visit were asked to participate in an extended telephone interview (the Missed Clinic Visit Telephone Interview) that covered some questions from the SAQ-Home and Clinic Interview. Therefore, there are differences in numbers of missing values between questions that include data from the extended interview versus those that do not include data from the extended interview.

<sup>&</sup>lt;sup>2</sup> Knee and hip replacement data, baseline through 30 months, is released in the dataset OUTCOMES.SAS7BDAT.

<sup>&</sup>lt;sup>3</sup> Participants were asked to bring all medications taken in the last 30 days (prescription, non-prescription, vitamins, supplements) to be recorded.

<sup>&</sup>lt;sup>4</sup> 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. <u>Drug data coding and analysis in epidemiologic studies</u>. Eur J Epidemiol. 1994 Aug;10(4):405-11.

# Clinic Visit (Variables with "V3" prefix)

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

p65 Blood pressure p66 Standing Height and Weight pp67-68 20-meter walk<sup>1</sup> pp69-70 Chair stands Knee x-ray<sup>2,3</sup> p96 OrthOne 1.0T knee MRI<sup>2,3</sup> p100

Notes:

<sup>1</sup> The two clinical sites interpreted the protocol for measuring the stop time in slightly different ways; see page 4, section 5 of the 20-meter Walk Operations Manual.

<sup>&</sup>lt;sup>2</sup> Starting at 60 months, knees with end-stage osteoarthritis (K/L 3.5 or 4) were excluded from x-ray lateral view and MRI exam.

<sup>&</sup>lt;sup>3</sup> 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.