### **MOST 30-MONTH FOLLOW-UP**

### DATASET DESCRIPTION

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This document describes the MOST 30-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

30-Month Telephone Interview and Clinic Visit (V2ENROLL.SAS7BDAT)Observations:2969 (1 record per participant)Annotated Forms: AnnotatedForms\_30m.pdfVariable Guide:VariableGuide\_V2ENROLL.pdfDistributions:Distributions\_V2ENROLL.pdf

The 30-month dataset (V2ENROLL.SAS7BDAT) includes clinical data from the 30month follow-up study contacts (N=2969), including a telephone interview, two selfadministered questionnaires (one done at home and the other done at the clinic), a clinic interview, and clinic visit. All participants not deceased or lost to follow-up were eligible for the 30-month clinic visit. If the participant did not consent to share data, data values are set to the missing value, "Not expected", in the dataset.

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.

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 'V2' 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:

Knee symptoms (pain, aching, and stiffness)

## Self-Administered Questionnaire (SAQ) – Home (Variables with "V2" prefix)

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

Joint pain, aching, and stiffness (homunculus diagram) Back pain and function<sup>1</sup> Arthritis diagnosis<sup>2</sup> Targeted arthritis medications for joint pain or arthritis Charlson Comorbidity Index – Katz Questionnaire Adaptation<sup>2,3</sup> Fractures<sup>2</sup>; Falls Current employment Late Life Function and Disability Instrument (LLFDI) – Modified Disability Component<sup>4,5</sup> Modified SF-12 U.S. version 1.0<sup>2,6</sup> CES-D (Depression scale)<sup>7</sup>

Notes:

<sup>1</sup> Responses to two back pain questions, "How many days did you stay in bed because of your back?" (V2BDDAY) and "How many days did you limit your activities because of your back?" (V2BPLAD) 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>2</sup> Participants who refused or were unable to participate in the 30-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>3</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). For more information refer to: Katz JN, Chang LC, Sangha O. Can comorbidity be measured by questionnaire rather than medical record review? Med Care, Volume 34(1). Pages 73-84. January 1996.

<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 this 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. 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.

<sup>6</sup> 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. For more information refer to: Ware JE, Kosinski M, Keller SD. SF-12: How to score the SF-12 Physical and Mental Health Summary Scores. Lincoln, RI: QualityMetric Incorporated, Third Edition, 1998.

<sup>7</sup> For more information refer to: Radloff, L.S. The CES-D scale: a self report Major Depressive Disorder scale for research in the general population. Applied Psychological Measurement, 1, 1977. pp385-401.

### Self-Administered Questionnaire (SAQ) - Clinic (Variables with "V2" prefix)

The SAQ-Clinic was administered during the 30-month clinic visit. The dataset includes the following components:

Modified WOMAC<sup>™</sup> knee pain and stiffness<sup>1,2</sup> Modified WOMAC<sup>™</sup> degree of difficulty performing daily activities<sup>1,2</sup> Knee pain visual analog scale (VAS) Modified KOOS Function in sports and recreational activities subscale<sup>3</sup> Modified WOMAC<sup>™</sup> Osteoarthritis Index – Hip pain<sup>1,2</sup>

Notes:

<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>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 (<u>http://www.auscan.org/womac</u>).

<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. The "Function in sport and recreation" subscale of the Knee Injury and Osteoarthritis Outcome Score (KOOS) was calculated according to the KOOS User's Guide, which can be found at the following website: http://www.koos.nu/

### Clinic Interview (Variables with "V2" prefix)

The clinic interview is an interviewer-administered questionnaire conducted during the 30-month clinic visit. The dataset includes the following components:

Knee pain, aching, and stiffness Knee buckling<sup>1</sup> Knee injury<sup>1</sup> Knee surgery<sup>1,2</sup> Hip pain, aching, and stiffness<sup>1,2</sup> Medication usage history (bisphosphonates, knee injections for arthritis<sup>1</sup>, testosterone, estrogen) Pregnancy/woman health history Medication use (vitamin E and C) Medication Inventory Form (MIF)<sup>3,4</sup>

#### Notes:

<sup>1</sup> Participants who refused or were unable to participate in the 30-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>2</sup> Knee and hip replacement data, baseline through 84 months, is released in the dataset OUTCOMES.SAS7BDAT.

<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>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 released in a separate dataset (V2MIF). 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 "V2" prefix)

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

Blood pressure Weight 20-meter walk Chair stands Knee and hip examination<sup>1</sup> Knee x-ray<sup>2</sup> OrthOne 1.0T knee MRI<sup>2</sup>

Notes:

<sup>1</sup>The knee and hip examination data is for a subset of participants. Eligibility for the exam is based on eligibility criteria outlined in the study protocol.

<sup>2</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.