Guide to Use of Data Sets in 2017 Release (updated July 14, 2020)

This data release includes both data gathered directly on case report forms (CRFs) and derived datasets. Datasets are provided in both SAS and CSV format. Documentation for each data with descriptions of the each field is provided in Excel format as well.

All records have been de-identified and stripped of dates. When merging data across files, the unique identifier "maskid" should be used to match participants. The temporal sequence of visits and outcome events are determined by the days post-randomization rather than dates. All baseline observations have days post-randomization defined as zero ("0") days.

Below is a list of the datasets included in the release. For each there is a SAS dataset (".sas7bdat"), a comma-delimited file (".csv"), and a data dictionary in MS Excel format (".xlsx"). The data dictionaries include "Form" in the filename if the data are directly from a CRF and "Derived" in the filename if the dataset is derived.

1. Key baseline variables – dataset name "keyvar". This dataset includes treatment arm assignment, indicators of baseline subgroup membership, clinical/subclinical CVD history, age at randomization, and (masked) clinical site number.

2. Case Report Form (CRF) data – these datasets include pertinent variables collected on study CRFs. Note that there are several datasets corresponding to blood pressure management. Those datasets will need to be merged together to create a full picture of the intervention implemented across the course of the study for individual participants. CRF datasets include:

CRF	Dataset Name
Inclusion/Exclusion Summary	incl_excl
Self-Administered Baseline History	bl_history
BP Management Form – Baseline	bp_manage_base
Intensive BP Management Form 1M Visit	intbp_manage_1m
Intensive BP Management Form 2M, 3M, 9M, ... PRN Visits	intbp_manage_2m
Intensive BP Management Form 18M, ... Milepost Visits	intbp_manage_18m
Intensive BP Management Form 6M, ... Milepost Visits	intbp_manage_6m
Standard BP Management 1M, 6M, 12M, 24M, ... and 72M Visits	stbp_manage_anfu
Standard BP Management 2M, 3M, 9M, PRN and non-annual Visits	stbp_manage_nanfu
BP Management Form Closeout Visit (both arms)	bp_manage_co
Blood Pressure Medication Management Log	bp_med_log_v2
Baseline Medications and Physical Exam Form	bl_meds_physexam
Baseline Medications and Physical Exam Form (with 4 meter walk)	bl_medsphys4m
Annual Medications and Physical Exam History Form	ahmedsphyexam
Annual Medications and Physical Exam History Form (with 4 meter walk)	ahmedsphyexam4m
MIND Screening Battery Baseline	bl_mindscreening
MIND Extended Battery Baseline	bl_mindextended
Self-Administered Men's Health	mens_health
Self-Administered Women's Health	womens_health
My Health	my_health

CRF	Dataset Name
Falls Self Efficacy	fse
Encounter and Disposition Form	encount_dispos
Encounter and Disposition - Closeout Form	enc_dis_closeout

3. Lab data – dataset name "labs". A derived dataset with summary of clinical laboratory measures. Observations have been summarized and collapsed into one per study visit.

4. ECG data – dataset name "ecg". A derived dataset with selected variables from study ECG readings.

5. SAE data – dataset name "safety_events_v2". A derived dataset with serious adverse event and follow-up time to SAE. File includes MedDRA coded events. Participants will appear more than once if multiple SAEs were observed. The file includes events only (i.e., no "censoring" observation is included for participants who did not have an SAE).

6. Outcome survival datasets – derived datasets with time-to-first-event information for study outcomes. User should refer to the SPRINT Protocol for specific definitions of study outcomes. Survival datasets include:

   albuminuriackd – incident albuminuria in the CKD subgroup
   albuminurianonckd – incident albuminuria in the non-CKD subgroup
   alldeath – all-cause mortality (adjudicated)
   ckdeventsnonckd – CKD events in the non-CKD subgroup
   ckdeventsckd – CKD events in the CKD subgroup
   cvddeath – cardiovascular deaths (adjudicated)
   egfreventsckd – eGFR events in the CKD subgroup
   egfreventsnonckd - eGFR events in the non-CKD subgroup
   esrd – end stage renal disease events (adjudicated)
   heartfailsurv – heart failure events (adjudicated)
   misurv – clinical myocardial infarction events (adjudicated)
   noncvddeath – non-cardiovascular deaths (adjudicated)
   nonmiacssurv – non-MI acute cardiovascular events (adjudicated)
   primarysurv - primary study outcome events (adjudicated)
   strokesurv – stroke events (adjudicated)
   vascularprocsurv – vascular procedures
   censored_prior – censoring times for analysis of CVD events prior to August 20, 2015

7. Outcome events datasets – derived datasets with information on recurrent, non-fatal, adjudicated study outcomes. Datasets include events only (there are no censoring values for participants without events). Outcome events datasets include:

   heartfailall - all adjudicated heart failures
   miall - all adjudicated MIs

nonmiacsall - all adjudicated non-MI ACS events
primaryall - all adjudicated primary outcome events
strokeall - all adjudicated strokes
vascularprocall - all vascular procedures (not an adjudicated outcome)

8. MIND MRI baseline datasets – derived datasets which include pertinent variables collected as part of the MRI ancillary study baseline exams and were performed in MIND study participants only. MIND MRI datasets include:

Description	Dataset Name
MRI total summary, baseline exam	mri_total_base
MRI vascular reactivity, baseline exam	mri_vr_base
MRI apparent division coefficient, baseline exam	mri_tr_base
MRI fractional anisotropy, baseline exam	mri_fa_base
MRI breath-hold number of activated voxels, baseline exam	mri_numact_vr_base
MRI mean cerebral blood flow, baseline exam	mri_cbf_base
MRI summary, baseline exam	mri_base
MRI abnormal results, baseline exam	mri_abnormal_base

All datasets with follow-up observations include an indicator variable ending in "_postI" to identify observations that occurred on or after August 20, 2015 which was the end of the active SPRINT intensive BP intervention.