The Metabolic Control Study Data Archive

The Metabolic Control Archive contains the Protocol, Forms, Study data, Paper and Dataset Integrity Check.

Archive files are organized into the following directories:

- Documents
- Forms
- Data
- Dataset Integrity Check (DSIC)

Documents

The Metabolic Control Documents directory contains:

- Data dictionary.docx: List of datasets available in subsequent transmission
- Protocol P-Metabolic Control Study.pdf: Protocol of how the study was designed.
- ProtocolP-ReadMe.rtf: Summary of Protocol and contents of files.

Forms

The Metabolic Control Forms directory contains the following:

- crfPAdmissionDischangeForm.pdf
- crfPAdverseEventForm.pdf
- crfPCGMSensorUseForm.pdf
- crfPClosedLoopTherapyForm.pdf
- crfPConcomMedincation.pdf
- crfPEnrollmentHxForm.pdf
- crfPFollowUpHxForm.pdf
- crfPHbA1cForm.pdf
- crfPHypoglycemicHyperglycemicEventsForm.pdf
- crfPInsulinManagementForm.pdf
- crfPMixedMealToleranceForm.pdf
- crfPNonProtocolVisitForm.pdf
- crfPPreExistingConditionsForm.pdf
- crfPSkinAssessForm.pdf

Data

The Metabolic Control data directory contains the following datasets in *SAS* format:

- contacts.sas7bdat: one record per visit per subject dataset
- gluindices.sas7bdat: one record per visit per subject dataset
- padvevent.sas7bdat: One record per Adverse Event Form
- pclactivedata.sas7bdat: Automatic control intervals of closed-loop system; loaded from Medtronic documentation
- pclhypereventsdetail.sas7bdat: One record per hyperglycemic event entered in Hyperglycemic Events child form, child table of tblPCLHypoHyperEvents
- pclhypoeventsdetail.sas7bdat: One record per hypoglycemic event entered in Hypoglycemic Events child form, child table of tblPCLHypoHyperEvents
- pclhypohyperevents.sas7bdat: One record per completed Hypoglycemic and Hyperglycemic Events Form
- pclinsulindata.sas7bdat: Insulin delivery data during closed-loop; loaded from Medtronic spreadsheet file
- pclmealdata.sas7bdat: Meal data during closed-loop; loaded from spreadsheet file supplied by clinical site
- pclrefglucdata.sas7bdat: Reference glucose data during closed-loop; loaded from spreadsheet file supplied by clinical site
- pclsensordata.sas7bdat: CGM data during closed-loop; loaded from Medtronic spreadsheet file
- pcltherapy.sas7bdat: One record per completed Closed Loop Therapy Information Form
- pconcommeddetail.sas7bdat: One record per medication on a Concomitant Medication Form
- pcrcadmissiondischarge.sas7bdat: One record per completed CRC Admission and Discharge Information Form
- pdatacgm.sas7bdat: One record per RT-CGM sensor reading per patient and device
- pdcahba1c.sas7bdat: One record per DCA2000 Hemoglobin A1c Test per patient
- penrollmenthx.sas7bdat: One record per Enrollment History Form per patient
- pfollowuphx.sas7bdat: One record per follow-up visit
- pinsmanage.sas7bdat: One record per Insulin Management form per patient
- plabresults.sas7bdat: One record per lab result received
- pmixedmeal.sas7bdat: Mixed Meal Tolerance Test data for subjects
- pnonvisit.sas7bdat: One record per Non-Protocol Visit per patient
- ppreexistcond.sas7bdat: One record per Pre-Existing Conditions Form
- psensoruse.sas7bdat: One record per completed CGM Use Form
- pskinassess.sas7bdat: One record per skin assessment
- ptroster.sas7bdat: One record per patient per protocol
- subjects.sas7bdat: one record per subject dataset

DSIC

The Metabolic Control Data Integrity Check (DSIC) directory contains:

- 15Dec2015 Metabolic DSIC.docx: A report of an examination of the Buckingham et al. in Diabetes Care, December 2013 Manuscript datasets for completeness by statisticians and quality control specialists at the Repository. This dataset was used to replicate Tables 1 and Supplementary Tables 1, 2 and 3. Published results from the Metabolic Control data were compared to values recalculated from the Metabolic Control datasets in the NIDDK repository.