

The CIT-07 Study Data Archive

The Islet Transplantation in Type 1 Diabetes (CIT-07) Archive contains the Study Data, Data Dictionary, and Dataset Integrity Check, and Documentation.

Note that the Data_Dictionary.xls file contains the data dictionaries for all of the datasets included in this data package.

Archive files are organized into the following directories:

- Data
- Dataset Integrity Check (DSIC)
- Documentation

Data

The CIT-07 data directory contains the following datasets with primary id (ACCESSION) in SAS format. Note that some CIT-08 visits are also included (Flag08).

- albumin_crea_gfr_components.sas7bdat
- albumin.sas7bdat
- alkphos.sas7bdat
- alt.sas7bdat
- ast.sas7bdat
- atherogenic.sas7bdat
- autoantibodies.sas7bdat
- beta_score.sas7bdat
- bilirubin.sas7bdat
- bloodsugar.sas7bdat
- bloodtype_hla.sas7bdat
- bun.sas7bdat
- calcium.sas7bdat
- central_hdl.sas7bdat
- central_ldl.sas7bdat
- central_total_cholesterol.sas7bdat
- central_triglycerides.sas7bdat
- cgms.sas7bdat
- chloride.sas7bdat
- cimt.sas7bdat
- clarke.sas7bdat
- co2.sas7bdat
- cpeptide_glucose_creatinine_v2.sas7bdat
- ddsv2.sas7bdat
- demographics.sas7bdat
- diastolic_blood_pressure.sas7bdat
- drug_dosev2.sas7bdat
- endpoints.sas7bdat
- eq5dv2.sas7bdat

- fsigt_airglu.sas7bdat
- fsigt_raw.sas7bdat
- gammagt.sas7bdat
- general_assessment.sas7bdat
- gfr_sharev2.sas7bdat
- hba1c_share.sas7bdat
- hematocrit.sas7bdat
- hemoglobin.sas7bdat
- hfsv2.sas7bdat
- hyporecall.sas7bdat
- hypo.sas7bdat
- ieq_infused.sas7bdat
- insulin.sas7bdat
- li.sas7bdat
- local_hdl.sas7bdat
- local_ldl.sas7bdat
- local_serum_creatinine.sas7bdat
- local_total_cholesterol.sas7bdat
- local_triglycerides.sas7bdat
- lymphocyte.sas7bdat
- mage.sas7bdat
- magnesium.sas7bdat
- manufacturingother.sas7bdat
- manufacturing.sas7bdat
- mean_insulin.sas7bdat
- medical_history.sas7bdat
- neutrophils.sas7bdat
- patientstatus.sas7bdat
- phosphorus.sas7bdat
- pilotendpoints.sas7bdat
- platelet.sas7bdat
- potassium.sas7bdat
- pra.sas7bdat
- pt.sas7bdat
- ptt.sas7bdat
- pulse.sas7bdat
- retinopathy.sas7bdat
- rudbeckclinical.sas7bdat
- safety.sas7bdat
- serology.sas7bdat
- sf36v2.sas7bdat
- sodium.sas7bdat
- systolic_blood_pressure.sas7bdat
- trough_level.sas7bdat
- tsh.sas7bdat
- wbc.sas7bdat
- weight.sas7bdat
- whocoding.sas7bdat

- /Data/Data_Dictionaries: This subdirectory contains contents listings for each of the datasets listed above. The documents contain a brief description of the corresponding dataset, as well as descriptions of the variables and any corresponding formats.

DSIC

The CIT-07 Data Integrity Check (DSIC) directory contains:

- CIT_07_DSIC.docx – A report of an examination of the CIT-07 datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Table 1 from the paper “Phase 3 Trial of Transplantation of Human Islets in Type 1 Diabetes Complicated by Severe Hypoglycemia” by Hering et al. Published results from the CIT-07 data were compared to values recalculated from CIT-07 archived datasets in the NIDDK repository.

Documentation

The CIT-07 Documentation directory contains:

- CIT-07 ClinicalCRFsAnnotated.pdf – Contains the Case Report Forms (CRFs), with the exception of SF-36 which was excluded because of copyright. This document can be used with the Data_Dictionary.xls file to find specific variables in the dataset.
- CIT-07 Forms Grid_V8.pdf – Contains information regarding the time points when data was collected.
- CIT-07 Monitoring Plan V5.0 16Oct12.pdf – Contains information regarding the monitoring plan for the study
- CIT-07 MOP version 8.0.pdf – Manual of Operation
- CIT-07 Protocol_Version 8.0_20Aug12.pdf – Protocol
- CIT-07 SpecificLabManualv8.0.pdf – Lab Manuals