

The CIT-04 Study Data Archive

The LEA29Y (Belatacept) Emory Edmonton Protocol (LEEP) and Extended Follow Up after Islet Transplantation in Type 1 Diabetes (CIT-04/08) Archive contains the Study Data, Data Dictionary, 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
- Documentation

Data

The CIT-04 data directory contains the following datasets with primary id (ACCESSION). Note that some CIT-08 visits are also included (Flag08).

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

- fsigt_airglu.txt
- fsigt_raw.txt
- gammagt.txt
- general_assessment.txt
- gfr_sharev2.txt
- hb1c_share.txt
- hematocrit.txt
- hemoglobin.txt
- hfsv2.txt
- hyporecall.txt
- hypo.txt
- ieq_infused.txt
- insulin.txt
- li.txt
- local_hdl.txt
- local_ldl.txt
- local_serum_creatinine.txt
- local_total_cholesterol.txt
- local_triglycerides.txt
- lymphocyte.txt
- mage.txt
- magnesium.txt
- manufacturingother.txt
- manufacturing.txt
- mean_insulin.txt
- medical_history.txt
- neutrophils.txt
- patientstatus.txt
- phosphorus.txt
- pilotendpoints.txt
- platelet.txt
- potassium.txt
- pra.txt
- pt.txt
- ptt.txt
- pulse.txt
- retinopathy.txt
- rudbeckclinical.txt
- safety.txt
- serology.txt
- sf36v2.txt
- sodium.txt
- systolic_blood_pressure.txt
- trough_level.txt
- tsh.txt
- wbc.txt
- weight.txt
- whocoding.txt

- /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.

Documentation

The CIT-04 Documentation directory contains:

- CIT-04CRFs.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.
- CIT04_Forms Grid Version 7.0 24Oct11.pdf – Contains information regarding the time points when data was collected.
- CIT04 MOP vs 7.0_18Jan2012.pdf – Manual of Operations
- CIT-04 Protocol_Version 8.0_17Jan13_and_CIT08 Protocol Version 6.0_25Apr2017.pdf – Protocol
- CIT 04 Site Specific Lab Manual v7.0_1.18.12.pdf – Lab Manuals
- CIT-04 SAP Version 1.0.pdf – Statistical Analysis Plan for Protocol CIT-04