

## **The CIT-01 Study Data Archive**

The Clinical Islet Transplantation Consortium 01 Study (CIT-01) Archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Check.

The Clinical Islet Transplantation consortium 01 study was a phase II, multicenter, open label, active control, randomized study. Twenty-four subjects were randomized to peritransplant intraportal and systemic treatment with either LMW-DS or heparin, targeting an activated partial thromboplastin time of  $150 \pm 10$  seconds and  $50 \pm 5$  seconds, respectively. C-peptide response was measured with a mixed meal tolerance test at 75 and 365 days after transplant.

Archive files are organized into the following directories:

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

### **Documents**

The CIT-01 Documents directory contains:

- 2325\_CIT01\_V7.0\_2 Sept10 FINAL Clean\_.pdf – Study protocol for the CIT-01 study
- CIT-01 Monitoring Plan Version 2.0.pdf – Monitoring plan for the CIT-01 study
- CIT-01MOPversion\_7.0\_Nov2010\_clean.pdf – Manual of procedures for the CIT-01 study
- LabMan\_CIT01\_7.0\_final.pdf – Lab manual for the CIT-01 study
- SAP\_CIT01\_Version\_2\_clean.pdf – Statistical analysis plan for the CIT-01 study

### **Forms**

The CIT-01 Forms directory contains:

- 06\_Norway Consent\_5.0\_101409\_Clean\_CIT01\_Norwegian\_FINAL.pdf – Norwegian consent form (in Norwegian)
- 07\_Sweden\_5.0\_101409\_Clean\_CIT01\_Swedish\_FINAL.pdf – Swedish consent form (in Swedish)
- 08\_Norway Consent\_5.0\_101409\_Clean\_CIT01\_English\_FINAL.pdf – Norwegian consent form (translated to English)
- 08\_Sweden Consent\_5.0\_101409\_Clean\_CIT01\_English\_FINAL.pdf – Swedish consent form (translated to English)
- CIT01\_FormsGrid\_v7.1\_Apr11\_clean.pdf – list of study forms in a grid describing the

time frame of their planned deployment

- CIT-01CRFs.pdf – compilation of study forms, including the following:
  - Clarke Survey
  - C-Peptide/Plasma Glucose
  - Donor CRF
  - General Assessment
  - GFR
  - Informed Consent
  - Islet Transplant
  - Laboratory
  - Medical and Diabetes History
  - PRA
  - Reduced Follow-Up
  - Second Transplant Qualification
  - Serology
  - Serum Pregnancy
  - Study Treatment Regimen
  - Third Transplant Qualification
  - Randomization Eligibility
  - Screening Eligibility
  - Blood Sugar Record and Hypoglycemic Events
  - Blood Type and HLA
  - CGMS
  - Adverse Event
  - Concomitant Medications
  - Crossmatch
  - Demographic
  - Full Hypo Score
  - Major Protocol Deviation
  - Minor Protocol Deviation
  - Physical Examination
  - Premature Discontinuation of Study Treatment
  - Retinopathy
  - Study Termination
  - Transplant Waitlist

## **Data**

The CIT-01 data directory contains the following files, and the following datasets in Windows-based SAS, v.7-8-9 format. Each dataset corresponds to the form of the same name:

- albumin.sas7bdat
- alkphos.sas7bdat
- alt.sas7bdat
- aptt.sas7bdat
- ast.sas7bdat
- autoantibodies.sas7bdat
- basophils.sas7bdat
- beta\_score.sas7bdat
- bilirubin.sas7bdat
- bloodsugar.sas7bdat
- bloodtype\_hla.sas7bdat
- cgms.sas7bdat
- clarke.sas7bdat
- conduction\_velocity.sas7bdat
- cpeptide\_glucose\_creatinine\_v2.sas7bdat
- crp.sas7bdat
- demographics.sas7bdat
- diastolic\_blood\_pressure.sas7bdat
- drugs.sas7bdat
- dtsqc.sas7bdat
- dtsqs.sas7bdat
- endpoints.sas7bdat
- eosinophils.sas7bdat
- fibrinogen.sas7bdat
- fsigt\_airglu.sas7bdat
- fsigt\_raw.sas7bdat
- general\_assessment.sas7bdat
- gfr\_sharev2.sas7bdat
- hba1c.sas7bdat
- hematocrit.sas7bdat
- hemoglobin.sas7bdat
- hypo.sas7bdat
- hyporecall.sas7bdat
- insulin.sas7bdat
- ldh.sas7bdat
- li.sas7bdat
- local\_hdl.sas7bdat
- local\_ldl.sas7bdat
- local\_serum\_creatinine.sas7bdat

- local\_total\_cholesterol.sas7bdat
- local\_triglycerides.sas7bdat
- lymphocyte.sas7bdat
- mage.sas7bdat
- mean\_insulin.sas7bdat
- medical\_history.sas7bdat
- monocytes.sas7bdat
- neutrophils.sas7bdat
- patientstatus.sas7bdat
- pilotendpoints.sas7bdat
- pk.sas7bdat
- planned\_visit\_dictionary.sas7bdat
- platelet.sas7bdat
- potassium.sas7bdat
- pra.sas7bdat
- pulse.sas7bdat
- rbldcount.sas7bdat
- rudbeckclinical.sas7bdat
- safety.sas7bdat
- serology.sas7bdat
- sf36v2.sas7bdat
- sodium.sas7bdat
- systolic\_blood\_pressure.sas7bdat
- urinealbumin.sas7bdat
- wbc.sas7bdat
- weight.sas7bdat
- whocoding.sas7bdat

Contents subfolder:

The Contents subfolder contains codebooks for the CIT-01 files in the main Data folder. These codebooks are:

- CIT\_Data\_Dictionary\_-\_HbA1c.xlsx
- Data\_Dictionary\_-\_Albumin.xlsx
- Data\_Dictionary\_-\_AlkPhos.xlsx
- Data\_Dictionary\_-\_ALT.xlsx
- Data\_Dictionary\_-\_APPT.xlsx
- Data\_Dictionary\_-\_AST.xlsx
- Data\_Dictionary\_-\_AutoAnitBodies\_U.xlsx
- Data\_Dictionary\_-\_Basophils.xlsx
- Data\_Dictionary\_-\_Beta\_Score.xlsx
- Data\_Dictionary\_-\_Bilirubin.xlsx
- Data\_Dictionary\_-\_Blood\_sugar.xlsx

- Data\_Dictionary\_-\_Blood\_Type\_-\_HYLA.xlsx
- Data\_Dictionary\_-\_CGMS.xlsx
- Data\_Dictionary\_-\_Cpeptide\_Glucose\_Creatinine.xlsx
- Data\_Dictionary\_-\_CRP.xlsx
- Data\_Dictionary\_-\_Demographics.xlsx
- Data\_Dictionary\_-\_Diastolic\_Blood\_Pressure.xlsx
- Data\_Dictionary\_-\_DTSQc.xlsx
- Data\_Dictionary\_-\_DTSQx.xlsx
- Data\_Dictionary\_-\_Eosinophils.xlsx
- Data\_Dictionary\_-\_Fibrinogen.xlsx
- Data\_Dictionary\_-\_FSIGT\_AIRglu.xlsx
- Data\_Dictionary\_-\_FSIGT\_Raw.xlsx
- Data\_Dictionary\_-\_General\_Assessment.xlsx
- Data\_Dictionary\_-\_GFR.xlsx
- Data\_Dictionary\_-\_Hematocrit.xlsx
- Data\_Dictionary\_-\_Hemoglobin.xlsx
- Data\_Dictionary\_-\_Hypo\_Recall.xlsx
- Data\_Dictionary\_-\_Insulin.xlsx
- Data\_Dictionary\_-\_LDH.xlsx
- Data\_Dictionary\_-\_LI\_Score.xlsx
- Data\_Dictionary\_-\_Local\_HDL.xlsx
- Data\_Dictionary\_-\_Local\_LDL.xlsx
- Data\_Dictionary\_-\_Local\_Serum\_Creatinine.xlsx
- Data\_Dictionary\_-\_Local\_Total\_Cholesterol.xlsx
- Data\_Dictionary\_-\_Local\_Triglycerides.xlsx
- Data\_Dictionary\_-\_Lymphocytes.xlsx
- Data\_Dictionary\_-\_Mage\_Score.xlsx
- Data\_Dictionary\_-\_Mean\_Insulin\_per\_kg.xlsx
- Data\_Dictionary\_-\_Medical\_History.xlsx
- Data\_Dictionary\_-\_Monocytes.xlsx
- Data\_Dictionary\_-\_Neutrophils.xlsx
- Data\_Dictionary\_-\_Patient\_Status.xlsx
- Data\_Dictionary\_-\_Pilots\_Primary\_Endpoint.xlsx
- Data\_Dictionary\_-\_PK.xlsx
- Data\_Dictionary\_-\_Platelets.xlsx
- Data\_Dictionary\_-\_Potassium.xlsx
- Data\_Dictionary\_-\_PRA.xlsx
- Data\_Dictionary\_-\_Primary\_and\_Key\_Secondary\_Endpoints.xlsx
- Data\_Dictionary\_-\_Pulse.xlsx
- Data\_Dictionary\_-\_RbldCount.xlsx
- Data\_Dictionary\_-\_RudBeckClinical.xlsx
- Data\_Dictionary\_-\_Safety.xlsx
- Data\_Dictionary\_-\_Serology.xlsx
- Data\_Dictionary\_-\_SF36.xlsx

- Data\_Dictionary\_-\_Sodium.xlsx
- Data\_Dictionary\_-\_Systolic\_Blood\_Pressure.xlsx
- Data\_Dictionary\_-\_UrineAlbumin.xlsx
- Data\_Dictionary\_-\_WBC.xlsx
- Data\_Dictionary\_-\_Weight.xlsx
- Data\_Dictionary\_-\_WHO\_Coding.xlsx
- Data\_Dictionary\_-\_Conduction\_Velocity.xlsx

## **DSIC**

The CIT-01 Data Integrity Check (DSIC) directory contains:

- CIT\_01\_DSIC\_V1.pdf - A report of an examination of the analysis and form datasets (von Zur-Mühlen paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the CIT-01 data were compared to values recalculated from CIT-01 archived analysis datasets in the NIDDK repository.