The GpCRC Study Data Archive

The Gastroparesis Clinical Research Consortium (GpCRC) Pilot Study of the Safety, Feasibility, and Potential Efficacy of Continuous Glucose Monitoring and Insulin Pump Therapy in Diabetic Gastroparesis (GLUMIT-DG) Archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Check.

The GLUMIT-DG is a multicenter, uncontrolled, open label treatment study created by the GpCRC to enroll patients for this pilot study to assess the safety of RT-CGM as an adjunct to self-monitoring blood glucose (SMBG) in guiding insulin pump therapy for 24 weeks by measuring mild, moderate, and severe hypoglycemic episodes in patients with type 1 or type 2 diabetes and gastroparesis.

Archive files are organized into the following directories:

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

Documentation

The GLUMIT_DG Documentation directory contains:

- GLUMIT_consent.pdf – Informed consent to participate in the GLUMIT-DC
- GLUMIT_protocol.pdf – Protocol for the GLUMIT-DC study
- GLUMIT_SOPs.pdf – Standard operating procedures for the GLUMIT-DC
- GLUMIT_PLoSOne.pdf - Publication

Forms

The GLUMIT_DG Forms directory contains:

- GLUMIT_forms.pdf – Contains the following blank forms:
    - BH – Baseline Medical History
    - BP – Blood Processing for Plasma
    - DR – Death Report
    - EG – Upper Endoscopy
    - EN – Enrollment
    - FH – Follow-up Medical History
    - GE – Gastric Emptying Scintigraphy Documentation
    - IE – Interim Event Report
    - LR – Laboratory Results

- MV – Missed or Incomplete Visit
- PE – Physical Examination
- RG – Registration
- ST – EGG and Caloric Satiety Test
- TD – Training Documentation
- WL – EGG and Water Load Satiety Test

Data

The GLUMIT data directory contains the following files, and the following datasets in Windows-based SAS, v.7-8-9 format:

- The following datasets correspond corresponding to the tables and figures included in the Pilot Study of the Safety, Feasibility, and Potential Efficacy of Continuous Glucose Monitoring and Insulin Pump Therapy in Diabetic Gastroparesis (GLUMIT-DG) primary results paper:
  - figure3a.sas7bdat
  - figure3b.sas7bdat
  - table1_s.sas7bdat
  - table2.sas7bdat
  - table3_s.sas7bdat
  - table4a.sas7bdat
  - table5_s.sas7bdat
  - tables1a.sas7bdat
  - bh.sas7bdat
  - eg.sas7bdat
  - fh.sas7bdat
  - gd.sas7bdat
  - ge.sas7bdat
  - lr.sas7bdat
  - pe.sas7bdat
  - rg.sas7bdat
  - st.sas7bdat
  - ug.sas7bdat
  - wl.sas7bdat

- /Data/Contents: Contains the following:
  - Data Dictionary.pdf – Contents listing for each of the datasets listed above.
  - GLUMIT_proc_contents.pdf

DSIC

The GLUMIT Data Integrity Check (DSIC) directory contains:

- GLUMIT_DSIC.pdf – A report of an examination of the GLUMIT datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Table 1 from the paper 'Glucose sensor-augmented continuous subcutaneous insulin infusion in patients with diabetic gastroparesis: An open-label pilot prospective study' by Calles-Escandón et al. Published results from the GLUMIT data were compared to values recalculated from GLUMIT archived datasets in the NIDDK repository.