

## **The NORIG Study Data Archive**

The Nortiptyline for Idiopathic Gastroparesis (NORIG) Archive contains the Protocol, Standard Operating Procedures, Forms, Study Data, and Dataset Integrity Check.

Archive files are organized into the following directories:

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

### **Documents**

The NORIG Documents directory contains:

- NORIG\_Protocol.pdf – Protocol for the NORIG trial
- GpCRC\_Bibliography.pdf – Published Manuscripts as of February 16, 2016
- NORIG\_SOPs.pdf – Standard Operating Procedures for the NORIG trial
- NORIG\_consent.pdf – Copy of the consent form for the NORIG trial
- NORIG\_genetic\_consent.pdf – Copy of the genetic consent form for the NORIG trial

### **Forms**

The NORIG Forms directory contains:

- NORIG\_Forms.pdf – Contains the following forms (Note that forms with multiple copies denote revisions of that form):
  - BC1/BC2 – Blood Collection for DNA, revisions 1 and 2
  - BH1/BH2 – Baseline Medical History, revisions 1 and 2
  - BP1/BP2 – Blood Processing for Plasma, revisions 1 and 2
  - CG1 – Genetic Consent Documentation
  - DD1 – Drug Dosing Determination and Dispensing
  - EG1 – Upper Endoscopy Documentation
  - FH1 – Follow-up Medical History
  - GE1 – Gastric Emptying Scintigraphy Documentation
  - GS1 – Gastrointestinal Symptom Rating Scale (GSRS)
  - IE1 – Interim Event Report
  - LR1 – Laboratory Results
  - PE1/PE2 – Physical Examination, revisions 1 and 2
  - PQ1 – Patient Health Questionnaire
  - RD1 – Study Drug Dispensing and Return

- RG1/RG2 – Registration
- RZ1/RZ2/RZ3 – Randomization, revisions 1, 2, and 3
- ST1/ST2/ST3 – ECG and Satiety Test, revisions 1, 2, and 3
- Note that copies of the following forms are not included in the data package due to copyright:
  - BD1 – Beck Depression Inventory
  - GD1 – Patient Assessment of Gastrointestinal Disorders – Symptom Severity Index
  - PI1 – Brief Pain Inventory
  - QF1 – SF-36v2 Health Survey
  - SE1 – State-Trait Anxiety Inventory

## **Data**

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

- /Data/Analysis\_Data/: The following datasets contain the data used to construct the corresponding tables and figures in the publication ‘Effects of Nortriptyline on Symptoms of Idiopathic Gastroparesis: The NORIG Randomized Clinical Trial’ by Parkman et al.
  - table1.sas7bdat
  - table2.sas7bdat
  - table3.sas7bdat
  - figure2.sas7bdat
  - figure3.sas7bdat
- /Data/Raw\_Data/: The following datasets contain the raw data corresponding to the form with the same name
  - bd1.sas7bdat
  - bh2.sas7bdat
  - dd1.sas7bdat
  - eg1.sas7bdat
  - fh1.sas7bdat
  - gd1.sas7bdat
  - ge1.sas7bdat
  - gs1.sas7bdat
  - ie1.sas7bdat
  - lr1.sas7bdat
  - pe2.sas7bdat
  - pi1.sas7bdat

- pq1.sas7bdat
- qf1.sas7bdat
- rd1.sas7bdat
- rg2.sas7bdat
- se1.sas7bdat
- st3.sas7bdat
- treatment.sas7bdat – This dataset contains the randomization groups for the subjects in the NORIG trial
- /Data/Contents: Contains the following:
  - figure2\_documentation.pdf – Contents for the figure2.sas7bdat dataset
  - figure3\_documentation.pdf – Contents for the figure3.sas7bdat dataset
  - raw\_datasets\_documentation.pdf – Contents for the 19 raw datasets listed above
  - table1\_documentation.pdf – Contents for the table1.sas7bdat dataset
  - table2\_documentation.pdf – Contents for the table2.sas7bdat dataset
  - table3\_documentation.pdf – Contents for the table3.sas7bdat dataset

## **DSIC**

The NORIG Data Integrity Check (DSIC) directory contains:

- NASH\_NORIG\_DSIC\_V1.pdf - This document includes a report of the examination of the table1, table2, and table3 analysis datasets (Parkman paper) for completeness by the Repository. Published results from a publication were compared to values recalculated from NASH NORIG archived analysis datasets in the NIDDK repository.
- NORIG\_Complete\_Data\_DSIC.pdf – A report of an examination of the NORIG raw datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Table 1, Table 2, and Table 3 from the paper ‘Effects of Nortiptyline on Symptoms of Idiopathic Gastroparesis: The NORIG Randomized Clinical Trial’ by Parkman et al. Published results from the NORIG data were compared to values recalculated from NORIG archived datasets in the NIDDK repository.

## **SAS Programs**

This directory contains the SAS programs which created the analysis data sets (table1.sas7bdat, table2.sas7bdat, table3.sas7bdat, figure2.sas7bdat, figure3.sas7bdat) in the Data directory.