**The APRON Study Data Archive**

Aprepitant for the Relief of Nausea in Patients with Chronic Nausea and Vomiting of Presumed Gastric Origin: A Multicenter, Randomized, Double-Masked, Placebo-Controlled Trial (APRON) Archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Check.

Aprepitant is an FDA-approved medication for the treatment of nausea following chemotherapy or surgery. Aprepitant is also used by some doctors to reduce nausea and vomiting in patients with gastroparesis, although the drug is not approved for this use. The Aprepitant for the Relief of Nausea in Patients with Chronic Nausea and Vomiting of Presumed Gastric Origin (APRON) study is a multicenter, randomized, placebo-controlled clinical trial designed to test the safety and efficacy of aprepitant in reducing symptoms among patients with gastroparesis.

Archive files are organized into the following directories:

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

**Documents**

The APRON Documents directory contains:

- APRON_consent.pdf
- APRON_genetic_consent.pdf
- APRON_protocol.pdf
- APRON_SOPs.pdf

**Forms**

The APRON Forms directory contains:

- APRON_forms_nocopyright.pdf

**Data**

The APRON 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:

- ae.sas7bdat

- apron_table1.sas7bdat
- bd.sas7bdat
- bh.sas7bdat
- dd1.sas7bdat
- dd2.sas7bdat
- ds.sas7bdat
- eg.sas7bdat
- fh.sas7bdat
- gd.sas7bdat
- ge.sas7bdat
- gs.sas7bdat
- lr.sas7bdat
- np.sas7bdat
- pe.sas7bdat
- pi.sas7bdat
- pq.sas7bdat
- qf.sas7bdat
- rd.sas7bdat
- rg.sas7bdat
- se.sas7bdat
- st.sas7bdat
- tx.sas7bdat

## **DSIC**

The APRON Data Integrity Check (DSIC) directory contains:

- APRON_DSIC_V1.pdf - A report of an examination of the analysis and form datasets (Pasricha paper)   for completeness by statisticians and quality control specialists at the Repository.   Published results from the APRON data were compared to values recalculated from APRON archived analysis datasets in the NIDDK repository.