

## ICCTG Data Archive

The ICCTG Archive distributed on this CD-ROM contains the study protocol, manual, procedures, and other descriptive documentation; study forms; data collected by the study; and analysis files.

The files are organized into the following directories:

- ICCTG\_BCG\_Documents
- ICCTG\_BCG\_Forms
- ICCTG\_BCG\_MOOP Protocol
- ICCTG\_BCG\_Data
- ICCTG\_BCG\_Integrity Check

### **ICCTG BCG Documents**

The ICCTG Documents directory contains two files:

- ICCTG\_Overview.pdf - Study design, inclusion and exclusion criteria, list of forms and the corresponding data sets.
- ICCTG\_Publications.doc - Publication list from 2007
- ICCTG\_Metadata - Web content

### **ICCTG BCG Forms**

The ICCTG Forms directory contains the document CRF\_Forms.pdf, which comprises a number of forms:

- Baseline Symptoms
- Adverse Events
- Concomitant Medications
- Demographics
- Instillation/Dosing Information
- Eligibility Confirmation
- Physical Exam
- Follow-Up Symptoms
- Clinical Laboratory Results
- Medical History
- MOS Sexual Functioning Scale
- Telephone Contact During Treatment
- Participant Closeout
- Randomization
- Health Status Questionnaire

### **ICCTG BCG MOOP Protocol**

The ICCTG MOOP Protocol directory contains two subdirectories:

- ICCTG\_Manual of Procedures (154 pages) ICCTG\_MOP\_V3\_0\_020930.pdf

- Summary of Protocol Amendments #1 (2 pages)
- Summary of Protocol Amendments #2 (3 pages) ICCTG\_Protocol\_Amend\_2\_020528.pdf
- ICCTG Protocol #2, Version 3.0, May 28, 2002 (86 pages) ICCTG\_Protocol\_V3\_0\_020528.pdf
- Visit Schedule Phase 1 - PhaseI\_Visit\_Sched\_VSTSCHIv1\_4.pdf
- Visit Schedule Phase 1 - PhaseII\_Visit\_Sched\_VSTSCHIIv1\_3.pdf
- Visit Schedule Phase 1 - PhaseIIR\_Visit\_Sched\_VSTSCHIIRv1.pdf

### **ICCTG BCG Data**

The ICCTG Data directory contains data and analysis files:

- ae\_orig\_p1.sas7bdat
- ae\_orig\_p2\_r.sas7bdat
- aelog\_orig\_p1.sas7bdat
- aelog\_orig\_p2\_r.sas7bdat
- bsym1\_derived.sas7bdat
- bsym2\_derived.sas7bdat
- cmed\_orig\_p1.sas7bdat
- demo\_derived.sas7bdat
- dose\_derived\_p1.sas7bdat
- formats.sas
- fusym\_derived\_p1.sas7bdat
- fusym\_derived\_p2\_r.sas7bdat
- hbegf\_pfu\_15\_correct4creatinine.sas7bdat
- iowa\_lab.sas7bdat
- iowa\_pfu\_15\_correct4creatinine.sas7bdat
- md\_apf.sas7bdat
- md\_clinical.sas7bdat
- md\_creatinine.sas7bdat
- md\_dilution\_factor.sas7bdat
- md\_egf.sas7bdat
- md\_hb\_egf.sas7bdat
- med\_derived.sas7bdat
- mos\_derived\_p1.sas7bdat
- primaryanaldata.sas7bdat
- ptcl\_derived\_p1.sas7bdat
- rand.sas7bdat
- rand\_arm.sas7bdat
- read\_in\_BCG\_data.sas
- rochester\_lab.sas7bdat
- sf36\_derived\_p1.sas7bdat
- sf36\_derived\_p2.sas7bdat

- sstopi\_derived\_p1.sas7bdat
- sstopii\_derived\_p2\_r.sas7bdat
- sym\_derived\_p1.sas7bdat
- sym\_derived\_p2\_r.sas7bdat
- tstop\_derived\_p1.sas7bdat
- tstop\_derived\_p2.sas7bdat
- void\_derived\_p1.sas7bdat
- void\_derived\_p2\_r.sas7bdat
- voidlog\_orig\_p1.sas7bdat
- voidlog\_orig\_p2\_r.sas7bdat
- wis\_derived\_p1.sas7bdat
- wis\_derived\_p2\_r.sas7bdat
- yale\_lab.sas7bdat

### **Data/Documents**

- Primary\_Endpoint\_Analyses.doc - “BCG Analyses for Primary Endpoint: Adjudicated GRA Exact Conditional Test(ECT) - Adjusted for Clinical Center”
- Proc\_Contents.doc - SAS contents document from the ICCTG group
- Proc\_Contents\_Supplement.doc - SAS contents for additional data files

### **ICCTG BCG Integrity Check**

The ICCTG Integrity Check directory contains a report of an examination of the repository for completeness by statisticians and quality control specialists at the Repository. Datasets were checked for completeness. The published data from the ICCTG study were compared to values recalculated from the ICCTG data in the NIDDK repository. These included blood pressure at baseline and during follow-up.

### **CD Content Summary**

ICCTG Data (47 files 17 MB) MS Word and SAS files

ICCTG Documents (3 files, 280 KB) MS Word, pdf file

ICCTG MOOP Protocol (7 files 1.6 MB) MS Word

ICCTG Forms (1 files 321 KB) pdf file

ICCTG Integrity Check (1 file ) pdf file

Total Data on CD: --- files, --- MB