

## **The PRIDE Study Data Archive**

The PRIDE Archive contains the Protocol, Manual of Operations, Forms, Study data, and data integrity check. The files are organized into the following directories:

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

### **PRIDE Documents**

The PRIDE Documents directory contains:

- PRIDE OM and Protocol.pdf -- PRIDE Protocol and Operations Manual.
  - Per E-Mail correspondence received 8/26/11, the Data Coordinating Center (DCC) has approved release of the Protocol, even though pages are marked “Confidential”.
- Investigator Directory 092004.doc -- Investigator Directory

Subdirectories include:

#### **PRIDE Documents\Intervention MOOP:**

- Intervention Lessons and Manuals

### **PRIDE Forms**

This subdirectory contains annotated data collection forms in PDF format. Variable names for each released data set are embedded on each data form. The two-letter prefix for each variable name is embedded at the bottom of each data form, and included in brackets (e.g., [XX]) in the form list below. The numerical value for check-box style categorical variables is noted near check-boxes on the form. Many value labels are also programmed as SAS user defined formats, see “PRIDE Data”, next section.

- PRIDE Annotated forms (non-copyrighted).pdf – Contains PDFs of all below forms, concatenated into one file:
  - Two Incontinence Questionnaire (2IQ) [TQ]
  - Bowel Habits Questionnaire [BH], [BI], [BJ], [BK]
  - Change of Status Form [SC]
  - Cystometrogram (CMG) and Leak Point Pressures (LPP) [C1], [C2], [C3]
  - Cost Analysis (Follow-up) [CF] ,..., [CM]
  - Cost Analysis (Baseline) [CA] ,..., [CE]
  - Demographics [DE]
  - Voiding Diary [D1], [D2]
  - Dipstick Urinalysis Form [UO]
  - Exit Questionnaire [EX], [EY]
  - Health History [H1] ,..., [H7]

- Health Utilities Index [HA] ,...., [HE]
- Height/Weight [HW]
- Incontinence Impact Questionnaire (IIQ) [I1], [I2], [I3]
- Randomization/Inclusion/Exclusion Checklist [X1], [X2]
- Intervention Record [IR]
- Maintenance Record [MR]
- Medications Form [M1], [M2]
- Motivation Maintenance Program Exit Questionnaire [XD]
- Motivation Questionnaire (Baseline) [MA] ,...., [MD]
- Motivation Questionnaire (Follow-up) [ME] ,...., [MH]
- Non-instrumented Uroflowmetry (NIF) [NI]
- Pad Test [PT]
- Paffenbarger Questionnaire [P1] ,...., [P2]
- Pelvic Muscle Questionnaire [P3] ,...., [P4]
- Pelvic Organ Prolapse Quantification [PQ]
- Pubococcygeus Contraction Assessment [PA]
- Serious Adverse Event (SAE) Report [E1], [E2], [E3]
- Participant Satisfaction [SX]
- Sexual Function Questionnaire [F1] ,...., [F4]
- Skills-based Maintenance Program Exit Questionnaire [XA], [XB]
- Sleep Questionnaire [S1] ,...., [S4]
- Stress Test [ST]
- Structured Education Program Exit Questionnaire [SE]
- Termination Report [TE]
- UI Symptoms Questionnaire [U1] ,...., [U9]
- Urethral Hypermobility (Q-Tip Test) [QT]
- Urogenital Distress Inventory (UDI) [UA], [UB]
- Vital Signs [VS]
- Weight/Abdominal Circumference [WA]
- Pride II Enrollment Form [EN]
- Willingness to Pay for Incontinence Improvement [W1] ,...., [W3]

Note: the following annotated data collection forms will *not* be released due to copyright issues. Two-letter prefixes associated with variables from these forms include:

- Beck Inventory: [B1], [B2], [B3], [B4]
- Food Frequency Questionnaire: [ZA], [ZB],....,[ZT]
- Health and Activity Form (SF-36): [FA], [FB],....,[FE]

### **PRIDE Data**

The PRIDE data directory contains the following raw datasets in SAS for Windows, v.7-8-9 format:

- Full0\_18nih.sas7bdat – Unique identifiers are ID and NVISIT. Contains data

associated with variables from most *raw* forms, and data associated with DCC-released *calculated* variables. To identify which data form a *raw* variable is associated with, match the two-letter variable prefix to that at the bottom of the annotated form. Two-variable prefixes associated with variables on copyrighted (non-released) forms are listed under “Pride Forms”.

- DCC-released *calculated* variables do not have a standard variable name format.
- sae0\_18.sas7bdat – Unique identifiers are ID and SAEnum.
- willpay.sas7bdat – Unique identifier is ID.

Subdirectories include:

#### **PRIDE Data\formats**

- Formats.sas7bcat – raw variable formats (value labels), including missing data qualifications
- Formats.sas – a program that includes additional formats that were utilized for analyses and other protocols

#### **PRIDE Data\Codebooks**

- contents full0\_18nih.pdf —Variable listing from dataset Full0\_18nih.sas7bdat
- contents sae0\_18.pdf —Variable listing from sae0\_18.sas7bdat
- contents willpay.pdf—Variable listing from willpay.sas7bdat

#### **PRIDE DSIC**

The PRIDE Data Integrity Check (DSIC) 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 PRIDE study were compared to values recalculated from the PRIDE data in the NIDDK repository.

#### **PRIDE Biosamples**

None expected.