

## **BE-DRI Data Archive Description**

The Behavior Enhances Drug Reduction of Incontinence Study (BE-DRI) data archive contains the study protocol, study forms; data collected by the study; and other descriptive documentation.

The archive is organized into the following directories:

- BE-DRI\_Documentation
- BE-DRI\_Forms
- BE-DRI\_Data
- BE-DRI\_DSIC

### **1. BE-DRI Documentation**

The “BE-DRI\_Documentation” directory contains three documents:

- BE-DRI Study Protocol - BE-DRI Protocol Version 043004.pdf
- BE-DRI\_Forms\_and\_Schedule.doc – table showing forms and the study schedule
- BE-DRI\_proc\_contents.rtf - variable names, formats, and descriptions from the BE-DRI SAS data files

### **2. BE-DRI Forms**

The “BE-DRI\_Forms” subdirectory contains 47 study forms in .pdf format.

- F201: Preliminary Screening Part I
- Form 201: Preliminary Screening Part I Question by Question Specifications Guide
- F202: Preliminary Screening Part II
- Form 202: Preliminary Screening Part II Question by Question Specifications Guide
- F203: Baseline Medication Audit
- Form 203: Baseline Medication Audit Question by Question Specifications Guide
- F204: Baseline History and Physical Exam
- Form 204: Baseline History and Physical Exam Question by Question Specifications Guide
- F205: Symptoms Checklist Patient Self Administered Survey
- Form 205: Symptoms Checklist Question by Question Specifications Guide
- F206: Baseline Bladder Diary Summary
- Form 206: Baseline Bladder Diary Summary Question by Question Specifications Guide
- F206A: 7-Day Bladder Diary Evaluation Diary A
- F206B: Intervention Bladder Diary -Diary B
- F206C: 7-Day Bladder Diary Follow-up Diary C
- F207: Baseline Patient Survey
- Form 207: Baseline Patient Survey Question by Question Specifications Guide
- F208: OAB-q Patient Survey
- Form 208: OAB-q Patient Survey Question by Question Specifications Guide
- F209: Eligibility Confirmation and Randomization Check
- Form 209: Eligibility Confirmation and Randomization Check Question by Question

- F211: Intervention Visit 1
- Form 211: Intervention Visit 1 Question by Question Specifications Guide
- F216: Visit 05 Bladder Diary Summary
- Form 216: VS05 Bladder Diary Summary Question by Question Specifications Guide
- F218: Baseline Expectation Survey
- F222: Intervention Visit 2
- Form 222: Intervention Visit 2 Question by Question Specifications Guide
- F233: Intervention Visits 3 & 4
- Form 233: Intervention Visits 3 and 4 Question by Question Specifications Guide
- F244: End of Stage 1 Report
- Form 244: End of Stage 1 Report Question by Question Specifications Guide
- F255: Exercise Questionnaire Self-Administered
- F256: Exercise Questionnaire Visit 5 and Beyond Self-Administered
- F261: UI Treatment Status
- Form 261: UI Treatment Status Question by Question Specifications Guide
- F262: SUI Treatment Status Question by Question Specifications Guide
- Form 263: Follow up Medication Audit Question by Question Specifications Guide
- Form 263: Follow-up Medication Audit Data Entry into DMS Question by Question Specifications Guide
- F264: Follow-Up PC and POPQ Assessment
- F265: Follow-Up Physical Systems Audit
- F266: Follow-Up Bladder Diary Summary VS06 -11
- Form 266: Follow-Up Bladder Diary Summary VS06-11 Question by Question Specifications Guide
- F267: Follow-up Patient Survey
- F280: Final Status, version 06/01/04 (A)
- Form 280: Final Status Question by Question Specifications Guide
- F288: 10-Week Expectation Survey

### **3. BE-DRI Data**

“BE-DRI\_Data” directory contains 28 sas7bdat files:

- f201.sas7bdat
- f202.sas7bdat
- f203.sas7bdat
- f204.sas7bdat
- f205.sas7bdat
- f205\_fu.sas7bdat
- f206.sas7bdat
- f207.sas7bdat
- f208.sas7bdat
- f208\_fu.sas7bdat

- f209.sas7bdat
- f211.sas7bdat
- f216.sas7bdat
- f218.sas7bdat
- f222.sas7bdat
- f233.sas7bdat
- f244.sas7bdat
- f255.sas7bdat
- f256.sas7bdat
- f261.sas7bdat
- f262.sas7bdat
- f263.sas7bdat
- f264.sas7bdat
- f265.sas7bdat
- f266.sas7bdat
- f267.sas7bdat
- f280.sas7bdat
- f288.sas7bdat

The table below describes the relationship between the data files and the forms used to collect the data.

<b>Form Name</b>	<b>Form PDF</b>	<b>SAS Data File</b>
F201: Preliminary Screening Part I	F201_060104a_posted_062404.pdf	f201.sas7bdat
Form 201: Preliminary Screening Part I Question by Question Specifications Guide	F201_QxQ_060104 (A).pdf	n/a
F202: Preliminary Screening Part II	F202_030405b.pdf	f202.sas7bdat
Form 202: Preliminary Screening Part II Question by Question Specifications Guide	F202qxq_030405b.pdf	n/a
F203: Baseline Medication Audit	F203_030405b.pdf	f203.sas7bdat
Form 203: Baseline Medication Audit Question by Question Specifications Guide	F203qxq_030405b.pdf	n/a
F204: Baseline History and Physical Exam	F204_032905.pdf	f204.sas7bdat
Form 204: Baseline History and Physical Exam Question by Question Specifications Guide	F204qxq_032905b.pdf	n/a
F205: Symptoms Checklist Patient Self Administered Survey	F205_60104_noprint.pdf	f205.sas7bdat

Form 205: Symptoms Checklist Question by Question Specifications Guide	F205_QxQ_060104 (A).pdf	f205_fu.sas7bdat
F206: Baseline Bladder Diary Summary	F206_121004a.pdf	f206.sas7bdat
Form 206: Baseline Bladder Diary Summary Question by Question Specifications Guide	F206qxq_110504_rev080505.pdf	n/a
F206A: 7-Day Bladder Diary Evaluation Diary A	F206A_060104_posted_0624204.pdf	n/a
F206B: Intervention Bladder Diary -Diary B	F206B_060104a_posted_062404.pdf	n/a
F206C: 7-Day Bladder Diary Follow-up Diary C	F206C_060404_posted_062404.pdf	n/a
F207: Baseline Patient Survey	F207_060104_posted_062404.pdf	f207.sas7bdat
Form 207: Baseline Patient Survey Question by Question Specifications Guide	F207_qxq60104a.pdf	n/a
F208: OAB-q Patient Survey	F208_060104_posted_071404.pdf	f208.sas7bdat
Form 208: OAB-q Patient Survey Question by Question Specifications Guide	F208_qxq60104a.pdf	f208_fu.sas7bdat
F209: Eligibility Confirmation and Randomization Check	F209d_071105.pdf	f209.sas7bdat
Form 209: Eligibility Confirmation and Randomization Check Question by Question Specifications Guide	F209_qxqd_071105.pdf	n/a
F211: Intervention Visit 1	F211_102004.pdf	f211.sas7bdat
Form 211: Intervention Visit 1 Question by Question Specifications Guide	F211_qxq102004_rev010605.pdf	n/a
F216: Visit 05 Bladder Diary Summary	F216_110504.pdf	f216.sas7bdat
Form 216: VS05 Bladder Diary Summary Question by Question Specifications Guide	F216qxq_110504a_rev080505.pdf	n/a
F218: Baseline Expectation Survey	F218_031505A.pdf	f218.sas7bdat
F222: Intervention Visit 2	F222_071905_B.pdf	f222.sas7bdat

Form 222: Intervention Visit 2 Question by Question Specifications Guide	F222_qxq071905b.pdf	n/a
F233: Intervention Visits 3 & 4	F233_010605b.pdf	n/a
Form 233: Intervention Visits 3 and 4 Question by Question Specifications Guide	F233qxq_010605_B.pdf	f233.sas7bdat
F244: End of Stage 1 Report	F244_102004.pdf	f244.sas7bdat
Form 244: End of Stage 1 Report Question by Question Specifications Guide	F244_qxq_102004a_rev010605.pdf	n/a
F255: Exercise Questionnaire Self-Administered	F255_120204.pdf	f255.sas7bdat
F256: Exercise Questionnaire Visit 5 and Beyond Self-Administered	F256_121504a.pdf	f256.sas7bdat
F261: UI Treatment Status	F261_090104a.pdf	f261.sas7bdat
Form 261: UI Treatment Status Question by Question Specifications Guide	F261qxq_090104.pdf	n/a
F262: SUI Treatment Status Question by Question Specifications Guide	F262_041206b.pdf	f262.sas7bdat
Form 263: Follow up Medication Audit Question by Question Specifications Guide	F263_qxq_041405b.pdf	f263.sas7bdat
Form 263: Follow-up Medication Audit Data Entry into DMS Question by Question Specifications Guide	F263qxq_DE_041405b.pdf	n/a
F264: Follow-Up PC and POPQ Assessment	F264_90104a.pdf	f264.sas7bdat
F265: Follow-Up Physical Systems Audit	F265_090104a.pdf	f265.sas7bdat
F266: Follow-Up Bladder Diary Summary VS06 -11	F266_022205a_rev041905.pdf	f266.sas7bdat
Form 266: Follow-Up Bladder Diary Summary VS06-11 Question by Question Specifications Guide	F266qxq_022205aJ_rev_080505.pdf	n/a

F267: Follow-up Patient Survey	F267_090104a.pdf	f267.sas7bdat
F280: Final Status, version 06/01/04 (A)	F280_060104a.pdf	f280.sas7bdat
Form 280: Final Status Question by Question Specifications Guide	F280_qxq_060104a.pdf	n/a
F288: 10-Week Expectation Survey	F288_031505a.pdf	f288.sas7bdat

#### 4. BE-DRI DSIC

- BE-DRI\_DSIC\_Version 1.0\_NoFullText.pdf – A report describing the results of an analysis by repository statisticians and quality control specialists to ensure that the dataset distributed by the repository is a true copy of the study data