

## **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<br>Question by Question Specifications<br>Guide                               | F205_QxQ_060104 (A).pdf             | f205_fu.sas7bdat |
| F206: Baseline Bladder Diary<br>Summary  | F206_121004a.pdf                    | f206.sas7bdat    |
| Form 206: Baseline Bladder Diary<br>Summary Question by Question<br>Specifications Guide                   | F206qxx_110504_rev080505.pdf        | n/a              |
| F206A: 7-Day Bladder Diary<br>Evaluation Diary A   | F206A_060104_posted_0624204.pdf     | n/a              |
| F206B: Intervention Bladder Diary<br>-Diary B  | F206B_060104a<br>_posted_062404.pdf | n/a              |
| F206C: 7-Day Bladder Diary<br>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<br>Question by Question Specifications<br>Guide                          | F207_qxx60104a.pdf                  | n/a              |
| F208: OAB-q Patient Survey   | F208_060104_posted_071404.pdf       | f208.sas7bdat    |
| Form 208: OAB-q Patient Survey<br>Question by Question Specifications<br>Guide                             | F208_qxx60104a.pdf                  | f208_fu.sas7bdat |
| F209: Eligibility Confirmation and<br>Randomization Check  | F209d_071105.pdf                    | f209.sas7bdat    |
| Form 209: Eligibility Confirmation<br>and Randomization Check Question<br>by Question Specifications Guide | F209_qxxd_071105.pdf                | n/a              |
| F211: Intervention Visit 1   | F211_102004.pdf                     | f211.sas7bdat    |
| Form 211: Intervention Visit 1<br>Question by Question Specifications<br>Guide                             | F211_qxx102004_rev010605.pdf        | n/a              |
| F216: Visit 05 Bladder Diary<br>Summary  | F216_110504.pdf                     | f216.sas7bdat    |
| Form 216: VS05 Bladder Diary<br>Summary Question by Question<br>Specifications Guide                       | F216qxx_110504a_rev080505.pdf       | n/a              |
| F218: Baseline Expectation Survey  | F218_031505A.pdf                    | f218.sas7bdat    |
| F222: Intervention Visit 2   | F222_071905_B.pdf                   | f222.sas7bdat    |

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|--|---------------------------------|---------------|
| 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           |

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|--|----------------------|---------------|
| 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