

SISTER Data Archive Description

The SISTER data archive contains the study protocol, manual, procedures, study forms; data collected by the study; analysis files, and other descriptive documentation.

The archive is organized into the following directories:

- Documents
- DSIC
- Forms
- Data

1. **Documents**

The “Documents” directory contains four documents:

- The Study Protocol (SISTER_Protocol_093002_rev102904.pdf) 34 pages
- The Quality Assurance Manual (manual_chpt5qa_102902.pdfs) 13 pages
- SISTER Data Dictionary.xls – variable names, formats, and descriptions from the SISTER SAS data files.
- Contents baseline and final.docx – Contents of the baseline and final datasets.
- Random Contents.docx – Contents of the random dataset.
- E_SISTER Codebooks.docx – Contents of the ESISTER datasets.

2. **DSIC**

The “DSIC” directory contains two documents:

- SISTER_IntegrityCheck_v1.0_burch_vs_sling.pdf - Data Set Integrity Check attempting to use the data to recreate the 2007 publication “Quality of life in women with stress urinary incontinence.”
- SISTER_IntegrityCheck_v1.0_quality_of_life.pdf - Data Set Integrity Check attempting to use the data to recreate the 2007 publication “Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence.”
- SISTER_IntegrityCheck_v1.0_ESister.pdf - Data Set Integrity Check attempting to use the data to recreate the 2012 publication “5-year continence rates, satisfaction and adverse events of burch urethropexy and fascial sling surgery for urinary incontinence.”

3. **Forms**

The “Forms” subdirectory contains 68 study forms in pdf format. The forms are organized into folders by type. See Appendix 1 of this document for a list of the SISTER forms.

4. **Data**

The “Data” folder contains the following 35 SISTER sas7bdat files:

- baseline.sas7bdat
- f01.sas7bdat

- f02.sas7bdat
- f04.sas7bdat
- f05.sas7bdat
- f06.sas7bdat
- f07.sas7bdat
- f08.sas7bdat
- f11.sas7bdat
- f13.sas7bdat
- f20.sas7bdat
- f21.sas7bdat
- f22.sas7bdat
- f23.sas7bdat
- f30.sas7bdat
- f31.sas7bdat
- f32.sas7bdat
- f33.sas7bdat
- f47.sas7bdat
- f51.sas7bdat
- f52.sas7bdat
- f53.sas7bdat
- f54.sas7bdat
- f55.sas7bdat
- f56.sas7bdat
- f57.sas7bdat
- f58.sas7bdat
- f59.sas7bdat
- f60.sas7bdat
- f80.sas7bdat
- f81.sas7bdat
- f93.sas7bdat
- f94.sas7bdat
- final.sas7bdat
- random.sas7bdat

The dataset names indicate the form from which the data in that dataset was collected.

It also contains three SAS catalogs:

- blformats.sas7bcats
- formats.sas7bcats
- fuformats.sas7bcats

The “Data/E_SISTER” folder contains the following 10 ESISTER sas7bdat files:

- f51_esister.sas7bdat
- f52_esister.sas7bdat
- f56_esister.sas7bdat
- f57_esister.sas7bdat
- f58_esister.sas7bdat
- f60_esister.sas7bdat
- f70_esister.sas7bdat
- f80_esister.sas7bd
- esister_analysis.sas7bdat
- finlstat.sas7bdat

The dataset names indicate the form from which the data in that dataset was collected.

It also contains one SAS catalog:

- formats.sas7bcat

Appendix 1: SISTEr Forms

Baseline Forms and QxQs

Form 00: Initiation Form and Locator Information, 07/01/02 (A)
form00_70102.pdf (2 pages)

Form 01: Preliminary Screening Part I, Version 07/01/02 (A)
Form01_70102.pdf (9 pages)

Form 02: Preliminary Screening Part II, Version 07/01/02(A)
Form02_70102.pdf (7 pages)

Question by Question Specifications Guide
Forms 01 and 02: Preliminary Screening Parts I and II
Version 07/01/02 (A)
Form0102_qxq_70102.pdf (22 pages)

Form 04: Baseline Physical Exam, Version 07/01/02 (A)
Form04_70102.pdf (6 pages)

Question by Question Specifications Guide
Form 04: Baseline Physical Exam Version 07/01/02 (A)
Form04_qxq_70102.pdf (8 pages)

Form 06: Baseline Pad Test and Voiding Diary Summary, Version 07/01/02 (A)
Form06_70102.pdf (5 pages)

Question by Question Specifications Guide
Form 06: Baseline Pad Test and Voiding Diary Summary Version 07/01/02 (A)_revised 01/21/03
Form06_qxq70102a_revised 012103.pdf (18 pages)

Form 07 BASELINE PATIENT SURVEY PART I Version 07/01/02 (A)
Form07_70102.pdf (14 pages)

Question by Question Specifications Guide
Form 07: Baseline Patient Survey Part I Version 07/01/02 (A)
Form07_qxq_70102.pdf (3 pages)

Form 08 BASELINE PATIENT SURVEY PART II Version 07/01/02 (A)
Form08_70102.pdf (16 pages)

Question by Question Specifications Guide
Form 08: Baseline Patient Survey Part II Version 07/01/02 (A)
Form08_qxq_70102.pdf (3 pages)

Form 13: Baseline Stress Test, Version 10/21/02 (A)
Form13_102102a.pdf (2 pages)

Question by Question Specifications Guide
Form 13: Baseline Stress Test Version 10/21/02 (A)
Form13_qxq_102102.pdf (2 pages)

Form 05: Baseline Urodynamic Studies, Version 07/25/03 (C)
Form 05 Baseline UDS 072503 _C_.pdf (8 pages)

Question by Question Specifications Guide
Form 05: Baseline Urodynamic Studies Version 07/25/03 (C)
Form 05 QxQ 072503 _C_.pdf (6 pages)

6 Week Forms and QxQs

Form 20: Post-Op Voiding Management Through 6 Weeks, Version 03/13/03 (B)
Form20_31303b.pdf (4 pages)

Question by Question Specifications Guide
Form 20: 6 Week Post-Operative Voiding Management Summary Version 03/13/03 (B)
Form20_qxq_031303B.pdf (5 pages)

Voided Volume vs. Catheter Volume Diary
Form20A_40102.pdf (4 pages)

Form 21: 6 Week Follow-Up Assessment, Part I (Interview), Version 07/01/02 (A)
Form21_070102.pdf (8 pages)

Question by Question Specifications Guide
Form 21: 6 Week Follow-Up Assessment, Part I Version 07/01/02 (A)
Form21_qxq_70102.pdf (7 pages)

Form 22: 6 Week Follow-Up Assessment, Part II, Version 07/01/02 (A)
Form22_70102.pdf (6 pages)

Question by Question Specifications Guide
Form 22: 6 Week Follow-up Assessment, Part II Version 07/01/02 (A)
Form22_qxq_70102.pdf (6 pages)

Form 23 6 WEEK PATIENT SURVEY Version 07/01/02 (A)
Form23_70102.pdf (9 pages)

Question by Question Specifications Guide
Form 23: 6 Week Patient Survey Version 07/01/02 (A)
Form23_qxq_70102.pdf (2 pages)

3 Month Forms and QxQs

Form 30: Post-Op Voiding Management Through 3 Months, Version 03/13/03 (B)
Form 30_31303b.pdf (4 pages)

Form 30: 3 Month Post-Operative Voiding Management Summary Version 03/13/03 (B)
Form 30_qxq_031303_B.pdf (5 pages)

Form 31: 3 Month Follow-Up Assessment, Part I (Interview), Version 07/01/02 (A)
Form 31_70102.pdf (11 pages)

Question by Question Specifications Guide
Form 31: 3 Month Follow-Up Assessment, Part I Version 07/01/02 (A)
Form 31_qxq_70102.pdf (10 pages)

Form 32: 3 Month Follow-Up Assessment, Part II, Version 07/01/02 (A)
Form 32_70102.pdf (5 pages)

Question by Question Specifications Guide
Form 32: 3 Month Follow-up Assessment, Part II Version 07/01/02 (A)
Form 32_qxq_70102.pdf (5 pages)

Form 33 3-MONTH PATIENT SURVEY Version 07/01/02 (A)
Form 33_70102.pdf (11 pages)

Question by Question Specifications Guide
Form 33: 3 Month Patient Survey Version 07/01/02 (A)
Form 33_qxq_70102.pdf (3 pages)

Adverse Event Forms and Miscellaneous Forms

Form 80: Final Status, Version 04/01/02 (A)
Form80_40102a.pdf (1 page)

All Other Follow-up Forms

Form 47: 6 MONTH FOLLOW-UP PATIENT SURVEY Version 09/06/02 (A)
Form 47_90602.pdf (14 pages)

Question by Question Specifications Guide
Form 47: 6 Month Patient Survey Version 09/06/02 (A)
Form 47_qxq_090602.pdf (3 pages)

Form 51: Follow-up Patient Interview 12/11/02 (A)_revised 03/16/05
Form 51_121102a_rev031605.pdf (7 pages)

Question by Question Specifications Guide

Form 51: Follow-Up Patient Interview Version 12/11/02 (A)

Form 51_qxq_121102a.pdf (6 pages)

Form 52: Follow-up Physician Assessment 06/07/05 (B)

Form 52_060705b.pdf (3 pages)

Question by Question Specifications Guide

Form 52: Follow-Up Physician Assessment Version 06/07/05 (B)

Form 52_qxq_060705b.pdf (3 pages)

Form 53: Follow-Up Stress Test, Version 09/06/02 (A)

Form 53_90602a.pdf (1 page)

Question by Question Specifications Guide

Form 53: Follow-Up Stress Test Version 09/06/02 (A)

Form 53_qxq_090602.pdf (1 page)

Form 54: Follow-Up POP-Q Exam, Version 09/06/02 (A)

Form 54_90602.pdf (1 page)

Question by Question Specifications Guide

Form 54: Follow-Up POP-Q Exam Version 09/06/02 (A)

Form 54_qxq_090602.pdf (2 pages)

Form 55: Follow-Up Urodynamic Studies, Version 10/07/04 (C)

Form 55_100704c.pdf (6 pages)

Form 56: Follow-Up Pad Test and Voiding Diary Summary,

Version 09/06/02 (A)_revised 03/16/05

Form 56_090602a_rev031605.pdf (6 pages)

Question by Question Specifications Guide

Form 56: Follow-Up Pad Test and Voiding Diary Summary Version 09/06/02 (A)_revised 07/03/03

Form 56qxq_90602a_revised_070303.pdf (17 pages)

Question by Question Specifications Guide

Form 57: Follow-Up Patient Survey Version 09/06/02 (A)

Form 57 QxQ 090602 (A).pdf (3 pages)

Form 57 FOLLOW-UP PATIENT SURVEY Version 09/06/02 (A)_revised 03/16/05

Form 57_090602a_rev031605.pdf (13 pages)

Form 58

12 & 24 MONTH FOLLOW-UP PATIENT SURVEY

PART II

Form 58 - 12 and 24 Month Patient Survey Part II 090602 (A)_rev070106.pdf (16 pages)

Question by Question Specifications Guide

Form 58: 12 & 24 Month Follow-Up Patient Survey Part II Version 09/06/02 (A)

Form 58_qxq_090602.pdf (3 pages)

Form 59: Follow-Up Q-Tip Test, Version 09/06/02 (A)

Form 59_90602.pdf (1 page)

Question by Question Specifications Guide

Form 59: Follow-Up Q-Tip Test Version 09/06/02 (A)

Form 59_qxq_090602.pdf (2 pages)

Form 60: 24 Month Physical Systems Update, Version 08/04/03 (A)_revised 03/16/05

Form 60_080403a_rev031605.pdf (1 page)

Question by Question Specifications Guide

Form 60: 24 Month Physical Systems Update Version 08/04/03 (A)_revised 11/24/03

Form 60_qxq_80403a_rev112403.pdf (2 pages)

Form 81: PATIENT SURVEY Version 08/30/04 (A)

Form 81_83004a.pdf (6 pages)

Procedural Guidelines: FM81 Patient Survey Version 08/30/04 (A)

Form 81_procedguid_083004_122304.pdf (1 page)

Retreatment Failure Forms

Question by Question Specifications Guide

Form 80: Final Status Version 04/01/02 (A)_revised 11/02/04

F80qxq_40102rev_110204.pdf (2 pages)

Form 80: Final Status, Version 04/01/02 (A)

form80_40102a.pdf (1 page)

Form 93: Reintervention or Treatment 04/08/03 (B)

Form93_40803b.pdf (3 pages)

Question by Question Specifications Guide

Form 93: Reintervention or Treatment Version 04/08/03 (B)

Form93_qxq_40803b.pdf (2 pages)

Form 94: Failure, version 08/05/04 (B)

Form94_Failure_80504b.pdf (1 page)

Question by Question Specifications Guide
Form 94: Failure
Version 08/05/04 (B)_revised 10/11/05
Form94_qxq_080504B_rev_101105.pdf

Surgical Forms and QxQs 070101 (A) and 111502 (A)

Form 10: Operative Measures, Version 11/15/02 (A)
Form10_111502a.pdf (8 pages)

Question by Question Specifications Guide
Form 10: Operative Measures Version 11/15/02 (A)_revised 101503
Form10qxq_111502a_rev101503.pdf(6 pages)

Form 11: Immediate Post-Operative Measures, Version 07/01/02 (A)
Form11_70102.pdf (6 pages)

Question by Question Specifications Guide
Form 11: Immediate Post-operative Measures Version 07/01/02 (A)
Form11_qxq_70102.pdf (6 pages)

E_Sister_Forms

Form 51 - Follow-Up Patient Interview 121102 (A).pdf
Form 52 - Follow-Up Physician Assessment 040803 (A).pdf
Form 56 - Follow-Up Pad Test and Voiding Diary Summary 090602 (A).pdf
Form 57 - Follow-Up Patient Survey 090602 (A).pdf
Form 58 - 12 and 24 Month Patient Survey Part II 090602 (A)_rev070106.pdf
Form 60 - 24 Month Physical Systems Update 080403 (A)_revised 112403.pdf
Form 70 - E-SISTER Participation Form 073004 (A).pdf
Form 80 - Final Status Form 040102 (A).pdf

E_Sister_QxQs

Form 70 QxQ 073004.pdf