

TOMUS Data Archive Description

The Trial of Mid-Urethral Slings Study (TOMUS) data archive contains the study protocol, study forms, data, and other descriptive documentation for both the TOMUS and the ETOMUS (Extended TOMUS) studies.

The archive is organized into the following directories:

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

Documents

The Documents directory contains the following documents:

- TOMUS Protocol.pdf - TOMUS Study Protocol
- TOMUS Papers Published.pdf – Bibliography of publications
- ETOMUS Protocol 022509.pdf – ETOMUS Study Protocol
- Codebook directory – Microsoft Word documents with each form annotated with descriptive statistics
 - F301 codebook.doc
 - F302 codebook.doc
 - F303 codebook.doc
 - F304 codebook.doc
 - F305 codebook.doc
 - F306 codebook.doc
 - F307 codebook.doc
 - F308 codebook.doc
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- F330 codebook.doc
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- F341 codebook.doc
- F347 codebook.doc
- F351 codebook.doc
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- F354 codebook.doc
- F356 codebook.doc
- F357 codebook.doc
- F360 codebook.doc
- F380 codebook.doc
- F381 codebook.doc
- F394 codebook.doc
- tomusbase codebook.doc - Codebook for TOMUS baseline dataset
- tomusbase_log.doc - A SAS log file for the program used to create the TOMUS baseline dataset
- tomusbase_uds codebook.doc - Codebook for TOMUS baseline UDS dataset
- tomusbase_uds_log.doc - A SAS log file for the program used to create the TOMUS baseline UDS dataset
- tomusfinal codebook.doc - Codebook for TOMUS final analysis dataset
- tomusfinal_log.doc - A SAS log file for the program used to create the TOMUS final analysis dataset
- tomusm12_uds codebook.doc - Codebook for TOMUS M12 UDS dataset
- tomusm12_uds_log.doc - A log file for the program used to create the TOMUS M12 UDS data
- **\Codebook\ETOMUS** directory
 - F370.doc
 - F371.doc
 - F372.doc
 - F373 QxQ.doc
 - F374.doc
 - F376.doc
 - F377.doc
 - F378.doc
- **\Contents directory** – Microsoft Word documents of the SAS Proc Contents output for each dataset, showing the number of observations, variables, and variable labels.
 - F301_contents.doc
 - F302_contents.doc
 - F303_contents.doc
 - F304_contents.doc
 - F305_contents.doc
 - F306_contents.doc
 - F307_contents.doc
 - F308_contents.doc
 - F309_contents.doc
 - F310_contents.doc
 - F311_contents.doc

- F312_contents.doc
- F313_contents.doc
- F314_contents.doc
- F315_contents.doc
- F316_contents.doc
- F318_contents.doc
- F320_contents.doc
- F321_contents.doc
- F322_contents.doc
- F326_contents.doc
- F327_contents.doc
- F328_contents.doc
- F330_contents.doc
- F331_contents.doc
- F341_contents.doc
- F347_contents.doc
- F351_contents.doc
- F352_contents.doc
- F353_contents.doc
- F354_contents.doc
- F356_contents.doc
- F357_contents.doc
- F360_contents.doc
- F380_contents.doc
- F381_contents.doc
- F394_contents.doc
- tomusbase_contents.doc
- tomusbase_uds_contents
- tomusfinal_contents.doc - Contents for TOMUS final analysis dataset
- tomusm12_uds_contents.doc
- **\Contents\ETOMUS** directory
 - Contents for All Forms.rtf – SAS Proc Contents output for all ETOMUS forms
 - Analysis files Contents.docx – SAS Proc Contents output for the ETOMUS analysis files
- **\Procedure Manuals**
 - Physical Exam Procedure Manual_032906A.pdf
 - Procedure Manual for Administration of the Pad Test and Voiding Diary_102706.pdf
 - Simple Bladder Testing Procedures Manual_052206_rev030207.pdf
 - UDS Reviewer Interpretive Guidelines_032906.pdf
 - Urodynamics Testing Procedures for the TOMUS Trial_032106_rev060206.pdf

Forms

The Forms directory contains the following documents:

- **\Forms** directory
 - F301_Baseline Interview Part I_032906 (A)_revised 040706.pdf
 - F302_Baseline Interview Part II_032706 (A)_rev080906.pdf

- F303_Baseline Medication Audit_032706 (A)_rev040606.pdf
- F304_Baseline Physical Exam_111207 (B).pdf
- F305_Urodynamic Studies_032906 (A).pdf
- F306_Baseline Pad Test and Voiding Diary Summary_032706 (A).pdf
- F307_Baseline Patient Survey_032706 (A)_rev051606.pdf
- F308_Baseline Pain Questionnaire_032706 (A).pdf
- F309_Randomization Assignment and Confirmation_041006 (A)_rev060106.pdf
- F310_Operative Measures_081007 (B).pdf
- F311_Discharge Measures_032706 (A)_rev083007.pdf
- F312_Patient Survey Part II_032706 (A)_rev061206.pdf
- F313_Baseline Simple Bladder Tests_050506 (A).pdf
- F314_Baseline Q-Tip Test_032706 (A).pdf
- F315_Urine Dipstick Results_092806 (C).pdf
- F316_Comorbidty Questionnaire_080906 (A).pdf
- F318_Surgical Pain Diary_032706 (A)_rev051706.pdf
- F320_Postoperative Voiding Management Through 2Weeks_042106 (A)_rev102706.pdf
- F321_2 Week Follow-Up Interviewversion 042106 (A)_rev101706.pdf
- F322_2 and 6 Week Follow-Up Physician Assessment_080107 (C).pdf
- F326_Pain Exam_051006 (B)_rev051706.pdf
- F327 2 and 6 Week Patient Survey_061606 (A).pdf
- F328 Follow-Up Pain Questionnaire_032706(A)_rev010907.pdf
- F330 6 Week Follow-Up PVR_051906 (A)_rev102706.pdf
- F331 6 Week Follow-Up Interview_051906 (A)_rev101706.pdf
- F341 6 Month Follow-Up Interview_050907 (B).pdf
- F347 6 Month Follow-Up Patient Survey_082806 (A)_rev020807.pdf
- F351 12 and 24 Month Follow-Up Interview_082806 (A)_rev101706.pdf
- F352 Follow-Up Physician Assessment_071907 (C).pdf
- F353 Follow-Up Simple Bladder Tests_030207 (B).pdf
- F354 Follow-Up POP-Q Exam_082806 (A).pdf
- F356 Follow-Up Pad Test and Voiding Diary Summary_082806 (A).pdf
- F357 12 and 24 Month Follow-Up Patient Survey_082806 (A)_rev010907.pdf
- F360 Follow-Up Medical Conditions Summary_082806 (A)_rev101706.pdf
- F380 Final Status_121106 (B).pdf
- F381 Treatment Prior to Early Termination_071907B.pdf
- F394 Failure_032706 (A)_rev121106.pdf
- **Forms\ETOMUS** directory
 - F370 Initiation 022509 (A).pdf
 - F371 Annual Follow-UP Interview 030909 (A).pdf
 - F372 Follow-Up Physician Assessment 030909 (A).pdf
 - F373 Incontinence Medication Audit 022009 (A).pdf
 - F373 Incontinence Medication Audit Report 022009 (A).pdf
 - F374 Follow-Up Exam 030909 (A).pdf
 - F376 Comorbidity Questionnaire 020509 (A).pdf
 - F377 Annual Follow-Up Patient Survey 020509 (A).pdf
 - F378 Final Status 020509 (A).pdf
 - F398 Treatment Prior to Early Termination 020509 (A).pdf
 - FE94 Failure 070809 (A).pdf
- **QxQ** directory

- F301 QxQ_032906 (A).pdf
- F302 QxQ_032706 (A).pdf
- F303 QxQ_032706 (A).pdf
- F304 QxQ_111207 (B).pdf
- F306 QxQ_032706 (A).pdf
- F307 QxQ_032706 (A).pdf
- F308, F318 & F328 QxQ_032706 (A)_rev080906.pdf
- F309 QxQ_041006 (A).pdf
- F310 QxQ_011706(A).pdf
- F311 QxQ_011706 (A).pdf
- F312 QxQ_032706 (A)_rev061206.pdf
- F313 QxQ for Data Entry_060606 (A)_rev111306.pdf
- F313 QxQ_050506 (A)_rev062206.pdf
- F314 QxQ_032706 (A).pdf
- F318 QxQ for Data Entry_082306 (A).pdf
- F353 QxQ for Data Entry_111306 (A).pdf
- F356 QxQ_082806 (A)_rev041609.pdf
- F380 QxQ_121106 (B).pdf
- F394 QxQ_032706 (A)_rev121106.pdf
- Guidelines for the Operationalization of the UA Requirement.pdf
- \QxQ\ETOMUS directory
 - F370 QxQ_022509 (A).pdf
 - F371 QxQ_030909 (A).pdf
 - F372 QxQ_090909 (A).pdf
 - F373 QxQ_032709.pdf
 - F374 QxQ_030909 (A)_rev090109.pdf
 - F376 QxQ_020509 (A).pdf
 - F377 QxQ_020509 (A)_rev061610.pdf
 - F378 QxQ_020509 (A).pdf
 - F390 QxQ_032706 (A)_rev050806.pdf
 - F395 QxQ_032706 (A).pdf
 - F396 QxQ_102606 (A).pdf
 - F398 QxQ_020509 (A).pdf
 - FE94 QxQ_070809 (A).pdf

Data

The Data directory contains the following datasets in SAS format:

- f301.sas7bdat
- f302.sas7bdat
- f303.sas7bdat
- f304.sas7bdat
- f305.sas7bdat
- f306.sas7bdat
- f307.sas7bdat
- f308.sas7bdat

- f309.sas7bdat
- f310.sas7bdat
- f311.sas7bdat
- f312.sas7bdat
- f313.sas7bdat
- f314.sas7bdat
- f315.sas7bdat
- f316.sas7bdat
- f318.sas7bdat
- f320.sas7bdat
- f321.sas7bdat
- f322.sas7bdat
- f326.sas7bdat
- f327.sas7bdat
- f328.sas7bdat
- f330.sas7bdat
- f331.sas7bdat
- f341.sas7bdat
- f347.sas7bdat
- f351.sas7bdat
- f352.sas7bdat
- f353.sas7bdat
- f354.sas7bdat
- f356.sas7bdat
- f357.sas7bdat
- f360.sas7bdat
- f380.sas7bdat
- f381.sas7bdat
- f394.sas7bdat
- formats.sas7bcat - SAS format file
- formats.xpt – SAS formats as a SAS transport file
- tomusbase.sas7bdat -TOMUS baseline dataset
- tomusbase_uds.sas7bdat - TOMUS baseline UDS dataset
- tomusfinal.sas7bdat - TOMUS final analysis dataset
- tomusm12_uds.sas7bdat - TOMUS M12 UDS dataset
- **CSV Data** directory
 - Contains CSV versions of the 41 SAS datasets in the Data folder
- **ETOMUS** directory
 - etomus_longitudinal.sas7bdat
 - f370.sas7bdat
 - f371.sas7bdat
 - f372.sas7bdat
 - f373.sas7bdat
 - f374.sas7bdat
 - f376.sas7bdat
 - f377.sas7bdat
 - f378.sas7bdat
 - finlstat.sas7bdat –ETOMUS main analysis dataset

- \CSV Data directory
 - Contains CSV versions of the 10 SAS datasets in the ETOMUS directory

DSIC

- The DSIC.pdf file contains the data set integrity check that was performed by comparing the TOMUS data to the “Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months” publication in *The Journal of Urology*, December 2012.
- The ETOMUS_DSIC.docx file contains the data set integrity check for the ETOMUS data. It is a report of an examination of the study analysis datasets for completeness by statisticians and quality control specialists at the repository. These datasets were used to replicate Tables 1 and 2 in the paper “5-Year Longitudinal Follow-up after Retropubic and Transobturator Midurethral Slings” published in *The Journal of Urology*, January 2015. Published results were compared to values recalculated from the ETOMUS analysis datasets.