The FDTT Study Data Archive

The FDTT Archive contains the Protocol, Standard Operating Procedures, Forms, Study data, published papers, and Dataset Integrity Check.

Archive files are organized into the following directories:

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

Documents

The FDTT Documents directory contains:

- BCM Data Letter Final.pdf –a letter documenting a data issue
- FDTT Data Collection.pdf – the data collection schedule for the study trial
- FDTT Protocol_12-09-2014.pdf – the Functional Dyspepsia Treatment Trial study protocol
- FDTT Questionnaire Copyright.pdf – a list of the study questionnaires with copyrights
- U01 DK 065713 PUBLICATIONS AUTHORED.pdf – Bibliography of all study publications

Documents\SOPs

The FDTT Documents\SOPs directory contains the following Standard Operating Procedures (SOP) related documents:

- AE form for use 06-11-2009.pdf – Adverse Event form
- AE source document 6-11-2009.pdf – Adverse Event source document
- CRF completion_7-8-2011.pdf – SOP for Data and Event Reporting
- Depression Screen SOP and letters.pdf – SOP for Participants who Screen Positive for Depression
- Dyspepsia Dose Card Drug Returns from Site NEW1 0_jan 9-2007.pdf – Drug Return form
- Dyspepsia SOP Site Medication Handling v2 1-18-07.pdf – SOP for Drug Procurement, Storage, Dispensing and Returns
- Dyspepsia SUBJECT SPECIFIC DAR for dose cards NEW1 0_jan 9-2007.pdf – Subject Specific Drug Accountability Record (Non Child Resistant)
- Dyspepsia SUBJECT SPECIFIC DAR for vials 1 0_jan 9-2007.pdf – Subject Specific Drug Accountability Record (Child Resistant)
- Dyspepsia Vial Drug Returns from Site NEW1 0_jan 9-2007.pdf – Return of Investigational Medicine (Child Resistant Vials)
- FDTT Codes used for Medical Conditions.pdf – List of Medical Condition Codes for the study
- FDTT Codes used for Medications.pdf – List of Medication Codes for the study
- HADS Results.pdf – Screenshot of an Excel spreadsheet used for scoring HADS Results
- HADS screening_11-14-06.pdf – SOP for Scoring the HADS Questionnaire
- IMRC Roles and Responsibilities Log.pdf – Roles and Responsibilities Signature Log
- Instructions for participant_12-1-06.pdf – Patient Instructions
- List of Antidepressants.pdf – List of Exclusionary Medications

- NIDDKUO1DK 065713 Study Unblinding SOP 10-12-06.pdf – SOP for Unblinding the Study Drug
- NIDDKUO1DK 065713.doc SOP for screening log 11-12-2006.pdf – SOP for Completion of Screening Log
- NIDDKUO1DK 065713.doc Screen Fail CRF.pdf – SOP for Screening Failure
- Patient Instructions Card DiagramREV2_1-29-07approved.pdf – Patient Dose Card Instructions
- Patient Instructions vial diagram_1-29-07approved.pdf – Patient Prescription Vial Instructions
- SCL-90-R SOP for ID numbers.pdf – SOP for SCL-90-R identification number assignment
- Serotonin Syndrome SOP.pdf – SOP for Serotonin Syndrome
- Side Effect Treatment Protocol.pdf – Protocol for treatment of side effects
- SOP for blood samples_FDTT_Nov09.pdf – SOP for Obtaining and Shipping Blood Samples
- SOP for Drug Held By Investigational team.pdf – SOP for Accountability and Storage of Study Medication
- SOP for SAE-AE and forms 7-7-2011.pdf – SOP for Adverse Event Reporting
- SOP Screening visit-Visit 1_11-11-06.pdf – SOP for Visit 1 – Screening Visit
- SOP Visit 2_11-11-06.pdf – SOP for Visit 2
- SOP Visit 3_11-11-06.pdf – SOP for Visit 3
- SOP Visit 4.pdf – SOP for Visit 4
- SOP Visit 5.pdf – SOP for Visit 5
- SOP Visit 6 11-13-06.pdf – SOP for Visit 6
- SOP Visit 7.pdf – SOP for Visit 7
- SOP Visit 8.pdf – SOP for Visit 8
- SOP Visit 9 11-13-06.pdf – SOP for Visit 9
- SOP Visit 10.pdf – SOP for Visit 10
- SOP Visit 11.pdf – SOP for Visit 11
- SOP Visit 12.pdf – SOP for Visit 12
- Study Patient Identification SOP_11-14-06 – SOP for De-Identification of Patient Data
- Urine Pregnancy Test SOP_7-7-2011 – SOP for Urine Pregnancy Test
- Waiver for Non CR Non- MCR site 3-2008.pdf – Waiver for Non-Child Resistant Unit Dose Card Packaging

Forms

The FDTT Forms directory contains the following 18 forms in PDF format:

- Add allergies page_1-4-2010.pdf – Additional Allergies
- Add conmed page_1-4-2010.pdf – Additional Concomitant Medication/Significant Non-Drug Therapy
- Add history page_1-4-2010.pdf – Relevant Medical History/Current Medical Conditions
- AE form for use 06-11-2009.pdf – Adverse Event Log
- Med Start ~ Stop CRF 4-2007.pdf – Medication Stop~Restart
- Satiety Test Rev5-15-08.pdf – Instructions and CRF for Satiety Testing
- Visit 1_3-11-2010.pdf – Visit 1 (Baseline info)
- Visit 2_12-1-2009.pdf – Visit 2
- Visit 3_3-11-2010.pdf – Visit 3
- Visit 4_1-4-2010.pdf – Visit 4

- Visit 5_1-4-2010.pdf – Visit 5
- Visit 6_12-1-2009.pdf – Visit 6
- Visit 7_12-1-2009.pdf – Visit 7
- Visit 8_12-1-2009.pdf – Visit 8
- Visit 9_12-1-2009.pdf – Visit 9
- Visit 10_12-1-2009.pdf – Visit 10
- Visit 11_12-1-2009.pdf – Visit 11
- Visit 12_12-1-2009.pdf – Visit 12

Data

The FDTT Data directory contains the following 37 datasets in *SAS* format:

- card1.sas7bdat
- card2.sas7bdat
- card3.sas7bdat
- card4.sas7bdat
- card5.sas7bdat
- card6.sas7bdat
- card8.sas7bdat
- card9.sas7bdat
- card10.sas7bdat
- card11.sas7bdat
- card12.sas7bdat
- card13.sas7bdat
- card14.sas7bdat
- card15.sas7bdat
- card16.sas7bdat
- card17.sas7bdat
- card18.sas7bdat
- card19.sas7bdat
- card21.sas7bdat
- card23.sas7bdat
- card25.sas7bdat
- card26.sas7bdat
- card27.sas7bdat
- card28.sas7bdat
- card33.sas7bdat
- card34.sas7bdat
- card36.sas7bdat
- card37.sas7bdat
- card38.sas7bdat
- card39.sas7bdat
- card40.sas7bdat

- card41.sas7bdat
- card42.sas7bdat
- genotype.sas7bdat
- primary_outcome.sas7bdat
- scl90.sas7bdat

Data\Contents

- FFDTT_CDR Data Dictionary.pdf – the study data dictionary, a copy of each form annotated with the field names and the dataset name (card#).
- primary_outcome dataset.pdf – output from SAS Proc Contents detailing the fields available on the primary_outcome dataset.

DSIC

The FDTT Data Integrity Check (DSIC) directory contains:

- A report of an examination of the study analysis datasets for completeness by statisticians and quality control specialists at the Repository. This dataset was used to replicate Tables 2 and 3 in the paper "Effect of Amitriptyline and Escitalopram on Functional Dyspepsia: A Multicenter, Randomized Controlled Study" published by The FDTT Research Group in Gastroenterology, August, 2015. Published results from the FDTT data were compared to values recalculated from the FDTT archived analysis datasets in the NIDDK repository.