

The FONT II Study Data Archive

The Novel Therapies for Resistant FSFS: Phase II Clinical Trial (FONT II) Archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Check.

The FONT II trial was a randomized, multicenter Phase I/II clinical trial designed to investigate the potential efficacy of novel therapies for resistant FSGS. Two different therapies, adalimumab (a human anti-TNF- α antibody) and galactose, were evaluated against standard conservative therapy for resistant FSGS, which consists of the combination of lisinopril, losartan, and atorvastatin.

Archive files are organized into the following directories:

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

Documents

The FONT II Documents directory contains:

- FONTII_MOP.pdf – Manual of procedures for the FONT II study
- FONTII_Protocol_V7.pdf – Protocol for the FONT II study (Version 7, from October 24, 2011)

Forms

The FONT II Forms directory contains:

- FORMS_TOC_01102017.pdf – Listing of all form numbers from the FONT II trial, the name of the form, and the corresponding dataset name
- Form205.pdf – Transfer Form: Includes data on participant site transfers
- Form210.pdf – Screening Form: Includes demographic data, inclusion and exclusion criteria, medical history, and medication history
- Form211.pdf – Cancer Screening Form: Includes data on cervical screening, breast cancer screening, colorectal screening, and prostate cancer screening
- Form216.pdf – Visit Form: Includes reasons for visit, symptoms since last visit, vital signs, and physical exam results
- Form230.pdf – On-Line Randomization Form: Includes data on eligibility and randomized treatment
- Form231.pdf – Study Exit Before Randomization Form: Includes data on reasons for leaving the study, such as developing an excluding condition

- Form232.pdf – Re-Enrollment Form: Includes data on why the participant was initially determined ineligible
- Form236.pdf – Health Information Survey SF-36 Form (Adults > 18 years): Includes data on limits to physical health, problems with work/activities as a result of health, and emotional health
- Form237.pdf – Pediatric Quality of Life Inventory Parent Report for Toddlers (ages 2-4): Includes data on physical functioning, emotional functioning, social functioning, and school functioning as reported by a toddler’s parent
- Form238.pdf – Pediatric Quality of Life Inventory Young Child Report (Ages 5-7): Includes data on physical functioning, emotional functioning, social functioning, and school functioning as reported by a child
- Form239.pdf – Pediatric Quality of Life Inventory Parent Report for Young Children (Ages 5-7): Includes data on physical functioning, emotional functioning, social functioning, and school functioning as reported by a child’s parent
- Form240.pdf – Pediatric Quality of Life Inventory Child Report (ages 8-12): Includes data on physical functioning, emotional functioning, social functioning, and school functioning as reported by a child
- Form241.pdf – Pediatric Quality of Life Inventory Parent Report for Children (ages 8-12): Includes data on physical functioning, emotional functioning, social functioning, and school functioning as reported by a child’s parent
- Form242.pdf – Pediatric Quality of Life Inventory Teen Report (ages 13-18): Includes data on physical functioning, emotional functioning, social functioning, and school functioning as reported by a teen
- Form243.pdf – Pediatric Quality of Life Inventory Parent Report for Teens (ages 13-18): Includes data on physical functioning, emotional functioning, social functioning, and school functioning as reported by a teen’s parent
- Form244.pdf – Medication Form: Includes data on non-study medications taken and study medication dispensing
- Form245.pdf – Study Medication Termination Form: Includes data on the name of medication terminated and the date of termination
- Form252.pdf – Long-term Monitoring Form: Includes data on symptoms in the past 4 weeks, medications, hospitalizations, vital signs, and physical exam results
- Form253.pdf – Treatment Satisfaction Questionnaire for Medication: Includes data on satisfaction/dissatisfaction with the study medication, side effects, and convenience of taking the study medication
- Form254.pdf – Semi-Annual Follow-up Starting with Month 24 Form: Includes data on any participant events since the last visit, including death, pregnancy, cardiovascular event, thromboembolic event, malignancy, and infection
- Form260.pdf – Adverse Event Report Form: Includes data on the type and severity of the event, whether or not it was related to the study drug, action taken, and expectedness of the event
- Form261.pdf – Serious Adverse Event Report Form: Includes data on the type and

severity of the event, whether or not it was related to the study drug, action taken, and expectedness of the event

- Form262.pdf – Hospitalization Form: Includes data on diagnosis, procedures done, and whether or not the hospitalization was related to the study drug
- Form263.pdf – Death Notification Form: Includes data and cause of death, as well as whether or not death was related to study medication
- Form271.pdf – Study Exit Form After Randomization: Includes data on reasons for study exit before study drug exposure and after study drug exposure
- Form278.pdf – Results of Non-transmitted Lab Data Form: Includes data on ANA, C3, and Palb
- Form279.pdf – Results of Local Laboratory and Blood Pressure Measurements Form: Includes data on lab results such as serum potassium, serum creatinine, and glucose, and sitting blood pressure measurements
- Form280.pdf – Urine Mailing Form: Includes data on the date, time, and type of collection
- Form283.pdf – Blood and Serum Mailing Form: Includes data on the collection date of the sample and the tests done
- Form286.pdf – Biopsy Mailing Form: Includes data on the pathology shipment
- Form287.pdf – Biopsy Results Form: Includes data on the number of slides received, the results of the biopsy review, and the evaluation of glomeruli
- Form288.pdf – Genetic Mutation Confirmation Form: Includes data on genetic testing done and any genetic mutations associated with the disease that were found
- Form294.pdf – Consent for Repositories Form: Includes data on whether or not a subject consented to having biological specimens and/or genetic samples stored in the repository, and any reasons for not consenting
- Form295.pdf – Biological Specimen Repository Mailing Form: Includes data for serum, plasma, and urine samples collected such as volume, number of tubes sent, and collection date and time
- Form296.pdf – NIDDK Genetics Initiative Phlebotomy (DNA) Mailing Form: Includes data for genetic samples collected including barcode, collection date, and subject information

Data

The FONT II data directory contains the following files, and the following datasets in Windows-based SAS, v.7-8-9 format. Each dataset corresponds to the form of the same name:

- FONTII_formats_01102017.sas – Formats file for the datasets listed below
- form205.sas7bdat
- form210.sas7bdat
- form211.sas7bdat

- form216.sas7bdat
- form230.sas7bdat
- form231.sas7bdat
- form232.sas7bdat
- form236.sas7bdat
- form237.sas7bdat
- form238.sas7bdat
- form239.sas7bdat
- form240.sas7bdat
- form241.sas7bdat
- form242.sas7bdat
- form243.sas7bdat
- form244_concmeds.sas7bdat – Listing of participant’s non-study medications
- form244_disp.sas7bdat – Listing of participant’s study medications dispensed
- form244_studymeds.sas7bdat – Listing of participant’s study medications prescribed, including dosage, dosing interval, and status
- form245.sas7bdat
- form252.sas7bdat
- form253.sas7bdat
- form254.sas7bdat
- form260.sas7bdat
- form261.sas7bdat
- form262.sas7bdat
- form263.sas7bdat
- form271.sas7bdat
- form278.sas7bdat
- form279.sas7bdat
- form280.sas7bdat
- form283.sas7bdat
- form286.sas7bdat
- form287.sas7bdat
- form288.sas7bdat
- form294.sas7bdat
- form295.sas7bdat
- form296.sas7bdat
- Data_Dictionary.pdf – Contents listing for the above datasets

Data\Analysis Data

This subdirectory contains analysis datasets for the FONT II study:

- cbl_serum.sas7bdat – Data on all serum tests, including results, reference ranges, and units
- cbl_urine.sas7bdat – Data on urine tests, including urine : protein creatinine ratio and collection dates
- font_ae.sas7bdat – Data on adverse events, including symptoms and visit
- font_palbap5supar.sas7bdat – Data on lab tests and results
- font_primary.sas7bdat – Analysis dataset for the primary outcome paper
- font_sae.sas7bdat – Data on serious adverse events (SAEs), including the type of event and the SAE criteria

DSIC

The FONT II Data Integrity Check (DSIC) directory contains:

- FONT_II_DSIC.pdf - A report of an examination of the analysis and form datasets (Trachtman paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the FONT II data were compared to values recalculated from FONT II archived analysis datasets in the NIDDK repository.