

Dialysis Access Consortium (DAC) - Fistula Study

The archive contains the study protocol and related descriptive documentation; study forms; and data collected by the study. The full trial name is “Clopidogrel Prevention of Early AV Fistula Thrombosis”.

The Official Archive is organized in four directories:

1. Documentation
2. Forms
3. Data
4. DSIC (Dataset Integrity Check)

The archive also contains this Roadmap document that describes the content of the archive.

1. Documentation

The Documentation directory includes:

- DAC_MOP.pdf- the the procedures manual for the manual for the consortium which recruited patients for two clinical trials performed under its auspices..
- MOP_Fistula.pdf- the procedures manual for the Fistula Study
- FistulaProtocol.pdf- the Fistula study protocol
- Fistula Study Codebook.pdf– the codebook for variables collected on the study data forms

2. Forms

The Forms directory holds 39 PDF files that represent 38 forms, of which 36 yield study data files. These forms are detailed in **Table 1** that associates each form with its corresponding data file and presents the complete name of the form to demonstrate its purpose. Many of the forms used in the Fistula Study are also used in the Graft Study which is the other clinical trial conducted by DAC. These common forms are highlighted in the table in yellow cells.

TABLE 1

Fistula Form*	Form Description	Fistula Data File
(*yellow highlight=forms common to Graft and Fistula trials)		
DATA FORMS		
dacA2_RandOnLineApplic	Fistula Study Randomization On-Line Application	a2_f_random.sas7bdat
dac301_FScreen	Screening Form	f301_f_screening.sas7bdat
dac302_fistulabaselinesdropout	Baseline Dropout Form	f302_f_dropout.sas7bdat
dac303_WasFistulaUsed	“Was the Fistula Actually Used” Form	f303_f_used.sas7bdat
dac304_fpatency	Patency Form	f304_f_patency.sas7bdat
dac305_fsuitab	Suitability Form	f305_f_suit.sas7bdat
dac306_fpilldisp	Pill Dispensing Form	f306_f_pills.sas7bdat

dac307_FStrtDial	Dialysis Status Check Form	f307_f_dialchk.sas7bdat
dac310_FistulaSuitQC	Suitability QC Check Form	f310_f_suitqc.sas7bdat
dac322_ptfamempinc	Patient Family, Employment and Income Form	f322_f_employinc.sas7bdat
dac324_bselinemedication_asp	Baseline Medication Tracking Form	f324_f_basemeds.sas7bdat
dac331_democom	Demographics, Comorbidity, and Dialysis History Form	f331_f_demo.sas7bdat
dac333_visitform	Q 11-23 on Visit Form	f333_f_symptoms.sas7bdat
	Visit Form	f333_f_visit.sas7bdat
dac334_medication_asp	Follow-up Medication Tracking Form	f334_f_fupmeds.sas7bdat
dac335_tmptdiscntd	Temporary Discontinuation of Therapy Form	f335_f_tmptdisc.sas7bdat
dac336_prmtpdiscntd	Permanent Discontinuation of Therapy Form	f336_f_permdisc.sas7bdat
dac337_reviewprmtpdiscntd	Review of Permanent Discontinuation of Therapy Form	f337_f_permdc_rev.sas7bdat
dac338_lof	Lost to Follow-up	f338_f_losttofup.sas7bdat
dac341_qoleng	Quality of Life Assessment (English Version)	f341_f_qol.sas7bdat
dac351_locallab	Local Biochemistry Laboratory Data Form	f351_f_labs.sas7bdat
dac352_fistprocedure	Access Repair / Access Event Procedure	f352_f_repair.sas7bdat
dac360_hospnotif	Clinical Center Hospitalization Notification Form	f360_f_hospnotif.sas7bdat
dac361_hosp	Clinical Center Hospitalization Form	f361_f_hospital.sas7bdat
dac363_transfbleedingepiso	Bleeding Episodes Form	f363_f_bleed.sas7bdat
dac364_PersistDisab	Persistent Disability / Incapacity Form	Never Used
dac365_LifeThreat	Life Threatening Event Form	f365_f_lifethreat.sas7bdat
dac366_BirthDefect	Birth Defect Event Form	Never Used
dac367_QCreviewTransfusionBleeding	QC Committee Review of Bleeding Episode	f367_f_bleed_review.sas7bdat
dac371_deathnot	Clinical Center Death Notification Form	f371_f_deathnotif.sas7bdat
dac372_deathrev	Clinical Center Death Review Form	f372_f_death.sas7bdat
dac373_deathcommrev	QC Committee Review Form	f373_f_death_review.sas7bdat

dac383_studychange	Patient Participated In One of the DAC Studies and Is Now Enrolled in the Other DAC Study Form	f383_f_othstudy.sas7bdat
dac385_RsnsNotEnrolledF	Reasons for Not Enrolling Patients in Fistula Study	f385_f_notenr.sas7bdat
dac387_RsnsNotEnrolledUnk	Reasons for Not Enrolling Patients with Unknown Access	f387_u_notenr.sas7bdat
dac390_VitalStatus	Annual Check on Vital Status for Inactive Patients Form	f390_f_vitalstat.sas7bdat
dacR5_SAE	Serious Adverse Event	r5_f_sae.sas7bdat
dacR5_SAE_Pg2	Serious Adverse Event, pg 2	contained in above file
NO FORM	Analysis dataset containing detail on the primary outcome, fistula thrombosis. Fistula thrombosis was determined by physical examination at 6 weeks	f_primary.sas7bdat
NO FORM	Analysis dataset containing details on the secondary outcome, failure of the fistula to become suitable for dialysis. Suitability was defined as use of the fistula at a dialysis blood pump rate of 300 m/min or more during 8 of 12 dialysis sessions.	f_secondary.sas7bdat
NO FORM	DCC categorization for ACE Inhibitors and ARBs	dacdrugs.sas7bdat
ADMINISTRATIVE FORMS		
dac395_mailingMcKesson	Mailing of Serum Specimen to McKesson	NO DATA FILE
dac396_mailingRutgers	Mailing of DNA/Plasma specimen to Rutgers	NO DATA FILE

3. Data

The Data folder contains 38 data files. 35 files contain forms related data and 3 files are analysis files. In Table 1, the analysis files are those with “No Form” indicated in Column 1.

4. Data Set Integrity Check (DSIC)

As a partial check of the integrity of DAC Fistula Study dataset archived in the NIDDK data repository, a set of tabulations was performed to verify that published results can be reproduced using the archived dataset. Analyses were performed to duplicate selected results for the data published by Dember et al in the *Journal of American Medical Association* in May 2008. Complete results are presented in the DSIC folder of the Official Archive.