

Dialysis Access Consortium (DAC) - Graft Study

The archive contains the study protocol and related descriptive documentation; study forms; and data collected by the study. The full trial name is “Aggrenox Prevention of Access Stenosis”.

The Official Archive is organized in four directories:

1. Documentation
2. Forms
3. Data
4. DSIC (Data Set 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 procedures manual for the consortium that recruited patients for two clinical trials conducted under its auspices (Graft and Fistula)
- MOP_Graft.pdf- the procedures manual for the Graft Study
- GraftProtocol.pdf- the Graft study protocol
- DAC Graft Study codebook.pdf– the codebook for variables collected on the study data forms

2. Forms

The Forms directory holds 41 PDF form files of which 37 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

Graft Form* (*yellow highlight=forms common to Graft and Fistula trials)	Description	Graft Data Files
DATA FORMS		
dacA1_RandOnLineApplic	Graft Study Randomization On-Line Application	a1_random.sas7bdat
dac311_GScreen	Screening Form	f311_screening.sas7bdat
dac312_graftbaselinedropout	Baseline Dropout Form	f312_basedropout.sas7bdat
dac313_GPostSurg	First Post Surgical Visit Form	f313_firstpostsurg.sas7bdat
dac314_gfupvisit	Monthly Graft Related Follow up Visit Form	f314_monthly.sas7bdat
dac315_gpilldisp	Pill Dispensing Form at Randomization	f315_pilldisp.sas7bdat
dac316_gpillcount	Pill Counting / Dispensing Form	f316_pillcountdisp.sas7bdat

dac317_reduceddose	Patient was Prescribed Reduced Dose of the Study Drug	f317_reduceddose.sas7bdat
dac322_ptfamempinc	Patient Family, Employment and Income Form	f322_g_employinc.sas7bdat
dac324_bselinemedication_asp	Baseline Medication Tracking Form	f324_g_basemeds.sas7bdat
dac331_democom	Demographics, Comorbidity, and Dialysis History Form	f331_g_demo.sas7bdat
dac333_visitform	Q 11-23 on Visit Form	f333_g_symptoms.sas7bdat
dac333_visitform	Visit Form	f333_g_visit.sas7bdat
dac334_medication_asp	Follow-up Medication Tracking Form	f334_g_fupmeds.sas7bdat
dac335_tmpdiscntd	Temporary Discontinuation of Therapy Form	f335_g_tmpdisc.sas7bdat
dac336_prmtpdiscntd	Permanent Discontinuation of Therapy Form	f336_g_permdisc.sas7bdat
dac337_reviewprmtpdiscntd	Review of Permanent Discontinuation of Therapy Form	f337_g_permdc_rev.sas7bdat
dac338_lof	Lost to Follow-up	f338_g_losttofup.sas7bdat
dac341_qoleng	Quality of Life Assessment (English Version)	f341_g_qol.sas7bdat
dac351_locallab	Local Biochemistry Laboratory Data Form	f351_g_labs.sas7bdat
dac353_monitoring	Ultrasound Monitoring Form: Access Blood Flow Surveillance	f353_ultrasound.sas7bdat
dac354_diagnosticprocedure	Diagnostic Procedure (Fistulogram, Angiogram, Venogram) Form	f354_diagproc.sas7bdat
dac355_accesseventproc	Access Repair / Access Event Procedure (Angioplasty and other procedures) Form	f355_repair.sas7bdat
dac356_sitefeailuret	Site Failure, Thrombosis (End Point) Form	f356_thromb.sas7bdat
dac358_GraftSecOutcome	Secondary Outcome Form	f358_secoutcome.sas7bdat
dac360_hospnotif	Clinical Center Hospitalization Notification Form	f360_g_hospnotif.sas7bdat
dac361_hosp	Clinical Center Hospitalization Form	f361_g_hospital.sas7bdat
dac363_transfbleedingepiso	Bleeding Episodes Form	f363_g_bleed.sas7bdat
dac364_PersistDisab	Persistent Disability / Incapacity Form	Never Used
dac365_LifeThreat	Life Threatening Event Form	f365_g_lifethreat.sas7bdat
dac366_BirthDefect	Birth Defect Event Form	Never Used
dac367_QCreviewTransfusionBleeding	QC Committee Review of Bleeding Episode	f367_g_bleed_review.sas7bdat

dac371_deathnot	Clinical Center Death Notification Form	f371_g_deathnotif.sas7bdat
dac372_deathrev	Clinical Center Death Review Form	f372_g_death.sas7bdat
dac373_deathcommrev	QC Committee Review Form	f373_g_death_review.sas7bdat
dac383_studychange	Patient Participated In One of the DAC Studies and Is Now Enrolled in the Other DAC Study Form	f383_g_othstudy.sas7bdat
dac386_RsnsNotEnrolledG	Reasons for Not Enrolling Patients in Graft Study	f386_g_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_g_vitalstat.sas7bdat
dacR5_SAE, dacR5_SAE_Pg2 NO FORM	Serious Adverse Event Analysis dataset containing detail on the primary outcome, loss of primary unassisted patency (i.e., patency without thrombosis or requirement for intervention)	r5_g_sae.sas7bdat g_primary.sas7bdat
NO FORM	Analysis dataset containing details on the secondary outcome, cumulative graft failure and death.	g_secondary.sas7bdat
NO FORM	DCC categorization for ACE Inhibitors and ARBs	g_acearb.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 41 data files. 38 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 Graft 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 *Bradley et al* in the *New England Journal of Medicine* in May 2009. Complete results are presented in the DSIC folder of the Official Archive.