DAC Study Form 301 - Fistula Study Screening Form F301_F_screening

This Form should be completed by a study coordinator when a patient is considered for entry into the DAC Fistula Full-Scale Study and/or has consented. In order for a patient to be randomized, this form, the consent, the visit form 333, the demographics / comorbidity / dialysis history form 331, the patient family, employment and income form 322, the baseline quality of life form 341, the baseline local lab form 351 and the baseline medication form 324 must be in the database.

If this form is completed and entered, and item 31 shows the patient is eligible, the patient is considered to be "enrolled" in the fistula study as of "Date of Screening/Enrollment".

1. Patient Identification Number..... ____ PID
2. Name Code..... _____
3. a. Visit Type .....B VIST
   b. Visit Number..... VISN
4. Today's Date: Date of Screening/Enrollment ..... __/__/__ ENROLL-DT
5. Patient's Planned Dialysis Unit ..... DIAL-UNIT

   Note: Use one of the codes for the dialysis unit from the list attached to the form

For re-enrolled patients:

6. a. Date of most recent previous enrollment in the fistula study .. __/__/__ PRE_ENROL-DT
   b. Date of most recent pre-randomization drop out in the fistula study ..... __/__/__ PRE_RAND-DO-DT
7. Sex (1=male, 2=female)..... SEX

INCLUSION CRITERIA

8. Date of Birth (mm/dd/yyyy) ..... __/__/__ DOB

   Note: The database will confirm that age is greater than or equal 18.

9. a. Has a date of an upper extremity fistula creation surgery been set? (code 0 = no, 1 = yes) ..... DT_SET

   Note: Tell the patient to stop aspirin.

   b. If Yes, what is the date..... __/__/__ SET_DT
   c. If No, are you confident that the date will be scheduled within 60 days?..... WILL_SET
   d. Where was the patient found (dialysis unit or hospital)? ..... PT_FOUND
   e. Location (hospital) where the fistula will be done ..... LOCATION

   Note: For d. and e. use one of the codes for the referring hospitals and the participating units from the list attached to this form.

Revised on 06/23/2004

DAC Study Form 301 - Fistula Study Screening Form

For the items 10 to 13 and 15 below, code 0 = no, 1 = yes

10. Does this patient have a life expectancy at least six months? ..... LIFE_EX

11. Is this patient capable of giving informed consent? ..... CONSENT

12. Is this patient able to do the tasks required? ..... TASK

13. Is this patient's personal physician (or team of physicians) willing to allow the patient to participate? ..... PHY_ALLOW

14. Hemodialysis Status ..... HEMODIAL
    1 = The patient is on chronic hemodialysis.
    2 = The patient is expected to start chronic hemodialysis within six months.
    3 = Other (If other, the patient is not eligible for the full-scale study)

15. Is this patient planning to remain at a participating dialysis unit for at least six months? REMAIN_DIAL

16. a. Aspirin, MI, CVA Status ..... ASPIRIN_STAT

    Code as follows:
    1 = Patient is not on aspirin
    2 = Patient is on aspirin but <u>has not</u> had a MI, a CVA or unstable angina in the last 12 months
    3 = Patient is on aspirin and <u>has</u> had a MI or a CVA or unstable angina in the past 12 months

Notes: Must be 1 or 2 in order for the patient to be eligible.

The database will confirm that aspirin has been discontinued at least seven days prior to surgery, if the patient is on aspirin.

b. If 16a = 2, date patient took last dose of aspirin ..... LAST_ASPIRIN_DT __/__/____

EXCLUSION CRITERIA

(Code 0 = no, 1 = yes for females, or 9 = N/A for males for Q. 17)

17. If the patient is a female, is she pregnant, or breastfeeding, or does she plan to be pregnant during the course of the Study? ..... PREGNANT

(Code 0 = no, 1 = yes, for each item below except item 27 a, b, c)

18. Does this patient have ongoing bleeding? ..... ONGOING_BLEED

19. Does this patient have a known bleeding disorder? ..... BLEED_DISORD

20. Has this patient had a bleeding episode requiring transfusion or hospitalization within 12 weeks of the date of enrollment? ..... BLEED_HOSP_TRANS

21. Does this patient have acute ulcer disease? ..... ULCER

Note: Acute ulcer disease is defined as a new diagnosis of peptic disease including esophagitis, gastritis, or ulcer or the initiation of treatment with proton pump inhibitors, H2 blockers or Helicobacter pylori therapy within three months prior to obtaining consent.

22. Does this patient require use of clopidogrel? ..... CLOPIDOGREL
23. Does this patient have a known allergy or hypersensitivity to clopidogrel? ..... ALLERGY-CLO
24. Does this patient have medical considerations making anti-platelet therapy dangerous? ANTI-PLATELE
25. Does this patient have a condition, which prohibits discontinuation of aspirin, non-steroidal anti-inflammatory drugs, warfarin, or systemic glucocorticoids at a dose greater than the equivalent of prednisone 15 mg/day for 6 weeks following fistula creation? ..... REQ-ASPIRIN
26. Does the patient have current unstable angina? ..... ANGINA

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27. a. Systolic blood pressure ..... S-BP
    b. Diastolic blood pressure ..... D-BP
    c. Date of measure ..... __ __ / __ __ / BP-DT
    d. Does this patient currently have uncontrolled hypertension with systolic blood pressure in excess of 200 mm Hg or diastolic blood pressure in excess of 115 mm Hg at the most recent clinic visit or post dialysis session? ..... HI-BP
28. Does this patient have known advanced liver disease with decompensated cirrhosis, jaundice, ascities or bleeding varices? ..... LIVER-DX
29. Does this patient have a history of non-compliance with medical care, such as skipping dialysis sessions or failing to take prescribed medications? ..... NON-COMPLIANCE
30. Does this patient have a current problem with substance abuse? ..... SUB-ABUSE
31. Is this patient enrolled in another intervention study (this includes the Graft Study)? OTHER-STUDY

Note: The database will confirm that all exclusion criteria are answered 0 = No.

32. Do these screening data show the patient to be eligible? ..... ELIGIBLE

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33. Statin status of the patient ..... STATIN-STAT

    0 = Did not come in on statin like Atorvastatin, Lovastatin, or Simvastatin
    1 = Came in on a statin like that and is stopping statins until completion of study drug treatment.
    2 = Came in on a statin like that and is switching to Fluvastatin
    3 = Came in on a statin like that and is switching to Pravastatin
    4 = Came in on a statin like that and will stay on it
    5 = Came in on a statin like that and is not sure what will do

Note: If the patient is on statins like Atorvastatin, Lovastatin, or Simvastatin, be sure that your principal investigator has considered whether the patient can switch from statins like Atorvastatin, Lovastatin, or Simvastatin to statins like Fluvastatin or Pravastatin.

201. User ID of person completing this form ..... COMP_BY

Clinical Center Use Only

Date Form Entered __ __/__ __/__ __ __ __

Person Entering this Form_____

DAC Study Form 302 - Fistula Study Dropout Form F302_F_DROPOUT

This Form is completed when it is determined that a patient who was enrolled in the Baseline of the DAC Fistula Full Scale Study will not be randomized.

1. Patient Identification Number ..... ___PID___
2. Name Code ..... _____
3. Date of Pre-Randomization Dropout ..... ___DROPOUT_DT___
4. Primary Reason for Pre-Randomization Dropout ..... REASON__

Note: These choices are in rank order. Please enter the first reason that applies.

1 = Graft was placed instead
2 = Fistula was not placed for some reason other than transplant or peritoneal dialysis
4 = We could not determine within 1 day what type of access was placed
5 = We could not get the blood results from the lab on time
6 = Patient ineligible due to taking aspirin before randomization
7 = Patient ineligible due to out of range lab values which have been entered into the study database
8 = Patient ineligible due to starting anti-platelet or anti-thrombotic therapy
9 = Fistula clotted prior to randomization
10 = Logistics reasons
20 = More than 45 days passed since Baseline data collection, and new data could not be collected
21 = More than 90 days passed since the consent form was signed, and a new consent could not be obtained
22 = Patient received a transplant
23 = Patient decided to go on peritoneal dialysis instead
24 = Patient ineligible due to developing an exclusion criteria
29 = Patient was lost to follow-up
30 = Patient Preference
31 = Study Team Preference
32 = Study enrollment period ended

5. Secondary Reason for Pre-Randomization Dropout ..... SND_REASON__
(Use codes from q.4)
6. If q.4 or q.5 is "Logistics reasons", or if q.4 = "Developed an exclusion criteria", describe what happened. COMMITS

201. Date this form completed ..... __/__/__FORM_DT
202. User ID of person completing this form ..... _____COMP_BY

Clinical Center Use Only

Date Form Entered __/__/____

Person Entering this Form _____

DAC Study Form 303 – DAC Fistula Study "Was the Fistula Actually Used" Form

F303_F_WASUSED

This form should be completed monthly for patients for whom it is reported on Form 305 (Q5c) that the fistula is not being used at the end of the suitability assessment but will be used in the future.

1. Patient Identification Number ..... PID
2. Patient Name Code ..... _____
3. a. Status check number ..... CHKN

   b. Status check date ..... ___/___/ CHK-DT
4. Was the study fistula used for dialysis during the last month? (0=no, 1=yes) ..... FIST-LM
5. If q. 5=no, which one of the following is true: ..... PRIM-AC

   1 = The fistula was removed/ligated

   2 = The fistula was not removed or ligated, but there was thrombosis and it will not be used in future

   3 = The fistula was abandoned for reason other than thrombosis

   4 = Another access was used, but fistula was not abandoned

Note: If Q5 = 1 (Yes) Q6=1, 2, 3, no further Form 303s are needed.

201. Date this form completed ..... __/__/_____
202. User ID of person completing this form ..... _____

Clinical Center Use Only
Date Form Entered __/__/_____
Person Entering this Form _____

DAC Study Form 304 - Fistula Patency F304-F_PATENCY

This form is completed, along with the "visit" form (333) and the QOL form 341, six weeks after the surgery. If the study drug was discontinued because of fistula thrombosis prior to six weeks, this form and the "visit" form 333 are completed 30 days after study drug is discontinued or at six weeks, whichever comes first. (Patency assessment only counts if it is done 40 to 50 days after surgery)

1. Patient Identification Number..... PID
   a. Patient Name Code .....
   b. Date of this six week visit..... __/__/ VISDT
   c. Was there a one day call to check on compliance?..... CALL1
      (0=no, 1=yes, 9=unknown)
   d. Date of the one day call ..... __/__/ CALL1_DT
   e. Was there a two week call to check on compliance and adverse events? CALL2
      (0=no, 1=yes, 9=unknown)
   f. Date of the two week call ..... __/__/ CALL2_DT

   Note: If there is an adverse event reported, make sure to file Form 333 and any other forms referred by it.

   g. Was there a four week call to check on compliance and adverse events? CALL4
      (0=no, 1=yes 9=unknown)
   h. Date of the four week call..... __/__/ CALL4_DT

   Note: If there is an adverse event reported, make sure to file Form 333 and any other forms referred by it.

2. a. Date the fistula placed..... __/__/ FIST_DT
   b. Where was it placed (location of the surgical center)?..... SURG_CTR
      (See the codes for the hospitals from Form 301)
   c. Surgeon ID..... SURG_ID
   d. Was ultrasound vascular mapping done before surgery? ..... US_VMAP
      (0=no, 1=yes, 9=unknown)
   e. Was patient on hemodialysis at time of fistula placement? (0=no, 1=yes) ..... DIAL_F_PLACE
   f. If no, is the patient on hemodialysis now?..... DIAL_NOW
3. Patient's dominant arm for eating (1= righthanded, 2= lefthanded) ..... DOM_ARM
4. Type of fistula
   a. Position..... POS
      1 = forearm 2 = upper arm
   b. Side (1= right, 2= left) ..... SIDE

c. Anastomosis ..... ANAST

1 = radial artery - cephalic vein
2 = ulnar artery - basilic vein
3 = brachial artery – cephalic vein
4 = basilic vein transposition
5 = unknown
6 = other (specify) _____ ANAST_OTHER

5. Previous access in the same arm? (0=no, 1=yes) ..... SAME_ARM
If YES,

a. Type (1=fistula, 2=graft, 3=both, 4=unknown) ..... SAME_ARM_TYPE

b. Position (1=forearm, 2=upper arm, 3=both) ..... SAME_ARM_POS

6. Previous access in the other arm? (0=no, 1=yes) ..... OTH_ARM

7. Were any repairs / procedures done on the fistula since it was placed? (0=no, 1=yes) ... REP_PROC

Note: If there were repairs done, make sure a Access Repair / Access Event Procedure Form 352 was completed.

8. Did any events occur to the fistula since it was placed? (0=no, 1=yes) ..... EVT

Note: If there were events, make sure a Access Repair / Access Event Procedure Form 352 was completed.

9. Was the fistula abandoned prior to this visit? (0=no, 1=yes) ..... F_ABAND

Note: If the fistula was identified as abandoned, Form 305 should not be completed.

For all patients for whom Q9 = No:

10. a. ID of Measurer 1 ..... MEAS1_ID

b. Bruit detectable along the vein at least 8 cm proximal to the arteriovenous anastomosis? (0=no, 1=yes) ..... BRUIT_VEIN

Note: Item 10b is used to determine the primary outcome of the study.

c. Bruit detectable at the arteriovenous anastomosis? (0=no, 1=yes) ..... BRUIT_ART

d. Thrill during systole? (0=no, 1=yes) ..... SYS_THRILL

e. Thrill during diastole? (0=no, 1=yes) ..... DIA_THRILL

f. In your clinical judgment, will this fistula eventually be usable for dialysis? (0=no, 1=yes, 9=unknown) ..... FIST_USABLE1

For QC patients:

g. ID of Measurer 2 ..... MEAS2_ID

h. Bruit detectable along the vein at least 8 cm proximal to the arteriovenous anastomosis? (0=no, 1=yes) ..... BRUT2_VEIN

i. In your clinical judgment, will this fistula eventually be usable for dialysis? (0=no, 1=yes, 9=unknown) ..... FIST_USABLE2

DAC Study Form 304 - Fistula Patency

For all patients:

11. Was a two-step basilic vein transposition lifting surgery planned? (0=no, 1=yes) SURG_PLANNED

12. Were clamps ever used on this patient? (0=no, 1=yes) CLAMPS

13. Was the patient taking his/her assigned DAC study drug for six weeks? (0 = no, 1 = yes, 11 = Pt died more than 6 weeks after randomization and there is no way we can know.) DRUG_6WK

14. If no, approximate date when patient quit taking the drug ____/____/____ QUIT_DT

    Note: If q.13 = no, make sure Form 335 or 336 is completed

15. Did the patient return his/her bottle? (0=no, 1=yes) BOTTLE_RTN

16. If yes, how many pills were in it? PILLS_IN

17. Which treatment group does the study team think this patient was randomized to? RX_GUESS

    1 = The team has been unblinded and knows it is placebo
    2 = The team believes this patient was randomized to placebo
    3 = The team does not know
    4 = The team believes this patient was randomized to active drug
    5 = The team has been unblinded and knows it is active drug

18. If Q17 = 1 or 5, Date of unblinding ____/____/_____ UNBLIND_DT

19. In retrospect, was there an appropriate fistula placement for a patient enrolled in the DAC fistula study? (0=no, 1=yes) FIST_PLACE

20. If no, please explain _____ NO_FST_RSN

201. Date this form completed ____/____/_____

202. User ID of person completing this form _____

Clinical Center Use Only

Date Form Entered ____/____/_____

Person Entering this Form _____

DAC Study Form 305 - Fistula Suitability Form

F305_F_SUIT

This form is to be used to assess the fistula suitability as follows:

- If the fistula was abandoned between 6 weeks and 150 days after fistula creation surgery, this form can be entered at the time it was abandoned.

- For **prevalent** patients (i.e., patients who started dialysis before fistula creation surgery): Fistula suitability outcome ascertainment will begin 120 days after creation of the fistula. The suitability assessment will be based on the 12 consecutive dialysis sessions starting with the first session of fistula use between 120 and 150 days after fistula creation. If the fistula has not been used by 150 days, it should be considered unsuitable.

- For **incident** patients (i.e., patients not yet on dialysis at the time of fistula creation surgery): Fistula suitability ascertainment will begin 120 days after fistula creation if dialysis is initiated within 120 days of fistula creation, or at the onset of initiation of dialysis if dialysis is initiated more than 120 days after fistula creation. If dialysis is initiated within 120 days of fistula creation, the suitability assessment will be based on the 12 consecutive dialysis sessions starting with the first session of fistula use between 120 and 150 days after creation, and will be considered unsuitable if it has not been used by 150 days (i.e., just as for prevalent patients). If dialysis is initiated more than 120 days after fistula creation, the suitability will be based on the first 12 consecutive dialysis sessions starting with the first session of dialysis.

1. Patient Identification Number..... PID
2. Patient Name Code ..... _____
3. Date suitability assessment completed ..... __/__/ VISDT
4. Why are you completing this form?..... FORMREASON

   1 = 30-60 days after initiation of dialysis for incident pts who started dialysis more than 120 days after surgery.
   2 = End of suitability ascertainment period for prevalent patients or for incident patients who start dialysis within 120 days after fistula creation surgery (or if fistula was abandoned after being used between the six week visit and 150 days after fistula creation surgery).
   3 = Fistula was abandoned prior to first use (Skip Q.5)
   4 = End of study data collection (q.3 should be dated 01/31/2008)

5. a. If q. 4 = 1 or 2, or 4 is the fistula being used? (0=no, 1=yes)..... FIST_USED
   b. If the fistula was ever used, when was it used for the first time?__/__/ FIST_DT
   c. If q. 5a = no, what is being planned?..... PLAN_FIST

      1 = The access will be used in the future (Complete Form 303)
      2 = A new access will be placed
      3 = Switched to modality other than hemodialysis (i.e., PD or transplant)
      4 = Catheter will be used on a permanent basis

6. If the fistula was abandoned prior the completion of suitability, what was the reason? ABAND_REASON

   1 = ligated for steal syndrome
   2 = ligated for infection
   3 = ligated for aneurysm
   4 = thrombosed
   5 = other, specify OTH_REASON

7. Have there been any procedures on the fistula since the 6-week visit? (0=no, 1=yes) .....PROCED

Note: If q.6 was answered or q.7 = Yes, complete Form 352.

8. Which treatment group does the study team think the patient was randomized?.....RAND_TREAT

1 = The team has been unblinded and knows it was placebo
2 = The team believes this patient was randomized to placebo
3 = The team does not know
4 = The team believes this patient was randomized to active drug
5 = The team has been unblinded and knows it was active drug

9. If q. 8 = 1 or 5, date of unblinding..... __/__/UNBLIND_DT

10. For patients not on chronic dialysis prior to creation of this fistula, date of first dialysis (using any access) ..... __/__/FST_DIAL_DT

Note: If the fistula was abandoned prior to first use, or the fistula was never used skip q. 11 - 23.

11. Were clamps used on this patient? (0=no, 1=yes) .....CLAMP

Please record minimal and mean dialysis blood flow between first hour of dialysis and before the last 15 minutes during the session. Report 12 consecutive sessions that actually occur. For sessions that are scheduled but do not occur, record the date of the scheduled session and indicate in the 4th column that the dialysis session was missed. **For prevalent patients,** the first session to be reported is the first session of fistula use between120 and 150 days after the fistula surgery. **For incident patients,** the first session to be reported is first session of fistula use between 120 and 150 days after the fistula surgery if dialysis is initiated within 120 days of fistula creation OR the first session of dialysis if dialysis initiation begins >120 days after fistula creation. List the sessions in the order that they occurred. If the patient missed a scheduled session and had a make-up session before the next scheduled session, please enter the blood flow obtained during the make-up session. For incident patients who initiate dialysis >120 days after fistula creation, the suitability assessment period will end with the 12th dialysis session that takes place, or by 60 days after initiation of dialysis, whichever comes earlier.

Date	Minimal blood flow	Mean blood flow	Reason blood flow not reported 1 = Patient missed dialysis session 2 = Fistula not used (Other access used for dialysis)
12. __/__/BF_DT1	BF1	MEAN_BF1	NO_BF_RSN1
13. __/__/BF_DT2	BF2	MEAN_BF2	NO_BF_RSN2
14. __/__/BF_DT3	BF3	MEAN_BF3	NO_BF_RSN3
15. __/__/BF_DT4	BF4	MEAN_BF4	NO_BF_RSN4

Date	Minimal blood flow	Mean blood flow	Reason blood flow not reported 1 = Patient missed dialysis session 2 = Fistula not used (Other access used for dialysis)
16. __/BF-DT5	BF5	MEAN-BF5	NO-BF-RSN5
17. __/BF-DT6	BF6	MEAN-BF6	NO-BF-RSN6
18. __/BF-DT7	BF7	MEAN-BF7	NO-BF-RSN7
19. __/BF-DT8	BF8	MEAN-BF8	NO-BF-RSN8
20. __/BF-DT9	BF9	MEAN-BF9	NO-BF-RSN9
21. __/BF-DT10	BF10	MEAN-BF10	NO-BF-RSN10
22. __/BF-DT11	BF11	MEAN-BF11	NO-BF-RSN11
23. __/BF-DT12	BF12	MEAN-BF12	NO-BF-RSN12
24. __/BF-DT13	BF13	MEAN-BF13	NO-BF-RSN13
25. __/BF-DT14	BF14	MEAN-BF14	NO-BF-RSN14
26. __/BF-DT15	BF15	MEAN-BF15	NO-BF-RSN15
27. __/BF-DT16	BF16	MEAN-BF16	NO-BF-RSN16

201. Date this form completed..... __/__/____

202. User ID of person completing this form .....__ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered __/__/____

Person Entering this Form_____

DAC Fistula Study Form 306 – Pill Dispensing Form F306 - F _ PILLS

This form is completed ONLY if drug was dispensed to the patient.

1. Patient Identification Number..... PID
2. Patient Name Code ..... _ _ _ _ _
3. Code number on the bottle dispensed ..... BOTTLECODE
4. Confirmation code for that bottle..... CONFIRMCODE
5. Date/time (24 hour clock) drug given to patient..... _ _/_ _/_ _ DISPENSE_DT
6. Statin status of the patient ..... STATIN_STAT

   0 = Did not come in on statin like Atorvastatin, Lovastatin, or Simvastatin
   1 = Came in on a statin like that and is stopping statins until completion of study drug treatment.
   2 = Came in on a statin like that and is switching to Fluvastatin
   3 = Came in on a statin like that and is switching to Pravastatin
   4 = Came in on a statin like that and will stay on it

7. If Q. 6 = 4, what daily dosage is the patient taking?..... STATIN_DOSE

   1 = 5 mg
   2 = 10 mg
   3 = 20 mg
   4 = 40 mg
   5 = 80 mg
   6 = other, specify_____ STATIN_DOSE_OTH

201. Date this form completed..... _ _/_ _/_ _ _ _

202. User ID of person completing this form ..... _ _ _ _ _ _ _ _

Clinical Center Use Only

Date Form Entered _ _/_ _/_ _ _ _

Person Entering this Form_____

Revised on 03/05/2003

DAC Study Form 307 – DAC Fistula Study Dialysis Status Check Form F307-f_DIALCHK

This form should be completed for "active" **incident** patients randomized at least 120 days ago. "Active" **incident** patients are patients who are not lost to follow-up and their fistula was **not** abandoned at the time of the patency assessment. This form should be completed monthly until the start of dialysis is reported (q.4=1).

1. Patient Identification Number ..... PID
2. Patient Name Code ..... _ _ _ _
3. a. Status check number ..... CHKN
   b. Status check date ..... _ _/_ _/ CHK-DT
4. Did the patient start dialysis within the last month (0=no, 1=yes)? ..... START_LM
5. If q. 4=yes, when did the patient start dialysis? ..... _ _/ START-DT

201. Date this form completed _ _/_ _/_ _ _ _
202. User ID of person completing this form _ _ _ _ _ _

Clinical Center Use Only

Date Form Entered _ _/_ _/_ _ _ _
Person Entering this Form _____

F310_F_SUIT QC

DAC Study Form 310 – DAC Fistula Study Suitability QC Check Form

This form should be completed for patients for whom either a) it is reported on Form 305 the fistula is not being used at the end of the suitability ascertainment period, but will be used in the future, or b) the fistula was being used during the suitability ascertainment period but did not fulfill the DAC Fistula Study criteria for suitability. The form should be filled out for the first dialysis session monthly for four consecutive months after the suitability ascertainment period.

1. Patient Identification Number ..... PID ____

2. Patient Name Code ..... ____

3. Month number ..... MONTH ____
(Note: Begin with month 1 for the start of the first month after suitability ascertainment)

4. Patient Status ..... STATUS ____
1 = Patient being followed on hemodialysis
2 = Patient has a functioning transplant
3 = Patient is on PD
4 = Patient is completely lost to follow up

5a. Date of first dialysis session for this calendar month? (mm/dd/yyyy) .. ____/____/ DIAL_DT ____
(Note: If the patient received a transplant or switched to PD, enter the date of the transplant or switch. If the patient is completely lost to follow up, enter the first day of the month.

5b. Was the study fistula used for dialysis during this session? ..... FIST_USED ____
0 = No, some other access was used
1=Yes, the study access was used
2 = Couldn't tell

6. If possible, review surgical, interventional radiology, or other records, and check:
Has another access been placed recently? ..... ANOTHER_ACCESS ____
(Note: The first time this form is used, check from the time the study access was placed until now. For the second, third, and fourth times this form is used, check for the last month.)
1 = Yes, a new access has been placed
2 = The records were checked and there was no evidence that another access has been placed
3 = Records could not be checked

7. Did the run sheet or other records mention the presence of a catheter? (0=no, 1=yes) ..... CATHETER ____

8. Access dressing documentation status during the session ..... ACCESS_DRESSING ____
0 = No documentation saying access dressing was changed
1 = Access dressing was changed

9. Using the run sheet or other records: what needle size was used at the session? ..... NEEDLE_SIZE ____
(Note: Use "99" for "nothing noted")

10. Status of fistula abandonment: was there any indication on the run sheet or other records? ..... FIST_ABAND ____
1 = There was an indication that the fistula has not been abandoned and may be used in the future.
2 = There was an indication that the fistula has been abandoned.
3 = Nothing noted

Note: Once the fistula has been abandoned (Item 10 = 2) or the patient has become completely lost (Item 4 = 4), no additional Form 310's need to be completed.

201. Date this form completed ..... ____/____/____
202. User ID of person completing this form ..... ____

Clinical Center Use Only
Date Form Entered ____/____/____
Person Entering this Form ____

Revised 05/25/2007

F322_F_Employ Inc

DAC Study Form 322 - Patient Family, Employment and Income Form

This Form should be completed by a study coordinator when a patient is considered for entry into either the DAC Graft Study or the DAC Fistula Study. In order for a patient to be randomized, this Form must have been entered in the database.

1. Patient Identification Number ..... ____ pid
2. Name Code..... ____
3. a. Visit Type ..... B visit
   b. Visit Number..... __ visn
4. Marital Status ..... _ marital

   1 = Single and never been married
   2 = Married
   3 = Common law marriage/Living together unmarried/partnered
   4 = Separated
   5 = Divorced
   6 = Widowed
   8 = Patient refuses to provide the data
   9 = Unknown

5. Household Size: (Enter 0=no, 1=yes, 8=patient refuses to provide the data, 9=unknown)
   a. Lives with spouse..... _ spouse
   b. Lives with children ..... _ child
   c. Lives with parent(s) ..... _ parent
   d. Lives with other relatives..... _ relative
   e. Lives with other roommates..... roommate
   f. Boarding house or rooming house ..... board_house
   g. Homeless..... _ homeless
   h. Institutionalized or in nursing home ..... _ institutio
   i. Lives alone..... _ alone
6. How many people live in the household? ..... __ hh_size
   (Code: 00 if homeless or institutionalized or nursing home or boarding house,
   99 if unknown or patient refuses to provide the data.)
7. Has the patient ever been employed for pay?..... _ employed
   (Code: 0=no, 1=yes, 8=patient refuses to provide the data, 9=unknown)
   (If no, skip to item 14 "Patient's current gross annual income")

8. Work status six months prior to initiation of any ESRD replacement therapy ..... _ work_stat

1 = Student, not employed 6 = Not working, seeking work, disabled

2 = Student, also employed
3 = Homemaker
4 = Not working, not seeking work, disabled
5 = Not working, not seeking work, not disabled
7 = Not working, seeking work, not disabled
8 = Employed full-time
9 = Employed part-time
10 = Retired
99 = Unknown

9. Current work status (Same codes as above) ..... cur_wk_stat
10. Current job title: (50 characters) _____ job_title
11. Current occupation code (from Forms manual code list) ..... cur_occu_cod
12. Primary reason for work status change (between pre-ESRD and current)? ..... work_stat_chg

    1 = There was no change
    2 = Due to time constraints of chronic kidney failure treatment
    3 = Due to complications of chronic kidney failure
    4 = Due to illness other than chronic kidney failure
    5 = Due to retirement
    6 = Other (50 characters) ..... _____ work_status_change_oth

13. What was the last year the patient was employed? ..... last_yr_employed

    Note: Enter current year for currently employed.

14. Patient's individual current gross annual income (include disability incomes) ..... gross_inc

    1 = < $7,500
    2 = 7,500 - 24,999
    3 = 25,000 - 49,999
    4 = 50,000 - 99,999
    5 = > 100,000
    6 = Patient refuses to provide the data
    9 = Unknown

15. Patient's total household gross annual income (include disability income) ..... total_inc

    1 = < $7,500
    2 = 7,500 - 24,999
    3 = 25,000 - 49,999
    4 = 50,000 - 99,999
    5 = > 100,000
    6 = Patient refuses to provide the data
    9 = Unknown

16. Is the patient receiving Disability Income?

    (Code: 0=no, 1=yes, 8=patient refuses to provide the data, 9=unknown) ..... disability_inc

201. Date this form completed ..... __/__/____
202. User ID of person completing this form ..... _____

Clinical Center Use Only

Date Form Entered __/__/____

Person Entering this Form _____

F324_F_-BASEMEDS

DAC Study Form 324 - Baseline Medication Form

This form should be entered at the baseline visit to record all medications the patient is currently taking. F324_F_-MEDHEADER

1. Patient Identification Number ..... PID
2. Patient Name Code ..... ____
3. a. Visit Type ..... B VIST
   b. Visit Number ..... VISN
   c. Visit Sequence Number ..... VISSEQ
4. Visit Date ..... __/FORM_DT
5. For aspirin, or enteric coated aspirin, how many per week? ..... ASPIRIN_WK
   (enter 2 if 2 per week; 7 if one per day; 14 if two per day, etc.)

For GRAFT STUDY:
For aspirin, or enteric coated aspirin, (ecotrin, aspirin), make sure the dose is correct. For other drugs, accurate dose data are not needed.

6. Medication record: You will be able to enter as many medications as you need. F324_F_-MEDLIST

If the patient is on any type of INSULIN, click on brand and enter "Humulin 50/50", and the correct DAC code will appear.

Medication Code* (from Code List)	Medication Name	Is this a PRN medication? (Code 0=no, 1=yes)	Is this drug given during the dialysis treatment? (Code 0=no, 1=yes)
GUID	BNAME _ GNAME	PRN	DIAL_USED

*Changed as of 7/1/05

201. User ID of person completing this form .....

Clinical Center Use Only

Date Form Entered __/__/____

Person Entering this Form _____

Revised on 7/11/2005

DAC Study Form 331 - Demographic/Comorbidity/Dialysis History Data F33LF Demo

This Form should be completed by a study coordinator when a patient is considered for entry into DAC Fistula full scale Study or DAC Graft full scale Study. In order for a patient to be randomized for the full scale studies, this form, the consent, the visit form, the screening form, the patient family, employment and income form, the baseline quality of life form, and the baseline local lab form must be in the database.

1. Patient Identification Number ..... ____ pid
2. Name Code..... ____
3. a. Visit type..... B vist
   b. Visit number..... visn
4. Visit date..... __/__/__ visdt
5. Patient's current (dry) weight in kilograms..... ___. wt-kg

DEMOGRAPHICS

6. Race (enter code number which applies)..... race

   1=American Indian/Alaska Native
   2=Asian
   3=Native Hawaiian or other Pacific Islander
   4=Black or African American
   5=White
   6=More than one race
   9=Unknown

7. Hispanic or Latino ethnicity (1=yes, 0=no, 9=unknown)..... hisp-lat
8. Can this patient speak English? (0=no, 1=yes)..... sp-english
9. a. Can the patient read and write in English? (0=no, 1=yes, 9=unknown) ..... rw-english
   b. Can the patient read and write in Spanish? (0=no, 1=yes, 9=unknown)..... rw-spanish
10. What is this patient's primary language? ..... prim-lang

    Code 1 = English, 2 = Spanish, 3 = French, 4 = Chinese, 5 = other, 6 = French Creole, 7 = Portuguese, 9 = unknown

11. Highest level of formal education achieved: ..... high-ed

    1 = <High school graduation
    2 = Completed high school
    3 = Completed technical school
    4 = At least one year of college
    5 = Completed college/university
    6 = College graduate with post graduate education
    8 = Patient refuses to provide the data
    9 = Unknown

12. Does the patient have outside insurance other than Medicare/Medicaid?..... out-insur

Revised on 02/10/2004

(0=no, 1=yes, 8=patient refuses to provide the data, 9=unknown)

13. Height (cm) ..... ht_cm

14. Is this an actual height? (1 = actual, 2 = based on recall, 3 = estimate) ..... true_ht

15. Date height measured/estimated ..... __/__/____ ht_dt
Note: For q.15: If month is unknown – use "06", if day is unknown – use "15".

16. Leg amputations
a. Left (0=none, 1=toe(s), 2=transmetatarsal, 3=below knee, 4=above knee) ..... l_leg_amp
b. Right (0=none, 1=toe(s), 2=transmetatarsal, 3=below knee, 4=above knee) ..... r_leg_amp

17. Pulse (non-dialysis, in sitting position) ..... pulse

SMOKING/ALCOHOL/DRUG HISTORY

18. Cigarette smoking status (0 = never, 1 = former, 2 = current, 9 = unknown) ..... smoke

19. Total number of years smoked ..... __ yrs_smoke

20. Number of packs per day ..... __. pks_smoke

21. For former smokers only: months since last smoked ..... __ last_smoke
Note: 12 months = 1 year, 120 months = 10 years, etc.

22. Is there a history of recreational drug use or does the patient currently use recreational drugs? ..... drug_abuse
(0=no, 1=yes, but more than 5 years ago, 2=yes, in the past 5 years, 9=unknown)
Note: Current recreational drug users are excluded on the screening form.

23. Is there a history of alcohol abuse or does the patient currently abuse alcohol? ..... alcohol_abus
(0=no, 1=yes, but more than 5 years ago, 2=yes, in the past 5 years, 9=unknown)
Note: Current alcohol abusers are excluded on the screening form.

DIABETES

24. Does the patient have a previous history of diabetes? (0=no, 1=yes) ..... diab_hx

25. Treatment for diabetes ..... diab_trt
0 = not applicable (the patient is not diabetic),
1 =diet alone,
2 = oral hypoglycemic agents,
3 = insulin,
4 = oral hypoglycemic agents and insulin

MEDICAL CONDITIONS

26. What is this patient's periodontal status? ..... edentulous

1 = no obvious cavities or gingivitis

2 = cavitis or gingivitis

3 = edentulous (partial or complete)

Is it known that the patient has this condition or is it noted in the chart? Code 1 = yes, 0 = no.

27. History of congestive heart failure ..... hf-hx
28. History of myocardial infarction ..... mi-hx
29. History of angina ..... angina-hx
30. Prior coronary angioplasty or bypass surgery ..... prior_bypass
31. Prior carotid endarterectomy ..... prior-ce
32. Current cardiac arrhythmias or conduction problems ..... cur_cardiac
33. Current pericardial disease or pericarditis ..... cur-peri'card
34. History of stroke or TIA ..... stroke-hx
35. History of claudication ..... claudi-hx
36. Known hypercoagulable state ..... hypercoag
37. History of lower extremity angioplasty or bypass surgery ..... le_angio_hx
38. History of deep venous thrombosis ..... thromb_hx
39. History of pulmonary embolism ..... pulm-embo_hx
40. History of hypertension ..... hyper-hx
41. Bleeding in the past year requiring hospitalization ..... bleed-yr
42. Transfusion in the past year ..... transfus-yr
43. Peptic disease requiring treatment in the past year ..... peptic-yr
44. Known hyperlipidemia ..... hyperlip
45. HIV positive ..... hiv
46. AIDS ..... aids
47. SLE ..... sle
48. Vasculitis ..... vasculitis
49. Is this patient currently taking anti-hypertensive agents? ..... anti-hyper_agent

RENAL AND DIALYSIS HISTORY SECTION

50. Is patient currently on dialysis? ..... __

0 = not currently on dialysis
1 = hemodialysis
2 = peritoneal dialysis
3 = never received dialysis
Note: *If never received dialysis, skip to item 54*

For 51 and 52: If month is unknown – use "06", if day is unknown – use "15".

51. Date of most recent initiation of chronic maintenance hemodialysis (mm/dd/yyyy) ..... __/__/__ hemo-dt

52. Date of first chronic maintenance dialysis (ESRD)..... __/__/__ dial-dt

If the patient has been on dialysis continually since they started, item 51 and item 52 are the same.

53. Was first dialysis hemodialysis or peritoneal? (1=hemo, 2=peritoneal) ..... frst_dial_typ

54. How many previous AV vascular access sites (graft or native fistula) used? (0 = none, 1 = 1, 2 = 2, ... 99 = unknown) ..... prev_access_site

55. Type of vascular access prior to study enrollment ..... access_typ

0 =	none	6 =	temporary internal jugular
1 =	AV graft - forearm	7 =	temporary subclavian
2 =	AV graft - upper arm	8 =	temporary femoral
3 =	AV graft – thigh	9 =	Tunneled internal jugular
4 =	AV fistula - forearm	10 =	Tunneled subclavian
5 =	AV fistula - upper arm	11 =	Tunneled femoral
		12 =	Tunnel with subcutaneous port
		98 =	Other

56. Side of vascular access prior to study enrollment (0 = none, 1 = right, 2 = left) ..... va_side

57. Previous central venous catheters - Subclavian? ..... prev_cath_subcl
(0 = none, 1=right, 2=left, 3=both, 4= yes, but side unknown, 9= don't know if they had it or not)

58. Previous central venous catheters - Internal jugular? ..... prev_cath_int_jug
(0 = none, 1=right, 2=left, 3=both, 4= yes, but side unknown, 9= don't know if they had it or not)

59. Have clamps been used on this patient? (0=no, 1=yes, 9=Unknown) ..... clamps

60. Primary underlying renal diagnosis (see codes below) ..... prim_renal_diag

1 = Glomerular Disease
2 = Polycystic Kidney Disease
3 = Hypertensive Nephrosclerosis
4 = Tubulointerstitial Diseases
5 = Urinary Tract Diseases (including obstruction)
6 = Absence of One Kidney (without other known cause)
7 = Diabetic Nephropathy

8 = Hereditary Nephritis
9 = Unknown with Proteinuria >3 g/day
10 = Unknown with Proteinuria 1-3 g/day
11 = Unknown with Proteinuria <1 g/day
12 = Ischemic Renal Disease
13 = Acute Renal Disease
14 = Other
89 = No Secondary Underlying Renal Diagnosis (for question 61 only)
99 = Unknown

61. Secondary underlying renal diagnosis (Use codes from Item 60) ..... sec_renal_diag __

TRANSPLANT

62. Is this patient on a transplant waiting list? ..... transplant_list

1 = yes
2 = no; determination of waiting list placement is in progress
3 = no; patient refuses a transplant
4 = no; patient told he/she was medically ineligible
5 = no; reason unknown or other
6 = no; family member will donate the kidney

201. User ID of person completing this form ..... _ _ _ _ _ _ _ _

Clinical Center Use Only

Date Form Entered _ _/_ _/_ _ _ _

Person Entering this Form _____

F333F_Visit
F333F_symptoms

DAC Study Form 333 – Visit/Symptom Form

This form is completed:

- at baseline, six weeks after the surgery and 30 days after the drug was discontinued for the fistula study
- at baseline, monthly during follow-up and 30 days after the drug was discontinued for the graft study.

1. Patient Identification Number ..... ____ PID
2. Patient Name Code ..... ____
3. a. Visit Type ..... VIST
   b. Visit Number ..... VISN
   c. Visit sequence number ..... VISSEQ
4. Date of Visit ..... __/__/__ VISDT

These items are for follow-up visits. Code 0=No, 1=Yes.

5. Does the unit nurse or other health care provider report any hospitalizations for this patient since his last DAC visit? ..... RN_HOSP
   If so, complete Form 361.
6. Does the unit nurse or other health care provider report any transfusions for this patient since his last DAC visit? ..... RN_TRAN
   If so, complete Form 363 if the patient had a bleeding episode.
7. Does the patient report any hospitalizations since his last DAC visit? ..... PT_HOSP
   If so, complete Form 361.
8. Does the patient report any transfusions since his last DAC visit? ..... PT_TRANS
   If so, complete Form 363 if the patient had a bleeding episode.
9. Does the patient report any access outpatient procedure since the last visit? ..... PT_SURG
   If so, complete Form 355 for the graft patients and Form 352 for the fistula patients.
10. Is the patient currently taking the drug? ..... PT_ON_MED
    If q. 10 = No, complete Form 335 or 336, as appropriate. Answer no if the patient has completed the 6 week course of study medication for the fistula study or if this is 30 days after the drug was discontinued (safety call).

These items are for all visits, including Baseline:

Enter a 1= yes for any symptom or problem the patient reports as having occurred as follows: For baseline – within the last month, for follow-up - since the patient's last DAC visit. Ask explicitly about the symptoms marked with asterisks. For these, enter 0=no or 1=yes. The number in brackets after the symptom is the MedDRA code.

11. *Nosebleeds* (10029802) ..... NOSE_BLEED
12. *Subconjunctival hemorrhage* (10042341) ..... SUB_HEMORR
13. *Other minor bleeding that does not lead to a clinic visit or a hospitalization* ..... MINOR_BLEED

DAC Study Form 333 – Visit/Symptom Form

14. *For patients on dialysis: prolonged bleeding from cannulation site* (If patient not on dialysis yet, enter "8") ..... PROLONG_BLEED
15. *Spontaneous bruising* (10041729) ..... EASY_BRUISING
16. *Headache* (10019211) ..... HEADACHE
17. *Heartburn/Dispepsia* (10019326) ..... HRTBURN_RFX
18. *Abdominal pain* (10000081) ..... ABDOM_PAIN
19. *Nausea/vomiting* (10028816) ..... NAUSEA_VOM
20. *Diarrhea* (10012727) ..... DIARRHEA
21. *Skin rash* (10040913) ..... RASH
22. *Hives* (10020197) ..... HIVES
23. *Other changes in vision or eye problems* ..... VISION_PROB

Make sure to ask the patient at the follow-up visit if he has any new symptoms, any problems with the study medication or any new significant health problems to report.

Ask the patient: "Do you have any other symptoms or problems to report?". You may enter more symptoms below:

Symptom	SYMPTOM

201. User ID of person completing this form ..... _ _ _ _ _ _ _ _

Clinical Center Use Only

Date Form Entered __/__/____

Person Entering this Form _____

F334F - PUPMEDS

DAC Study Form 334 - New or Change of Medication Form

F334_F_MEDHEADER

This form should be considered at every follow-up visit to record any new or stopped medications

1. Patient Identification Number ..... PID _ _ _ _ _ _ _
2. Patient Name Code ..... _ _ _ _ _
3. a. Visit Type ..... F VIST
   b. Visit Number ..... VISN
   c. Visit sequence number ..... VISSEQ
4. Visit Date ..... _ _ / _ _ / FORM_DT
5. For aspirin, or enteric coated aspirin, how many per week? ..... ASPIRIN_WK _ _
   (enter 0 if 0 per week, 2 if 2 per week; 7 if one per day; 14 if two per day, etc.)

For GRAFT STUDY :

For aspirin, or enteric coated aspirin, (ecotrin, aspirin), make sure the dose is correct. For other drugs, accurate dose data are not needed.

6. Medication adjustment record: Look at the last visit's medication flow sheet, which will come up on the screen. Indicate whether the medications from that list are current or stopped. Then list each drug being added. You will be able to enter as many medications as you need. Indicate the date of prescription change (start or stop). If you do not know the exact day, use "15".

If the patient is on any type of INSULIN, click on brand and enter "Humulin 50/50", and the correct DAC code will appear.

F334_ _ _MEDLIST

Medication Code* (from Code List)	Medication Name	Is this a PRN medication ? (Code 0=no, 1=yes)	Is this drug given during the dialysis tretament? (Code 0=no, 1=yes)	Change 1=Start 0=Stop 9=Current	Date (mm/dd/yyyy) of Prescription Change (Start or Stop)
GUID	B NAME GNAME	PRN	DIAL_USED	MED_CHG_TYPE	MED_CHG_DT
					_ _ / _ _ / _ _ _ _
					_ _ / _ _ / _ _ _ _
					_ _ / _ _ / _ _ _ _
					_ _ / _ _ / _ _ _ _
					_ _ / _ _ / _ _ _ _

*Changed as of 7/1/05

201. User ID of person completing this form ..... _ _ _ _ _ _ _ _

Clinical Center Use Only

Date Form Entered _ _ / _ _ / _ _ _ _

Person Entering this Form _____

F335_F_TEMPDISC

DAC Study Form 335 - Temporary Discontinuation of Therapy

This Form should be completed by a study coordinator when a patient discontinues and restarts therapy for either study. This form must be completed to document any time that a patient's medications are stopped prior to surgery.

1. Patient Identification Number ..... ___ PID
2. Name Code..... _____
3. Date of discontinuation..... __/__/__ DC_DT

   Note: If the drug has not yet been started and must be temporarily discontinued, enter the randomization date as the "date of the discontinuation".

4. a. Date study therapy restarted (at any dose)..... __/__/ RESTART_DT

   Note: If the therapy is not restarted yet, leave this date blank and fill it in later. You will get weekly e-mail reminders that this information needs to be added.

   b. If the study therapy will never be re-started, give reason..... DC_RSN
   1 = permanently discontinued (file form 336)
   2 = patient died (file forms 371 & 372)
   3 = patient lost to follow-up (file form 338)

5. Was this associated with a hospitalization? (0 = no, 1 = yes) ..... ASSOC_HOSP
6. If yes, what was the admission date of that hospitalization?..... __/__/ ADMIT_DT
7. Was the patient instructed to discontinue therapy by a health care provider?..... INSTRUC_DC

   (0 = no, 1 = yes)

8. Was this temporary stop primarily due to a planned surgery, a patient medical condition, a possible side effect or a logistic problem?..... _

   1 = required discontinuation prior to surgery or medical procedure/test DC_REASON
   2 = medical condition
   3 = possible side effect
   4 = logistic problem

9. Describe briefly what happened.

COMMENTS_EDIT

201. Date this form completed..... __/__/_____
202. User ID of person completing this form..... _____

Clinical Center Use Only

Date Form Entered __/__/_____

Person Entering this Form_____

DAC Study Form 336 - Permanent Discontinuation of Therapy F336_F_PERMDISC

This Form should be completed by a study coordinator when a patient discontinues therapy. All randomized patients need to be followed until the primary outcome is reached or the study ends regardless whether they are taking the medication. For 30 days after the drug is discontinued, information on SAEs should be collected. The DCC will schedule a conference call with PI, coordinator, DCC and the Quality Control Committee to discuss any permanent discontinuation of therapy not related to reaching a primary outcome (reasons 11, 13, 14, 15).

1. Patient Identification Number..... ___PID___
2. Name Code..... _____
3. Reason you have discontinued study drug..... DC_DRUG

   1 = New diagnosis that requires use of the study drug or another anti-platelet or anti-thrombotic agent
   2 = Patient insists on taking study drug
   3 = Referring physician insists on giving this patient study drug
   4 = Serious adverse event that precludes further use of study drug
   5 = Life threatening side effects
   6 = Annoying side effects persisting on rechallenge
   Note: Make sure to describe what you did to rechallenge when answering q.6.
   11 = Fistula clotted from thrombosis
   13 = Patient reached end point for the graft study due to access procedure or thrombosis
   14 = Patient who is undergoing regular hemodialysis reached end point in the graft study due to 12 weeks passing without access being used
   15 = Incident patient reached end point in the graft study due to loss of both audible bruit and palpable thrill before the first use of the access
   16 = Fistula patient had to stop study drug for a medical condition or a planned surgery toward the end of the 6 week drug administration period (no time to re-start drug)
   17 = Graft was ligated and abandoned because of steal syndrome within 30 days of placement
   19 = Patient has withdrawn his consent to take the study medications
   20 = Patient's physician will no longer allow patient to continue to take the study medications
   22 = Severe non-life threatening side effects
   23 = Patient is lost to follow-up (e.g., patient chose to withdraw from the study, renal transplantation, change to peritoneal dialysis, transfer to a facility where cannot be followed, protocol violation).
   Note: Make sure Form 338 is completed
   24 = Graft Study data collection ended

4. If Q.3 = 19, what is the consent status (Code 0 = no, 1 = yes, 9 = N/A to the study the pt was in.):
   a. Patient withdrew consent to do fistulograms..... FIST_CONSENT
   b. Patient withdrew consent to do transonic measurements ..... TRANS_CONSENT
   c. Patient withdrew consent for hospitalizations and bleeding tracking .HOSP_BLEED_CONSENT
   d. Patient withdrew consent for database tracking ..... DB_CONSENT

DAC Study Form 336 - Permanent Discontinuation of Therapy

5. Does the study team think this patient was on active drug or placebo?..... DRUG_GUESS
   Use codes 1 to 5
   1 = The team has been unblinded and knows it is placebo
   2 = The team believes this patient was randomized to placebo
   3 = The team does not know
   4 = The team believes this patient was randomized to active drug
   5 = The team has been unblinded and knows it is active drug
6. If q. 5 = 1 or 5, date of unblinding..... __ __ / __ __ / UNBLIND_DT
7. Date of discontinuation:..... __ __ / __ __ / DC_DT
   Note: If the drug has not yet been started and must be permanently discontinued, enter the randomization date as the "date of discontinuation".
8. Describe in detail what happened in the text field below. Use the back of this sheet too.

COMMENTS_EDIT

201. Date this form completed..... __ __ / __ __ / __ __ __ __
202. User ID of person completing this form..... __ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered __ __ / __ __ / __ __ __ __

Person Entering this Form _____

F337_F_PERMDC-REV

DAC Study Form 337 – Cessation Committee: "Review of Permanent Discontinuation of Therapy" Form

1. Patient Identification Number ..... PID ____
2. Name Code ..... ____
3. a. Date of Permanent Discontinuation of Therapy (Form 336, Q. 7) ..... __/F336-DT ____
   b. Date of this review ..... __/REV-DT ____
4. Stop point the clinic felt the patient had reached? ..... STOP-DT __

   0 = CC unblinded to randomized meds, but not a stop point
   1 = New diagnosis that requires use of the study drug or another anti-platelet or anti-thrombotic agent
   2 = Patient insists on taking study drug
   3 = Referring physician insists on giving this patient study drug
   4 = Serious adverse event that precludes further use of study drug
   5 = Life threatening side effects
   6 = Annoying side effects persisting on re-challenge
   11 = Fistula clotted from thrombosis
   13 = Patient reached end point for the graft study due to access procedure or thrombosis
   14 = Prevalent patient reached end point in the graft study due to 12 weeks passing without access being used
   15 = Incident patient reached end point in the graft study due to loss of both audible bruit and palpable thrill before the first use of the access
   16 = Fistula patient had to stop study drug for a medical condition or a planned surgery toward the end of the 6 week drug administration period (no time to re-start drug)
   17 = Graft was ligated and abandoned because of steal syndrome within 30 days of placement
   19 = Patient has withdrawn his consent to take the study medications
   20 = Patient's physician will no longer allow patient to continue
   22 = Severe non-life threatening side effects
   23 = Patient is lost to follow-up (e.g., patient chose to withdraw from the study, renal transplantation, change to peritoneal dialysis, transfer to a facility where cannot be followed, protocol violation).

5. a. Consensus of Clinical Management Subcommittee and DCC ..... CONSENSUS __

      0 = Not a stop point
      1 = Confirm the stop point the clinic felt the patient had reached
      2 = A different stop point

   b. If "2", which stop point? (use codes from item 4) ..... DIF_STOP __

6. Necessity of Unblinding ..... UNBLIND __

      1 = Do not unblind
      2 = Unblind
      3 = Already unblinded

DAC Study Form 337 – Cessation Committee: "Review of Permanent Discontinuation of Therapy" Form

7. a. Which blinded medication does the Primary Cessation Review Subcommittee stop point reviewer believe the patient was on? ..... BLIND-MED

1 = The reviewer has been unblinded and knows it is placebo
2 = The reviewer believes this patient was randomized to placebo
3 = The reviewer does not know
4 = The reviewer believes it is active drug
5 = The reviewer has been unblinded and know it is active drug

b. If 1 or 5, date of unblinding ..... __/__/____ UNBLIND-DT

8. Does the Primary Cessation Review Subcommittee stop point reviewer think this was related to the patient's randomized drug intervention? (0=no, 1=yes, 9=couldn't tell) ..... DRUG-INTRV

9. Comments of reviewer. (Write in as much as you wish. Use back of sheet if necessary.)

COMMENTS_EDIT

201. Date this form completed..... __/__/____

202. User ID of person completing this form ..... _____

Clinical Center Use Only

Date Form Entered __/__/____

Person Entering this Form _____

F338_F_LOSTTOFUP

DAC Study Form 338 – Lost to Follow-up

This Form should be completed by a study coordinator when a patient is truly lost to follow-up and all efforts to keep the patient in the study have been exhausted. If a lost to follow-up patient comes back to the study, please, contact the DCC.

1. Patient Identification Number..... _ _ _ _ _ _ PID
2. Name Code..... _ _ _ _ _
3. Was the patient on drug before he/she was lost to follow-up (0=no, 1=yes) ..... ON_DRUG

   Note: If Q. 3=yes, make sure Form 336 is completed.
4. Reason patient was lost to follow-up..... RSN

   1 = Patient has transferred to peritoneal dialysis
   2 = Patient has undergone renal transplantation
   3 = Patient has moved and the study team can no longer perform study related procedures
   Note: (Make sure you have the patient's new address and phone number.)
   4 = Patient is truly lost and the team cannot find him no matter what we do
   5 = Patient transferred to facility where follow-up is not possible.
   Note: (Make sure Form 382 is completed.)
   6 = Protocol violation: A patient with the wrong type of vascular access was randomized and therefore needs to be withdrawn from the study ("Fistula study patient" received graft or vice versa).
   7 = Patient has withdrawn consent for any further data collection
   8 = Recovery of renal function
5. Most recent date the study team was able to contact the patient _ _ / _ _ / _ _ _ _ LOST_DT

   Note: If patient has transferred to peritoneal dialysis or received renal transplantation, enter the start date of peritoneal dialysis or the date of transplantation.
6. Describe in detail what happened in the text field below. Use the back of this sheet too.

COMMENTS_EDIT

201. Date this form completed..... _ _ / _ _ / _ _ _ _
202. User ID of person completing this form..... _ _ _ _ _ _ _ _

Clinical Center Use Only

Date Form Entered _ _ / _ _ / _ _ _ _

Person Entering this Form _____

Revised on 06/23/2004

DAC Study Form 341 - Quality of Life F341_F_QOL

The questions should be asked at the beginning and again at the end of the trial for the fistula study or quarterly for the graft study (except for questions 6 and 7, which should be asked at the beginning of the trial ONLY if the patient has previously had an access).

1. Patient Identification Number ..... ___pid__
2. Patient Name Code ..... _____
3. a. Visit Type ..... VIST
   b. Visit Number ..... VISN
   c. Visit sequence number ..... VISSEQ
4. Was the assessment administered in (1=English, 2=Spanish, 3 = French, 4 = French Creole, 5 = Portuguese) ..... LANG
5. Was the assessment (1=self administered, 2=interviewer administered) ..... ADMINISTR

WHEN ANSWERING THE FIRST 2 QUESTIONS, THINK ABOUT ANY PROBLEMS WITH YOUR DIALYSIS ACCESS (GRAFT, FISTULA, CATHETER) OR FROM TESTS OR OPERATIONS ON YOUR ACCESS.

6. During the PAST 3 MONTHS, how much pain or discomfort have you had due to your dialysis access?

PAIN

a. None	1
b. Very mild	2
c. Moderate	3
d. Severe	4
e. Very severe	5

7. During the PAST 3 MONTHS, how much have you worried about your dialysis access?

WORRIED

a. Not at all	1
b. Slightly	2
c. Moderately	3
d. Quite a bit	4
e. Extremely	5

BELOW IS A STATEMENT WITH WHICH YOU MAY AGREE OR DISAGREE. USING THE CHOICES BELOW, INDICATE YOUR AGREEMENT WITH THE STATEMENT. PLEASE BE OPEN AND HONEST IN YOUR RESPONSE.

8. I am satisfied with my life. SATISFIED

a. Strongly disagree	1
b. Disagree	2
c. Slightly disagree	3
d. Neither agree nor disagree	4
e. Slightly agree	5
f. Agree	6
g. Strongly agree	7

201. Date this form completed..... __ __/__ __/__ __ __ __

202. User ID of person completing this form .....__ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered __ __/__ __/__ __ __ __

Person Entering this Form_____

DAC Study Form 351 - Local Biochemistry Lab Form F351_F_LABS

This form is completed with the results received from the Local Biochemistry Laboratory. Use the most recent value available. Serum values (q. 4 – 7) at baseline may be taken anytime in the past three years. Follow-up values are collected monthly for graft study and must be after randomization. Follow-up values are not done for fistula study.

1. Patient Identification Number ..... ____ PID
2. Patient Name Code ..... ____
3. a. Visit Type ..... VIST
   b. Visit Number ..... VISN
   c. Visit sequence number ..... VISSEQ

Serum Values

4. a. creatinine (mg/dL) ..... CREATININE
   b. date sample drawn ..... __/__/____ CREAT-DT

   Note: The database will calculate
   Cockcroft Gault Creatinine clearance = (140-age) x (wt in kg) (x .85 for female) / Serum creatinine in mg/dl x 72

5. a. calcium (mg/dL) ..... __.__ CA
   b. date sample drawn ..... __/__/____ CA-DT
6. a. phosphorus (mg/dL) ..... PHOSPHORUS
   b. date sample drawn ..... __/__/____ PHOS-DT
7. a. albumin (g/dL) ..... __.__ ALBUMIN

   (For Graft Study: MUST have access creation surgery within 45 days)

   b. date sample drawn ..... __/__/____ ALB-DT
8. a. intact PTH (pg/ml) ..... ____ INTACT-PTH

   (For Graft Study only, if available)

   b. date sample drawn ..... __/__/____ PTH-DT

Whole Blood Values

9. a. hemoglobin (g/dL) ..... __.__ HEMOGLOBIN
   b. date sample drawn ..... __/__/____ HG-DT

   (MUST have access creation surgery within 45 days)

10. a. hematocrit (%) ..... __.__ HEMATOCRIT
    b. date sample drawn ..... __/__/____ HEMATOCRIT-D
11. a. platelet count (cells / mm^3) ..... ____ PLT-CT

Revised on 02/13/2003

(MUST be ≥ 75,000 cells / mm^3)

b. date sample drawn..... ___/___/__PLT-DT

(MUST have access creation surgery within 45 days)

Coagulation

12. a. INR..... __.__ INR

(If available, must be within 45 days)

b. date sample drawn..... ___/___/__INR-DT

13. a. partial thromboplastin time (PTT, sec) ..... ___.__ PTT

(If available, must be within 45 days)

b. date sample drawn..... ___/___/__PTT-DT

c. upper limit of normal PTT at this lab (sec)..... ___ UP-PTT

Pregnancy

14. a. If a pregnancy test was done, what was the result

(0=Negative, 1=Positive)..... __ PREG

b. Date the test was done ..... ___/___/__PREG-DT

Dialysis Prescription

This data is collected at the follow-up visits for patients on dialysis who are enrolled in the Graft Study.

15. Pre-dialysis BUN (mg/dL)..... ___.__ PRE-BUN

16. Post-dialysis BUN (mg/dL) ..... ___.__ POST-BUN

17. Date sample drawn..... ___/___/__BUN-DT

201. Date this form completed..... ___/___/_____

202. User ID of person completing this form ..... _____

Clinical Center Use Only

Date Form Entered ___/___/_____

Person Entering this Form _____

F352_F_REPAIR

DAC Fistula Study Form 352 –Access Repair / Access Event Procedure Form

This form is completed whenever a thrombosis occurred and/or access procedure designed to maintain or restore access function is done. If a thrombosis occurred, complete this form after you know whether a procedure was done to attempt to restore the access function.

1. Patient Identification Number ..... __ __ PID __ __
2. Patient Name Code ..... __ __ __ __ __
3. Date of access procedure ..... __ __ / __ __ / PROC-DT
   Note: If a thrombosis occurred and there was no procedure done, enter here the date of thrombosis. If "other" even occurred and no procedure done, enter date of "other" event.
4. a. Did any event happen to the fistula?(0=no, 1=yes) ..... HAS_EVT __
   b. If q. 4a=Yes, what was the event? ..... EVENT __

   1 = ligated for steal syndrome
   2 = ligated for infection
   3 = ligated for aneurysm
   4 = thrombosed
   5 = other, specify _____ OTH-EVT __

   c. If q. 4b=1-4, date the fistula thrombosed / was ligated..... __ __ / THROMB_DT __ __ __ __
   d. If q. 4b=4 (thrombosis), was this confirmed by a member of the DAC study team? (0=no, 1=yes) ..... CONFIRM __
   e. If q. 4d=Yes, date staff confirmed ..... __ __ / __ __ / CONF-DT __ __ __ __
   f. If q. 4d=Yes, who confirmed the thrombosis ..... __ __ __ CONF-ID __ __
5. What was the revision that was done on the fistula? ..... REVISION __

   0 = none
   1 = surgical
   2 = non-surgical
   3 = both surgical and non-surgical

6. Was there use of graft material? (0=no, 1=yes) ..... G-MATERIAL __
7. Was the anastomosis revised? (0=no, 1=yes) ..... ANAS_REVISED __
8. Was a different artery used? (0=no, 1=yes) ..... DIFF-ARTERY __
9. Was a different vein used? (0=no, 1=yes) ..... DIFF-VEIN __
10. a. Surgical thrombectomy? (0=no, 1=yes) ..... SURG-THROMB __
    b. If yes, was it successful? (0 = no, 1 = yes) ..... SURG-SUCC __
11. Ligation of collateral veins? (0=no, 1=yes) ..... LIG_COL_VEIN __
12. Radiologic angioplasty? (0=no, 1=yes) ..... RADIO_ANGIO __
13. a. Radiologic thrombectomy? (0=no, 1=yes) ..... RADIO-THROMB __
    b. If yes, was it successful? (0 = no, 1 = yes) ..... RADIO_SUC __

201. Date this form completed ..... __ __ / __ __ / __ __ __ __
202. User ID of person completing this form ..... __ __ __ __ __ __ __ __

Revised on 01/23/2004

Clinical Center Use Only

Date Form Entered __ __/__ __/__ __ __ __

Person Entering this Form_____

Revised on 01/23/2004

F360. F - HOSPNOTIF

DAC Study Form 360 – Clinical Center Hospitalization Notification Form

This form is completed within one week after learning the patient is hospitalized and the hospitalization meets the definition used in the study. For the purpose of the DAC Studies, a "hospitalization" is defined as an event that requires medical attention (including medical care or on-site observation) overnight. If the hospitalization was solely for placement of the study access, this form need not be completed. If the admission date is before the consent was signed, this form need not be completed.

1. Patient Identification Number..... PID
2. Patient Name Code ..... _____
3. Date of Hospital Admission..... __/__/ HOSP_ADMT_DT
4. Is the patient still in the hospital? ..... HOSP_STILL

   (0=No – Discharged, 1=No, died, 2=Yes, still in hospital)
5. Primary reason for hospitalization..... HOSP_PRIM

   (from code list on Form 361, pg. 361.3-361.12)
6. Secondary reason for hospitalization..... HOSP_SEC

   (from code list on Form 361, pg. 361.3-361.12)
7. What is the current thought of the Principal Investigator regarding whether this hospitalization was related to the patient's randomized study intervention? ..... INTER_REL

   0 = **Not related to the study drug.**
   1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.
   2 = **Possibly related to the study drug.**
   3 = **Probably related to the study drug.** This sort of event is commonly associated with the study intervention or a temporal relationship with the study intervention exists and no other etiology is apparent.
   4 = **Definitely related to the study drug**
   8 = N/A, patient is not randomized
8. If the event was definitely, probably or possibly related to the study medication (i.e. q. 7 = 2, 3 or 4), then what was the expectedness of it? ..... INTER_REL_EXP

   1 = Unexpected - not mentioned in the informed consent
   2 = Expected, but of greater severity than mentioned in the informed consent.
   3 = Expected and accurately described in the informed consent.
9. What was the severity of the event? ..... INTER_REL_SEV

   1 = Mild - awareness of the sign or symptom, but easily tolerated
   2 = Moderate - enough discomfort to interfere with usual activity
   3 = Severe - incapacitating, with inability to do usual work or activity

Revised on 02/25/2003

201. Date this form completed..... __ __/__ __/__ __ __ __

202. User ID of person completing this form .....__ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered __ __/__ __/__ __ __ __

Person Entering this Form _____

F361-F_HOSPITAL

DAC Study Form 361 – Clinical Center Hospitalization Form

This form is completed with the Principal Investigator or attending physician within two weeks after a patient is discharged or dies in the hospital. This review should be based on the hospital discharge summary or a phone call to the attending physician.

If you receive a discharge summary, keep it on file with this form. The discharge summary will need to be copied and sent to the DCC if this hospitalization is selected for complete review.

If the event leading to hospitalization began during a dialysis treatment, file a photocopy of that dialysis treatment's run sheet with this form and the discharge summary.

1. Patient Identification Number ..... PID
2. Patient Name Code ..... _____
3. a. Date of Hospital Admission ..... __/__/ADMIT_DT
   b. Name of Hospital _____
   c. Was the patient discharged (code=1) or did the patient die in the hospital (code=2)... DISC_DEATH
   d. Date of Death or Discharge ..... __/__/dd_dt
4. Primary reason for this hospitalization ..... PRIM_RSN
   (from code list on pages 361.3 to 361.12)
5. Secondary reason for this hospitalization
   (from code list on pages 361.3 to 361.12) ..... SEC_RSN
6. a. Was there a surgery? (0=no, 1=yes, 9=unknown) ..... SURG
   b. If yes, was it planned? (0=no, 1=yes 9=unknown) ..... SURG_PLANNED
7. Was drug discontinued? ..... DC_DRUG
   (0=no, 1=yes, 8=N/A, patient is not randomized, 9=N/A, already off drug)
   Note: If Yes, be sure to file Form 335 for temporary discontinuation, or Form 336 for permanent discontinuation of therapy.
8. Was an access diagnostic procedure done? (0=no, 1=yes) ..... DIAG_PROC
   Note: If Yes, be sure to file Form 354.
9. For a graft patient, was access repair or replacement done or for a fistula patient, was there an access repair/event? (0=no, 1=yes) ..... REP_REPL
   Note: If Yes, be sure to file Form 355 (or Form 352 for a fistula patient).
10. Was there a bleeding episode (0=no, 1=yes) ..... BLD_EPI
    Note: If yes, be sure to file Form 363.
11. Did the event lead to permanent disability? (0 = no, 1 = yes) ..... PERM_DISA

12. a. Which treatment does the study team think the patient was randomized to? ....RX_GUESS

1 = The team has been unblinded and knows it is placebo
2 = The team believes it is placebo
3 = The team does not know
4 = The team believes it is active drug
5 = The team has been unblinded and knows it is active drug
8 = N/A, patient is not randomized

b. If 1 or 5, date of unblinding ..... __/__/_____ UNBLIND_DT

13. What is the current thought of the Principal Investigator regarding whether this hospitalization was related to the patient's randomized study intervention? ..... HOSP_REL

0 = **Not related to the study drug.**
1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.
2 = **Possibly related to the study drug.**
3 = **Probably related to the study drug.** This sort of event is commonly associated with the study intervention or a temporal relationship with the study intervention exists and no other etiology is apparent.
4 = **Definitely related to the study drug**
8 = N/A, patient is not randomized

14. If the event was definitely, probably or possibly related to the study medication (i.e. Q13 = 2, 3 or 4), then what was the expectedness of it? ..... HOSP_EXP

1 = Unexpected - not mentioned in the informed consent
2 = Expected, but of greater severity than mentioned in the informed consent.
3 = Expected and accurately described in the informed consent.

15. What was the severity of the event? ..... HOSP_SEV

1 = Mild - awareness of the sign or symptom, but easily tolerated
2 = Moderate - enough discomfort to interfere with usual activity
3 = Severe - incapacitating, with inability to do usual work or activity

16. Did another event occur during this hospitalization, which caused prolongation of the hospitalization? (0=no, 1=yes)..... OTH_EVENT

Note: Generally this means an event occurred that would have led to a hospitalization of NON-hospitalized patient.

17. If yes, what was the reason for the prolongation? (from code list on pages 361.3 to 361.12) ..... _____ PROL_RSN

18. What is the current thought of the Principal Investigator regarding whether this prolongation of hospitalization was related to the patient's randomized study intervention? ..... PROL-REL

0 = **Not related to the study drug.**
1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.
2 = **Possibly related to the study drug.**
3 = **Probably related to the study drug.** This sort of event is commonly associated with the study intervention or a temporal relationship with the study intervention exists and no other etiology is apparent.
4 = **Definitely related to the study drug**
8 = N/A, patient is not randomized

19. If the event was definitely, probably or possibly related to the study medication (i.e. Q18 = 2, 3 or 4), then what was the expectedness of it? ..... PROL-EXP

1 = Unexpected - not mentioned in the informed consent
2 = Expected, but of greater severity than mentioned in the informed consent.
3 = Expected and accurately described in the informed consent.

20. What was the severity of the event? ..... PROL_SEV

1 = Mild - awareness of the sign or symptom, but easily tolerated
2 = Moderate - enough discomfort to interfere with usual activity
3 = Severe - incapacitating, with inability to do usual work or activity

201. Date this form completed..... __ __/__ __/__ __ __ __

202. User ID of person completing this form .....__ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered __ __/__ __/__ __ __ __

Person Entering this Form _____

DAC Studies: Hospitalization Admission and Discharge Code List of Diagnoses and Procedures (For Form 361)

Instructions to Coding: When parentheses ( ) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
Note: A terminal code of 0 indicates a procedure.

An asterik (*) indicates that the disease or condition is also classified as an "infection outcome".

1. ISCHEMIC HEART DISEASE (IHD)

Also see category: coronary heart disease (CHD) or coronary artery disease (CAD)

01AA(_)	Chest pain of non-cardiac or unclear etiology (R/O MI admission)
01AB(_)	CAD
01AC(_)	Angina
01AD0	Bypass surgery (CABG)
01AE0	Coronary angiography
01AF0	Coronary angioplasty (PTCA) or atherectomy
01AG	Myocardial infarction (acute)(MI)
01AH	Cardiac arrest

2. CONGESTIVE HEART FAILURE (CHF)

02AA(_)	CHF
02AB(_)	CHF due to volume overload
02AC(_)	Pulmonary edema (cardiogenic)
02AD(_)	Pleural effusions
02AE0	Thoracentesis (diagnostic or therapeutic)
02AF	Cardiogenic shock

3. ARRHYTHMIAS AND CONDUCTION PROBLEMS

03AA(_)	Syncope (also presyncope and syncopal episode)
03AB(_)	Atrial fibrillation
03AC(_)	Ventricular tachycardia
03AD(_)	Supraventricular tachycardia
03AE(_)	Sick sinus (tachy-brady) syndrome
03AF(_)	Atrioventricular conduction block
03AG(_)	Hyperkalemia
03AH(_)	Other new or other arrhythmia and conduction problem
03AI0	Cardioversion
03AJ0	Electrophysiologic studies (EPS)

03AK0 Pacemaker placement
03AL0 Pacemaker malfunction/repair

4. OTHER HEART DISEASES AND CONDITIONS (OHD)

04AA(_) Pericarditis
04AB(_) Endocarditis
04AC(_) Myocarditis
04AD(_) Cardiomyopathy (without IHD or CHF)
04AE(_) Pericardial effusion
04AF(_) Aortic valve stenosis or insufficiency
04AG(_) Mitral valve stenosis, regurgitation, or prolapse
04AH(_) Other valve defect
04AI(_) Other condition
04AJ0 Cardiac tamponade
04AK0 Pericardiocentesis
04AL0 Aortic valve replacement
04AM0 Mitral valve replacement
04AN0 Balloon valvuloplasty

5. HYPERTENSION (HTN)

05AA(_) Hypertensive crisis or accelerated HTN

6. CEREBRAL VASCULAR DISEASE (CVD)

06AA(_) Transient ischemic attack (TIA)
06AB(_) Cerebral vascular accident (CVA)
06AC(_) Carotid artery stenosis
06AD(_) Cerebral artery aneurysm
06AE(_) Subarachnoid or cerebral hemorrhage
06AF(_) Other CVD condition
06AG0 Carotid endarterectomy (CEA)
06AH0 Carotid angiogram

7. PERIPHERAL VASCULAR DISEASE (PVD)

07AA(_) Deep vein thrombosis (DVT)
07AB(_) Pulmonary embolism
07AC(_) Peripheral vascular disease
07AD(_) Ischemic foot ulcers
07AE(_) Gangrene of toes or foot*
07AF(_) Abdominal aortic aneurysm (AAA)
07AG(_) Thoracic aortic aneurysm (TAA)
07AH(_) Hemorrhage from ruptured vascular aneurysm
07AI(_) Aortic aneurysm (not specified)

07AJ(_) Other aneurysm
07AK(_) Mesenteric ischemia or infarction (ischemic bowel)
07AL(_) Cellulitis (non-access related)*
07AM(_) Gangrene with septicemia-shock due to PVD
07AN(_) Other condition due to PVD or other disorder of arteries
07AO(_) Polyarteritis nodosa and other arteritides
07AP Arterial embolism
07AQ0 AAA repair
07AR0 TAA repair
07AS0 Angioplasty for PVD
07AT0 Bypass graft for PVD
07AW0 Amputation site: toe(s)
07AX0 transmetatarsal
07BA0 Left below the knee amputation
07BB0 Right below the knee amputation
07BC0 Left above the knee amputation
07BD0 Right above the knee amputation

8. DIABETES MELLITUS (DM) AND ENDOCRINE DISORDERS

08AA(_) Diabetic foot infection*
08AB(_) Gangrene of foot or toes (absence of PVD)*
08AC(_) Hypothyroidism
08AD(_) Other disorders of the thyroid gland
08AE Diabetes with ketoacidosis
08AF Diabetes with hyperosmolar state or coma
08AG Hypoglycemic coma
08AH0 Pancreatic transplant
08AI(_) Other endocrine disorder

9. RESPIRATORY DISEASE

09AA(_) Asthma
09AB(_) COPD
09AC(_) Bronchitis
09AD(_) Pneumothorax
09AE(_) Empyema*
09AF(_) Lung abscess*
09AG(_) Pulmonary TB*
09AH(_) Respiratory failure not requiring intubation and mechanical ventilation
09AI(_) Respiratory failure requiring intubation and mechanical ventilation
09AJ(_) Adult respiratory distress syndrome (ARDS)
09AK Respiratory failure of unknown cause
09AL(_) Other respiratory disease
09AM(_) Pulmonary hemorrhage
09AN( ) Pneumonia (nosocomial)*

09AO( ) Pneumonia (community acquired)*
09AP( ) Pneumonia-sepsis*
09AQ( ) Pneumonia (bacterial)*
09AR( ) Pneumonia (fungal)*
09AS( ) Pneumonia (viral)*
09AT( ) Pneumocystis pneumonia*
09AU( ) Aspiration pnoumonia*
09AV( ) Pneumonia (unspecified pathogon)*
09AW0 Open lung biopsy
09AX0 Lung lobectomy
09AY( ) Upper respiratory tract disorders
09AZ0 ENT procedures

10. MALIGNANCY

10AA(_) Hematologic malignancy (AML, ALL, CLL)
10AB(_) Lymphoma (unspecified)
10AC(_) Hodgkin's lymphoma
10AD(_) Non-Hodgkin's lymphoma
10AE(_) Multiple myeloma
10AF(_) Colon cancer
10AG(_) Breast cancer
10AH(_) Prostatic cancer
10AI(_) Ovarian cancer
10AJ(_) Lung cancer
10AK(_) Gastric cancer
10AL(_) Pancreatic cancer
10AM(_) Thyroid cancer
10AN(_) Cervical cancer
10AO(_) Endometrial cancer
10AP(_) Primary cancer of liver
10AQ(_) Head and neck squamous cell carcinoma
10AR(_) Testicular cancer
10AS(_) Renal cancer
10AT(_) Bladder cancer
10AU(_) Melanoma
10AV(_) Other skin cancer
10AW(_) Other malignancy or neoplasia
10AX(_) Metastatic carcinoma unknown primary
10AY(_) Complication(s) of pre-admission diagnosed cancer
10BA0 Diagnosis: surgical biopsy
10BB0 other procedure for biopsy
10BC0 other diagnostic procedure
10CA0 Treatment: radiation therapy
10CB0 chemotherapy
10CC0 surgical excision

10CD0 other treatment

11. HEPATOBILIARY DISEASE

11AA(_) Hepatitis B
11AB(_) Hepatitis C
11AC(_) Toxic/drug-induced hepatitis
11AD(_) Hepatitis (other; unknown cause)
11AE(_) Cirrhosis
11AF(_) Ascites
11AG(_) Portal hypertension or esophageal varices
11AH(_) Variceal bleed
11AI(_) Hepatic failure/severe dysfunction
11AJ(_) Cholecystitis/cholangitis*
11AK(_) Other hepatobiliary disease
11AL Biliary sepsis*
11AM0 Cholecystectomy
11AN0 Liver transplant
11AO0 Shunt procedure
11AP0 Paracentesis (diagnostic or therapeutic)

12. MUSCULOSKELETAL AND CONNECTIVE TISSUE DISEASES

12AA(_) Gout
12AB(_) Wegener's granulomatosis
12AC(_) Systemic vasculitis
12AD(_) SLE
12AE(_) Avascular necrosis
12AF(_) Osteomyelitis*
12AG(_) Septic arthritis*
12AH(_) Back problems
12AI(_) Other musculoskeletal or connective tissue disease
12AJ0 Bone fracture
12AK0 Parathyroidectomy
12AL0 Carpal tunnel surgery
12AM0 Arthroscopy
12AN0 Hip replacement
12AO0 Knee replacement
12AP0 Knee procedures (other than replacement)
12AQ0 Internal fixation or surgical reduction of bone fracture
12AR0 Other orthopedic surgery
12AS0 Back and/or neck procedure
12AT( ) Hyperparathyroidism
12AU( ) Hypoparathyroidism
12AV0 Other calcium-phosphorus disorder

13. GASTROINTESTINAL CONDITIONS (GI)

13AA(_)	Upper GI bleed
13AB(_)	Lower GI bleed
13AC(_)	GI bleeding, site unknown
13AD(_)	Peptic ulcer disease
13AE(_)	Gastritis
13AF(_)	Reflux esophagitis (with or without hiatal hernia)
13AG(_)	Diverticulitis*
13AH(_)	Colonic polyps
13AI(_)	Ulcerative colitis (UC)
13AJ(_)	Enteritis (Crohn's disease)
13AK(_)	Septicemia due to peritonitis*
13AL(_)	Pancreatitis
13AM(_)	Necrotising enterocolitis*
13AN(_)	*C. difficile* associated enterocolitis*
13AO(_)	Peritonitis*
13AP(_)	Fungal peritonitis*
13AQ(_)	Appendicitis*
13AR(_)	Ischemic bowel
13AS(_)	Intra-abdominal abscess*
13AT(_)	Abdominal pain, cause unknown
13AU(_)	Malabsorption
13AV(_)	Perforated viscus (peptic ulcer or bowel)*
13AX(_)	Gastroparesis
13BA0	Colectomy (partial or total)
13BB0	Gastrectomy
13BC0	Colostomy or ileostomy
13BD0	Gastrostomy/enterostomy
13BE0	Appendectomy
13BF0	Laparotomy
13BG0	Other GI condition or procedure

14. NONVASCULAR NERVOUS SYSTEM DISEASES

14AA(_) Mental status change (acute)
14AB(_) Seizure disorder
14AC(_) Disequilibrium - syndrome
14AD(_) Coma-stupor (traumatic cause)
14AE(_) Coma-stupor (toxic-drug induced)
14AF(_) Coma-stupor (metabolic cause, non-diabetic)
14AG(_) Coma-stupor (anoxic encephalopathy)
14AH(_) Coma-stupor (other unknown cause)
14AI(_) Alcohol non-accidental
14AJ(_) Drug overdose
14AK(_) Head trauma
14AL(_) Parkinson's disease
14AM(_) Multiple sclerosis
14AN(_) Subdural or epidural hematoma
14AO(_) Depression
14AP(_) Nervous system neoplasm
14AQ(_) Alcohol/drug abuse related (detoxification included)
14AR(_) Other psychiatric or mental disorder
14AS(_) Viral meningitis*
14AT(_) Meningitis (non-viral)
14AU(_) Other CNS infection*
14AV(_) Ataxia
14AW(_) Cranial or peripheral nerve disorder
14AX(_) Other nonvascular nervous system condition
14AY(_) Suicide attempt

15. URINARY TRACT CONDITIONS

15AA(_) Urinary tract infection requiring antibiotics*
15AB(_) Nephrolithiasis
15AC(_) Benign prostatic hypertrophy
15AD(_) Prostatitis
15AE(_) Orchitis
15AF(_) Cystic kidney disease (PKD or acquired)
15AG(_) Cyst-related hemorrhage
15AH(_) Cyst-related infection
15AI(_) Urinary tract hemorrhage
15AJ0 Nephrectomy unilateral
15AK0 Nephrectomy bilateral
15AL0 Prostatectomy (radical)
15AM0 Transurethral prostatectomy (TURP)
15AN0 Other transurethral procedures (cystoscopy included)
15AO0 Other urologic procedure
15AP(_) Hematuria

15AQ Acute Transplant Rejection

16. **HIV/AIDS**

16AA(_) AIDS-related infection*
16AB(_) Other AIDS-related condition (non-infection)
16AC(_) HIV positive

17. **OPHTHALMOLOGIC CONDITIONS**

17AA(_) Retinal or vitreous hemorrhage
17AB(_) Endophthalmitis*
17AC(_) Other disorder of the eye
17AD0 Iris or lens procedure (cataract surgery included)
17AG0 Orbital procedure (vitrectomy included)
17AH0 Retina procedure (laser surgery included)
17AI0 Other ophthalmologic procedure

18. **INFECTIONS**

18AA(_) Abscess (lung, empyema, intra-abdominal, brain, soft tissue --not access-related)*
18AB(_) Miliary TB*
18AC(_) Extrapulmonary TB*
18AD(_) Disseminated candidiasis*
18AE(_) Other fungal infection**
18AF(_) Viral infection (including CMV)*
18AG(_) Other viral infection (not hepatitis)*
18AH(_) Protozoan or parasitic infection (not PCP)*
18AI(_) Other infection (not recorded in previous category)*
18AJ Septic shock*
18AK Bacteremia (known source not access-related)*
18AM Bacteremia (unknown source, not access-related)*

19. **NON-MALIGNANT HEMATOLOGIC CONDITIONS**

19AA(_) Coagulation disorders
19AB(_) Thrombocytopenia (secondary)
19AC(_) Thrombocytopenia (idiopathic)
19AD(_) Disseminated intravascular coagulation
19AE(_) Other consumption coagulopathy
19AF(_) Thrombotic thrombocytopenic purpura (TTP) and hemolytic uremic syndrome (HUS)
19AG0 Other

20. **HEMODIALYSIS VASCULAR ACCESS COMPLICATIONS**

20AA0	Elective surgical access repair
20AB(_)	Soft tissue infection, cellulitis, abscess (access related)*
20AC	Bacteremia or sepsis, access related*
20AD(_)	Clotted access
20AE(_)	Venous thrombosis, access related
20AF(_)	Arterial thrombosis or embolism, access related
20AG(_)	Steal syndrome, limb ischemia, access related
20AH	Hemorrhage from vascular access
20AI(_)	Nerve entrapment, access related
20AJ0	Fistulogram, arteriogram, or other invasive imaging procedure
20AK0	Access declotting procedure
20AL0	Angioplasty or stent placement for vascular access
20AM0	Non-elective surgical access repair
20AN0	Temporary access placement
20AO(_)	Pneumothorax, hemothorax as result of temporary access placement
20AP(_)	Subclavian vein stenosis as result of temporary access
20AQ0	New access creation (AV-fistula)
20AR0	New access placement (AV-graft)
20AS(_)	Other access-related condition
20AT0	Other access-related procedure

21. OTHER HEMODIALYSIS COMPLICATIONS

21AA	Uremia
21AB	Hemorrhage from dialysis circuit
21AC	Air embolism
21AD	Anaphylaxis, treatment related
21AE	Hemolysis, treatment related
21AF	Electrolyte and acid-base disorder (other than hyperkalemia), treatment related
21AG	Dialysis-induced hypotension
21AH	Other accident related to treatment
21AI	Febrile reaction, not infection
21AJ	Start of hemodialysis

22. OTHER SURGICAL PROCEDURES

22AA(_)	Trauma
22AB(_)	Major hemorrhage (not C1 or pulmonary)
22AC(_)	Hemorrhagic shock
22AD0	Skin graft/skin ulcer debridement
22AE0	Hernia procedure
22AF0	Other elective surgery procedure
22AG0	Kidney transplant

23. OTHER

23AA	Withdrawal from dialysis
23AB	Other hemorrhage
23AC	Other trauma
23AD	Drug overdose (accidental)
23AE	Accident unrelated to treatment
23AF	Drug reaction (anaphylaxis)
23AG	Drug reaction (not anaphylaxis, not overdose)
23AH	Other electrolyte/acid-base disorder, not treatment related
23AI	Cachexia
23AJ	Hospitalization for transplant evaluation

24. **UNKNOWN**

25. **HEMODIALYSIS VASCULAR ACCESS COMPLICATIONS RELATED TO THE ACCESS PUT IN FOR DAC**

25AA0	Elective surgical access repair
25AB(_)	Soft tissue infection, cellulitis, abscess (access related)*
25AC	Bacteremia or sepsis, access related*
25AD(_)	Clotted access
25AE(_)	Venous thrombosis, access related
25AF(_)	Arterial thrombosis or embolism, access related
25AG(_)	Steal syndrome, limb ischemia, access related
25AH	Hemorrhage from vascular access
25AI(_)	Nerve entrapment, access related
25AJ0	Fistulogram, arteriogram, or other invasive imaging procedure
25AK0	Access declotting procedure
25AL0	Angioplasty or stent placement for vascular access
25AM0	Non-elective surgical access repair
25AN0	Temporary access placement
25AO(_)	Pneumothorax, hemothorax as result of temporary access placement
25AP(_)	Subclavian vein stenosis as result of temporary access
25AS(_)	Other access-related condition
25AT0	Other access-related procedure
25 AU	Access placement (only when hospitalization is prolonged by a complication)

F363_F_BLEED

DAC Study Form 363 – Bleeding Episode Form

This form is completed for enrolled patients whenever a patient has a transfusion in the dialysis unit for a bleeding event or a patient has a bleeding episode that leads to an outpatient visit, the withholding or discontinuation of study medication or a hospitalization. This form is not needed if the bleeding does not lead to an outpatient visit, holding or discontinuing study medication or a hospitalization.

1. Patient Identification Number..... PID
2. Patient Name Code ..... _____
3. Date of bleeding episode..... __/__/ BLEED_DT
4. Was this associated with an outpatient visit? (0=no, 1=yes)..... OUT_VIS
5. If yes, date of visit..... __/__/ OUT_VIS_DT
6. Was this associated with a hospitalization? (0=no, 1=yes) ..... HOSP_REL
7. If yes, date of admission ..... __/__/ HOSP_ADMIT_DT
   Note: If yes, complete Clinical Center Hospitalization Form 361
8. Was the use of inotropic support noted in the discharge summary? (0=no, 1=yes)..... INOTROPIC_REQ
9. Was emergency surgery required? (0=no, 1=yes) ..... SURG_REQ
10. Was this a fatal bleed? (0=no, 1=yes)..... FATAL_BLEED
11. If yes, date of death..... __/__/ DEATH_DT
    Note: If yes, complete a clinical center Death Notification From 371
12. In the opinion of the study team at your center, was this a life threatening bleed? (0=no, 1=yes) ..... LIFE_THRET
    Note: If you answered YES, you may need to complete item 35 on page 2.
13. Vitreous hemorrhage (0=no, 1=yes)..... INTRAOC_BLEED
    (Does not include conjunctival bleeding.)
14. Was there a sustained loss of vision? (0=no, 1=yes)..... VISION_LOSS
15. GI bleeding? (0=no, 1=yes) ..... GI_BLEED
16. Symptomatic intracranial bleeding? (0=no, 1=yes)..... INTRAC_BLEED
17. If 16=Yes, confirmed by imaging study or autopsy? (0=no, 1=yes, 9=unknown)..... IMG_AUTOP_CONF
18. Pulmonary bleeding? (0=no, 1=yes)..... PULM_BLEED
19. Intra-articular hemorrhage? (0=no, 1=yes)..... INTRAART_HEM
20. Retroperitoneal bleeding? (0=no, 1=yes) ..... RETROP_BLEED
21. Other significant bleeding? (0=no, 1=yes) ..... BLEED_OTH
22. If 21=Yes, give the site of bleeding:..... BLEED_OTH_DESC
23. Transfusion? (0=no, 1=yes)..... TRANS

24. a. If 23=Yes, where was the transfusion done? ..... TRANS_LOC
    1 = participating unit or hospital 2 = other

    b. If the transfusion was done in a participating unit or hospital, use the codes from Form 301, pp. 301.4 - 301.6 of this form to specify where ..... __ PART_LOC

    c. If the transfusion was done in a non-participating unit or hospital, specify where ..... _____

25. Was the patient given platelets? (0=no, 1=yes) ..... PLATES

26. Number of units ..... PLATES_UNITS

27. Was the patient given packed red blood cells or whole blood? (0=no, 1=yes) ..... RED_CELLS

28. Number of units ..... RED_CELLS_UNITS

29. Was the study medication stopped due to the episode? ..... STOP_MED

    (0=no, 1=yes, 9=N/A – already off drug)

    Note: If Yes, complete Form 335: Temporary Discontinuation of Therapy, or Form 336: Permanent Discontinuation of Therapy

30. Most recent hemoglobin prior to the bleed or the event (g/dL) ..... HGB

31. Date sample drawn ..... __/__/__ HGB_DT

32. Was hemoglobin drawn during the event (0=no, 1=yes) ..... HG_EVENT

33. Minimum hemoglobin during the event ..... MIN_HGB

34. Date sample drawn ..... __/__/ MIN_HGB_DT

35. Difference between the most recent hemoglobin prior the bleed or the event and the minimum hemoglobin during the event (item 30 – item 33) ..... DIF_HGB

36. If none of following occurred:
    - An emergency surgical intervention was required (item 9 above)
    - there was a symptomatic intracranial bleeding (item 16 above)
    - transfusion of more than 4 units of packed RBC was required (items 27, 28)
    - a drop in Hgb of ≥ 5 g/dl (item 30 – item 33 above),

    but the study team considers this a life threatening bleed (item 12 above), you need to write a brief text explanation:

    OTH_RSN_EDIT

37. a. Which treatment does the study team think the patient was randomized to? ..... R2_TREAT

1 = The team has been unblinded and knows it is placebo
2 = The team believes it is placebo
3 = The team does not know
4 = The team believes it is active drug
5 = The team has been unblinded and knows it is active drug
8 = N/A, patient not randomized

b. If 1 or 5, date of unblinding ..... __ __/__ __/ UNBL-DT

38. What is the current thought of the Principal Investigator regarding whether this bleeding episode was related to the patient's randomized study intervention? ..... PI-THOUGHT

0 = **Not related to the study drug.**
1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.
2 = **Possibly related to the study drug.**
3 = **Probably related to the study drug.** This sort of event is commonly associated with the study intervention or a temporal relationship with the study intervention exists and no other etiology is apparent.
4 = **Definitely related to the study drug**
8 = N/A, Patient not randomized

39. If the event was definitely, probably or possibly related to the study medication (i.e. q.38= 2, 3 or 4), then what was the expectedness of it? ..... EXPECT

1 = Unexpected - not mentioned in the informed consent
2 = Expected, but of greater severity than mentioned in the informed consent.
3 = Expected and accurately described in the informed consent.

Note: If this was a drug related life-threatening bleed, it can only be classified as "1 - unexpected", or "2 - expected, but of greater severity".

40. What was the severity of the event? ..... SEVERITY

1 = Mild - awareness of the sign or symptom, but easily tolerated
2 = Moderate - enough discomfort to interfere with usual activity
3 = Severe - incapacitating, with inability to do usual work or activity

41. Did the event lead to permanent disability? (0 = no, 1 = yes) ..... PERM-DISA

201. Date this form completed ..... __ __/__ __/__ __ __ __
202. User ID of person completing this form ..... __ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered __ __/__ __/__ __ __ __

Person Entering this Form _____

F365_F_LIFETHREAT

DAC Study Form 365 – Life Threatening Event Form

This form should be completed for all patients who have a life threatening adverse experience while they are taking the study drug. This form should NOT be completed if the event is already described on a hospitalization or a bleeding form.

1. Patient Identification Number..... PID
2. Name code ..... _____
3. Date of the event ..... ___/___/EVENT_DT
4. Describe what happened.

EVENT_DESC

5. What is the current thought of the Principal Investigator regarding whether this event was related to the patient's randomized study intervention? ..... EVENT_RELATE

   0 = **Not related to the study drug.**
   1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.
   2 = **Possibly related to the study drug.**
   3 = **Probably related to the study drug.** This sort of event is commonly associated with the study intervention or a temporal relationship with the study intervention exists and no other etiology is apparent.
   4 = **Definitely related to the study drug**
   8 = N/A, patient is not randomized

6. If the event was definitely, probably or possibly related to the study medication (i.e. Q5 = 2, 3 or 4), then what was the expectedness of it?..... EXPECT

   1 = Unexpected - not mentioned in the informed consent
   2 = Expected, but of greater severity than mentioned in the informed consent.

DAC Study Form 365 – Life Threatening Event Form

201. Date this form completed..... __ __/__ __/__ __ __ __
202. User ID of person completing this form .....__ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered __ __/__ __/__ __ __ __

Person Entering this Form_____

F367_F_BLEED_REVIEW

DAC Study Form 367 – QC Committee: "Review of Bleeding Episode" Form

1. Patient Identification Number..... PID
2. Name Code.....
3. a. Date of transfusion/bleeding episode (Form 363, Q. 3)..... ___/___/ BLD-DT
   b. Date of this review..... ___/___/ REV-DT
4. Consensus of QC Committee and DCC..... DCC-CONS
   1 = Major bleed
   2 = Life-threatening bleed
   3 = Re-classified as neither major nor life-threatening bleed
   4 = Fatal bleed
5. Does the QC Committee think this was related to the patient's randomized drug intervention? (0=no, 1=yes, 9=couldn't tell)..... DRUG-RELATED
6. Comments of reviewer and any action taken. (Write in as much as you wish. Use back of sheet if necessary.)

COMMENTS

201. Date this form completed..... ___/___/_____
202. User ID of person completing this form.....

Clinical Center Use Only

Date Form Entered ___/___/_____

Person Entering this Form_____

DAC Study Form 371 - Clinical Center Death Notification Form F371_F_DEATHNOTF

This form is completed as soon as the Clinical Center becomes aware that an enrolled patient has died. Remember to submit a Clinical Center Death Review Form 372 and the Clinical Center Death Review Packet to the DCC within six weeks after the date of death.

1. Patient Identification Number ..... PID _ _ _ _ _ _
2. Patient Name Code ..... _ _ _ _ _ _
3. Date of Death ..... _ _/_ _/ DEATH_DT _ _ _ _
4. Primary cause of death..... PRIMARY_CAUSE _ _ _ _ _

   Note: Use the codes from Form 372.

5. What is the current thought of the Principal Investigator regarding whether this death was related to the patient's randomized study intervention?..... _

   0 = **Not related to the study drug.** MED_RELATED
   1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.
   2 = **Possibly related to the study drug.**
   3 = **Probably related to the study drug.** This sort of event is commonly associated with the study intervention or a temporal relationship with the study intervention exists and no other etiology is apparent.
   4 = **Definitely related to the study drug**
   8 = N/A, patient is not randomized
   9 = At this time we do not know if the death was related to the study drug

6. If the event was definitely, probably or possibly related to the study medication (i.e. 5 = 2, 3 or 4), then what was the expectedness of it?..... _

   1 = Unexpected - not mentioned in the informed consent MED_EVENT
   2 = Expected, but of greater severity than mentioned in the informed consent.

201. Date this form completed ..... _ _/_ _/_ _ _ _ _

202. User ID of person completing this form ..... _ _ _ _ _ _ _ _ _

Clinical Center Use Only

Date Form Entered _ _/_ _/_ _ _ _ _

Person Entering this Form _____

F372_F_DEATH

DAC Study Form 372 – Clinical Center Death Review Form

This form is completed by the Principal Investigator and submitted to the DCC within six weeks after the date of death. A Death Notification Report will be sent by e-mail with instructions concerning the Death Review Packet assembly. This form must be entered before the packet is sent to the DCC. A member of the SAE Committee will review the packet.

Part 1: To be completed by the Study Coordinator:

1. Patient Identification Number ..... PID
2. Patient Name Code ..... _____
3. Date of Death ..... __/__/DEATH_DT
4. Date Death Review Packet submitted to DCC ..... __/__/_____
5. Where did the death occur? ..... DEATH_LOCATION

   1 = In a hospital, in the emergency room
   2 = In a hospital, not in the emergency room
   3 = In the dialysis unit
   4 = In a nursing home or other skilled care facility
   5 = In the patient's home
   6 = Other known location
   7 = Location unknown

6. Was an autopsy performed? (0=no, 1=yes, 9=unknown) ..... AUTOPSY
   If YES, be sure to include the autopsy form in the Death Review Packet.

DAC Study Form 372 – Clinical Center Death Review Form

Part 2: To be completed by the Principal Investigator:

7. For Causes of Death, use the Form 272 Death Code List.

   a. Primary Cause of Death ..... PRIMARY_CAUSE

   b. Secondary Cause of Death ..... SECONDARY_CAUSE

   c. Other Cause of Death ..... OTHER_CAUSE1

   d. Other Cause of Death ..... OTHER_CAUSE2

8. Narrative summary from the Principal Investigator of the events leading to the patient's death and the circumstances surrounding the death. Write in as much as you wish. Use additional pages if necessary. This will be key-entered, but need not be re-key verified.

NARRATIVE_EDIT

9. a. Which treatment does the study team think the patient was randomized to? ..... RX_GUESS

1 = The team has been unblinded and knows it is placebo
2 = The team believes it is placebo
3 = The team does not know
4 = The team believes it is active drug
5 = The team has been unblinded and knows it is active drug
8 = N/A, patient is not randomized

b. If 1 or 5, date of unblinding ..... __/__/UNBLIND_DT

10. What is the current thought of the Principal Investigator regarding whether this death was related to the patient's randomized study intervention? ..... MED_RELATED

0 = **Not related to the study drug.**
1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.
2 = **Possibly related to the study drug.**
3 = **Probably related to the study drug.** This sort of event is commonly associated with the study intervention or a temporal relationship with the study intervention exists and no other etiology is apparent.
4 = **Definitely related to the study drug**
8 = N/A, patient is not randomized

11. If the event was definitely, probably or possibly related to the study medication (i.e. 10 = 2, 3 or 4), then what was the expectedness of it? ..... MED_EVENT

1 = Unexpected - not mentioned in the informed consent
2 = Expected, but of greater severity than mentioned in the informed consent.

201. Date this form completed ..... __/__/_____

202. User ID of person completing this form ..... _____

Clinical Center Use Only

Date Form Entered __/__/_____

Person Entering this Form _____

DAC STUDY/CAUSES OF DEATH
(FOR FORM 372)

CATEGORIES

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.
An asterisk (*) indicates that the disease or condition is also classified as an infection outcome.

1. ISCHEMIC HEART DISEASE (IHD)

01DA Sudden death (due to IHD)
01DB Myocardial infarction (acute) (MI)
01DC Angina:2
01DD Atherosclerotic heart disease (CAD):2
01DE Other acute and subacute forms of ischemic heart disease
01DF Old myocardial infarction:2
01DG Other forms of chronic ischemic heart disease:2

2. CONGESTIVE HEART FAILURE (CHF)

02DA CHF
02DB CHF or pulmonary edema due to exogenous fluid (volume overload)
02DC Pulmonary edema (cardiogenic)
02DD Cardiogenic shock

3. ARRHYTHMIAS AND CONDUCTION PROBLEMS

03DA Sudden death (due to arrhythmia, not due to IHD)
03DB Atrioventricular conduction block
03DC Sick sinus syndrome
03DD Atrial fibrillation
03DE Ventricular tachycardia
03DF Other cardiac arrhythmia and conduction disorder
03DG Hyperkalemia

4. OTHER HEART DISEASES AND CONDITIONS (OHD)

04DA Sudden death (due to heart conditions other than IHD/arrhythmia)

04DB Pericarditis
04DC Endocarditis *
04DD Myocarditis
04DE Pericardial effusion:2
04DF Cardiac tamponade
04DG Aortic valve stenosis or insufficiency:2
04DH Mitral valve stenosis, regurgitation, or prolapse:2
04DI Other valve defect:2
04DJ Prosthetic valve malfunction:2
04DK Cardiomyopathy (without IHD or CHF)

5. HYPERTENSION (HTN)

05DA Hypertensive crisis or accelerated HTN

6. CEREBRAL VASCULAR DISEASE (CVD)

06DA Cerebral vascular accident (CVA)
06DB Carotid artery stenosis:2
06DC Cerebral artery aneurysm:2
06DD Subarachnoid or cerebral hemorrhage
06DE Other cerebrovascular disease

7. PERIPHERAL VASCULAR DISEASE (PVD)

07DA Hemorrhage from ruptured vascular aneurysm
07DB Peripheral vascular disease:2
07DC Deep vein thrombosis (DVT):2
07DD Pulmonary embolism (PE)
07DE Abdominal aortic aneurysm (AAA):2
07DF Thoracic aortic aneurysm (TAA):2
07DG Aortic aneurysm (not specified as AAA or TAA):2
07DH Other aneurysm:2
07DI Arterial embolism and thrombosis
07DJ Mesenteric ischemia or infarction/ischemic bowel
07DK Gangrene with septicemia-shock due to PVD *
07DL Polyarteritis nodosa and other arteritides:2
07DM Other disorders of arteries:2

8. DIABETES MELLITUS (DM) AND ENDOCRINE DISORDERS

08DA Diabetes mellitus, Type I (insulin dependent):2
08DB Diabetes mellitus, Type II (non insulin dependent, could be insulin required):2
08DC Diabetes mellitus, type unclassified or unknown:2

08DD Diabetes with ketoacidosis
08DE Diabetes with hyperosmolar state or coma (hyperglycemia)
08DF Diabetes with other coma
08DG Hypoglycemia coma
08DH Diabetic foot infection *
08DI Hypothyroidism:2
08DJ Disorders of the thyroid gland:2
08DK Other endocrine disorder:2

9. RESPIRATORY DISEASE

09DA Asthma
09DB COPD exacerbation
09DC Bronchitis (chronic):2
09DD COPD:2
09DE Pneumonia (community acquired)*
09DF Pneumonia (nosocomial)*
09DG Pneumonia-sepsis*
09DH Pneumonia (bacterial)*
09DI Pneumonia (fungal)*
09DJ Pneumonia (viral)*
09DK Pneumocystis pneumonia*
09DL Pneumonia (unspecified pathogen)*
09DM Empyema*
09DN Lung abscess*
09DO Pneumothorax
09DP Pulmonary hemorrhage
09DQ Cor pulmonale:2
09DR Pulmonary TB*
09DS Aspiration pneumonia
09DT Adult Respiratory Distress Syndrome (ARDS)
09DU Respiratory failure of unknown cause

10. MALIGNANCY

10DA Hematologic malignancy (AML, CML, ALL, CLL)
10DB Lymphoma (unspecified)
10DC Hodgkin's lymphoma
10DD Non-Hodgkin's lymphoma
10DE Multiple myeloma
10DF Colon cancer
10DG Breast cancer
10DH Prostatic cancer
10DI Ovarian cancer
10DJ Lung cancer

10DK Gastric cancer
10DL Pancreatic cancer
10DM Thyroid cancer
10DN Cervical cancer
10DO Endometrial cancer
10DP Primary cancer of the liver
10DQ Head and neck squamous cell carcinoma
10DR Testicular cancer
10DS Renal cancer
10DT Bladder cancer
10DU Melanoma
10DV Other skin cancer
10DW Other malignancy or neoplasia
10DX Metastatic cancer with unknown primary
10DY Patient ever on immunosuppressive therapy

11. HEPATOBILIARY DISEASE

11DA Hepatitis B
11DB Hepatitis C
11DC Toxic/drug induced hepatitis
11DD Hepatitis (other unknown cause)
11DE Cirrhosis:2
11DF Ascites:2
11DG Portal hypertension or esophageal varices:2
11DH Hemorrhage from esophageal varices
11DI Hepatic (liver) failure/severe hepatic dysfunction
11DJ Polycystic liver disease:2
11DK Cholecystitis/cholangitis*
11DL Biliary sepsis*
11DM Other hepatobiliary disease

12. MUSCULOSKELETAL AND CONNECTIVE TISSUE DISEASES

12DA Wegener's granulomatosis
12DB Systemic vasculitis
12DC Rheumatoid arthritis:2
12DD SLE
12DE Osteomyelitis*
12DF Septic arthritis*
12DG Osteoporosis:2
12DH Bone fracture(s):2
12DI Renal osteodystrophy:2
12DJ Hyperparathyroidism:2
12DK Hypoparathyroidism:2

12DL Other disorder of calcium and phosphorus metabolism
12DM Other musculoskeletal or connective tissue disease:2

13. GASTROINTESTINAL CONDITIONS (GI)

13DA Upper GI bleed
13DB Lower GI bleed
13DC GI bleeding, site unknown
13DD Peptic ulcer disease:2
13DE Gastritis:2
13DF Diverticulosis:2
13DG Ulcerative colitis (UC):2
13DH Enteritis (Crohn's disease):2
13DI Perforation of peptic ulcer
13DJ Perforation of bowel
13DK Diverticulitis*
13DL Necrotizing enterocolitis*
13DM *C. difficile* associated enterocolitis*
13DN Peritonitis*
13DO Appendicitis*
13DP Septicemia due to peritonitis*
13DQ Fungal peritonitis*
13DR Pancreatitis
13DS Intra-abdominal abscess*
13DT Arteriovenous malformation (AVM)
13DU Other GI condition:2

14. NONVASCULAR NERVOUS SYSTEM DISEASES

14DA Dementia (Alzheimer's):2
14DB Dementia (other, unknown, including dialysis dementia):2
14DC Seizure disorder (chronic):2
14DD Seizure episode
14DE Depression:2
14DF Suicide (not due to withdrawal from dialysis, which is code 23DA)
14DG Drug overdose (alcohol/drug abuse--street drugs or other non-accidental chemical abuse)
14DH Subdural or epidural hematoma (spontaneous or traumatic)
14DI Meningitis (non viral, bacterial, or fungal or TB)*
14DJ Brain abscess*
14DK Other CNS infection*
14DL Head trauma (brain injury)
14DM Ischemic brain damage, anoxic encephalopathy
14DN Other psychiatric or mental disorder:2
14DO Parkinson's disease:2

14DP Multiple sclerosis (MS):2
14DQ Other demyelinating diseases of CNS:2
14DR Cranial or peripheral nerve disorder:2
14DS Other nonvascular nervous system condition

15. URINARY TRACT CONDITIONS

15DA Urinary tract infection (chronic UTIs):2
15DB UTI-septicemia*
15DC Nephrolithiasis:2
15DD Prostatitis*
15DE Benign prostatic hypertrophy:2
15DF Orchitis*
15DG Cystic kidney disease (PKD or acquired):2
15DH Cyst-related hemorrhage
15DI Cyst-related infection*
15DJ Urinary tract hemorrhage
15DK Hemorrhage from renal transplant site
15DL Other renal and urologic condition (excluding ESRD)

16. HIV/AIDS

16DA HIV positive (not AIDS)
16DB AIDS
16DC AIDS-related infection
16DD Other AIDS-related condition (not infection)

17. OPHTHALMOLOGIC CONDITIONS

17DA Endophthalmitis*
17DB Legally blind:2

18. INFECTIONS (NOT ACCESS RELATED)

18DA Abscess (not recorded in previous category)*
18DB Other infection (not recorded in previous category)*
18DC Septic shock*
18DD Septicemia (bacteremia) (known source, not access related)*
18DE Septicemia (bacteremia) (unknown source, not access related)*
18DF Extrapulmonary TB*
18DG Miliary TB*
18DH Disseminated candida infection*
18DI Other fungal infection*
18DJ Viral infection (CMV)*
18DK Other viral infection (not hepatitis)*

18DL Protozoan or parasitic infection (not PCP)*

19. NON-MALIGNANT HEMATOLOGIC CONDITIONS

19DA Anemia:2
19DB Bone marrow depression:2
19DC Leukocytopenia:2
19DD Coagulation disorder:2
19DE Thrombocytopenia:2
19DF Disseminated intravascular coagulation
19DG Other consumption coagulopathy:2
19DH Thrombotic thrombocytopenic purpura (TTP) and hemolytic uremic syndrome (HUS)
19DI Other non-malignant hematologic condition

20. HEMODIALYSIS VASCULAR ACCESS COMPLICATIONS

20DA Septicemia (bacteremia) access related*
20DB Hemorrhage from vascular access
20DC Venous thrombosis access related:2
20DD Arterial thrombosis or embolism access related
20DE Other access infection
20DF Other complication of temporary access placement

21. OTHER HEMODIALYSIS COMPLICATIONS

21DA Hemorrhage from dialysis circuit
21DB Air embolism
21DC Anaphylaxis, treatment related
21DD Hemolysis, treatment related
21DE Electrolyte and acid-base disorder, treatment related (other than hyperkalemia)
21DF Dialysis-induced hypotension
21DG Other accident related to treatment

22. OTHER SURGICAL COMPLICATIONS

22DA Hemorrhage from surgery
22DB Complications from surgery
22DC Complications from anesthesia

23. OTHER

23DA Withdrawal from dialysis::2
23DB Other hemorrhage

23DC Cachexia
23DD Other trauma
23DE Drug overdose (accidental)
23DF Accident unrelated to treatment
23DG Drug reaction, anaphylaxis
23DH Drug reaction, not anaphylaxis, not overdose
23DI Other electrolyte and acid-base disorder (not related to hemodialysis treatment)
23DJ Homicide
23DK Refusal of lifesaving therapy

24. UNKNOWN

24DA Sudden death, unknown cause
24DB Other death, unknown cause

F373_F _DEATH_REV

DAC Study Form 373 – QC Committee Death Review Form

1. Patient Identification Number ..... PID
2. Patient Name Code ..... _____
3. Date of Death ..... ___/ DEATH_DT
4. Date Reviewed ..... ___/ REV_DT
5. Death Codes from the Clinical Center Form 372
   a. Primary Cause of Death CAUSE1
   b. Secondary Cause of Death CAUSE2
   c. Other Cause of Death CAUSE3
   d. Other Cause of Death CAUSE4
6. a. Consensus of QC Committee on Primary Cause ..... QC_CONS

   0 = Disagree with Clinical Center on Primary Cause

   1 = Agree with Clinical Center on Primary Cause

   b. If q. 6a = 0, what does the Committee think is the Primary Cause of Death QC_CAUSE
7. a. Which treatment does the reviewer think the patient was randomized to? ..... RX_GUESS

   1 = The team has been unblinded and knows it is placebo
   2 = The team believes it is placebo
   3 = The team does not know
   4 = The team believes it is active drug
   5 = The team has been unblinded and knows it is active drug
   8 = N/A, patient is not randomized

   b. If 1 or 5, date of unblinding ..... ___/ UNBLIND_DT
8. What is the current thought of the reviewer regarding whether this death was related to the patient's randomized study intervention? ..... MED_RELATED

   0 = **Not related to the study drug.**
   1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.
   2 = **Possibly related to the study drug.**
   3 = **Probably related to the study drug.** This sort of event is commonly associated with the study intervention or a temporal relationship with the study intervention exists and no other etiology is apparent.
   4 = **Definitely related to the study drug**
   8 = N/A, patient is not randomized
9. If the event was definitely, probably or possibly related to the study medication (i.e., 8 = 2, 3 or 4), then what was the expectedness of it? ..... MED_EXP

   1 = Unexpected - not mentioned in the informed consent
   2 = Expected, but of greater severity than mentioned in the informed consent.

Revised on 09/29/2006

10. Comments of the reviewers

COMMENTS_EDIT

201. Date this form completed..... __ __/__ __/__ __ __ __

202. User ID of person completing this form .....__ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered __ __/__ __/__ __ __ __

Person Entering this Form_____

F383_F +-OTHSTUDY

DAC Study Form 383 - Patient Participated In One of the DAC Studies and Is Now Enrolled in the Other DAC Study Form

This Form should be completed by a study coordinator when a patient who has finished his participation in one of the DAC studies and is now enrolled in the other DAC study.

1. Patient Identification Number for the Fistula study..... FPID
2. Patient Identification Number for the Graft study..... GPID
3. Name Code.....
4. What was the first study in which the patient participated (F = Fistula, G = Graft) ..... STUDY 1

201. Date this form completed..... __/__/_____

202. User ID of person completing this form.....

Clinical Center Use Only
Date Form Entered __/__/_____
Person Entering this Form_____

Revised on 02/06/2003

F385_F_NOT ENR

DAC Fistula Study
Reasons for not enrolling patients

Start date: __/__/_____ (START_DT) **End date:** __/__/_____ (END_DT) **Center:** ___ (CC_N)

1	Patient cannot discontinue aspirin for the 6 weeks of the study	RSN01
2	Patient cannot discontinue anticoagulants other than aspirin for the 6 weeks of the study for a medical reason	RSN02
3	Patient cannot discontinue systematic glucocorticoids for the 6 weeks of the study	RSN03
4	By the time patient was found, surgery was less than seven days away and patient has taken aspirin	RSN04
5	Patient refuses to participate	RSN05
6	Patient has some medical condition that makes antiplatelet therapy dangerous	RSN06
7	Patient is already on clopidogrel and cannot go off of it	RSN07
8	Site is not prepared to enroll patients who speak this language	RSN08
9	Patient has had a bleeding episode in the last 12 weeks	RSN09
10	Patient is known to have a history of non-compliance	RSN10
11	Patient is not competent	RSN11
12	Did not find out about patient in time	RSN12
13	Patient has a bleeding disorder	RSN13
14	Patient cannot discontinue non-steroidals for the six weeks of the study for medical reason	RSN14
15	Patient has acute ulcer disease	RSN15
16	Patient has uncontrolled hypertension	RSN16
17	Patient has advanced liver disease	RSN17
18	Patient is known to have an active substance abuse	RSN18
19	Patient is enrolled in another interventional study	RSN19
20	Patient is a female who is: pregnant or trying to get pregnant or breastfeeding	RSN20
21	We know that this patient's physician does not agree to allow patients in the study	RSN21
22	This patient's personal physician will not allow this patient to participate in the study	RSN22
23	Out of area	RSN23
24	Prednisone dose too large to enroll	RSN24
25	Too sick	RSN25
26	No surgery date scheduled - waiting to consent	RSN26
27	Fistula Revision	RSN27
28	In jail	RSN28

Revised on 09/25/2006

DAC Fistula Study
Reasons for not enrolling patients

29 Study team preference ..... __ __ RSN29
30 Age limit ..... __ __ RSN30
31 Low platelets ..... __ __ RSN31
32 Fresenius ..... __ __ RSN32
33 No IRB approval yet ..... __ __ RSN33
34 Patient has a known allergy or hypersensitivity to clopidogrel ..... __ __ RSN34
35 Missed - out of town for Steering ..... __ __ RSN35
36 Plasmapheresis ..... __ __ RSN36
37 Cannot dispense drug – lives in nursing home ..... __ __ RSN37
38 Tenckhoff ..... __ __ RSN38
39 No show for surgery ..... __ __ RSN39
40 Leg fistula ..... __ __ RSN40
41 Nocturnal dialysis patient ..... __ __ RSN41
42 Already failed fistula study ..... __ __ RSN42
43 Previously consented/randomized ..... __ __ RSN43
44 Patient expired before surgery ..... __ __ RSN44
45 Home dialysis ..... __ __ RSN45
46 Patient did not want to discontinue aspirin ..... __ __ RSN46

F387-U-NOTENR

DAC Studies

Reasons for not enrolling patients when **type** of surgery is unknown

Start date: __/__/_____ (START_DT) **End date:** __/__/_____ (END_DT) **Center:** __ (CC_N)

1	Patient is not competent	RSN01
2	Patient refuses to participate	RSN02
3	Patient has acute ulcer disease	RSN03
4	Patient require warfarin, dipyridamole or other antiplatelet agent other than aspirin	RSN04
5	Patient is known to have a current problem with substance abuse	RSN05
6	We know that this patient's physician does not agree to allow patients in the study	RSN06
7	Patient is enrolled in another interventional study	RSN07
8	Site is not prepared to enroll patients who speak this language	RSN08
9	Surgical revision	RSN09
10	MI on ASA	RSN10
11	Out of area	RSN11
12	ASA	RSN12
13	Patient on PD	RSN13
14	Too sick	RSN14
15	In jail	RSN15
16	Non-compliant	RSN16
17	Transplant	RSN17
18	Receiving Tessio Catheter	RSN18
19	Patient in nursing home	RSN19
20	Recent GI bleed	RSN20
21	Deceased prior to approaching	RSN21
22	Known substance abuse	RSN22
23	Age limit	RSN23
24	Patient refused access	RSN24
25	Received a graft (fistula only site)	RSN25

Revised on 09/25/2006

F390_F_VITALSTAT

DAC Study Form 390 - Annual Check on Vital Status to Inactive Patients

This form should be completed for "inactive" randomized patients (patients who have completed participation in the Study) annually from the patient's randomization date (i.e., F12, F24, F36, etc). It is also completed for non-randomized patients annually from the patient's consent date (use F12, F24, etc.). Once a patient has died and a form is entered with dialysis status = 0, no further forms need to be completed.

1. Patient Identification Number ..... PID
2. Patient Name Code ..... _____
3. Visit Date ..... __/__/__ VISDT
4. Visit Type ..... F VIST
5. Visit Number ..... VISN
6. Vital Status (0=dead, 1=alive, 9=unknown) ..... VITAL_STATUS
   If the patient's status is unknown, check with your state's department of vital statistics.
   It is critical to determine the vital status of each patient each year.
7. Dialysis Status ..... DIAL_STATUS
   Patient is:
   - 0 = Dead (use death date for q.3)
   - 1 = Currently refusing any dialysis
   - 2 = Currently refusing dialysis "as prescribed"
   - 3 = Currently on in-center hemodialysis at original unit
   - 4 = Currently on in-center hemodialysis elsewhere
   - 5 = Currently on home hemodialysis
   - 6 = Currently on peritoneal dialysis
   - 7 = Had a transplant
   - 8 = Regained renal function
   - 10 = Has not yet started dialysis
   - 99= Unknown

8. Is the patient still in the geographic area of his or her initial dialysis unit? (0=no, 1=yes, 9=unknown) ..... AREA

201. Date this form completed ..... __/__/_____
202. User ID of person completing this form ..... _____

Clinical Center Use Only
Date Form Entered __/__/_____
Person Entering this Form _____

DAC Study Report R5 – Serious Adverse Event Report

The first page of the report will be generated automatically as soon as a form is entered which triggers the report.

If the SAE is (possibly probably, or definitely) related to the study medication (item 12, code 2, 3 or 4) and unexpected (including life threatening events) or expected, but more severe than described in the consent (item 13, code 1 or 2), then it is an SAE, which needs to be reported immediately to FDA following the procedure described below. Deaths with unknown relationship to the study drug will be reported following the same procedure.

- The first page will be e-mailed to the Clinical Center, the NIH and the DCC.
- If this is one of your Center's first few SAEs, call the DCC
- After receiving this first page of the report, the Clinical Center personnel will have to fill in and key-enter the second page.
- The whole report has to be forwarded to the Project Officer at the NIH, and the local IRB and the DCC.
- The NIH will report the SAE to the FDA.

If the SAE is either expected, or not related to the study medication, then this is an SAE, which needs to be reported to the FDA as a part of an annual summary of SAEs and the procedure is the following:

- The first page will be e-mailed to the Clinical Center and the DCC.
- After receiving this first page of the report, the Clinical Center personnel will have to fill in and key-enter the second page.
- The whole report has to be forwarded the DCC.
- These reports will be summarized annually and will be submitted by the DCC to the NIH and by the Clinical Center to the local IRB.
- The NIH will report these SAEs to the FDA annually.

The fax number for the Project Office at the NIH (John Kusek / Catherine Meyers) is:

(301) 480 3510

The fax number for the DCC is: (216) 445 2781

DAC Study Report R5 – Serious Adverse Event Report R5_F_SAE

Page 1 of this report is generated automatically every time when a form, which triggers the report, is completed. This page is e-mailed to the Clinical Center, the NIH and the DCC depending on the relation of the event to the study drug medication and on the expectedness of the event.

1. Patient ID *(comes from the form which triggered the report)* PID
2. Patient Name Code *(comes from the form which triggered the report)*
3. Patient's Study *(comes from the consent form)*
4. Clinical Center *(comes from the form which triggered the report)* CC_N
5. Principal Investigator's Name *(comes from the dataset)*
6. Date of Report *(today's date filled in automatically)* REP_DT
7. Date of Event *(comes from the form which triggered the report)* ENENT_DT

Patient Information

8. Gender (1 = Female, 2 = Male) (*comes from Form 301 / 311*)
   Race (*comes from Form 331)*
9. Age (*calculate as of today*)
10. Date of Randomization (*comes from the randomization table*)
11. **Type of SAE (0 = No, 1 = Yes)** SAE_TYPE
    1 = Death *(comes from Form 371)*
    Primary cause of death *(comes from Form 371)*
    2 = Major Additional Information for a Death *(comes from Form 372)*
    Primary cause of death (comes from Form 372)
    3 = Admission for Required Hospitalization *(comes from Form 360)*
    Primary reason for hospitalization (comes from Form 360)
    4 = Major Additional Information for Required Hospitalization *(comes from Form 361)*
    Primary reason for hospitalization (comes from Form 361)
    5 = Prolongation of Existing Hospitalization *(comes from Form 361)*
    Reason for prolongation of existing hospitalization (comes from Form 361)
    6 = Permanent Disability *(comes from Form 364)*
    7 = Life threatening event *(comes from Form 363 or 365)*
    Was this a life threatening bleed?
    8 = Congenital abnormality *(comes from Form 366)*
12. Relationship of the event to the study medication (*comes from the form which triggered the report*) MED_RELATED
    0 = Not related
    1 = Unlikely to be related
    2 = Possibly related
    3 = Probably related
    4 = Definitely related
    8 = N/A, patient has not been randomized yet
    9 = At this time we do not know if the death was related to the study drug
13. In case the event is related to the study medication (code 2, 3, or 4 from Item 12), the expectedness of the event is *(comes from the form which triggered the report)* EXPECTED

1 = Unexpected - not mentioned in the informed consent.
2 = Expected, but of greater severity than mentioned in the informed consent.
3 = Expected and accurately described in the informed consent.

14. The severity of the event is *(comes from the form which triggered the report)*
1 = Mild - awareness of the sign or symptom, but easily tolerated
2 = Moderate - enough discomfort to interfere with usual activity
3 = Severe - incapacitating, with inability to do usual work or activity

SEVERITY

Page 2 – The Clinical Center personnel need to fill out this form and key-enter it immediately after page 1 of the report is received. The whole report will then need to be forwarded to the DCC, and if the event in both unexpected and related to the study medication (see introduction explanation on p. 1) – to the Project Officer at the NIH and the local IRB.

Patient ID ..... _ _ _ _ _ _ _

Patient Name Code ..... _ _ _ _ _ _

Date of Event ..... _ _/_ _/_ _ _ _

Type of Event, which triggered the report ..... _ _ _

Nature of Event

15. Full clinical description (including symptoms and diagnosis) to the extent required by your local IRB

DESCRIPTION-EDIT

16. Date faxed to the DCC ..... _ _/_ _/ SUBMIT-DT

Reporter Information

Physician in Charge:

Name: _____ Signature: _____

Date Signed: _____ SIGN-DT

Name of the person completing this page: _____

Signature of the person completing this page: _____

Date this page completed: ..... _ _/_ _/_ _ _ _

DAC Study A1 – Graft Study Randomization On Line Application

1. Patient Identification Number..... ___ PID
2. Patient Name Code ..... _____
3. Date/time graft placed (24 hour clock) ..... __ __/__ __/__ __ __ __ __ __:__ __ SURG_DT

   Record the time that the patient reaches the recovery room.
4. Location: 1 = Forearm, 2 = Upper arm or other location ..... ACCESS_LOC

Computer will check eligibility and make sure that all Baseline data are in the database, and that less than 45 days have passed since Baseline/Demographic data collection, and that two or fewer days have passed since the date graft placed, and that no more than 90 days have passed since the patient consented.

5. Is the patient currently receiving hemodialysis? (0 = no, 1 = yes) ..... HEMODIAL
6. Which closet is the drug coming from ..... __ __

202. Date entered ..... __ __/__ __/__ __ __ __ FORM_DT

/

Actual Rand date

A2_F_RANDOM

DAC Study A2 – Fistula Study Randomization On Line Application

1. Patient Identification Number..... PID ___ ___ ___ ___ ___ ___
2. Patient Name Code ..... ___ ___ ___ ___
3. Date/Time fistula was placed..... ___ ___/___ ___/___ ___ ___ ___/___ ___:___ ___ SURG_DT

   Note: Use 24 hour clock. Record the time that the patient reaches the recovery room.
4. Location: 1 = forearm, 2 = upper arm, 3 = other ..... ACCESS_LOC ___

Computer will check eligibility and make sure that item 4 = 1 or 2, that all Baseline data are in the database, and that less than 45 days have passed since Baseline/Demographic data collection, and that at most one day has passed since the date fistula placed, and that no more than 90 days have passed since the patient consented.

5. Is the patient currently receiving hemodialysis? (0 = no, 1 = yes)..... HEMODIAL ___
6. Which closet is the drug coming from? ..... CLOSET ___ ___

202. Date entered ..... ___ ___/___ ___/___ ___ ___ ___

Revised on 07/27/2004