

# F300

## Hemodialysis Fistula Maturation Study (HFM/MANVAS Studies) Monthly Follow Up Form (Form # 300)

This form is completed once a month from surgery until 3 months after the study fistula has been abandoned.

If the Form 300 is being completed within the visit window it applies to, Q.4 (date of visit or phone contact) is the date you *finished* collecting the data.

If the Form 300 is being completed late because you missed a Form 300 for a given visit window, Q.4 will be the “High Date” (the last date) found under “Labels for Monthly Visits” (from the Visit Windows Report).

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1. Identification Number PID 2. Alphacode AC 3. Visit Month Number VIST 4. Date of visit or phone contact: mm/dd/yyyy VISIT\_DT

**For Month 1 (Item 3 = 1) only – Double check**

5. Did the patient return to the OR in the early post-op period (within 2 weeks) after AVF creation surgery for access related complications? (0=no, 1=yes) .....OR\_RETURN  
(If yes, be sure to complete and Access Event Form 422.)

**For all monthly visits**

- 6. a. Did any access event happen to the **study fistula** since the last monthly Form 300 (or since surgery, if this is the first Form 300)?  
(0=no, 1=yes, one; 2=yes, two or more).....ACC\_EVENT
- b. If yes, what was the date the first event became known to the study team since the last monthly Form 300? (mm/dd/yyyy) ..... ACC\_EVENT\_DT  
(Complete Study Fistula Access Event Form 422 (for each event))
- 7. a. Was a diagnostic study done on the **study fistula** since the last monthly Form 300? (0=no, 1=yes, one; 2=yes, two or more) .....DIAG\_STUDY
- b. If yes, what was the date of the first diagnostic study since the last monthly Form 300? (mm/dd/yyyy) .....DIAG\_STUDY\_DT  
(Complete Study Fistula Diagnostic Study Form 424 (for each diagnostic study))
- 8. a. Was an access intervention done on the **study fistula** since the last monthly Form 300? (0=no, 1=yes, one; 2=yes, two or more) ..... ACC\_INTERV
- b. If yes, what was the date of the first intervention since the last monthly Form 300? (mm/dd/yyyy) ..... ACC\_INTERV\_DT  
(Complete Study Fistula Access Intervention Form 423 (for each intervention))

- 9. a. Did the patient have a *reportable* hospitalization since the last monthly Form 300\*?  
(0=no, 1=yes, once; 2 = yes, two or more times)..... PT\_HOSP  
*(\*Complete Clinical Center Hospitalization Notification Form 511 only if study participation caused the hospitalization or if the hospitalization caused the patient to miss a dialysis session in his/her dialysis unit)*
- b. If yes, what was the admission date of the first *reportable* hospitalization since the last monthly Form 300? (mm/dd/yyyy) ..... PT\_HOSP\_DT
- 10. a. Did anything occur relating to a **non-study access** since the last monthly Form 300? Consider both access events to current non-study accesses and creation of new, non-study accesses. (0=no, 1=yes, one occurrence; 2=yes, two or more occurrences) .. OTH\_ACC\_EVENT
- b. If yes, what was the date of the first non-study access event since the last monthly Form 300? (mm/dd/yyyy) ..... OTH\_ACC\_EVENT\_DT  
*(Complete Non-Study Access Event Tracking Form 421(for each event))*
- 11. a. Did the patient have a bloodstream infection (bacterial or fungal) since the last monthly Form 300? (0=no, 1=yes, one; 2= yes, two or more)..... BLOOD\_INFECT
- b. If yes, were any of the bloodstream infections related to a vascular access? (0=no, 1=yes) .....RELATED\_VASACC

**Dialysis Status and Study Fistula Cannulation Attempts**

- 12. a. Is the patient currently receiving maintenance dialysis? (0=no, 1=yes)..... MAINT\_DIAL  
*If q. 12a = no (patient is not receiving maintenance dialysis), skip to q. 23*
- b. **For patients who started dialysis for the first time since the last Form 300,** what was the start date of dialysis? (mm/dd/yyyy) ..... DIAL\_DT
- 13. If q. 12a = yes (patient is receiving maintenance dialysis), has cannulation been attempted on the study fistula since the last monthly Form 300? (0=no, 1=yes)..... CANN\_ATTEMPT  
*If yes, complete a Cannulation Form 302 for each attempt at cannulation up until and including the first successful cannulation*
- 14. What access was used this post surgery month (use DCC provided visit schedule)? ACC\_USED  
(1=study fistula was used at all sessions, 2=a central venous catheter was used for some sessions, 3=an AV graft was used for some sessions, 4=a non-study fistula was used for some sessions, 5= a PD catheter was used for some sessions)
- 15. Does the patient have a central venous dialysis catheter in place? (0=no, 1=yes) ..VEN\_DIAL\_CATH

**Dialysis adequacy information**

- 16. Was kinetic modeling done since the last monthly Form 300? .....KM\_DONE  
(0=no, 1=yes, on the study fistula using two needles the entire session, 2=other)  
[It is expected that each patient will have kinetic modelling done once each month. If the kinetic modelling was not done (Q16=0), leave the items below blank.]
- 17. Date of most recent monthly routine clinical urea kinetic modeling (mm/dd/yyyy) ..... KM\_DT

- 18. a. Pre-dialysis BUN (mg/dL) on that date..... PRE\_BUN
- b. Post-dialysis BUN (mg/dL) on that date.....POST\_BUN
- 19. URR (MANVAS only) ..... URR
- 20. Pre-dialysis weight (kg) on that date.....PRE\_WT
- 21. Post-dialysis weight (kg) on that date .....POST\_WT
- 22. Duration of the dialysis (minutes) ..... DIAL\_DUR

**Study Fistula Cannulation Plan Status**

- 23. Cannulation plans ..... CANN\_PLANS
  - 1 = Patient is not on hemodialysis and there are no plans to cannulate the study fistula in the next post surgery month (use DCC provided visit schedule)
  - 2 = Patient is on hemodialysis and there are no plans to cannulate the study fistula in the next post surgery month (use DCC provided visit schedule)
  - 3 = Patient is not on hemodialysis and **there are plans for first cannulation** in the next post surgery month (use DCC provided visit schedule)
  - 4 = Patient is on hemodialysis and **there are plans for first cannulation** in the next post surgery month (use DCC provided visit schedule)
  - 5 = The study fistula is already being used routinely (use code for use with either one or two needles)
  - 6 = Patient is on peritoneal dialysis and there are no plans to cannulate the study fistula in the next post surgery month (use DCC provided visit schedule)
  - 7 = Patient is on peritoneal dialysis and there **are plans to cannulate** the study fistula in the next post surgery month (use DCC provided visit schedule)
  - 9 = It is unknown whether there are plans to cannulate the study fistula in the next post surgery month (use DCC provided visit schedule)

*If first cannulation will be soon, check on this patient at least once a week. If this first cannulation is likely to be done between 10 and 26 weeks after the study fistula creation surgery, schedule a precannulation ultrasound right before the first cannulation attempt. Complete Cannulation Form 302 as soon as cannulation is attempted.*

**Information Source**

- 24. How data on this form were obtained (respond 0=no, 1=yes)
  - a. Talked to patient or family/caregiver in person? .....IN\_PERSON
  - b. Talked to patient or family/caregiver by phone? ..... PHONE
  - c. Talked to a member of the surgery team? ..... SURG\_TEAM
  - d. Talked to staff at current/planned/future dialysis unit? ..... DIAL\_UNIT
  - e. Reviewed medical records? ..... RECORDS\_REV
  - f. Talked to the nephrology office practice including residents, fellows and physician extenders (not at the dialysis unit)? ..... NEPHR\_OFFICE

**Transplant Status**

- 25. a. Did the patient receive a transplant since the last monthly Form 300? (0=no, 1=yes)..... TRANSPLANT
- b. If yes, what was the date of the transplant? (mm/dd/yyyy) .....TRANSPLANT\_DT  
*(If yes, follow the same ultrasound schedule for the patient as you would, even if no transplant was done.)*
- 200. Date this form completed (mm/dd/yyyy) ..... COMP\_DT
- 201. Username of person completing/reviewing completeness of this form.....COMP\_USER

**Clinical Center Use Only**

Date Form Entered (mm/dd/yyyy) \_\_\_\_/\_\_\_\_/\_\_\_\_ ENTER\_DT

Username of person entering this form \_\_\_\_\_ ENTER\_USER