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).

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