F422

Hemodialysis Fistula Maturation Study (HFM/MANVAS Studies)
Study Fistula: Access Event Form (Form # 422)

- Fill this form out for **each** incident of thrombosis.

- Fill this form out only once for an isolated occurrence or the start of a series of chronic occurrences of the following conditions: access-related hand ischemia, infiltration, AVF bleeding, AVF infection, pseudoaneurysm/aneurysm, non-infectious fluid collection, or ipsilateral arm edema. In the case of infiltration, enter each incident of infiltration that requires a new needle placement, interruption of dialysis or interruption of study fistula use.

1. Identification Number PID   2. Alphacode AC   3. Visit Number VIST   4. Date event became known to study team: mm/dd/yyyy VIST_DT

5. Did any event reported on this form lead to abandonment of the study fistula? (0=no, 1=yes) ...... ABANDONMENT
   Note: If yes, please fill out Study Access Abandonment Form 426

6. Month/year this event was first reported/noted (mm/yyyy) ....FIRST_RPT_DT

What was the event?

7. a. Thrombosis (0=no, 1=yes) .... THROMBOSIS

   b. If q. 7a=yes, thrombosis date (mm/dd/yyyy) .... THROMBOSIS_DT

   c. If q. 7a=yes, was a repair attempted? (0=no, 1=yes)....................................REPAIR_ATTEMPT
      Note: If yes, please fill out Study Access Intervention Form 423

8. Access-related hand ischemia .... HAND_ISCHEMIA
   0=no, 1=yes requiring intervention, 2=yes, but not severe enough to require intervention at this time
   Note: If yes, please fill out Study Access Intervention Form 423

9. a. Infiltration (0=no, 1=yes) ....INFILTRATION

   b. If q. 9a=yes, did infiltration lead to inability to use the study fistula for treatment? ...... STOP_USAGE
      0=no,
      1=yes, leading to inability to use the study fistula for that one treatment,
      2=yes, leading to inability to use the study fistula for more than one treatment

   c. If q. 9a=yes, did it require an endovascular or surgical intervention? (0=no, 1=yes)...... INFILTRATION_INTERVENTION
      Note: If q. 9c = yes, please fill out Study Access Intervention Form 423

10. a. AVF bleeding (0=no, 1=yes).. BLEEDING

    b. If q. 10a = yes, was therapy required? ....BLD_THERAPY
       0=none,
       1=medical therapy only,
       2=surgical or endovascular intervention
       Note: If 10b = 2, please fill out Study Access Intervention Form 423

11. a.   AVF infection (0=no, 1=yes) .... INFECTION

    b.   If q. 11a=yes, was this:
        b1.   endovascular infection (0=no, 1=yes) .... ENDOVASC_INF
        b2.   overlying cellulitis or wound infection (0=no, 1=yes) .... CELLULITIS
        b3.   infectious fluid collection (0=no, 1=yes).. INF_FLUID

    c.   If q. 11a=yes, did the patient develop:
        c1.   bacteremia (0=no, 1=yes) .... BACTEREMIA
        c2.   endocarditis (0=no, 1=yes) .... ENDOCARDITIS
        c3.   osteomyelitis (0=no, 1=yes) .... OSTEOMYELITIS
        c4.   septic arthritis (septic joint) (0=no, 1=yes).. SEPTIC_ARTH
        c5.   septic emboli (0=no, 1=yes) .... SEPTIC_EMBO
        c6.   other systemic infection (0=no, 1=yes) .... SYSTEMIC_OTH

    d.   If q. 11a=yes, did the patient require surgical intervention? (0=no, 1=yes)........ INFECTION_INTERVENTION
    Note: If yes, please fill out Study Access Intervention Form 423

12. Pseudoaneurysm/aneurysm ....ANEURYSM
    0=no or not so much as to require intervention,
    1=yes, requiring intervention

    Note: If yes, please fill out Study Access Intervention Form 423

13. Non-infectious fluid collection ....FLUID
    0=no or not so much as to require intervention,
    1=yes, requiring intervention

    Note: If yes, please fill out Study Access Intervention Form 423

14. Ipsilateral arm edema (occurring or persisting more than two weeks after surgery)...........EDEMA
    0=no
    1=yes, persistent and requiring intervention
    2=yes, but not requiring intervention at this time

    Note: If yes, please fill out Study Access Intervention Form 423

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