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..... __ __ __ __ __ __
2. Patient Name Code ..... __ __ __ __
3. Date of bleeding episode..... __ __ /__ __ /__ __ __ __
4. Was this associated with an outpatient visit? (0=no, 1=yes)..... __
5. If yes, date of visit..... __ __ / __ __ / __ __ __ __
6. Was this associated with a hospitalization? (0=no, 1=yes) ..... __
7. If yes, date of admission ..... __ __ / __ __ / __ __ __ __
   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)..... __
9. Was emergency surgery required? (0=no, 1=yes) ..... __
10. Was this a fatal bleed? (0=no, 1=yes)..... __

11. If yes, date of death..... __ __ / __ __ / __ __ __ __

    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) ..... __

    Note: If you answered YES, you may need to complete item 35 on page 2.

13. Vitreous hemorrhage (0=no, 1=yes)..... __
    (Does not include conjunctival bleeding.)
14. Was there a sustained loss of vision? (0=no, 1=yes)..... __
15. GI bleeding? (0=no, 1=yes)..... __
16. Symptomatic intracranial bleeding? (0=no, 1=yes)..... __
17. If 16=Yes, confirmed by imaging study or autopsy? (0=no, 1=yes, 9=unknown)..... __
18. Pulmonary bleeding? (0=no, 1=yes)..... __
19. Intra-articular hemorrhage? (0=no, 1=yes)..... __
20. Retroperitoneal bleeding? (0=no, 1=yes) ..... __
21. Other significant bleeding? (0=no, 1=yes) ..... __
22. If 21=Yes, give the site of bleeding:..... _____
23. Transfusion? (0=no, 1=yes)..... __

24. a. If 23=Yes, where was the transfusion done? .....__
    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 .....__ __ __ __

    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).....__

26. Number of units .....__ __

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

28. Number of units .....__ __

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

    (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).....__ __. __

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

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

33. Minimum hemoglobin during the event .....__ __. __

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

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

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:

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

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 ..... __ __ / __ __ / __ __ __ __

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

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? .....__

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? .....__

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).....__

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

Clinical Center Use Only

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

Person Entering this Form_____