

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 Form 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)_

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- 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

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