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
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)

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

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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?
	 Not related to the study drug. 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. Possibly related to the study drug. 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. Definitely related to the study drug 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?
	 Mild - awareness of the sign or symptom, but easily tolerated Moderate - enough discomfort to interfere with usual activity Severe - incapacitating, with inability to do usual work or activity
41.	Did the event lead to permanent disability? (0 = no, 1 = yes)
201. 202.	Date this form completed
	Clinical Center Use Only
	Date Form Entered//
	Person Entering this Form