

DAC Study Form 365 – Life Threatening Event Form

This form should be completed for all patients who have a life threatening adverse experience while they are taking the study drug. This form should NOT be completed if the event is already described on a hospitalization or a bleeding form.

1. Patient Identification Number..... _ _ _ _ _
2. Name code _ _ _ _ _
3. Date of the event _ _ / _ _ / _ _ _ _
4. Describe what happened.

5. What is the current thought of the Principal Investigator regarding whether this event 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 is not randomized

6. If the event was definitely, probably or possibly related to the study medication (i.e. Q5 = 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.

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

Clinical Center Use Only

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

Person Entering this Form_____