

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.

DAC Study Form 365 – Life Threatening Event Form

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 _____