

## DAC Study Form 364 – Persistent Disability/Incapacity Form

This form should be completed for all patients who experience persistent disability/incapacity while they are taking the study drug. The general definition is that if the patient has to change work or adapt his/her work or requires new assistance for the performance of activities of daily living for a period of more than three months (giving time for rehab treatment to be done), then there is a persistent and significant disability. This form should NOT be completed if the event is already described on a hospitalization 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.

3 = Expected and accurately described in the informed consent.

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7. 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

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 _____