DAC Study Form 366 – Birth Defect Event Form

This form should be completed for all patients who become natural parents of children with birth defects while they are taking the study medication.

1. Patient Identification Number..... __ __ __ __ __ __
2. Name code .....__ __ __ __
3. Date of the child birth ..... __ __ / __ __ / __ __ __ __
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.

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 .....__ __ __ __ __ __ __ __

Clinical Center Use Only

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

Person Entering this Form_____