

Site Number:
Date of Report:
Person Completing Form:

Participant ID:
Participant Letters:

Complete this form upon confirmation that a study participant is pregnant, regardless of assigned treatment group. No further study medication should be given.

Additional form(s) that need to be completed:
Adverse Event Report Form
Pregnancy Outcome Report Form (when pregnancy has ended)

A. PREGNANCY INFORMATION

1. Date of positive pregnancy test:

____ / ____ / ____
DAY MONTH YEAR

2. Date of last menstrual cycle:

____ / ____ / ____
DAY MONTH YEAR

3. Estimated date of delivery:

____ / ____ / ____
DAY MONTH YEAR

4. Is the participant planning on carrying the pregnancy to term?

Yes No Unknown

5. Is the participant willing to continue with future follow-up visits?

Yes No Unknown

6. Has the participant's obstetric care provider been informed of her participation in this study?

Yes No Unknown

B. PREGNANCY HISTORY

1. Record total number of prior pregnancies (not including this one):

 unknown

2. Has the participant ever had a pregnancy complication?

Yes No Unknown

If YES,

a. Has the participant ever had a miscarriage?

Yes No Unknown

b. Has the participant ever had a pregnancy that resulted in a stillbirth?

Yes No Unknown

c. Has the participant ever had a pregnancy result in neonatal death?

Yes No Unknown

d. Has the participant ever had a pre-term delivery (< 37 gestational weeks)?

Yes No Unknown

e. Has the participant ever had a post-term delivery (> 42 gestational weeks)?

Yes No Unknown