

Site Number: _____ Screening ID: _____ - ____ First 3 Letters of First Name: _____

Complete this form upon confirmation that a study participant is pregnant, regardless of assigned treatment group. Coded study medication *must* be stopped immediately.

Additional form(s) that need to be completed:

- Adverse Event Report Form (MMF07)
- Pregnancy Outcome Report Form (MMF09R)*
- Medication Withdrawal Form (MMF08W)
- * When pregnancy has ended

A. REPORT INFORMATION

Pregnancy Identification Number: **## ##**

1. Report Date:

____ / ____ / ____
MM DD YYYY

2. Last attended study visit prior to the confirmed pregnancy:

- | | | | |
|--|--|---|---|
| <input type="checkbox"/> ₃ Week 1 | <input type="checkbox"/> ₇ Month 2 | <input type="checkbox"/> ₁₇ Month 12 | <input type="checkbox"/> ₂₉ Month 24 |
| <input type="checkbox"/> ₄ Week 2 | <input type="checkbox"/> ₈ Month 3 | <input type="checkbox"/> ₂₀ Month 15 | |
| <input type="checkbox"/> ₅ Week 3 | <input type="checkbox"/> ₁₁ Month 6 | <input type="checkbox"/> ₂₃ Month 18 | |
| <input type="checkbox"/> ₆ Week 4 | <input type="checkbox"/> ₁₄ Month 9 | <input type="checkbox"/> ₂₆ Month 21 | |

B. PREGNANCY INFORMATION

1. Date of positive pregnancy test:

____ / ____ / ____
MM DD YYYY

2. Date of last menstrual cycle:

____ / ____ / ____
MM DD YYYY

3. Estimated date of delivery:

____ / ____ / ____
MM DD YYYY

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

Y N

5. Has the coded study medication been stopped?

Y N

IF YES, a Medication Withdrawal Form (MMF08W) must be completed.

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

Y N

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

Y N

C. PREGNANCY HISTORY

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

2. Has the participant ever experienced a complication of pregnancy?

Y N

IF YES,

a. Has the participant ever experienced a spontaneous miscarriage?

Y N

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

Y N

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

Y N

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

Y N

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

Y N

Initials (first, middle, last) of person completing this form:

F M L

Date form completed:

____ / ____ / ____
MM DD YYYY

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*