

Site Number: _____ Participant ID: _____ Participant Letters: _____

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

If participant is male:
Complete this form upon confirmation that a study participant's partner is pregnant, regardless of assigned treatment group. Study medication can continue to be dispensed.

A. PREGNANCY INFORMATION

1. Date of positive pregnancy test: * / /
DAY MONTH YEAR
 Unknown
2. Date of last menstrual cycle: * / /
DAY MONTH YEAR
 Unknown
3. Estimated date of delivery: * / /
DAY MONTH YEAR
 Unknown
4. Is the participant or partner 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 or partner'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 or partner ever had a pregnancy complication? * Yes No Unknown
 - If YES,
 - a. Has the participant or partner ever had a miscarriage? * Yes No Unknown
 - b. Has the participant or partner ever had a pregnancy that resulted in a stillbirth? * Yes No Unknown
 - c. Has the participant or partner ever had a pregnancy result in neonatal death? * Yes No Unknown
 - d. Has the participant or partner ever had a pre-term delivery (< 37 gestational weeks)? * Yes No Unknown
 - e. Has the participant or partner ever had a post-term delivery (> 42 gestational weeks)? * Yes No Unknown