## To be completed by female participants/subjects only.

1. Date pregnancy information obtained:
2. Is the participant/subject pregnant?

Yes No (Skip to Q8) Unknown (Skip to Q8)

## Current Pregnancy

1. Was birth control being used?

Yes No Unknown

* 1. If Yes, indicate all forms of contraception used (choose all that apply):

Oral contraceptives–combined pill (“the pill”)

Oral contraceptives–progestin-only pill (“mini-pill”)

Transdermal patch (i.e., Ortho Evra)

Shot/injection (i.e., Depo-Provera)

Vaginal ring (i.e., NuvaRing)

Implantable devices with hormone (i.e., ParaGuard, Mirena)

Abstinence

None of these

* 1. Last date birth control used:

1. Date of last menstrual period:
2. Date pregnancy confirmed:
3. Estimated delivery date (EDD):
   1. Was the EDD based on an ultrasound?

Yes No Unknown

1. Was prenatal testing performed?

Yes No Unknown

* 1. If Yes, please complete the following questions regarding prenatal testing:

1: Pregnancy Information Table

| Prenatal Test | Date(s) of Testing | Results of Test | Comments |
| --- | --- | --- | --- |
| Ultrasound |  |  |  |
| Amniocentesis |  |  |  |
| Screening for neural tube defects |  |  |  |
| Screening for gestational diabetes before or at 28 weeks |  |  |  |
| Screening for asymptomatic bacteriuria before or at 16 weeks gestation |  |  |  |
| Hepatitis B specific antigen screening at first visit |  |  |  |
| HIV screening at first visit |  |  |  |
| Group B streptococcus screening (GBS) at 35 to 37 weeks |  |  |  |
| Maternal serum alpha fetoprotein |  |  |  |
| Other, specify: |  |  |  |

1. Did/Has the participant/subject experienced any complications during this pregnancy?

Yes No Unknown

* 1. If Yes, specify:

1. Did/Has the participant/subject experienced any infections or illnesses during this pregnancy?

Yes No Unknown

* 1. If Yes, specify:

## Pregnancy History

1. Has the participant/subject ever been pregnant?

Yes No (STOP) Unknown (STOP)

1. Prior pregnancy (both to term and not to term):
   1. Number of prior pregnancies:
   2. Full-term (≥ 37 weeks) births:
   3. Pre-term (< 37 weeks) births:
2. Did a birth defect occur in any previous pregnancy?

Yes No Unknown

* 1. If Yes, specify birth defect:

1. Did a miscarriage (≤ 20 weeks) or stillbirth (> 20 weeks) occur in any previous pregnancy?

Yes No Unknown

* 1. If Yes, in what week of pregnancy did the miscarriage or stillbirth occur? week(s):

1. Has the participant/subject ever had exposure to any of the following during pregnancy?

Concurrent medication

Exposure to X-ray

Teratogens

Alcohol

Smoking

Other specify:

## General Instructions

This case report form (CRF) contains data elements related to pregnancy and should only be completed by females. It is important to be very explicit and detailed when completing this form to ensure the relevant and accurate data is collected. All items on this CRF are Exploratory.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Date/Time–Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times (http://www.iso.org/iso/home.html). The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).
* Is this participant/subject pregnant?–No additional instructions
* Was birth control being used?
* If Yes, indicate all forms of contraception used/last date used–Choose all that apply
* Date of last menstrual period–No additional instructions
* Date pregnancy confirmed–No additional instructions
* Estimated delivery date (EDD)/ Was the EDD based on an ultrasound?–No additional instructions
* Was prenatal testing performed?/If Yes, please complete the following questions regarding prenatal testing–No additional instructions
* Did/Has the participant/subject experienced any complications during this pregnancy?–No additional instructions
* Did/Has the participant/subject experienced any infections or illnesses during this pregnancy?–No additional instructions
* Has the participant/subject ever been pregnant?–No additional instructions
* Prior pregnancy–Complete information for both to term and not to term
* Did a birth defect occur in any previous pregnancy?–No additional instructions
* Did a miscarriage (≤ 20 weeks) or stillbirth (> 20 weeks) occur in any previous
* pregnancy?–No additional instructions
  + If Yes, in what week of pregnancy did the miscarriage or stillbirth occur?–Record in week(s)
* Has the participant/subject ever had exposure to any of the following during pregnancy?–No additional instructions