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

1. Date pregnancy outcome obtained:
2. Was the outcome of the participant’s/subject’s most recent pregnancy a live born infant?

[ ]  Yes (Skip to Q2) [ ]  No (Complete Q1a–c ONLY) [ ]  Unknown (STOP, you are finished)

If No, complete the following and then STOP, you are finished

* 1. Pregnancy outcome:

[ ]  Elective termination [ ]  –Spontaneous abortion [ ]  Fetal death/stillbirth [ ]  Unknown [ ]  Therapeutic abortion or elective termination [ ]  Miscarriage [ ]  Still birth [ ]  Currently pregnant [ ]  Live birth

* 1. Outcome date:
	2. Was the fetus normal?

[ ]  Yes [ ]  No, describe: [ ]  Unknown

1. Delivery type? (Choose only one)
	1. [ ]  Spontaneous
	2. [ ]  Induced; specify reason: (Choose all that apply)

[ ]  Hemorrhage and Placental Complications

[ ]  Hypertension, Preeclampsia or Eclampsia

[ ]  Rupture of Membranes–Premature, Prolonged

[ ]  Maternal Conditions Complicating Pregnancy/Delivery

[ ]  Fetal Conditions Complicating Pregnancy/Delivery

[ ]  Malposition and Malpresentation of Fetus

[ ]  Late Pregnancy

[ ]  Prior Uterine Surgery

[ ]  Other, specify:

[ ]  Unknown

1. Delivery route? (Choose only one)
	1. [ ]  Vaginal
	2. [ ]  Cesarean section, complete the following:
		1. Specify reason:
		2. Timing of cesarean:

[ ]  Emergency [ ]  Elective

* 1. [ ]  Unknown
1. Delivery modality type:

[ ] Breech [ ] Cephalic [ ] Unknown

1. Did the participant/subject experience any complications during labor/delivery?

[ ]  Yes [ ]  No [ ]  Unknown

If Yes, specify:

1. Did the participant/subject require tocolytic agents during preterm labor?

[ ]  Yes [ ]  No [ ]  Unknown

If Yes, specify:

## Details of Most Recent Live Birth

1. Birth date:
2. Birth sex:

[ ]  Male [ ]  Female [ ]  Unknown

1. Birth weight:

[ ]  ounces [ ]  grams

1. Birth length:

[ ]  in [ ]  cm

1. Was the child delivered full–term?

[ ]  Yes [ ]  No [ ]  Unknown

1. Indicate gestational age GA (weeks):
2. 5–minute APGAR score:
3. 10–minute APGAR score:
4. Mother’s weight at the time of birth:

[ ]  lb [ ]  kg

1. Any abnormal fetal diagnostic tests performed during pregnancy?

[ ]  Yes [ ]  No [ ]  Unknown

If Yes, complete the dates of testing and the test results:

1: Pregnancy Outcome Table

| Date(s) of Testing  | Results of Fetal Diagnostic Testing |
| --- | --- |
|  | Results: |
|  | Results: |
|  | Results: |

1. Were there any congenital anomalies?

[ ]  Yes [ ]  No [ ]  Unknown

If Yes, specify:

(Complete an adverse event form if the participant/subject was enrolled in the study at the time of the birth.)

1. Were there other newborn complications?

[ ]  Yes [ ]  No [ ]  Unknown

If Yes, specify:

1. Did the newborn experience any abnormalities of placenta or umbilical cord?

[ ]  Yes [ ]  No [ ]  Unknown

If Yes, specify:

## General Instructions

This case report form (CRF) contains data elements related to pregnancy outcome 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 ( [ISO website](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.).
* Pregnancy most recent live born infant – If 'Yes' is answered, skip to question 2. If 'No' is answered, then complete questions 1a–1c only. If 'Unknown' is answered, then Stop.
* Pregnancy outcome type – –Choose one. Answer for the female participant/subject only (not the partner). Only answered if No was answered for "Was the outcome of the participant's/subject's most recent pregnancy a live born infant?" Complete this question, outcome date, and was the fetus normal and then stop completing the form.
* Delivery or pregnancy termination date and time – Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times ( [ISO website](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.).
* Delivery by cesarean reason – Answer only if Cesarean was the delivery route.
* Date and time of child birth –– Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times ( [ISO website](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.).
* APGAR five minute score – Record the score (0 – 10 points, inclusive)
* APGAR ten minute score – –Record the score (0 – 10 points, inclusive)