



MTN-011 (135)

PO-1 (442)

Visit Code

Outcome Number

Participant ID

- - - 0
 Protocol PTID Chk Cohort

Pregnancy Outcome

Outcome unobtainable.
Go to page 2.

If Outcome Number recorded above is 2 or greater, go to item 2.

1. How many pregnancy outcomes resulted from this reported pregnancy?

2. Outcome Date:
 dd MMM yy

3. Place of delivery/outcome: home unknown
 hospital other, specify: _____
 clinic

4. Specify outcome *Mark only one.*

Items 4a-4f: If the pregnancy or outcome was associated with maternal complications or symptoms that would otherwise be reported as an AE, report these on an AE Log. Complete an EAE Reporting form, if applicable.

- 4a. full term live birth (≥ 37 weeks)
- 4b. premature term live birth (< 37 weeks)
- 4c. stillbirth/intrauterine fetal demise (≥ 20 weeks)
- 4d. spontaneous abortion (< 20 weeks)
- 4e. ectopic pregnancy
- 4f. therapeutic/elective abortion
- 4g. other, specify: _____

4a1. Method:
 C-section
 standard vaginal
 operative vaginal
If full term live birth, go to item 6.

5. Provide a brief narrative of the circumstances: _____

6. Were there any complications related to the pregnancy outcome? *yes* *no* *If no, go to item 7 on page 2.*

6a. Delivery-related complications: *Mark "none" or all that apply.*

- 6a1. none
- 6a2. intrapartum hemorrhage
- 6a3. postpartum hemorrhage
- 6a4. non-reassuring fetal status
- 6a5. chorioamnionitis
- 6a6. other, specify: _____

6b. Non-delivery-related complications: *Mark "none" or all that apply.*

- 6b1. none
- 6b2. hypertensive disorders of pregnancy
- 6b3. gestational diabetes
- 6b4. other, specify: _____

Pregnancy Outcome (PO-1)	
Purpose:	This form is used to report pregnancy outcome information for a pregnancy reported post-enrollment. Complete this form when information about a pregnancy outcome becomes available to study staff or when it is determined that pregnancy outcome is unobtainable.
General Information/ Instructions:	A Pregnancy Outcome form is required for each Pregnancy Report form that is completed for a participant.
Item-specific Instructions:	
Visit Code:	Record the visit code of the participant's corresponding Pregnancy Report form.
Outcome Number:	A pregnancy outcome can be an infant or fetus. The conception of twins, for example, will result in reporting of two outcomes. For a pregnancy resulting in one outcome, record "1" here. For a pregnancy with multiple outcomes, record the outcome number corresponding to the outcome data recorded on the form.
Outcome unobtainable:	If it is determined that an outcome is unobtainable (i.e., the participant refuses further contact), mark the "Outcome unobtainable" box at the top of the page and fax both pages of this form to SCHARP DataFax.
Item 1:	If the pregnancy results in two or more outcomes, complete a Pregnancy Outcome form for each outcome. Each Pregnancy Outcome form will have the same visit code, but different outcome numbers (for example, one Pregnancy Outcome form will have an outcome number =1 and the second form will have an outcome number =2, and so on).
Item 4:	If the outcome is spontaneous fetal death, still birth, spontaneous abortion, therapeutic/elective abortion, or ectopic pregnancy, the outcome itself is not an adverse experience (AE). If a therapeutic/elective abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Experience (AE) Log, if prior to termination, with "procedure/surgery" marked under item 7, "Treatment." If there are any maternal complications as a result of the pregnancy outcome, refer to the protocol, Study-specific Procedures (SSP) manual, and <i>Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2</i> for guidance on AE and expedited AE reporting requirements.
Item 4a1:	"Operative vaginal" delivery includes delivery with forceps and/or vacuum.
Item 5:	Include information on medical conditions associated with the outcome, including early contractions, rupture of membranes, and cramping, along with actions taken as a result of these conditions.



MTN-011 (135)

PO-2 (443)

Visit Code

Outcome Number

Participant ID

- - - 0
 Protocol PTID Chk Cohort

Pregnancy Outcome

No data recorded on this page.

7. Were any fetal/infant congenital anomalies identified? *yes* *no* *unknown* → *If no or unknown, go to the statement above item 8.*

7a. Congenital anomalies identified *Mark all that apply. Complete AE Log and EAE Reporting form.*

<input type="checkbox"/> central nervous system, cranio-facial	<input type="checkbox"/> musculoskeletal/extremities	<input type="checkbox"/> cranio-facial (structural)
<input type="checkbox"/> central nervous system, spinal	<input type="checkbox"/> physical defect	<input type="checkbox"/> hematologic
<input type="checkbox"/> cardiovascular	<input type="checkbox"/> skin	<input type="checkbox"/> infectious
<input type="checkbox"/> renal	<input type="checkbox"/> genitourinary	<input type="checkbox"/> endocrine/metabolic
<input type="checkbox"/> gastrointestinal	<input type="checkbox"/> chromosomal	<input type="checkbox"/> other
<input type="checkbox"/> pulmonary		

7b. Describe the congenital anomaly/defect: _____

Complete items 8–13 for live births only. Otherwise, end of form.

8. Infant gender: *male* *female*

9. Infant birth weight: kg OR *unavailable*

10. Infant birth length: cm OR *unavailable*

11. Infant birth head circumference: cm OR *unavailable*

12. Infant birth abdominal circumference: cm OR *unavailable*

13. Infant gestational age by examination: *weeks* *days* OR *unavailable* → *If unavailable, end of form.*

13a. Method used to determine gestational age: *Ballard* *Dubowitz* *other, specify:* _____

Pregnancy Outcome (PO-2)	
Item-specific Instructions:	
Visit Code:	Record the visit code that is present on page 1 of this form.
No data recorded on this page:	This box should only be marked if the "outcome unobtainable" box is marked on page 1. This box must only be marked if all items on the page are left blank.
Outcome Number:	Record the outcome number that is present on page 1 of this form.
Item 7a:	If a woman on study has a baby with a congenital anomaly, report the event on an Adverse Experience (AE) Log, if prior to termination. On the AE Log, record "Congenital Anomaly in Offspring" on Item 1, record the Outcome Date as the Onset Date, and record the specific anomaly on the Comments line. Also submit an Expedited Adverse Event (EAE) Reporting form.
Items 9-12:	Record the information as documented in medical records. If no medical record documentation of the information is available, complete this item based on participant report. Mark the "unavailable" box if no medical record documentation is available and the participant does not know the information.
Item 13:	Record the infant's gestational age at birth. If the infant's gestational age is determined using the Ballard method, please record "0" in the "days" box. Mark the "unavailable" box if no medical record documentation of the infant's gestational age is available.