

Site Number:
Date of Visit:
Person Completing Form:

Participant ID:
Participant Letters:

Complete this form when the outcome of an active pregnancy becomes known. Complete this form for all participants that become pregnant during the course of the trial.

A. PREGNANCY OUTCOME INFORMATION

1. Is the outcome of the pregnancy unknown due to loss of participant to follow-up? Yes No

If YES, **STOP HERE**

2. Date pregnancy ended: / /
DAY MONTH YEAR

3. Was the pregnancy terminated as a result of an induced abortion? Yes No Unknown

If YES,

a. Was the reason for the abortion medically indicated? Yes No Unknown

If YES, **Complete Adverse Event Report Form**

1) Specify reason:

4. Did the pregnancy result in a miscarriage? **Complete Adverse Event Report Form** Yes No Unknown

5. Did the pregnancy result in a live birth or multiple live births? Yes No Unknown

6. Did the pregnancy result in a stillbirth? Yes No Unknown

If YES, **Complete Adverse Event Report Form**

a. Did the stillbirth have any congenital malformations? Yes No Unknown

If YES,

1) Specify:

b. Did the stillbirth have any other complications? Yes No Unknown

If YES,

1) Specify:

7. Record number of infants (both living and deceased) the birth resulted in: unknown

8. Were there any complications during the delivery? Yes No Unknown

9. Was an HbA1c measured at any time during the pregnancy? Yes No Unknown

If YES,

a. Record HbA1c: % unknown

b. Date measured: / /
DAY MONTH YEAR

10. Is the participant currently breastfeeding? Yes No Unknown

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Complete Section B to record the details of any live birth(s).

B. INFANT INFORMATION

	0 1	0 2	0 3
1. Birth Order:			
2. Sex (M/F):	<input type="radio"/> M <input type="radio"/> F	<input type="radio"/> M <input type="radio"/> F	<input type="radio"/> M <input type="radio"/> F
3. Gestational age:	___ wks <input type="checkbox"/> unknown	___ wks <input type="checkbox"/> unknown	___ wks <input type="checkbox"/> unknown
4. Birth weight:	___ gm <input type="checkbox"/> unknown OR ___ lbs ___ oz <input type="checkbox"/> unknown	___ gm <input type="checkbox"/> unknown OR ___ lbs ___ oz <input type="checkbox"/> unknown	___ gm <input type="checkbox"/> unknown OR ___ lbs ___ oz <input type="checkbox"/> unknown
5. One minute APGAR score:	___ <input type="checkbox"/> unknown	___ <input type="checkbox"/> unknown	___ <input type="checkbox"/> unknown
6. Five minute APGAR score:	___ <input type="checkbox"/> unknown	___ <input type="checkbox"/> unknown	___ <input type="checkbox"/> unknown
7. Was the infant born with any congenital malformations?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
a. If YES*, specify:			
8. Was the infant born with other complications?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
a. If YES*, specify:			
9. Was the infant admitted to the Neonatal Intensive Care Unit (NICU) at any time*?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
10. Was the infant discharged from the hospital alive?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
If YES,			
a. Date discharged:	___/___/___ DAY MONTH YEAR	___/___/___ DAY MONTH YEAR	___/___/___ DAY MONTH YEAR
If NO*,			
b. Date of death:	___/___/___ DAY MONTH YEAR	___/___/___ DAY MONTH YEAR	___/___/___ DAY MONTH YEAR
c. Specify cause of death:			

* Requires completion of an Adverse Event Report Form