Site Number: Participant ID:
Date of Visit: Participant Letters:
Person Completing Form:

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

Site Number: Participant ID:
Date of Visit: Participant Letters:
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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):	○ M ○ F	○ M ○ F	○ M ○ F
3. Gestational age:	__ __ wks □ unknown	__ __ wks □ unknown	__ __ wks □ unknown
4. Birth weight:	__ __ __ __gm □ unknown OR __ __ lbs __ __ oz □ unknown	__ __ __ __ gm □ unknown OR __ __ lbs __ __ oz □ unknown	__ __ __ __ gm □ unknown OR __ __ lbs __ __ oz □ unknown
5. One minute APGAR score:	__ __ □ unknown	__ __ □ unknown	__ __ □ unknown
6. Five minute APGAR score:	__ __ □ unknown	__ __ □ unknown	__ __ □ unknown
7 Was the infant born with any congenital malformations?	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown
a. If YES*, specify:			
8 Was the infant born with other complications?	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown
a. If YES*, specify:			
9.Was the infant admitted to the Neonatal Intensive Care Unit (NICU) at any time*?	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown
10 Was the infant discharged from the hospital alive?	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ 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