

Site No: _____ Screening ID: _____ - ____ First 3 Letters of First Name: _____

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. Indicate the Pregnancy Identification Number: _____

The *Pregnancy Identification Number* is located on the subject's initial Pregnancy Confirmation Form (MMF09)

2. Is the outcome of the pregnancy unknown due to loss of participant to follow-up? Y N

IF YES, STOP HERE

3. Date pregnancy ended: _____ / _____ / _____
MM DD YYYY

4. Was the pregnancy terminated as a result of an induced abortion? Y N

IF YES,

a. Was the reason for the abortion medically indicated? Y N

IF YES*,

1. Specify reason: _____

5. Did the pregnancy result in a spontaneous miscarriage*? Y N

6. Did the pregnancy result in a live birth or multiple live births? Y N

7. Did the pregnancy result in a stillbirth? Y N

IF YES*,

a. Did the stillbirth have any congenital malformations? Y N

IF YES,

1. Specify: _____

b. Did the stillbirth have any other complications? Y N

IF YES,

1. Specify: _____

8. Indicate number of infants (both living and deceased) the birth resulted in: _____

9. Were there any complications during the delivery? Y N

10. Was an HbA1c measured at any time during the pregnancy? Y N

IF YES,

a. Indicate HbA1c: _____ %

b. Date measured: _____ / _____ / _____
MM DD YYYY

11. Is the participant currently breastfeeding? Y N

* Requires completion of an Adverse Event Report Form (MMF07)

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

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B. INFANT INFORMATION

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

1. Indicate the Pregnancy Identification Number: _____

2. Birth Order:

3. Indicate sex (M/F):

M F

M F

M F

4. Indicate gestational age:

____ wks

____ wks

____ wks

5. Indicate birth weight:

_____ gm

_____ gm

_____ gm

OR

OR

OR

____ lbs ____ oz

____ lbs ____ oz

____ lbs ____ oz

6. **1 minute** APGAR score:

7. **5 minute** APGAR score:

8. Was the infant born with any congenital malformations?

Y N

Y N

Y N

a. IF YES*, specify:

9. Was the infant born with other complications?

Y N

Y N

Y N

a. IF YES*, specify:

10. Was the infant admitted to the Neonatal Intensive Care Unit (NICU) at any time*?

Y N

Y N

Y N

11. Was the infant discharged from the hospital alive?

Y N

Y N

Y N

IF YES,

a. Date discharged:

____/____/_____
MM DD YYYY

____/____/_____
MM DD YYYY

____/____/_____
MM DD YYYY

IF NO*,

b. Date of death:

____/____/_____
MM DD YYYY

____/____/_____
MM DD YYYY

____/____/_____
MM DD YYYY

c. Specify cause of death:

* Requires completion of an Adverse Event Report Form (MMF07)

† If more space is needed, attach additional copies of the second page of this form

Initials (first, middle, last) of person completing this form:

F M L

Date form completed:

____/____/_____
MM DD YYYY

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