DMID Protocol 21-0012

Pregnancy Follow-Up Telephone Contact Phone Log+

PTID ___ ___ ___ ___ ___ ___ ___ ___ ___

The frequency of follow-up and number of follow-up visits depends on how far along in the pregnancy the subject is when the pregnancy is initially reported, as well as the study product under investigation. At a minimum, follow-up telephone contact should be made with the subject every 12-16 weeks during the course of the pregnancy, following delivery, and at approximately one month following birth (if live birth) or one to two months following a still birth.

Date (ddMMMyyyy)	**Contact Made?**	**Name of Caller**	**Comments**	**Caller Initials and Date**
	☐ No ☐ Yes			
	☐ No ☐ Yes			
	☐ No ☐ Yes			
	☐ No ☐ Yes			
	☐ No ☐ Yes			
	☐ No ☐ Yes			
	☐ No ☐ Yes			
	☐ No ☐ Yes			
	☐ No ☐ Yes			
	☐ No ☐ Yes			
	☐ No ☐ Yes			

+ = This form does not appear in Medidata

DMID 21-0012

Script for Pregnancy Follow-Up Contact

A review is to be conducted **by telephone once every 12-16 weeks** during pregnancy, as well as after delivery and one or two months after delivery. Some information may need to be obtained from medical records or contact with the subject's physician. Site staff should:

- Confirm individual contacted is the subject or a family member, physician or other contact approved by the subject
- Identify the subject by name and association with the study
- Confirm that the subject provided consent to be contacted to collect information about herself, and agrees to continue providing information for the study, or to contact the other individual.
- For live birth, confirm the subject's consent/parental permission to collect the child's identifiable private information from:
    - the mother's delivery record and the child's medical records,
    - contact with a parent, or
    - contact with a child's primary physician.
- Explain the purpose of the call is to follow-up with the individual on the course of the pregnancy

This script/guidance may be used for telephone or in-clinic contacts with the subject.

Record answers on the Pregnancy Report, Pregnancy History, Pregnancy Outcome and Medical History Log, if appropriate.

The following questions are asked:

General *To be asked during every contact during pregnancy.*

- How are you doing?

Pregnancy Status *To be asked during every contact during pregnancy.*

- Are you still pregnant? *If No, please explain.*

Current Pregnancy Information *To be asked during the initial contact.*

- Are you expecting a single infant or twins or triplets?
- When was your last menstrual period?
- Do you know your delivery date?
    - *If Yes, provide the estimated delivery date.*
- Was your delivery date determined by ultrasound?
    - *If Yes, provide the estimated date of the ultrasound.*

Study Information *To be asked during the initial contact.*

- Are you willing to continue with the remaining scheduled study visits?
- May we contact you in the future to collect information regarding your pregnancy?

- May we speak with another family member or friend if you are not available?
- Are you willing to sign a form releasing your medical records to us? What is your obstetrician's name and phone number?

Previous Pregnancy Information *To be asked during the initial contact.*

- How many times have you been pregnant in the past (including your current pregnancy)?
- How many of your prior pregnancies resulted in a live birth?
- Of these live births, did you have any preterm births?
- What was the gestational age of these preterm births?
- Did you have any deliveries after 40 weeks of pregnancy?
- How many weeks after your due date did you deliver?
- Did any of your prior pregnancies result in stillborn births? *If Yes, how many?*
- Did any of your prior pregnancies result in spontaneous abortions or miscarriage? *If Yes, how many?*
- Have you ever had an elective abortion or therapeutic abortion? *If Yes, how many?*
- Have any of your prior pregnancies included a diagnosis of a congenital anomaly? *If Yes, please explain.*

Current Pregnancy Information *To be asked during every contact during pregnancy.*

- Are you aware of any complications of your pregnancy (for example, fever, bleeding, elevated blood pressure, blood sugar, etc)?
- Study staff should review the subject's medical record or consult the subject's primary care physician to determine the exact diagnosis. The following is a list of terms specific for pregnant women.
    - Abruptio placentae
    - Abnormal bleeding/hemorrhage
    - Anaphylaxis
    - Bacteremia
    - Chorioamnionitis
    - Coagulation disorders
    - Eclampsia
    - Endometritis
    - Fetal distress
    - Fever > 100.4 ˚F or 38.0ºC
    - Gestational diabetes
    - GBS-positive
    - Oligohydramnios
    - Placenta previa
    - Polyhydramnios

- Pre-eclampsia
- Pregnancy induced hypertension
- Preterm labor

- Have there been any other complications during the course of this pregnancy? *If Yes, please explain.*

If the subject experienced any maternal complication during this pregnancy complete the Adverse Event form even if the AE start date is outside of the AE reporting period for the study.

- What is your height and pre-pregnancy weight?
  - What date was the height and weight measured?

Pregnancy Risk Factors *To be asked during every contact during pregnancy.*

- Are you taking any new medications?
- Have there been any changes to previously reported medications that you have been taking during this pregnancy?
  If Yes, complete a Concomitant Medications form.

Reminders *To be stated during every contact during pregnancy.*

Please call us if you experience any of the following:

- Any events that are unusual or of particular concern
- Any serious events, such as a hospitalization or a major change in health status

Other *To be asked during every contact during pregnancy.*

- May I answer any questions?
- Please feel free to contact us at anytime. Do you need our phone number again?
- I will contact you again to follow-up on your pregnancy in 12-16 weeks or after the baby is born.
- Please inform us if you deliver before your expected due date.

Outcome of Pregnancy *To be asked at the contact made within 1 to 2 weeks after delivery.*

If permission has been given, medical records may need to be obtained to collect answers to the questions in this section. Answers are recorded on the Pregnancy Outcome Form. If there were ***multiple babies****, photocopy the page and complete for each baby.*

- Was there a live birth delivery?
  - If no, please provide the outcome and information you are comfortable sharing. Was the baby stillborn, or did you have a miscarriage or abortion?
  - What was the date of delivery or termination?

- What is your end-of-pregnancy weight?
    - What date was the weight measured?
- Are you aware of any complications of your pregnancy (for example, fever, bleeding, elevated blood pressure, blood sugar, etc)?
- Study staff should review the subject's medical record or consult the subject's primary care physician to determine the exact diagnosis. The following is a list of terms specific for pregnant women.
    - Abruptio placentae
    - Abnormal bleeding/hemorrhage
    - Anaphylaxis
    - Bacteremia
    - Chorioamnionitis
    - Coagulation disorders
    - Cord prolapse
    - Eclampsia
    - Emergency C-section due to fetal distress
    - Endometritis
    - Fetal distress
    - Fever > 100.4 ˚F or 38.0ºC
    - GBS-positive
    - Gestational diabetes
    - Oligohydramnios
    - Placenta previa
    - Polyhydramnios
    - Pre-eclampsia
    - Pregnancy induced hypertension
    - Preterm labor

  If Yes, complete the Adverse Event form.

- For **live birth or still birth** only:
    - Did you have a C-section?
    - Was it a boy or a girl?
    - What was the gestational age of the baby? (Weeks and days)
    - Are you aware of any complications in the baby?
        - Study staff should review the infant's medical record or consult the infant's primary care physician to determine if the baby was small, large or normal for his or her gestational age, and to determine the pH of the umbilical cord.
    - What was the birth weight of the baby?
    - What were the length of the baby at birth and the frontal occipital circumference?

  - Do you know the Apgar score for the baby at 1 and 5 minutes?
- Is there a congenital anomaly? *If Yes, please explain.*
  If Yes, complete the Adverse Event form for a Serious Adverse Event even if it is outside the AE reporting period. Additional information may be required to complete this form.
- May we contact you again in a month or so to get more information?

- For **spontaneous, elective or therapeutic abortion** only:
  - What was the gestational age of the fetus? (Weeks and days)
  - Were there any abnormalities? *If Yes, please explain.*
  - If the abortion was for therapeutic reasons, was it due to the mother or the fetus?

One-Month Follow-Up *To be asked at the contact made one month later, for **live birth** only.*
If permission has been given, medical records may need to be obtained to collect answers to the questions in this section. Answers are recorded on the Pregnancy Outcome Form.

- Was the infant diagnosed with any congenital anomalies? *If Yes, please explain.*
  If Yes, complete the Adverse Event form for a Serious Adverse Event.
- Has the infant been ill or hospitalized since birth? *If Yes, please explain.*

One or Two-Month Follow-Up *To be asked at the contact made one or two months later, for **still birth** only.*
If permission has been given, medical records may need to be obtained to collect answers to the questions in this section. Answers are recorded on the Pregnancy Outcome Form.

- Was an autopsy done?
- Was the reason for the still birth determined? *If Yes, please explain.*

DMID 21-0012 Data Collection Form

Pregnancy Report and Follow-Up (XPD)

PTID ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Date of initial report: ___ ___/___ ___ ___/___ ___ ___ ___(dd/MMM/yyyy)

Pregnancy Follow-Up – *Update as Applicable During Follow-Up*

Was follow-up contact made with the subject during the pregnancy? ☐ No ☐ Yes

If Yes, list dates that contact was made, and update the other sections of this form, as necessary.

#	Date (dd/MMM/yyyy)	+Staff Initials	#	Date (dd/MMM/yyyy)	+Staff Initials
1	___ ___/___ ___ ___/___ ___ ___ ___		5	___ ___/___ ___ ___/___ ___ ___ ___	
2	___ ___/___ ___ ___/___ ___ ___ ___		6	___ ___/___ ___ ___/___ ___ ___ ___	
3	___ ___/___ ___ ___/___ ___ ___ ___		7	___ ___/___ ___ ___/___ ___ ___ ___	
4	___ ___/___ ___ ___/___ ___ ___ ___		8	___ ___/___ ___ ___/___ ___ ___ ___	

Maternal Information – *Complete at Time of Initial Report*

Indicate the source of information: (may check Yes to more than one)

Mother: ☐ No ☐ Yes
Family member: ☐ No ☐ Yes
Physician/medical chart: ☐ No ☐ Yes
Other: ☐ No ☐ Yes, specify: _____

Pregnancy Status – *Update as Applicable During Follow-Up*

Pregnancy status:
☐ Pregnancy ongoing
☐ Outcome known
☐ Outcome unknown (subject lost to follow-up or refused to provide further information)

For known pregnancy outcomes, record pregnancy outcome data for each fetus.

Current Pregnancy Information – *Complete at Time of Initial Report*

Number of fetuses: ___

Date of last menstrual period: ___ ___/___ ___ ___/___ ___ ___ ___(dd/MMM/yyyy)

Estimated delivery date: ___ ___/___ ___ ___/___ ___ ___ ___(dd/MMM/yyyy)

How was estimated delivery date determined?
☐ Last menstrual period
☐ Ultrasound

If ultrasound, estimated date of exam: ___ ___/___ ___ ___/___ ___ ___ ___(dd/MMM/yyyy)

Pre-pregnancy weight:	Date of pre-pregnancy weight: __ __ / __ __ __ / __ __ __ __ (ddMMMyyyy) ☐ exact date ☐ day only unknown ☐ day and month unknown ☐ day, month, and year unknown	Weight units: ☐ Pounds ☐ Kilograms	Weight: ___ ___ ___ . ___

Previous Pregnancy Information – *Complete at Time of Initial Report*

Gravida (total number of pregnancies including the current pregnancy): ___ ___ ☐ Unknown

Excluding the current pregnancy, provide numbers for the following (record "0" if none):

Para events

Live births: ___ ___ ☐ Unknown

- Extremely preterm (EPT) births (< 25 weeks): ___ ___ ☐ Unknown
- Very preterm (VPT) births (25 0/7 – 31 6/7 weeks): ___ ___ ☐ Unknown
- Early preterm births (32 0/7 – 33 6/7 weeks): ___ ___ ☐ Unknown
- Late preterm births (34 0/7 – 36 6/7 weeks): ___ ___ ☐ Unknown
- Early term births (37 0/7 - 38 6/7 weeks): ___ ___ ☐ Unknown
- Full term births (39 0/7 - 40 6/7 weeks): ___ ___ ☐ Unknown
- Late term births (41 0/7 - 41 6/7 weeks): ___ ___ ☐ Unknown
- Post term births (≥ 42 0/7 weeks): ___ ___ ☐ Unknown

Stillbirths (≥20 weeks): ___ ___ ☐ Unknown

Spontaneous abortion/miscarriage (<20 weeks): ___ ___ ☐ Unknown

Elective abortions: ___ ___ ☐ Unknown

Therapeutic abortions: ___ ___ ☐ Unknown

Therapeutic abortions are defined as abortions due to medical reasons for the mother or fetus.

Any major congenital anomalies with a previous pregnancy? ☐ No ☐ Yes ☐ Unknown

If Yes, specify: _____

Current Pregnancy Information – *Update as Applicable During Follow-Up*

Did the subject experience any of the maternal complications listed below during this pregnancy? ☐ No ☐ Yes ☐ Unknown

If Yes, complete an Adverse Event/Serious Adverse Event form, as appropriate.

Abruptio placentae	Eclampsia	Oligohydramnios
Abnormal bleeding/hemorrhage	Endometritis	Placenta previa
Anaphylaxis	Fetal distress	Polyhydramnios
Bacteremia	Fever > 100.4 ˚F or 38.0ºC	Pre-eclampsia
Chorioamnionitis	Gestational diabetes	Pregnancy induced hypertension
Coagulation disorders	GBS-positive	Preterm labor

Did the subject experience any other maternal complications during this pregnancy? ☐ No ☐ Yes ☐ Unknown

If Yes, complete an Adverse Event/Serious Adverse Event form, as appropriate.

Pregnancy Risk Factors – *Update as Applicable During Follow-Up*

Has the subject taken any medications during the pregnancy (over-the-counter and prescription)? ☐ No ☐ Yes ☐ Unknown

If Yes, complete the Concomitant Medications form.

Comments: _____

_____

_____

_____

Signature: _____ Date (ddMMMyyyy): _____

Signature: _____ Date (ddMMMyyyy): _____

Signature: _____ Date (ddMMMyyyy): _____

DMID 21-0012 Data Collection Form

Pregnancy Outcome (X1D, X2D, X3D, X4D)

PTID ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Birth order Number (if singleton enter '1') ___

Pregnancy outcome (for this fetus):
- ☐ Live birth
- ☐ Spontaneous abortion/miscarriage (<20 wks)
- ☐ Still birth (≥ 20 weeks)
- ☐ Elective abortion
- ☐ Therapeutic abortion

If spontaneous abortion/miscarriage, still birth, or therapeutic abortion, complete an AE/SAE form.

Indicate the source of information: (may check Yes to more than one)

Mother:	☐ No	☐ Yes
Family member:	☐ No	☐ Yes
Physician/medical chart:	☐ No	☐ Yes
Other:	☐ No	☐ Yes, specify: _____

Maternal Outcome

Complete this section only once. If there are multiple fetuses, these data will be entered in Medidata RAVE for the first fetus only.

End of pregnancy weight:	Date of end of pregnancy weight:	Weight units:	Weight:
	__ __ / __ __ __ / __ __ __ __ (ddMMMyyyy) ☐ exact date ☐ day only unknown ☐ day and month unknown ☐ day, month, and year unknown	☐ Pounds ☐ Kilograms	___ ___ ___ . ___

Labor, Delivery, and Post-Partum Information

Complete this section only once. If there are multiple fetuses, these data will be entered in Medidata RAVE for the first fetus only.

Did the subject experience any of the maternal complications listed below during labor, delivery, or post-partum? ☐ No ☐ Yes ☐ Unknown ☐ N/A

If Yes, complete an Adverse Event/Serious Adverse Event form, as appropriate.

Abruptio placentae	Eclampsia	GBS-positive
Abnormal bleeding/hemorrhage	Emergency Cesarean section due to fetal distress	Oligohydramnios
Anaphylaxis		Placenta previa
Bacteremia	Endometritis	Polyhydramnios
Chorioamnionitis	Fetal distress	Pre-eclampsia
Coagulation disorders	Fever > 100.4 ˚F or 38.0ºC	Pregnancy induced hypertension
Cord prolapse	Gestational diabetes	Preterm labor

Did the subject experience any other maternal complications during this pregnancy? ☐ No ☐ Yes ☐ Unknown

If Yes, complete an Adverse Event/Serious Adverse Event form, as appropriate.

Complete the following sections once for each fetus.

Was there any fetal distress during labor and delivery? ☐ No ☐ Yes ☐ Unknown ☐ N/A

If Yes, complete an Adverse Event form.

Neonatal Outcome – Live Birth and Still Birth Only

Date of live birth or still birth: ___ ___/___ ___ ___/___ ___ ___ ___(dd/MMM/yyyy)

Delivery: ☐ Vaginal ☐ Cesarean Section

Sex: ☐ Male ☐ Female

Infant/fetal gestational age at live birth or still birth: ___ ___ weeks and ___ days

Size for gestational age: ☐ SGA ☐ AGA ☐ LGA

Pregnancy Outcome (X1D, X2D, X3D, X4D)

PTID ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Birth order Number (if singleton enter '1') ___

Infant Measurements

Birth weight:	Weight units: ☐ Pounds ☐ Kilograms	Weight: ___ ___ . ___
Length:	Length units: ☐ Inches ☐ Centimeters	Length: ___ ___ . ___
Frontal occipital circumference (FOC):	FOC units: ☐ Inches ☐ Centimeters	FOC: ___ ___ . ___

Apgar score, 1 minute (leave blank for Still Birth): ___ ___

Apgar score, 5 minutes (leave blank for Still Birth): ___ ___

Cord pH: ___ . ___

Congenital anomalies: ☐ No ☐ Yes *(If Yes, complete an AE for form for a Serious Adverse Event.)*

One-Month Follow-Up – Live Birth Only

Has the infant been diagnosed with any congenital anomalies since birth? *(Not previously reported above)* ☐ No ☐ Yes ☐ Unknown

If, Yes, complete an AE form for Serious Adverse Event.

Has the infant been ill or hospitalized? (*Does not include well-child visits)* ☐ No ☐ Yes ☐ Unknown

If Yes, specify: _____

One or Two-Month Follow-Up – Still Birth Only

Was there an autopsy? ☐ No ☐ Yes ☐ Unknown

If Yes, was an etiology for the still birth identified? ☐ No ☐ Yes ☐ Unknown

If Yes, specify: _____

Pregnancy Outcome – Spontaneous, Elective or Therapeutic Abortion Only

Date of termination: ___ ___/___ ___ ___/___ ___ ___ ___(dd/MMM/yyyy)

Fetal gestational age at termination: ___ ___ weeks and ___ days

Any abnormality in product of conception? ☐ No ☐ Yes ☐ Unknown ☐ N/A

If Yes, specify: _____

Reason for therapeutic abortion:
☐ Maternal condition/disease
☐ Fetal condition/disease

Comments: _____

Signature: _____ Date (ddMMMyyyy): _____

Signature: _____ Date (ddMMMyyyy): _____

Signature: _____ Date (ddMMMyyyy): _____

+ = *This question does not appear in Medidata RAVE* Version 1.0; 14MAY2021