CTEP CLINICAL TRIAL PREGNANCY AND LACTATION INFORMATION FORM

Instructions:

This form must be used to report any pregnancy in a clinical trial participant. This form must also be used for lactation exposure. In addition, this form should be used if the Clinical Investigator is made aware of a pregnancy in a partner of the study participant. This form must be submitted along with a Complete CTEP-AERS Report by the Clinical Investigator or his/her designee.

In addition, as soon as becoming aware of the pregnancy outcome (in either the study participant or their partner), an Amendment to the CTEP-AERS ticket accompanied by an updated Pregnancy Information Form should be submitted.

Timelines for submitting this form are dictated by the CTEP-AERS reporting timelines for pregnancy and its outcome found in the *NCI Guidelines: Adverse Event Reporting Requirements* [Section 5.6.6]. It should be submitted within these timelines even if not all the information is available at that time.

1. ADMINISTRATIVE INFORMATION

This section is to be filled out by the Clinical Investigator or designee.

SAE Report #[1]	CTEP Protocol #	Study Participant ID#

Initial Report Date:	Follow-up Report Date:
DD-MMM-YY	DD-MMM-YY

Principal Investigator	Reporter	Reporter Telephone #	Reporter FAX #

[1] CTEP-AERS ticket #, Medidata Rave report #, or other electronic identifier for the associated SAE Report submitted to CTEP.

2. PREGNANCY INFORMATION & HISTORY (To be filled out by the Clinical Investigator based on the information coming from the study participant only. The partner should not be consented or contacted, nor should her medical records be directly accessed.)

The **Pregnant Individual** is: ☐ The Study Participant ☐ The **Partner** of the Study Participant

Event	Date	Est.*
last menstrual period		☐
conception		☐
estimated delivery	DD-MMM-YY	

** Check box at right if the date is estimated*

Outcome		Date
Pregnancy Ongoing	☐	
Live Birth	☐	
Miscarriage	☐	
Therapeutic/elective abortion	☐	
Ectopic pregnancy	☐	
Unknown/Not Reported	☐	DD-MMM-YY
Lost to Follow-up	☐	
Stillbirth	☐	

Tests Performed During Pregnancy:

☐ CVS:
☐ Amniocentesis:
☐ Ultrasound:

Birth control method(s):

☐ Unknown
☐ Oral (pills)
☐ Rhythm
☐ Condom
☐ Diaphragm
☐ Intrauterine device (IUD)
☐ Other, specify:
☐ Abstinence
☐ Withdrawal
☐ Spermicide
☐ Vasectomy
☐ Tubal ligation
☐ Progestin injection or implant

Reproductive history:

# of pregnancies:	#
# of abortions:	#
# of miscarriages:	#
# of stillbirths:	#
# of deliveries:	#
children born with defects:	#

☐ Unknown

Risk factors:

☐ Alcohol
☐ Diabetes
☐ Infection
☐ Smoking
☐ Drug abuse
☐ Other, specify:

☐ Unknown

3. FETAL OUTCOME

☐ Normal ☐ Serious outcome, specify:
☐ Unknown ☐ Stillbirth/miscarriage:
☐ Not Reported Death date, if applicable:

(Enter death date in the format "DD-MMM-YY")

Information relevant to death/abnormality:

4. LACTATION EXPOSURE (*please describe duration of exposure*)

5. CONCOMITANT MEDICATIONS (Study Participant)

Please complete for all relevant medications taken before and during pregnancy by **Study Participant** and during lactation exposure for the infant. Include study drug(s), prescription and OTC medications, vitamins, and herbal supplements. Insert additional rows as necessary.

Medication (generic or trade name)	**Route** (oral, IV, etc.)	**Regimen** (amount, schedule)	**Start Date** (DD-MMM-YY)	**End Date** (DD-MMM-YY, or leave blank)	**Exposure Time** (gestational weeks)

6. ADDITIONAL INFORMATION REGARDING PREGNANCY AND/OR LACTATION EXPOSURE