

Pregnancy Form Completion Guideline

Any pregnancy that occurs after treatment with an investigational product must be reported per the study protocol. The Investigator must permanently discontinue investigational product and notify the Sponsor of the pregnancy. The Pregnancy Form should be completed and emailed to the Sponsor **within 24 hours** of becoming aware of the pregnancy.

Safety Reporting Email Address:

connectsafety.sm@thermofisher.com and pv@connectpharm.com

Pregnancy is not considered to be an AE however, if the outcome of a pregnancy meets the criteria for an SAE (ie, ectopic pregnancy, spontaneous abortion includes miscarriage and missed abortion, intrauterine fetal demise, neonatal death, or congenital anomaly [in a live-born baby, a terminated fetus, an intrauterine fetal demise, or a neonatal death]), the investigator should follow the procedures for reporting SAEs.

The Investigator must attempt to follow the pregnancy to term or termination to report an outcome and health status of the mother and child.

Please note: The Sponsor has delegated Pharmacovigilance (PV) services (eg, pregnancy and safety report case processing) to PPD. PPD PV will return confirmation of receipt which should be filed with a copy of the Pregnancy Form at the site. The Medical Monitor or PPD Safety Scientist may contact you with any follow-up questions related to the report. PPD will follow up approximately 30 days after the expected delivery date for neonatal status and information.

The following instructions are intended to assist the investigator and study coordinators when completing the Pregnancy Form for any CONNECT protocol or program.

Report Information

- **Date Investigator Became Aware:** Enter the date when the investigator first became aware of the confirmed pregnancy (DD/MMM/YYYY).
- **Report Type:** Indicate whether this is an initial report or a follow-up report by checking the appropriate box. Select Initial if this is the first report of the pregnancy. Select Follow-up and specify the version number (starting from 1) if this report provides additional information after the initial report.
- **Date of Report:** Record the date when the pregnancy form is completed

(DD/MMM/YYYY).

- **Protocol No.:** Record the Protocol number.

Participant Information

- **Participant ID:** This is the ID assigned to the subject at screening.
- **Date of Birth:** Date of the female participant's birth (DD/MMM/YYYY).
- **Height:** Enter mother's height. Choose the unit of measurement (inches or cm).
- **Weight:** Enter the mother's weight. Choose the unit of measurement (lbs or kg).
- **Medical history:** Indicate any pre-existing medical conditions by checking the appropriate boxes. If the mother has no pre-existing condition, then check "none."
- **Family history:** Indicate any relevant family medical history by checking the appropriate boxes. If there is no relevant family medical history, then check "none."

Pregnancy Information:

- **Date of last menstrual period (LMP):** Enter the date of the first day of the last menstrual period (DD/MMM/YYYY).
- **Gestational age at the time of last study drug intake:** Provide the gestational age in weeks and days when the participant last took the study drug and the method of determination: ultrasound or LMP.
- **Expected Date of Delivery:** Enter the date delivery of the neonate is expected (DD/MMM/YYYY).
- **Date of Blood or Serum β -hCG Test Positive:** Enter the date when the blood or serum β -hCG test was found to be positive (DD/MMM/YYYY).
- **Date of Ultrasound Examination Positive:** Enter the date when the ultrasound examination confirmed pregnancy (DD/MMM/YYYY). If applicable, provide the gestational age determined by the ultrasound.
- **Method of Contraception:** Indicate the method(s) of contraception used.

Concomitant Medications: Provide details of medications taken by the mother during the pregnancy.

Fertility History: This section aims to gather detailed information about your fertility history, including pregnancies and any related complications. Please provide accurate and complete information.

Did the Participant Withdraw from the Trial?: Choose Yes or No. If yes, indicate the specific date of withdrawal (DD/MMM/YYYY) and tick the reason for

withdrawal as pregnancy or specify if other reason

Investigational Product:

- **Date of Informed Consent:** This is the date when the participant signed the informed consent to participate in the clinical trial (DD/MMM/YYYY).
- **Design:** Indicate whether the study design is open-label or blinded. If the blinding was broken, specify the date it occurred (DD/MMM/YYYY).
- **Date of last study drug administration before pregnancy was confirmed** (DD/MMM/YYYY)

Relevant Laboratory and Non-laboratory Tests This section is for diagnostics conducted during the pregnancy (eg, Maternal Serum Alpha-Fetoprotein (MSAFP), chorionic villi sampling, amniocentesis, etc). Include the date of result (DD/MMM/YYYY), the test result, and the test reference range, as applicable.

Pregnancy Outcomes This section is intended to capture the outcomes of a pregnancy. If the pregnancy is ongoing, there is no need to fill out sections related to the pregnancy outcome or fetal status at this stage. Complete this section if the pregnancy has reached a conclusion.

- **Pregnant outcome:** Please check the box that best describes the outcome of the pregnancy (e.g., delivery, therapeutic abortion, spontaneous abortion, stillbirth, etc.).

Newborn Information

This section is intended to capture detailed information about the newborn. If this is the initial report of pregnancy, there is no need to fill out this section at this stage.

Please only complete this section if the pregnancy has resulted in a live birth.

- **Date of Birth:** Please enter the neonate date of birth (DD/MMM/YYYY).
- **Fetal/Newborn Status:** Please check the box that best describes the status of the fetus/newborn (eg, normal, birth defects, other, please specify).
- **Gestational Age at Birth:** Enter the gestational age at the time of birth.
- **Newborn Gender:** Please check the box that corresponds to the newborn's gender.
- **Body Length:** Enter newborn body length and specify the unit of measurement.
- **Weight:** Enter newborn weight and specify the unit of measurement.
- **Apgar Score:** Enter the Apgar score (assessment of newborn physical condition) performed at 1 and 5 minutes after birth.
- **Significant Medical Condition:** Please indicate whether the newborn has

any significant medical conditions, If yes, specify the significant medical condition and provide details and description of results, assessments, or other relevant information in the space provided.

Additional Information If there are any details or information not covered in the above sections, please provide them here. This section allows you to include any supplementary data that may be relevant or necessary for completeness.

Investigator/ Reporter Information The investigator must sign to attest that they have reviewed the Safety Report and agree with its content.

- **Site Address:** Provide the complete address of the study site
 - **Reporter:** Person filing the report contact information.
- Investigator signature with date:** The investigator should provide their signature in this space and enter the date when signed (DD/MMM/YYYY).