The Antiretroviral Pregnancy Registry

Instructions for completing the FOLLOW-UP FORMS

General Guideline: Date format should always be entered as *DD/MMM/YYYY*

Patient (Log) ID: The Registry assigned Log ID number.

Please indicate **UNK** or **N/A** for any data points where the information is unknown or not applicable.

1. Maternal Information

1.1 **Clinical Study:** Indicate if the patient is participating in a clinical study by checking "Yes", "No", or "Unknown".

- If no, move to Subsection 2 and do not check a response for "Was the clinical study conducted in pregnant women?"
- If yes, provide the study protocol number and check "Yes," "No" or "Unknown" for "Was the clinical study conducted in pregnant women?"

2.1 Clinical Indication:

- Indication for ARV/AV (select all that appl at time of outcome)

2. Fetal Outcome

If there are multiple outcomes (e.g., twins, triplets) complete a Follow-up Form for each baby.

2. 1 **Birth Defect Noted:** *Was a structural birth defect noted?* Check "Yes", "No", or "Unknown".

- If no, move to section 2.2: Outcome.
- If yes, list each specific defect in Section 3: Birth Defects.
- If unknown, the case will not be included in the Registry analysis.

2.2 **Outcome:** Check the applicable outcome: "Live Infant", "Spontaneous abortion*", "Induced abortion", or "Stillbirth*".

*(A **spontaneous abortion** is defined by the Registry as a fetal loss occurring earlier than 20 weeks. A **stillbirth** is a fetal death occurring greater than or equal to 20 weeks, or if the fetus weighs 500 grams or more.)

- If either Spontaneous or Induced abortion or Stillbirth is checked, list the factors that may have had an impact on the fetal loss in Section 4: Fetal Loss.

2.3 **Date of Outcome:** Provide the outcome date of the live infant or date the fetal loss occurred in *DD/MMM/YYYY* format.

2.4 **Gender:** Check the appropriate gender: "Male" or "Female".

2.5 **Length:** Provide the length of the infant at outcome and the appropriate metric used ("centimeter" or "inch").

2.6 **Gestational Age:** Provide the gestational age at outcome.

2.7 **Birth Weight:** Provide the birth weight of the infant at outcome and the appropriate metric used (grams or pounds/ounces).

2.8 **Head Circumference:** Provide the infant's head circumference at outcome and the appropriate metric used ("centimeter" or "inch").

3. Birth Defects

- List the structural birth defect(s)
- Indicate if the defect(s), was attributed to the antiviral therapy by recording:
  - 1 for Yes
  - 2 for No
  - 3 for Unknown
- Indicate other factors that might have contributed to this outcome by recording:
  - 1 for Maternal Age
  - 2 for Unknown
  - 3 for Other, specify. *If other, please specify the contributing factor.*

4. Fetal Loss (Stillbirth, Spontaneous or Induced Abortion)

Provide factors other than the birth defects that may have had an impact on the fetal loss.

****ANTIVIRAL THERAPY DURING PREGNANCY FORM**

Update the "Antiviral Therapy During Pregnancy" data form provided at Registration once outcome is obtained.

The Registry is not designed to monitor all types of events that might occur during pregnancy, labor and delivery, or other neonatal or post-natal events other than defects. If such events occur the provider is encouraged to contact the manufacturer of the individual drug and/or FDA. FDA can be reached by faxing the information to 800-FDA-0178 or at http://www.fda.gov/medwatch/.

ANTIRETROVIRAL PREGNANCY REGISTRY FOLLOW-UP FORM

Fax to: 1-800-800-1052 (US, Canada)
+1-910-256-0637 (International)
Email to: SM_APR@APRegistry.com

FOR OFFICE USE ONLY (3)
Registry Patient ID _____ HCP ID _____
Date Case Closed _____ _____ _____ ☐ Phone
DD MMM YYYY

Patient (Log) ID: _____ ***The Registry assigned, non-patient identifying patient ID number or Sponsor Manufacturer Control Number (MCN)***

1. MATERNAL INFORMATION

1.1 Is the patient enrolled in a clinical study? *(treatment or observational study)* ☐ Yes ☐ No ☐ Unknown

If yes, provide the protocol number _____

Was the clinical study conducted in pregnant women? ☐ Yes ☐ No ☐ Unknown

1.2 Please confirm clinical indication for current ARV/AV exposure (select all that apply at time of outcome)

- ☐ HIV Treatment
- ☐ HIV Prevention
  - ☐ Post-Exposure Prophylaxis (PEP)
  - ☐ Pre-Exposure Prophylaxis (PrEP)
- ☐ Hepatitis B
- ☐ Hepatitis C

2. FETAL OUTCOME

2.1 Birth Defect Noted? ☐ Yes *(If yes, list on page 4)* ☐ No ☐ Unknown

2.2 Outcome:

- ☐ Live Infant
- ☐ Abortion, Spontaneous
- ☐ Abortion, Induced
- ☐ Stillbirth
- ☐ Fetal loss due to maternal death

FOR REGISTRY USE ONLY
Baby ID: _____

If a fetal loss, go to page 4: Birth Defects (section 3) and/or other factors that may have contributed to the fetal loss (section 4)

2.3 Date of Outcome: _____ _____ _____ (DD MMM YYYY)

2.4 Gender: ☐ Male ☐ Female

2.5 Length: _____ ☐ cm. ☐ in.

2.6 Gestational Age: _____ weeks

2.7 Birth Weight: _____ ☐ grams ☐ lbs/oz.

2.8 Head Circumference: _____ ☐ cm. ☐ in.

NOTES:

- **If DEFECT or FETAL LOSS, go to page 4**
- **Please update the ANTIVIRAL THERAPY DURING PREGNANCY FORM when reporting pregnancy outcome. The form includes the initial information provided to the Registry at registration.**

HEALTH CARE PROVIDER INFORMATION

Name _____ Specialty _____
Address _____ Phone _____
_____ Fax _____
_____ Email _____
Alternate Contact _____
Provider's Signature _____ Date _____ _____ _____ (DD MMM YYYY)

ANTIRETROVIRAL PREGNANCY REGISTRY FOLLOW-UP FORM

FOR OFFICE USE ONLY (4)

Registry Patient ID _____

Patient (Log) ID: _____ ***Registry assigned ID number or Sponsor MCN***

Complete this page ONLY if there is a <u>birth defect</u> or information on a <u>fetal loss</u> (stillbirth, spontaneous or induced abortion)

3. BIRTH DEFECTS – *List birth defects below.*

	Birth defect *(list birth defect)*	***Was the defect attributed to antiviral therapy?*** *1 = Yes* *2 = No* *3 = Unknown*	***Other factors that might contribute to this outcome*** *1 = Maternal age* *2 = Unknown* *3 = Other, specify*
1.			
2.			
3.			
4.			
5.			
6.			

4. FETAL LOSS (STILLBIRTH, SPONTANEOUS, INDUCED ABORTION, OR FETAL LOSS DUE TO MATERNAL DEATH)

List factors, other than birth defects, that may have had an impact on the fetal loss.

1.	
2.	
3.	
4.	

Please <u>update</u> the ANTIVIRAL THERAPY DURING PREGNANCY FORM when reporting pregnancy outcome. The form includes the initial information provided to the Registry at registration.

Thank you for your participation in the Antiretroviral Pregnancy Registry