

The Antiretroviral Pregnancy Registry

Instructions for Completing the REGISTRATION FORMS

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

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

Date first seen during this pregnancy: Provide the date first seen in *DD/MMM/YYYY* format.

1. Maternal Information

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

- If no, move to Subsection 1.2
- If yes, provide the study protocol number and check “Yes” or “No” if conducted in pregnant woman

Last Menstrual Period (LMP): Provide the LMP date in *DD/MMM/YYYY* format.

Corrected Estimated Date of Delivery (EDD): Provide the EDD based on the 20 week prenatal test, especially if this is the date being used to calculate gestational age for medication exposures and outcome.

Patient Age: Provide age of the pregnant woman at time of conception.

Race: Check the appropriate box for the pregnant woman’s race.

2. Prenatal Tests

2.1 Prenatal Test Done: Indicate if a prenatal test was done by checking “Yes”, “No”, or “Unknown”.

- If no, move to Section 3: Clinical Indicators.
- If yes, provide the date in *DD/MMM/YYYY* format, or the gestational age, of when the prenatal test was performed and what prenatal test was conducted (ie., Ultrasound, Amniocentesis, MSAFP). If “Other” specify the prenatal test performed.

2.2 Evidence of a Structural Defect: Indicate if a structural defect(s) was identified on a prenatal test by checking “Yes”, “No” or “Unknown” by each prenatal test done.

- If no, move to Section 3: Clinical Indicators.
- If yes, provide the structural and/or chromosomal defect(s).

3. Clinical Indicators (at the START of pregnancy)

3.1 Clinical Categories as Defined by the CDC: www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm

Check **all** appropriate categories as they apply as close to the beginning of the pregnancy as possible.

- **Category A:** Consists of one or more of the CDC defined Category A conditions in a person with documented HIV infection. Conditions in Categories B and C must not have occurred.
- **Category B:** Consists of symptomatic conditions in an HIV-infected person not included in Category C and meeting at least one of the two Category B conditions. For classification purposes, someone previously treated for a Category B condition but who is now asymptomatic should be classified in Category B.
- **Category C:** Includes the clinical conditions listed in the AIDS surveillance case definition. For classification purposes, once a Category C condition has occurred, the person will remain in Category C.

3.2 CD4 + T-cell Categories: Check the appropriate range for the counts as they were as close to the beginning of the pregnancy (not applicable should be marked if the patient is not HIV positive).

3.3 Hepatitis Severity Indicator: Check the appropriate indication for severity of the hepatitis at a time as close to the beginning of the pregnancy as possible (not applicable should be marked if the patient does not have hepatitis or if Pugh score is not yet known).

ANTIVIRAL THERAPY DURING PREGNANCY FORM

- **Med Code:** Indicate the code number from the list provided. If a drug is not listed, provide the name of the drug.
- **Total Daily Dose:** Provide the total daily dose with units (e.g., stavudine 80 mg, ZDV (IV) 650 mg).
- **Route:** Provide the code “1” for oral, “2” for IV, and “3” for subcutaneous (sub-Q).
- **Pt taking Meds at Conception?:** “1” if yes at conception, “2” if during pregnancy, “3” if unknown.
- **Gestation Week Course Began:** Indicate the gestation week (if unknown and a date the therapy began is available, that is sufficient) when treatment began.
- **Date Treatment Began or Gestational Age Course Began:**
 - Provide start date in *DD/MMM/YYYY* format, **OR**
 - Provide gestational age course began. If gestational age is known, check the calculation source: LMP or Corrected EDD. This will help to ensure the Registry is calculating from the same date.
- **Date Treatment Stopped or Ongoing:**
 - Provide date, or gestation week, treatment stopped in *DD/MMM/YYYY* format, **OR**
 - Check “Ongoing” if treatment continues following outcome of pregnancy.

Please write “unk” or “N/A” on the forms if any information is unknown or not applicable.

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 the FDA. FDA can be reached by faxing the information to 800-FDA-0178 or at <http://www.fda.gov/Safety/MedWatch/default.htm>

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