

# ***The Antiretroviral Pregnancy Registry***

## **Instructions for Completing the REGISTRATION FORMS**

**Patient (Log) ID:** The Registry assigned number for the patient assigned at registration number

**Date first seen:** This date is only required for providers who have committed to provide all pregnancy exposures to antiretroviral drugs reports at their site.

### **1. Maternal Information**

- 1.1 **Clinical Study:** Indicate if the patient is in a clinical study and if yes, whether the study is being conducted in pregnant women. If yes, please provide the study/protocol number.
- 1.2 **Last Menstrual Period:** Provide the date of the woman's last menstrual period.
- 1.3 **Corrected Estimated Date of Delivery:** If available, an 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. Preferred over the LMP.
- 1.4 **Patient Age:** Provide age of the pregnant woman at time of conception.
- 1.5 **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.
  - If no, move to section 3: Clinical Indicators
  - If yes, continue by providing the date or gestational age when the test was done and which test was done. Go to section 2.2.
- 2.2 **Evidence of a Structural Defect:** Indicate if a structural defect(s) was identified on a prenatal test.
  - If no, move to section 3: Clinical Indicators
  - If yes, continue by providing the structural and/or chromosomal defect(s) identified and by what test the defect was identified. Go to section 3.

### **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](http://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).

### **4. ANTIVIRAL THERAPY DURING PREGNANCY FORM**

- **Course:** Enter the number of the course of treatment for each medication (i.e. if the patient received 2 courses of the same medication, list them separately and number each sequentially).
- **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 Gestation Week Calculated:** Indicate the date *or* the gestational age when therapy began for each course, but not both.
- **Gestation Week or Date Therapy was Discontinued or if Continued Following Delivery:** Provide date or gestation week or if therapy continues through and continuing at delivery, check "ongoing" box. Do not check the "ongoing" box if only providing registration information. This box should only be checked when providing outcome information.

**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 FDA. FDA can be reached by faxing the information to 800-FDA-0178 or at <http://www.fda.gov/medwatch/>.

**Phone Contact:** US/Canada Phone: 800-258-4263 (Toll Free) or 910-256-0238  
UK, Germany, France Phone: 00800-5913-1359 (Toll Free)  
International Phone: +910-256-0238 (US) or +32-2-714-5028 (Europe)  
**Address:** Research Park, 1011 Ashes Drive, Wilmington, NC 28405  
**Internet:** [www.APREgistry.com](http://www.APREgistry.com)

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# ANTIRETROVIRAL PREGNANCY REGISTRY REGISTRATION FORM

Fax to: 800-800-1052 (US, Canada)  
+910-256-0637 (International) or +32-2-714-5024 (Europe)  
00800-5812-1658 (UK, Germany, France)

FOR OFFICE USE ONLY

(1)

Registry Patient ID \_\_\_\_\_ HCP ID \_\_\_\_\_  
 Pro  Retro  100% provider   
 Country \_\_\_\_\_ State \_\_\_\_\_  
 Report type Orig U/L  MP  Current U/L  MP   
 Registry date of notification \_\_\_\_\_  Phone

Patient (Log) ID: \_\_\_\_\_ Registry assigned ID number \_\_\_\_\_  
*Note: To help assure patient anonymity the Registry uses a Registry assigned patient ID to refer to your patient to obtain follow-up and outcome information.*

Date patient first seen during this pregnancy  
 Date: \_\_\_\_\_ M \_\_\_\_\_ D \_\_\_\_\_ Y

## 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 trial conducted in pregnant women?  Yes  No  Unknown
- 1.2 Last Menstrual Period \_\_\_\_\_ M \_\_\_\_\_ D \_\_\_\_\_ Y
- 1.3 Corrected EDD \_\_\_\_\_ M \_\_\_\_\_ D \_\_\_\_\_ Y (e.g., by ultrasound)
- 1.4 Patient Age: \_\_\_\_\_ (at conception)
- 1.5 Race:  White  Black  
 Hispanic  Asian  
 Other \_\_\_\_\_ (specify)

## 2. PRENATAL TESTS

- 2.1 Was a prenatal test done?  
 No (go to section 3)  
 Yes (complete below and question 2.2)  
 Date when test(s) done:  
 (✓) test(s)  Ultrasound \_\_\_\_\_ date  
 Ultrasound \_\_\_\_\_ date  
 Ultrasound \_\_\_\_\_ date  
 Amniocentesis \_\_\_\_\_ date  
 MSAFP/serum markers \_\_\_\_\_ date  
 Other: \_\_\_\_\_ date  
 Unknown (go to section 3)

- 2.2 Is there evidence of a structural defect from one or more of these prenatal tests?  
 No (go to section 3)  
 Yes (complete below, then go to section 3)  
 Specify structural defect \_\_\_\_\_  
 (✓) test(s) where defect noted  
 Ultrasound \_\_\_\_\_ date  
 Amniocentesis \_\_\_\_\_ date  
 MSAFP/serum markers \_\_\_\_\_ date  
 Other: \_\_\_\_\_ date  
 Unknown (go to section 3)

## 3. CLINICAL INDICATORS (at the START of pregnancy)

- 3.1 Clinical Categories (✓ all that apply at the start of pregnancy):  
 A. Asymptomatic, acute (primary) HIV or PGL\*  
 B. Symptomatic, not (A) or (C) conditions  
 C. Other AIDS-indicator conditions and/or CD4<200  
 D. HIV prophylaxis  
 E. Hepatitis B (HBV)  
 F. Hepatitis C (HCV)  
 \*PGL-persistent generalized lymphadenopathy  
 For additional descriptions of categories refer to the 1993 CDC revised classification system, December 1992 issue of MMWR
- 3.2 CD4+ T-cell Categories (at start of pregnancy)  
 ≥ 500 μL  
 200-499 μL  
 <200 μL  
 Not applicable
- 3.3 Hepatitis Severity Indicator (at start of pregnancy):  
 A. Compensated liver disease (Pugh score <7)  
 B. Decompensated liver disease (Pugh score ≥7)  
 C. Not applicable

Complete applicable information on: ANTIVIRAL THERAPY DURING PREGNANCY Form

## HEALTH CARE PROVIDER INFORMATION

Name \_\_\_\_\_ Specialty \_\_\_\_\_  
 Address \_\_\_\_\_ Phone \_\_\_\_\_  
 \_\_\_\_\_ Fax \_\_\_\_\_  
 Alternate Contact \_\_\_\_\_ Email \_\_\_\_\_  
 Provider's Signature \_\_\_\_\_ Date \_\_\_\_\_ M \_\_\_\_\_ D \_\_\_\_\_ Y

**ANTIRETROVIRAL PREGNANCY REGISTRY**  
**ANTIVIRAL THERAPY DURING PREGNANCY**  
*(Initiated at registration and completed at follow-up)*

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(2)

Registry ID \_\_\_\_\_

Update

Patient (Log) ID: \_\_\_\_\_ *The Registry assigned, non-patient identifying patient ID number*

Complete as much of this page as applicable at Registration. A copy of this form will be sent to you in the expected month of delivery for completion.

**4. ANTIVIRAL THERAPY DURING PREGNANCY**

1. Use the med. codes below for antiviral medication taken during pregnancy. If not coded, **Specify Medication**.

- |   |  |
|---|--|
| 1. Abacavir (ZIAGEN <sup>®</sup> , ABC)                         | 13.5 Zidovudine generic – Cipla  |
| 2. Didanosine (VIDEX <sup>®</sup> , VIDEX <sup>®</sup> EC, ddl) | 13.6 Zidovudine generic – Mylan  |
| 2.1 Didanosine generic – Barr Labs                              | 13.7 Zidovudine generic - Hetero   |
| 2.2 Didanosine generic - Aurobindo                              | 13.99 Zidovudine (unknown manufacturer)  |
| 2.99 Didanosine (unknown manufacturer)                          | 14. Amprenavir (AGENERASE <sup>®</sup> , APV)  |
| 3. Efavirenz (SUSTIVA <sup>®</sup> , EFV)                       | 15. Indinavir (CRIXIVAN <sup>®</sup> , IDV)  |
| 3.1 Efavirenz (STOCRIN <sup>®</sup> , EFV)                      | 16. Delavirdine mesylate (RESCRIPTOR <sup>®</sup> , DLV)                               |
| 3.99 Efavirenz (unknown manufacturer)                           | 17. Lopinavir+ritonavir (KALETRA <sup>®</sup> , LPV/r)                                 |
| 4. Lamivudine (EPIVIR <sup>®</sup> , 3TC)                       | 18. Abacavir+lamivudine+zidovudine (TRIZIVIR <sup>®</sup> , TZV)                       |
| 4.99 Lamivudine (unknown manufacturer)                          | 19. Tenofovir disoproxil fumarate (VIREAD <sup>®</sup> , TDF)                          |
| 5. Lamivudine+zidovudine (COMBIVIR <sup>®</sup> , ZDV+3TC)      | 20. Adefovir dipivoxil (HEPSERA <sup>®</sup> , ADV)                                    |
| 5.99 Lamivudine+zidovudine (unknown manufacturer)               | 21. Enfuvirtide (FUZEON <sup>®</sup> , T-20)   |
| 6. Nelfinavir (VIRACEPT <sup>®</sup> , NFV)                     | 22. Atazanavir sulfate (REYATAZ <sup>®</sup> , ATV)                                    |
| 7. Nevirapine (VIRAMUNE <sup>®</sup> , NVP)                     | 23. Emtricitabine (EMTRIVA <sup>®</sup> , FTC)   |
| 7.99 Nevirapine (unknown manufacturer)                          | 24. Fosamprenavir calcium (LEXIVA <sup>®</sup> , FOS)                                  |
| 8. Ritonavir (NORVIR <sup>®</sup> , RTV)                        | 25. Abacavir+lamivudine (EPZICOM <sup>®</sup> , EPZ)                                   |
| 9. Saquinavir (FORTOVASE <sup>®</sup> , SQV-SGC)                | 26. Tenofovir disoproxil fumarate+emtricitabine (TRUVADA <sup>®</sup> , TVD)           |
| 10. Saquinavir mesylate (INVIRASE <sup>®</sup> , SQV-HGC)       | 27. Entecavir (BARACLUDE <sup>®</sup> , ETV)   |
| 11. Stavudine (ZERIT <sup>®</sup> , d4T)                        | 28. Tipranavir (APTIVUS <sup>®</sup> , TPV)  |
| 11.1 Stavudine generic - Mylan                                  | 29. Efavirenz+tenofovir disoproxil fumarate+emtricitabine (ATRIPLA <sup>™</sup> , ATR) |
| 11.99 Stavudine (unknown manufacturer)                          | 30. Telbivudine (TYZEKA <sup>®</sup> , SEBIVO <sup>®</sup> , LdT)                      |
| 12. Zalcitabine (HIVID <sup>®</sup> , ddC)                      | 31. Darunavir (PREZISTA <sup>™</sup> , DRV)  |
| 13. Zidovudine (RETROVIR <sup>®</sup> , ZDV)                    | 32. Raltegravir (ISENTRESS <sup>™</sup> , RAL)   |
| 13.1 Zidovudine generic – Ranbaxy                               | 33. Maraviroc (SELZENTRY <sup>™</sup> , CELSENTRI <sup>™</sup> , MVC)                  |
| 13.2 Zidovudine generic– Teva/GSK                               | 34. Etravirine (INTELENCE <sup>™</sup> , ETR)  |
| 13.3 Zidovudine generic – Roxane/BI                             |  |
| 13.4 Zidovudine generic – Aurobindo                             |  |

2. In the following table, describe each course or change in route for each applicable therapy.

Course	Med. Code (1-28) or if no code indicated, please write medication name Specify if Generic	Total Daily Dose (mg/day or mg/kg/hr) *please indicate	Route (enter code) 1 = oral 2 = IV 3 = sub-Q	Pt Taking Med. at Conception? 1 = Yes 2 = No 3 = Unknown	Date Treatment Course Began (M/D/Y) <b>OR</b> gestational age (0 = prior to conception) If calculated by gestational age: <input type="checkbox"/> (from LMP) <input type="checkbox"/> (by corrected EDD)		Date Treatment Stopped (m/d/y) (Note: Ongoing = ongoing following delivery)
	<input type="checkbox"/> generic						or <input type="checkbox"/> ongoing
	<input type="checkbox"/> generic						or <input type="checkbox"/> ongoing
	<input type="checkbox"/> generic						or <input type="checkbox"/> ongoing
	<input type="checkbox"/> generic						or <input type="checkbox"/> ongoing
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	<input type="checkbox"/> generic						or <input type="checkbox"/> ongoing

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