The Antiretroviral Pregnancy Registry

Instructions for Completing the REGISTRATION FORM

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

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

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

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 Subsection1.2
- If yes, provide the study protocol number and indicate whether the study was conducted in pregnant women by checking "Yes" or "No"

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

1.3 Corrected Estimated Date of Delivery (CEDD): Provide the CEDD based on the 20 week prenatal test, especially if this is the date being used to calculate gestational age for medication exposures and outcome. If a date is entered here, prenatal test name(s) and date(s) must be entered in Section 2.1.

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 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, the prenatal test was performed and the name of the prenatal test (i.e., 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, specify the structural and/or chromosomal defect(s).

3. Clinical Indicators (at the START of pregnancy)

3.1 Indication for ARV (Check all that apply)

3.2 Earliest CD4 + T-cell Categories (in this pregnancy): 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 infected).

3.3 Worst Disease Severity Indicator (by history):

- **HIV:** Check the appropriate category for the worst disease severity experienced by the patient at any time since becoming infected (not applicable should be marked if the patient is not HIV infected). Clinical categories A, B and C are as defined by the CDC www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm
  - **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.
  - **Category D:** CD4 <200 cells/µL
- **Hepatitis:** Check the appropriate category for the worst disease severity experienced by the patient at any time since becoming infected (not applicable should be marked if the patient does not have hepatitis).

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

Revised (November 2013)

The Antiretroviral Pregnancy Registry

Instructions for Completing the 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., 80 mg, 2 tabs, 2 mg/kg/hr, etc.).
- **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.
- **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. If CEDD is checked, prenatal test name(s) and date(s) must be entered on page 1 Section 2.1.
- **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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ANTIRETROVIRAL PREGNANCY REGISTRY
REGISTRATION FORM

Fax to: +1-800-800-1052 (US, Canada)
+1-910-256-0637 (International) or +32-2-714-5024 (Europe)
0800-5812-1658 (UK, Germany, France)
0800-892-1119 (Brazil)

FOR OFFICE USE ONLY (1)
Registry Patient ID _____ HCP ID _____
Prospective ☐ Retrospective ☐ 100% provider ☐
Country _____ State _____
Registry date of notification _____ _____ _____ ☐ Phone

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

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: _____ _____ _____
DD MMM YYYY

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 Last Menstrual Period _____ _____ _____
DD MMM YYYY

1.3 Corrected EDD _____ _____ _____ *(e.g., by ultrasound)*
DD MMM YYYY

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 OR Gestational Age 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?

☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐Yes ☐No ☐Unknown. If yes, Specify defect _____

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

3.1 Indication for ARV *(✓ all that apply)*:
☐ HIV Infected
☐ HIV Non-Infected
☐ Post-Exposure Prophylaxis (PEP)
☐ Pre-Exposure Prophylaxis (PrEP)
☐ Hepatitis B
☐ Hepatitis C

For additional descriptions of categories refer to the 1993 CDC revised classification system, December 1992 issue of MMWR

3.2 Earliest CD4+ T-cell Categories *(in this pregnancy)*
☐ ≥ 500 μL
☐ 200-499 μL
☐ <200 μL
☐ Not applicable

3.3 Worst Disease Severity Indicator (by history):

HIV
☐ A. Asymptomatic, acute (primary) HIV or PGL (persistent generalized lymphadenopathy)
☐ B. Symptomatic, not (A) or (C) conditions
☐ C. Other AIDS-indicator conditions
☐ D. CD4 <200 cells/μL
☐ E. Not applicable

Hepatitis
☐ 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 _____ _____ _____
DD MMM YYYY

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

FOR OFFICE USE ONLY: (2)
Registry ID_____
☐ Update

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

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®, ABC)**
1.1	**Abacavir generic – Hetero**
1.2	**Abacavir generic – Apotex**
1.99	**Abacavir (unknown manufacturer)**
2.	**Didanosine (VIDEX®, VIDEX® EC, ddI)**
2.1	**Didanosine generic – Teva Pharmaceuticals**
2.2	**Didanosine generic – Aurobindo**
2.3	**Didanosine generic – Mylan**
2.99	**Didanosine (unknown manufacturer)**
3.	**Efavirenz (SUSTIVA®, EFV)**
3.1	**Efavirenz (STOCRIN®, EFV)**
3.2	**Efavirenz generic – Hetero**
3.99	**Efavirenz (unknown manufacturer)**
4.	**Lamivudine (EPIVIR®, 3TC)**
4.1	**Lamivudine generic – Hetero**
4.2	**Lamivudine+tenofovir df generic – Hetero**
4.3	**Lamivudine generic – Apotex**
4.4	**Lamivudine generic – Aurobindo**
4.99	**Lamivudine (unknown manufacturer)**
5.	**Lamivudine+zidovudine (COMBIVIR®, ZDV+3TC)**
5.1	**Lamivudine+zidovudine generic – Hetero**
5.2	**Lamivudine+zidovudine generic – Teva Pharmaceuticals**
5.3	**Lamivudine+zidovudine generic – Aurobindo**
5.4	**Lamivudine+zidovudine generic – Lupin**
5.99	**Lamivudine+zidovudine (unknown manufacturer)**
6.	**Nelfinavir (VIRACEPT®, NFV)**
7.	**Nevirapine (VIRAMUNE®, VIRAMUNE® XR™, NVP)**
7.1	**Nevirapine generic – Hetero**
7.2	**Nevirapine generic – Prinston**
7.3	**Nevirapine generic – Sciegen**
7.4	**Nevirapine generic – Apotex**
7.5	**Nevirapine generic – Aurobindo**
7.6	**Nevirapine generic – Strides**
7.99	**Nevirapine (unknown manufacturer)**
8.	**Ritonavir (NORVIR®, RTV)**
9.	**Saquinavir (FORTOVASE®, SQV-SGC)**
10.	**Saquinavir mesylate (INVIRASE®, SQV-HGC)**
11.	**Stavudine (ZERIT®, d4T)**
11.1	**Stavudine generic – Mylan**
11.2	**Stavudine generic – Aurobindo**
11.3	**Stavudine generic – Cipla**
11.4	**Stavudine generic – Hetero**
11.99	**Stavudine generic – unknown manufacturer**
12.	**Zalcitabine (HIVID®, ddC)**
13.	**Zidovudine (RETROVIR®, ZDV)**
13.1	**Zidovudine oral generic – Ranbaxy**
13.2	**Zidovudine oral generic – Teva/GSK**
13.3	**Zidovudine oral generic – Roxane/BI**
13.4	**Zidovudine oral generic – Aurobindo**
13.5	**Zidovudine oral generic – Cipla**
13.6	**Zidovudine oral generic – Mylan**
13.7	**Zidovudine oral generic – Hetero**
13.8	**Zidovudine oral generic – HEC Pharm**
13.99	**Zidovudine oral (unknown manufacturer)**
14.	**Amprenavir (AGENERASE®, APV)**
15.	**Indinavir (CRIXIVAN®, IDV)**
16.	**Delavirdine mesylate (RESCRIPTOR®, DLV)**
17.	**Lopinavir+ritonavir (KALETRA®, ALUVIA®, LPV/r)**
18.	**Abacavir+lamivudine+zidovudine (TRIZIVIR®, TZV)**
19.	**Tenofovir disoproxil fumarate (VIREAD®, TDF)**
19.1	**Tenofovir disoproxil fumarate generic – Hetero**
19.99	**Tenofovir disoproxil fumarate (unknown manufacturer)**
20.	**Adefovir dipivoxil (HEPSERA®, ADV)**
20.1	**Adefovir dipivoxil generic – Sigmapharm**
20.99	**Adefovir dipivoxil (unknown manufacturer)**
21.	**Enfuvirtide (FUZEON®, T-20)**
22.	**Atazanavir sulfate (REYATAZ®, ATV)**
23.	**Emtricitabine (EMTRIVA®, FTC)**
24.	**Fosamprenavir calcium (LEXIVA®, FOS)**
25.	**Abacavir+lamivudine (EPZICOM®, EPZ)**
26.	**Tenofovir disoproxil fumarate+emtricitabine (TRUVADA®, TVD)**
27.	**Entecavir (BARACLUDE®, ETV)**
28.	**Tipranavir (APTIVUS®, TPV)**
29.	**Efavirenz+tenofovir disoproxil fumarate+emtricitabine (ATRIPLA™, ATR)**
30.	**Telbivudine (TYZEKA®, SEBIVO®, LdT)**
31.	**Darunavir (PREZISTA®, DRV)**
32.	**Raltegravir (ISENTRESS® RAL)**
33.	**Maraviroc (SELZENTRY®, CELSENTRI®, MVC)**
34.	**Etravirine (INTELENCE®, ETR)**
35.	**Rilpivirine (EDURANT®, RPV)**
36.	**Rilpivirine+Emtricitabine+Tenovfovir Disoproxil Fumarate (COMPLERA®, CPA; EVIPLERA®, EPA)**
37.	**Elvitegravir+Cobicistat+Emtricitabine+Tenofovir Disoproxil Fumarate (STRIBILD™, STB)**
38.	**Dolutegravir (TIVICAY®)**

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

***Med. Code* (1-38) or if no code indicated, please write medication name and indicate if generic**		***Total Daily Dose (mg/day or mg/kg/hr)***	***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 (DD/MMM/YYYY) OR Gestational Age Course Began (0 weeks = prior to conception)*** If gestational age, calculation source: ☐ *(LMP)* ☐ *(corrected EDD)*	***Date Treatment Stopped (DD/MMM/YYYY) OR Ongoing?*** (Note: Ongoing = ongoing Following delivery)
Course						
						or ☐ ongoing
						or ☐ ongoing
						or ☐ ongoing
						or ☐ ongoing
						or ☐ ongoing
						or ☐ ongoing
						or ☐ ongoing