

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 Subsection 1.2
 - 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/ μ L
- **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).

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>

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)
0800-892-1472 (Brazil)
Email to: SM_APR@INCRResearch.com

FOR OFFICE USE ONLY (1)
Registry Patient ID _____ HCP ID _____
Prospective Retrospective 100% Provider
Registry date of notification _____ Phone
DD MMM YYYY

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

Country of report origin _____ State (U.S. only) _____
Date patient first seen during this pregnancy or Sponsor date of notification of 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
 Amniocentesis _____ date
 Cystic Fibrosis Mutation Analysis _____ date
 Fetal Echo _____ date
 First Trimester Screen _____ date
 MSAFP/serum markers _____ date
 Nuchal Translucency _____ date
 Other (specify): _____ 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 _____
 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
- 3.2 Earliest CD4+ T-cell Categories (*in this pregnancy*)
 ≥ 500 cells/μL
 200-499 cells/μL
 <200 cells/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

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

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

Registry ID _____

HCP ID _____

Update

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.

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

4. ANTIRETROVIRAL THERAPY DURING PREGNANCY

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

1. Abacavir (ZIAGEN®, ABC) – ViiV/GSK	9. Saquinavir (FORTOVASE®, SQV-SGC) – Roche (no longer manuf.)
1.1 Abacavir generic – Hetero	10. Saquinavir mesylate (INVIRASE®, SQV-HGC) – Roche
1.2 Abacavir generic – Apotex	11. Stavudine (ZERIT®, d4T) – BMS
1.3 Abacavir generic – Mylan	11.1 Stavudine generic – Mylan
1.4 Abacavir generic – Strides	11.2 Stavudine generic – Aurobindo
1.5 Abacavir generic – Aurobindo	11.3 Stavudine generic – Cipla
1.6 Abacavir generic – Cipla	11.4 Stavudine generic – Hetero
1.99 Abacavir generic (unknown manufacturer)	11.99 Stavudine generic (unknown manufacturer)
2. Didanosine (VIDEX®, VIDEX® EC, ddl) – BMS	12. Zalcitabine (HIVID®, ddC) – Roche (no longer manuf.)
2.1 Didanosine generic – Teva	13. Zidovudine (RETROVIR®, ZDV) – ViiV/GSK
2.2 Didanosine generic – Aurobindo	13.1 Zidovudine oral generic – Ranbaxy (no longer manuf.)
2.3 Didanosine generic – Mylan	13.2 Zidovudine oral generic – ViiV/GSK
2.99 Didanosine (unknown manufacturer)	13.3 Zidovudine oral generic – West-Ward
3. Efavirenz (SUSTIVA®, EFV) – BMS	13.4 Zidovudine oral generic – Aurobindo
3.1 Efavirenz (STOCRIN™, EFV) – Merck	13.5 Zidovudine oral generic – Cipla
3.2 Efavirenz generic – Hetero	13.6 Zidovudine oral generic – Mylan
3.3 Efavirenz generic - Aurobindo	13.7 Zidovudine oral generic – Hetero
3.99 Efavirenz (unknown manufacturer)	13.8 Zidovudine oral generic – Sunshine Lakes (no longer manuf.)
4. Lamivudine (EPIVIR®, 3TC) – ViiV/GSK	13.9 Zidovudine oral generic – Ipca (no longer manuf.)
4.1 Lamivudine generic – Hetero	13.99 Zidovudine oral (unknown manufacturer)
4.2 Lamivudine+tenofovir df generic – Hetero	14. Amprenavir (AGENERASE®, APV) – ViiV/GSK (no longer manuf.)
4.3 Lamivudine generic – Apotex	15. Indinavir (CRIXIVAN®, IDV) – Merck
4.4 Lamivudine generic – Aurobindo	16. Delavirdine mesylate (RESCRIPTOR®, DLV) – ViiV/GSK
4.5 Lamivudine generic – Silarx/Lannett	17. Lopinavir+ritonavir (KALETRA®, ALUVIA®, LPV/r) – Abbvie
4.6 Lamivudine generic – Lupin	17.1 Lopinavir+ritonavir generic – Silarx/Lannett
4.7 Lamivudine generic – Mylan	17.99 Lopinavir+ritonavir (unknown manufacturer)
4.8 Lamivudine generic – Cipla	18. Abacavir+lamivudine+zidovudine (TRIZIVIR®, TZV) – ViiV/GSK
4.99 Lamivudine (unknown manufacturer)	18.1 Abacavir+lamivudine+zidovudine generic – Lupin
5. Lamivudine+zidovudine (COMBIVIR®, CBV) – ViiV/GSK	18.99 Abacavir+lamivudine+zidovudine (unknown manufacturer)
5.1 Lamivudine+zidovudine generic – Hetero	19. Tenofovir disoproxil fumarate (VIREAD®, TDF) – Gilead
5.2 Lamivudine+zidovudine generic – Teva	19.1 Tenofovir disoproxil fumarate generic – Hetero
5.3 Lamivudine+zidovudine generic – Aurobindo	19.2 Tenofovir disoproxil fumarate generic – Apotex
5.4 Lamivudine+zidovudine generic – Lupin	19.3 Tenofovir disoproxil maleate generic – Mylan
5.5 Lamivudine+zidovudine generic – Strides	19.4 Tenofovir disoproxil phosphate generic – Zentiva
5.6 Lamivudine+zidovudine generic – Mylan	19.5 Tenofovir disoproxil succinate generic – Reddys (no longer partic.)
5.99 Lamivudine+zidovudine (unknown manufacturer)	19.99 Tenofovir disoproxil fumarate (unknown manufacturer)
6. Nelfinavir (VIRACEPT®, NFV) – ViiV/Pfizer	20. Adefovir dipivoxil (HEPSERA®, ADV) – Gilead
7. Nevirapine (VIRAMUNE®, VIRAMUNE® XR™, NVP) – BI	20.1 Adefovir dipivoxil generic – SigmaPharm
7.1 Nevirapine generic – Hetero	20.99 Adefovir dipivoxil (unknown manufacturer)
7.2 Nevirapine generic – Prinston	21. Enfuvirtide (FUZEON®, T-20) – Roche
7.3 Nevirapine/nevirapine ER generic – Sciegen (no longer manuf.)	22. Atazanavir (REYATAZ®, ATV) – BMS
7.4 Nevirapine/nevirapine ER generic – Apotex	23. Emtricitabine (EMTRIVA®, FTC) – Gilead
7.5 Nevirapine/nevirapine ER generic – Aurobindo	24. Fosamprenavir calcium (LEXIVA®, FOS) – ViiV/GSK
7.6 Nevirapine generic – Strides	25. Abacavir+lamivudine (EPZICOM®, KIVEXA®, EPZ) – ViiV/GSK
7.7 Nevirapine ER generic – Sandoz	25.1 Abacavir+lamivudine generic – Teva
7.8 Nevirapine generic – Cipla	25.2 Abacavir+lamivudine generic –Reddys (no longer partic.)
7.9 Nevirapine ER generic – Alvogen	25.3 Abacavir+lamivudine generic – Aurobindo
7.10 Nevirapine ER generic – Teva	25.4 Abacavir+lamivudine generic – Cipla
7.11 Nevirapine/nevirapine ER generic – Mylan	25.5 Abacavir+lamivudine generic – Lupin
7.12 Nevirapine ER generic - Macleods	25.99 Abacavir+lamivudine (unknown manufacturer)
7.99 Nevirapine (unknown manufacturer)	
8. Ritonavir (NORVIR®, RTV) – Abbvie	
8.1 Ritonavir generic – West-Ward	
8.99 Ritonavir (unknown manufacturer)	

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26.	Tenofovir disoproxil fumarate+emtricitabine (TRUVADA®, TVD) – Gilead	32.	Raltegravir (ISENTRESS®, RAL) – Merck
26.1	Tenofovir disoproxil fumarate+emtricitabine generic – Apotex	33.	Maraviroc (SELZENTRY®, CELSENTRI®, MVC) – ViiV/GSK
26.2	Tenofovir disoproxil maleate+emtricitabine generic – Mylan	34.	Etravirine (INTELENCE®, ETR) – Janssen
26.3	Tenofovir disoproxil succinate+emtricitabine generic – Reddys (no longer partic.)	35.	Rilpivirine (EDURANT®, RPV) – Janssen
26.4	Tenofovir disoproxil phosphate+emtricitabine generic – Zentiva	36.	Rilpivirine+emtricitabine+tenofovir disoproxil fumarate (COMPLERA®, CPA; EVIPLERA®, EPA) – Gilead
26.99	Tenofovir disoproxil fumarate+emtricitabine generic – (unknown manuf.)	37.	Elvitegravir+cobicistat+emtricitabine+tenofovir disoproxil fumarate (STRIBILD®, STB) – Gilead
27.	Entecavir (BARACLUDE®, ETV) – BMS	38.	Dolutegravir (TIVICAY®, DTG) – ViiV/GSK
27.1	Entecavir generic – Teva	39.	Elvitegravir (VITEKTA®, EVG) – Gilead
27.2	Entecavir generic – Aurobindo	40.	Cobicistat (TYBOST®, COBI) – Gilead
27.3	Entecavir generic – Amneal	41.	Abacavir+dolutegravir+lamivudine (TRIUMEQ®, TRI) – ViiV/GSK
27.4	Entecavir generic – Cipla	42.	Darunavir+cobicistat (PREZCOBIX™, REZOLSTA™, PCX) – Janssen
27.5	Entecavir generic – Accord	43.	Atazanavir+cobicistat (EVOTAZ™, EVO) – BMS
27.99	Entecavir (unknown manufacturer)	44.	Lamivudine+raltegravir (DUTREBIS™, DUT) – Merck (no longer manuf.)
28.	Tipranavir (APTIVUS®, TPV) – BI	45.	Elvitegravir+cobicistat+emtricitabine+tenofovir alafenamide (GENVOYA®, GEN) – Gilead
29.	Efavirenz+tenofovir disoproxil fumarate+emtricitabine (ATRIPLA®, ATR) – Gilead	46.	Rilpivirine+emtricitabine+tenofovir alafenamide (ODEFSEY®, ODE)– Gilead
29.1	Efavirenz+tenofovir disoproxil phosphate+emtricitabine generic – Teva	47.	Emtricitabine+tenofovir alafenamide (DESCOVY®, DVY) – Gilead
29.2	Efavirenz+tenofovir disoproxil phosphate+emtricitabine generic - Zentiva	48.	Tenofovir alafenamide (VEMLIDY®, VEM) – Gilead
29.99	Efavirenz+tenofovir disoproxil +emtricitabine (unknown manufacturer)	49.	Dolutegravir+ Rilpivirine (JULUCA®, DTG+RPV– ViiV/GSK
30.	Telbivudine (TYZEKA®, LdT) – Novartis		
30.1	Telbivudine (SEBIVO®, LdT) – Novartis		
31.	Darunavir (PREZISTA®, DRV) – Janssen		
31.1	Darunavir generic – Teva		
31.99	Darunavir (unknown manufacturer)		

4.2. In the following table, describe each course or change in route for each applicable therapy.								Calculation Source (FOR OFFICE USE ONLY)	
								<input type="checkbox"/> LMP	<input type="checkbox"/> corrected EDD
Course	Med. Code (1-48) if no code indicated, please write medication name and indicate if generic	Blinded therapy?	Total <u>Daily Dose</u>	Unit - mg/day - tab. /cap. - mg/kg/hr - mL	Route (enter code) 1 = oral 2 = IV 3 = SubQ/IM	Pt Taking Med. Prior to Conception? 1 = Yes 2 = No 3 = Unknown	Date Treatment Course Began (DD-MMM-YYYY) OR Gestational Age Course Began (0 weeks = prior to conception)	Date Treatment Stopped (DD/MMM/YYYY), Gestational Week Course stopped OR Ongoing? (Note: Ongoing = ongoing following delivery)	
		<input type="checkbox"/>						or <input type="checkbox"/> ongoing	
		<input type="checkbox"/>						or <input type="checkbox"/> ongoing	
		<input type="checkbox"/>						or <input type="checkbox"/> ongoing	
		<input type="checkbox"/>						or <input type="checkbox"/> ongoing	
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		<input type="checkbox"/>						or <input type="checkbox"/> ongoing	