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).

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@INCResearch.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)		2.2 Is there evidence of a structural defect from one or more of these prenatal tests?
☐	Ultrasound _____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐	Ultrasound _____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐	Amniocentesis _____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐	Cystic Fibrosis Mutation Analysis_____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐	Fetal Echo _____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐	First Trimester Screen _____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐	MSAFP/serum markers _____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐	Nuchal Translucency _____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐	Other (specify):_____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐	Unknown *(go to section 3)*	

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 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

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**
1.1	Abacavir generic – Hetero
1.2	Abacavir generic – Apotex
1.3	Abacavir generic – Mylan
1.4	Abacavir generic – Strides
1.5	Abacavir generic – Aurobindo
1.6	Abacavir generic – Cipla
1.99	Abacavir generic (unknown manufacturer)
2.	**Didanosine (VIDEX®, VIDEX® EC, ddI) – BMS**
2.1	Didanosine generic – Teva
2.2	Didanosine generic – Aurobindo
2.3	Didanosine generic – Mylan
2.99	Didanosine (unknown manufacturer)
3.	**Efavirenz (SUSTIVA®, EFV) – BMS**
3.1	**Efavirenz (STOCRIN™, EFV) – Merck**
3.2	Efavirenz generic – Hetero
3.3	Efavirenz generic – Aurobindo
3.4	Efavirenz generic – Mylan
3.5	Efavirenz generic – Strides
3.99	Efavirenz (unknown manufacturer)
4.	**Lamivudine (EPIVIR®, ZEFFIX®, 3TC) – ViiV/GSK**
4.1	Lamivudine generic – Hetero
4.2	No longer in use (see 51.1)
4.3	Lamivudine generic – Apotex
4.4	Lamivudine generic – Aurobindo
4.5	Lamivudine generic – Silarx/Lannett
4.6	Lamivudine generic – Lupin
4.7	Lamivudine generic – Mylan
4.8	Lamivudine generic – Cipla
4.9	Lamivudine generic – Strides
4.99	Lamivudine (unknown manufacturer)
5.	**Lamivudine+zidovudine (COMBIVIR®, CBV) – ViiV/GSK**
5.1	Lamivudine+zidovudine generic – Hetero
5.2	Lamivudine+zidovudine generic – Teva
5.3	Lamivudine+zidovudine generic – Aurobindo
5.4	Lamivudine+zidovudine generic – Lupin
5.5	Lamivudine+zidovudine generic – Strides
5.6	Lamivudine+zidovudine generic – Mylan
5.99	Lamivudine+zidovudine (unknown manufacturer)
6.	**Nelfinavir (VIRACEPT®, NFV) – ViiV/Pfizer**
7.	**Nevirapine (VIRAMUNE®, VIRAMUNE® XR™, NVP) – BI**
7.1	Nevirapine generic – Hetero
7.2	Nevirapine generic – Prinston
7.3	Nevirapine/nevirapine ER generic – Sciegen (no longer manuf.)
7.4	Nevirapine/nevirapine ER generic – Apotex (no longer manuf.)
7.5	Nevirapine/nevirapine ER generic – Aurobindo
7.6	Nevirapine generic – Strides
7.7	Nevirapine ER generic – Sandoz
7.8	Nevirapine generic – Cipla
7.9	Nevirapine ER generic – Alvogen
7.10	Nevirapine ER generic – Teva
7.11	Nevirapine/nevirapine ER generic – Mylan
7.12	Nevirapine ER generic – Macleods
7.99	Nevirapine (unknown manufacturer)
8.	**Ritonavir (NORVIR®, RTV) – Abbvie**
8.1	Ritonavir generic – West-Ward
8.99	Ritonavir (unknown manufacturer)
9.	**Saquinavir (FORTOVASE®, SQV-SGC) – Roche (no longer manuf.)**
10.	**Saquinavir mesylate (INVIRASE®, SQV-HGC) – Roche**
11.	**Stavudine (ZERIT®, d4T) – BMS**
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) – Roche (no longer manuf.)**
13.	**Zidovudine (RETROVIR®, ZDV) – ViiV/GSK**
13.1	Zidovudine oral generic – Ranbaxy (no longer manuf.)
13.2	Zidovudine oral generic – ViiV/GSK
13.3	Zidovudine oral generic – West-Ward
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 – Sunshine Lakes (no longer manuf.)
13.9	Zidovudine oral generic – Ipca (no longer manuf.)
13.99	Zidovudine oral (unknown manufacturer)
14.	**Amprenavir (AGENERASE®, APV) – ViiV/GSK (no longer manuf.)**
15.	**Indinavir (CRIXIVAN®, IDV) – Merck**
16.	**Delavirdine mesylate (RESCRIPTOR®, DLV) – ViiV/GSK**
17.	**Lopinavir+ritonavir (KALETRA®, ALUVIA®, LPV/r) – Abbvie**
17.1	Lopinavir+ritonavir generic – Silarx/Lannett
17.99	Lopinavir+ritonavir (unknown manufacturer)
18.	**Abacavir+lamivudine+zidovudine (TRIZIVIR®, TZV) – ViiV/GSK**
18.1	Abacavir+lamivudine+zidovudine generic – Lupin
18.99	Abacavir+lamivudine+zidovudine (unknown manufacturer)
19.	**Tenofovir disoproxil fumarate (VIREAD®, TDF) – Gilead**
19.1	Tenofovir disoproxil fumarate generic – Hetero
19.2	Tenofovir disoproxil fumarate generic – Apotex
19.3	Tenofovir disoproxil maleate generic – Mylan
19.4	Tenofovir disoproxil phosphate generic – Zentiva
19.5	Tenofovir disoproxil succinate generic – Dr. Reddys (no longer partic.)
19.6	Tenofovir disoproxil fumarate generic – Aurobindo
19.7	Tenofovir disoproxil fumarate generic – Macleods
19.8	Tenofovir disoproxil fumarate generic - Strides
19.9	Tenofovir disoproxil fumarate generic - Zentiva
19.10	Tenofovir disoproxil fumarate generic - Qilu
19.99	Tenofovir disoproxil fumarate (unknown manufacturer)
20.	**Adefovir dipivoxil (HEPSERA®, ADV) – Gilead**
20.1	Adefovir dipivoxil generic – SigmaPharm
20.99	Adefovir dipivoxil (unknown manufacturer)
21.	**Enfuvirtide (FUZEON®, T-20) – Roche**
22.	**Atazanavir (REYATAZ®, ATV) – BMS**
23.	**Emtricitabine (EMTRIVA®, FTC) – Gilead**
24.	**Fosamprenavir calcium (LEXIVA®, FOS) – ViiV/GSK**

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

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Registry ID_____
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☐ 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)*

25.	**Abacavir+lamivudine (EPZICOM®, KIVEXA®, EPZ) – ViiV/GSK**
25.1	Abacavir+lamivudine generic – Teva
25.2	Abacavir+lamivudine generic – Dr. Reddys (no longer partic.)
25.3	Abacavir+lamivudine generic – Aurobindo
25.4	Abacavir+lamivudine generic – Cipla
25.5	Abacavir+lamivudine generic – Lupin
25.99	Abacavir+lamivudine (unknown manufacturer)
26.	**Tenofovir disoproxil fumarate+emtricitabine (TRUVADA®, TVD) – Gilead**
26.1	Tenofovir disoproxil fumarate+emtricitabine generic – Apotex
26.2	Tenofovir disoproxil maleate+emtricitabine generic – Mylan
26.3	Tenofovir disoproxil succinate+emtricitabine generic – Dr. Reddys (no longer partic.)
26.4	Tenofovir disoproxil phosphate+emtricitabine generic – Zentiva
26.5	Tenofovir disoproxil fumarate+emtricitabine generic – Aurobindo
26.6	Tenofovir disoproxil fumarate+emtricitabine generic - Zentiva
26.99	Tenofovir disoproxil fumarate+emtricitabine generic – (unknown manuf.)
27.	**Entecavir (BARACLUDE®, ETV) – BMS**
27.1	Entecavir generic – Teva
27.2	Entecavir generic – Aurobindo
27.3	Entecavir generic – Amneal
27.4	Entecavir generic – Cipla
27.5	Entecavir generic – Accord
27.6	Entecavir generic – Prinston
27.99	Entecavir (unknown manufacturer)
28.	**Tipranavir (APTIVUS®, TPV) – BI**
29.	**Efavirenz+tenofovir disoproxil fumarate+emtricitabine (ATRIPLA®, ATR) – Gilead**
29.1	Efavirenz+tenofovir disoproxil phosphate+emtricitabine generic – Teva
29.2	Efavirenz+tenofovir disoproxil phosphate+emtricitabine generic - Zentiva
29.99	Efavirenz+tenofovir disoproxil +emtricitabine (unknown manufacturer)
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)
32.	**Raltegravir (ISENTRESS®, RAL) – Merck**
33.	**Maraviroc (SELZENTRY®, CELSENTRI®, MVC) – ViiV/GSK**
34.	**Etravirine (INTELENCE®, ETR) – Janssen**
35.	**Rilpivirine (EDURANT®, RPV) – Janssen**
36.	**Rilpivirine+emtricitabine+tenofovir disoproxil fumarate (COMPLERA®, CPA; EVIPLERA®, EPA) – Gilead**
37.	**Elvitegravir+cobicistat+emtricitabine+tenofovir disoproxil fumarate (STRIBILD®, STB) – Gilead**
38.	**Dolutegravir (TIVICAY®, DTG) – ViiV/GSK**
39.	**Elvitegravir (VITEKTA®, EVG) – Gilead**
40.	**Cobicistat (TYBOST®, COBI) – Gilead**
41.	**Abacavir+dolutegravir+lamivudine (TRIUMEQ®, TRI) – ViiV/GSK**
42.	**Darunavir+cobicistat (PREZCOBIX™, REZOLSTA™, PCX) – Janssen**
43.	**Atazanavir+cobicistat (EVOTAZ™, EVO) – BMS**
44.	**Lamivudine+raltegravir (DUTREBIS™, DUT) – Merck (no longer manuf.)**
45.	**Elvitegravir+cobicistat+emtricitabine+tenofovir alafenamide (GENVOYA®, GEN) – Gilead**
46.	**Rilpivirine+emtricitabine+tenofovir alafenamide (ODEFSEY®, ODE)– Gilead**
47.	**Emtricitabine+tenofovir alafenamide (DESCOVY®, DVY) – Gilead**
48.	**Tenofovir alafenamide (VEMLIDY®, VEM) – Gilead**
49.	**Dolutegravir+ rilpivirine (JULUCA®, DTG+RPV) – ViiV/GSK**
50.	**Efavirenz+lamivudine+tenofovir disoproxil fumarate (SYMFI LO™, EFV+3TC+TDF) – Mylan**
51.	**Lamivudine+tenofovir disoproxil fumarate (CIMDUO™, 3TC+TDF) –Mylan**
51.1	Lamivudine+tenofovir disoproxil fumarate generic – Hetero
51.99	Lamivudine+tenofovir disoproxil fumarate (unknown manufacturer)
52.	**Bictegravir+emtricitabine+tenofovir alafenamide (BIKTARVY®, B/F/TAF) - Gilead**

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

Calculation Source (FOR OFFICE USE ONLY) ☐*LMP* ☐*corrected EDD*

Course	*Med. Code* (1-52) *if no code indicated, please write medication name and indicate if generic*	*Blinded therapy?*	*Total Daily Dose*	*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)
		☐						or ☐ ongoing
		☐						or ☐ ongoing
		☐						or ☐ ongoing
		☐						or ☐ ongoing
		☐						or ☐ ongoing
		☐						or ☐ ongoing
		☐						or ☐ ongoing