2010_V1.0.0 Matrices - Print Matrix

Generated By: Chelsea Krotje Protocol Data Manager

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2010_V1.0.0 Matrices: Print Matrix

Folder: PRINT

Form: SCR10001: IMPAACT 2010 Screening Failure and Non-Enrollment Results

INSTRUCTIONS: Complete this form for mother-infant pairs for whom informed consent for study participation was obtained but who were not enrolled in the study for any reason.

1. - Did the mother-infant pair fail any of the protocol-specified Inclusion Criteria?	Yes ☐ No ☐
a. - Mother is at least 18 years of age.	Passed ☐ Failed ☐ Not Evaluated ☐
b. - Mother is willing and able to provide written informed consent for her and her infant's participation in this study.	Passed ☐ Failed ☐ Not Evaluated ☐
c. - Mother has confirmed HIV-1 infection based on documented testing of two samples collected at different time points, as defined in Protocol Section 4.1.2.	Passed ☐ Failed ☐ Not Evaluated ☐
d. - At screening, mother is ART-naïve, as defined in Protocol Section 4.1.3.	Passed ☐ Failed ☐ Not Evaluated ☐
e. - At screening, mother has a Grade 1 or lower (< 2.5 x ULN) ALT and AST, based on testing of samples collected within 14 days prior to study entry.	Passed ☐ Failed ☐ Not Evaluated ☐
f. - At screening, mother has a Grade 2 or lower (≤1.8 x ULN) creatinine, based on testing of samples collected within 14 days prior to study entry.	Passed ☐ Failed ☐ Not Evaluated ☐
g. - At screening, mother has a Grade 2 or lower (≥60 mL/min) estimated creatinine clearance (CrCl; Cockcroft-Gault formula), based on testing of samples collected within 14 days prior to study entry.	Passed ☐ Failed ☐ Not Evaluated ☐
h. - At screening and at study entry, no evidence of multiple gestation or fetal anomalies, as assessed by best available method.	Passed ☐ Failed ☐ Not Evaluated ☐
i. - At study entry, mother is pregnant with gestational age of 14-28 weeks, defined as greater than 13 weeks plus six days and less than 28 completed weeks gestation, estimated by best available method.	Passed ☐ Failed ☐ Not Evaluated ☐
j. - At study entry, mother expects to remain in the geographic area of the study site during pregnancy and for 50 weeks postpartum.	Passed ☐ Failed ☐ Not Evaluated ☐
2. - Did the mother-infant pair meet any of the protocol-specified Exclusion Criteria?	Yes ☐ No ☐
a. - Mother is currently incarcerated or involuntarily confined in a medical facility.	Passed ☐ Failed ☐ Not Evaluated ☐

b. - Mother is currently receiving a psychoactive medication for treatment of a psychiatric illness.	Passed ☐ Failed ☐ Not Evaluated ☐
c. - Mother is currently receiving treatment for active tuberculosis.	Passed ☐ Failed ☐ Not Evaluated ☐
d. - Mother is currently receiving treatment for active hepatitis C infection.	Passed ☐ Failed ☐ Not Evaluated ☐
e. - Mother is expected to require treatment with interferon and/or ribavirin for hepatitis C infection during the study follow-up period.	Passed ☐ Failed ☐ Not Evaluated ☐
f. - Mother has a history of hypersensitivity or clinically significant adverse reaction to any of the ARVs included in the three study drug regimens (ever), as determined by the site investigator or designee based on maternal report and available medical records.	Passed ☐ Failed ☐ Not Evaluated ☐
g. - Mother has a history of clinically significant heart disease and/or known prolonged QTc interval (ever), as determined by the site investigator or designee based on maternal report and available medical records.	Passed ☐ Failed ☐ Not Evaluated ☐
h. - Mother has a history of suicidal ideation or attempt (ever), as determined by the site investigator or designee based on maternal report and available medical records.	Passed ☐ Failed ☐ Not Evaluated ☐
i. - Mother has a history of Zika virus infection, diagnosed or suspected, during the current pregnancy, as determined by the site investigator or designee based on maternal report and available medical records.	Passed ☐ Failed ☐ Not Evaluated ☐
j. - Mother has a history of receipt of any antiretroviral medication within six months prior to study entry, with the exception of receipt of up to 14 days of ARVs during the current pregnancy, as determined by the site investigator or designee based on maternal report and available medical records.	Passed ☐ Failed ☐ Not Evaluated ☐
k. - Mother has a history of receipt of any prohibited medication within 14 days prior to study entry (see Protocol Section 5.9), as determined by the site investigator or designee based on maternal report and available medical records.	Passed ☐ Failed ☐ Not Evaluated ☐
l. - Mother has a history of clinically significant acute illness requiring systemic treatment and/or hospitalization within 14 days prior to study entry, as determined by the site investigator or designee based on maternal report and available medical records.	Passed ☐ Failed ☐ Not Evaluated ☐
m. - Mother has a history of unstable liver disease (defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, esophageal or gastric varices, or persistent jaundice) or known biliary abnormalities (with the exception of Gilbert's syndrome or asymptomatic gallstones) within 14 days prior to study entry, as determined by the site investigator or designee based on maternal report and available medical records.	Passed ☐ Failed ☐ Not Evaluated ☐

n. - Mother or fetus has any other condition that, in the opinion of the site investigator or designee, would make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.	Passed ☐ Failed ☐ Not Evaluated ☐
3 - Are there any additional reason(s) why the mother-infant pair was not enrolled in this study?	Yes ☐ No ☐
a. - Mother did not return to clinic.	Yes ☐ No ☐
b. - Mother died.	Yes ☐ No ☐
c. - Pregnancy ended before enrollment occurred.	Yes ☐ No ☐
d. - Consent withdrawn.	Yes ☐ No ☐
If Yes, specify reason [200]:	_____
e. - Mother not willing or unable to participate.	Yes ☐ No ☐
If Yes, specify reason [200]:	_____
f. - Mother-infant pair could not be enrolled within the protocol-specified timeframes due to administrative or logistical issues.	Yes ☐ No ☐
If Yes, specify [200]:	_____
g. - Other	Yes ☐ No ☐
If Yes, specify [200]:	_____

INSTRUCTIONS: For IMPAACT 2010: Refer to Protocol Sections 7.2 and 7.3 for reporting requirements.

For diagnoses criteria refer to appendix 100 located at the DMC Portal (https://www.fstrf.org).

SECTION A	SECTION A
Adverse Event Identifier	
1. - What is the adverse event term [200]?	
2. - What is the severity grade of the adverse event?	1 - Grade 1 ☐ 2 - Grade 2 ☐ 3 - Grade 3 ☐ 4 - Grade 4 ☐ 5 - Grade 5 ☐ Not Gradable ☐
3. - What is the date the adverse event started?	
4. - Is the adverse event a sign/symptom or abnormal laboratory event associated with a reported diagnosis?	Yes ☐ No ☐
5. - Specifically, is the adverse event an abnormal laboratory event?	Yes ☐ No ☐
6. - Is the adverse event still ongoing?	Yes ☐ No ☐
7. - On what date did the adverse event end?	
8. - What was the outcome of the adverse event?	Recovered/resolved ☐ Recovering/resolving ☐ Recovered/resolved with sequelae ☐ Not recovered/not resolved ☐ Fatal ☐ Unknown ☐
9. - Is the adverse event related to or was action taken with one or more of the study treatment medications?	Yes ☐ No ☐
a. - Name of study treatment medication [70]:	
a1. - Is the adverse event related to the medication listed in '9a'?	Related ☐ Not related ☐
a2. - What action was taken with the medication listed in '9a'?	Dose not changed ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted ☐ Drug withdrawn ☐ Not applicable ☐ Unknown ☐
b. - Name of study treatment medication [70]:	

b1. - Is the adverse event related to the medication listed in '9b'?	Related ☐ Not related ☐
b2. - What action was taken with the medication listed in '9b'?	Dose not changed ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted ☐ Drug withdrawn ☐ Not applicable ☐ Unknown ☐
c. - Name of study treatment medication [70]:	_____
c1. - Is the adverse event related to the medication listed in '9c'?	Related ☐ Not related ☐
c2. - What action was taken with the medication listed in '9c'?	Dose not changed ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted ☐ Drug withdrawn ☐ Not applicable ☐ Unknown ☐
d. - Name of study treatment medication [70]:	_____
d1. - Is the adverse event related to the medication listed in '9d'?	Related ☐ Not related ☐
d2. - What action was taken with the medication listed in '9d'?	Dose not changed ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted ☐ Drug withdrawn ☐ Not applicable ☐ Unknown ☐
e. - Name of study treatment medication [70]:	_____
e1. - Is the adverse event related to the medication listed in '9e'?	Related ☐ Not related ☐
e2. - What action was taken with the medication listed in '9e'?	Dose not changed ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted ☐ Drug withdrawn ☐ Not applicable ☐ Unknown ☐
10. - Is the adverse event related to the (study number) (procedure)?	Related ☐

	Not related ☐
	Not applicable ☐
SECTION B	SECTION B
11. - Does the adverse event meet ICH criteria as serious?	Yes ☐
	No ☐

If Yes, indicate the category of the adverse event that classified the event as "serious".
Select all that apply.

a. - Death	☐
b. - Life threatening	☐
c. - Hospitalization	☐
d. - Significant Disability	☐
e. - Congenital Anomaly or Birth Defect	☐
f. - Other Medically Important Event	☐

12. - Was this adverse event reported through DAERS?	Yes ☐
	No ☐
a. - Date EAE first reported to DAERS:	
b. - DAERS EAE Number:	
13. - Date of initial report:	

Form: ADM10000: Permanent Study Treatment Discontinuation

1. - Permanent study treatment discontinuation date:	
2. - Select the **primary reason** for study treatment discontinuation:	
a. - If Other, specify [70]:	
3. - Describe the primary reason for permanent study treatment discontinuation [200]:	

```
Primary Reasons for Study Treatment Discontinuation:
COMPLETED AS DEFINED BY THE PROTOCOL
ADVERSE EVENT
CLINICAL OR LABORATORY EVENT THAT DOES NOT MEET AE CRITERIA
DEATH
VIROLOGIC FAILURE
LACK OF EFFICACY
DISEASE PROGRESSION
CONFOUNDING MEDICAL CONDITION
NEED FOR PROHIBITED MEDICATION
NEED FOR NON-PROHIBITED MEDICATION
WITHDRAWAL BY PARTICIPANT
PARTICIPANT REFUSAL TO CONTINUE STUDY DRUG WHILE REMAINING ON
STUDY
NON-COMPLIANCE WITH STUDY DRUG
NON-COMPLIANCE WITH STUDY REQUIREMENTS
LOST TO FOLLOW-UP
INCARCERATION
ELIGIBILITY FAILURE DETERMINED AFTER STUDY ENTRY
UNEXPECTED CLOSURE OF SITE
UNEXPECTED CLOSURE OF STUDY
UNEXPECTED CLOSURE OF ARM
OTHER
```

Form: ADM10001: Study Discontinuation

1. - Study discontinuation date:	
2. - Select the **primary reason** for study discontinuation:	COMPLETED AS DEFINED BY THE PROTOCOL ☐ DEATH ☐ ENROLLED FETUS RESULTED IN A FETAL DEMISE ☐ ENROLLED PREGNANT MOTHER EXPERIENCED A FETAL DEMISE ☐ CONFOUNDING MEDICAL CONDITION ☐ SEVERE DEBILITATION ☐ LOST TO FOLLOW-UP ☐ DID NOT RETURN TO CLINIC ☐ NOT ABLE TO GET TO CLINIC ☐ MOVED ☐ INCARCERATION ☐ NON-COMPLIANCE WITH STUDY REQUIREMENTS ☐ WITHDRAWAL BY PARENT/GUARDIAN ☐ WITHDRAWAL BY PARTICIPANT ☐ ELIGIBILITY FAILURE DISCOVERED AFTER STUDY ENTRY ☐ UNEXPECTED CLOSURE OF SITE ☐ OTHER ☐
a. - If Other, specify [70]:	
3. - Describe the primary reason for study discontinuation [200]:	

1. - Was the study participant expected to receive study defined treatment on the current step for this study? **NOTE:** Study treatment refers to the study drug regimen to which the mother was randomly assigned, consistent with Protocol Section 5.1. Contact the protocol data managers if the mother does not receive study treatment at Entry.	Yes ☐ No ☐
2. - Did the participant start the study/step defined treatment at this visit or since the last visit?	Yes ☐ No ☐
a. - Indicate the reason that the study participant did not start study/step defined treatment	WITHDRAWAL BY PARTICIPANT ☐ DID NOT RETURN TO CLINIC ☐ ELIGIBILITY FAILURE DISCOVERED AFTER STUDY ENTRY ☐ NEED FOR PROHIBITED MEDICATION ☐ DEATH ☐ OTHER ☐
If Other, specify [70]:	_____
3. - What was the date of the first known dose of study/step defined treatment?	_____

Form: ADM10010: IMPAACT 2010 Death Report

INSTRUCTIONS: This form is added to the folder when the reason for study discontinuation is reported as death.

Date of death: _____

What is the primary source of the cause of death?

- ☐ Autopsy
- ☐ Clinical record
- ☐ Contact with physician or primary care provider
- ☐ Death certificate
- ☐ Information from friends or relatives
- ☐ Obituary
- ☐ Other

If Other, specify [200]: _____

Brief narrative description of death. Add rows as necessary.

Brief narrative [200]: _____

Is there any information available about the cause of death?

- ☐ Yes
- ☐ No

What is the primary cause of death? [70] _____

Based on the above narrative, select the category that best defines the primary cause of death:

- ☐ Non-study drug toxicity
- ☐ Study drug toxicity
- ☐ HIV infection or HIV associated illness other than TB
- ☐ Non-HIV diagnosis other than TB
- ☐ Attributed to TB
- ☐ Other

If Other, specify [200]: _____

INSTRUCTIONS: Complete and update this form as needed to document the study visit contacts as per protocol. This includes telephone visit evaluations.

1. - What is the visit/contact date? _____

2. - What is the visit/contact end date? _____

3. - Did the visit/contact occur?
- ☐ Yes
- ☐ No

If No, indicate the primary reason for the missed visit/contact:
- ☐ Transportation problem
- ☐ Scheduling problem
- ☐ Participant is too ill to come to clinic or is hospitalized
- ☐ Caregiver/guardian illness
- ☐ Unable to contact participant or caregiver
- ☐ Other family issues
- ☐ Problem with medical insurance
- ☐ Study on hold
- ☐ Participant incarcerated
- ☐ Other

If Other, specify [200]: _____

4. - What is the source of this information?
- ☐ Clinic/Research study visit
- ☐ Other contact with participant
- ☐ Contact with health care provider/physician
- ☐ Contact with family or designated contact person
- ☐ Hospital chart only
- ☐ No information or no contact
- ☐ Other

If Other, specify [200]: _____

INSTRUCTIONS:
• Maintain the log by adding a new row for each new medication that is started. If a medication is taken at more than one dose or frequency, a separate entry is required for each dose and frequency.

• If a medication is started and stopped, but then started again at a later time, a separate entry is required for each discrete initiation of the medication.

• For vaccinations, enter each dose administered as a separate entry; enter the date of administration as the start date and the end date.

• For injectable contraceptives and other medications administered by injection, enter each injection as a separate entry; enter the date of injection as the start date and the end date.

• For contraceptive patches, rings, and implants, enter the date of placement as the start date and enter the date of removal as the end date.

For IMPAACT 2010:

• For Mothers: Use this form as a continuing log of medications—other than the study drugs listed in Protocol Section 5.1—that are required to be entered into eCRFs per Protocol Sections 5.8 and 6.11. Enter all ARVs received prior to and during the current pregnancy, prior to enrollment, on this form. Any ARVs defined as "study drug" should be reported on the TXW10001: Treatment Log.

• For Infants: Refer to Protocol Section 5.8 and Table 4 in Protocol Section 6.14 for reporting requirements. Use this form as a continuing log of medications taken from birth and throughout the infant's time on study. Enter all ARVs into this form.

1. - Medication name [70]: _____

2. - Indicate primary disease category
- ☐ HIV
- ☐ Active TB
- ☐ Latent TB
- ☐ Hepatitis B
- ☐ Hepatitis C
- ☐ General concomitant medication
- ☐ Traditional Medication

3. - Primary indication:
- ☐ Prophylaxis
- ☐ Optimized background regimen
- ☐ Treatment

4. - Single Dose [nnnn.nnn] _____

a. - Units:
- ☐ mL
- ☐ mg

	mg/mL ☐ Other ☐
b. - If Other, specify [70]:	
5. - Frequency	
a. - If Other, specify [70]:	
6. - Start date	
7. - Started prior to study?	Yes ☐ No ☐
8. - Ongoing	Yes ☐ No ☐
9. - End date	

```
Dates are reported in the format dd/MMM/yyyy with a three-letter abbreviation for
the month. For example, 15/JAN/2015. A complete date is preferred for the
medication therapy start date.
If the day of the event is unknown, report the month and year: un/MMM/yyyy
If the month of the event is unknown report the year: un/UNK/yyyy
If the exact year is unknown report the estimated year: un/UNK/yyyy
```

Site awareness date: _____

NOTE: For a deviation that applies to a single date, please enter the same date for both the start and stop dates below.

Deviation start date: _____

Deviation stop date: _____

Has or will this deviation be reported to local IRB/EC?
- Yes ☐
- No ☐

Has or will this deviation be reported to DAIDS as a critical event?
- Yes ☐
- No ☐

Type of deviation:
- Inappropriate enrollment ☐
- Failure to follow trial randomization or blinding procedures ☐
- Study product management deviation ☐
- Study product dispensing error ☐
- Conduct of non-protocol procedure ☐
- Breach of confidentiality ☐
- Physical assessment deviation ☐
- Lab assessment deviation ☐
- Use of non-IRB/EC-approved materials ☐
- Informed assent/consent process deviation ☐
- Other ☐

NOTE: Please include the following information in your description below:

• Explain the reason for deviation

• Risk/benefit ratio for the participant(s)

• Integrity of the research data

• Participant's willingness (or parent/legal guardian's willingness) to continue study participation

Description of deviation [800]: _____

Describe any corrective actions taken to address this deviation [800]: _____

Describe any preventive actions taken to prevent recurrence [800]: _____

Deviation reported by (staff name) [70]: _____

NOTE: The deviation should be reported by the responsible/communicating site staff member (IoR or other designee).

Report date: 14 Jun 2017

Was a DXA scan performed?	Yes ☐ No ☐
If No, specify reason not performed [70]:	_____
Indicate the type of DXA scan performed. Check all that apply.	
Hip	☐
Lumbar Spine	☐
Whole Body	☐
Indicate the start date of exam:	_____
Indicate the end date of exam:	_____
Was the DXA scan information sent to the central reader?	Yes ☐ No ☐
Indicate date sent to central reader:	_____

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Folder: PRINT

Form: DXW10000: IMPAACT 2010 Congenital Anomalies

INSTRUCTIONS: If completing this form for an enrolled infant, report any suspected and/or confirmed congenital anomalies on the ADE10002: Adverse Event Log **prior** to completion of this form.
Refer to Protocol Section 6.16 for detailed reporting requirements.
Please provide as much detail as possible when describing an anomaly.
When uploading photographs, utilize the File Exchange Utility found on the Frontier Science Portal Website (http://www.frontierscience.org/).

Select the congenital anomaly to be described: **NOTE:** If reporting a congenital anomaly for a subsequent pregnancy, leave this field blank.	
Provide a detailed narrative about the anomaly [200]:	
Enter the date that the anomaly was first identified:	
Indicate the number of photographs uploaded to the File Exchange Utility [nn]:	

Form: DXW10001: IMPAACT 2010 Targeted Pregnancy Diagnoses

INSTRUCTIONS:

At study entry: Record any pregnancy complications during the index pregnancy up to the time of enrollment.

At delivery: Record any new pregnancy complications that occur during the index pregnancy from the time of enrollment up to 14 days postpartum that have not been previously reported.

For subsequent pregnancies: Record any pregnancy complications identified during the subsequent pregnancy or up to 14 days postpartum.

Any pregnancy complications reported on this form that meet protocol-defined AE criteria per Protocol Section 7.2 must also be reported on the ADE10002: Adverse Event Log (Multi).

Are there any new targeted pregnancy diagnoses that are required to be reported? Yes ☐ No ☐

Indicate what type of pregnancy the diagnoses are being reported for: Index ☐ Subsequent ☐

Indicate if any of the following have been diagnosed:

Was maternal Zika virus infection suspected or confirmed during the current pregnancy? Yes ☐ No ☐

Provide a narrative surrounding the condition [400]: _____

Diagnosis: Abortion, spontaneous/miscarriage

time of onset was at 23 weeks and 4 days, report 23 weeks. If diagnosed postpartum, leave this field blank.

Diagnosed? ☐

Number of completed gestational weeks at time of onset [nn]. _____

Diagnosis: Abortion, therapeutic

Diagnosed? ☐

Number of completed gestational weeks at time of onset [nn]. _____

Diagnosis: Bleeding, vaginal

Diagnosed? ☐

Number of completed gestational weeks at time of onset [nn]. _____

Diagnosis: Cord prolapse

Diagnosed? ☐

Number of completed gestational weeks at time of onset [nn]. _____

Diagnosis: Febrile morbidity

Diagnosed? ☐

Number of completed gestational weeks at time of onset [nn]. _____

Diagnosis: Eclampsia

Diagnosed? ☐

Number of completed gestational weeks at time of onset [nn]. _____

Diagnosis: Pre-eclampsia

Diagnosed? ☐

Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	HELLP syndrome
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Hypertension, chronic, in pregnancy
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Hypertension, pregnancy-induced
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Hematoma, vaginal or vulvar
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Hemorrhage with hemodynamic instability, intrapartum
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Hemorrhage requiring surgical procedure, intrapartum
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Hemorrhage requiring transfusion, intrapartum
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Hemorrhage with hemodynamic instability, postpartum
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Hemorrhage requiring surgical procedure, postpartum
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Hemorrhage requiring transfusion, postpartum
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Incompetent cervix, prophylactic cerclage
Diagnosed?	☐

Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Incompetent cervix, emergent cerclage
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Incompetent cervix, no cerclage
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Intrauterine fetal demise
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Intrauterine growth restriction (IUGR)
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Significant growth lag
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Oligohydramnios
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Polyhydramnios
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Placenta, abruptio
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Placenta accreta
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Placenta increta
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Placenta percreta
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Placenta previa

Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Placenta, unspecified
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Pregnancy, ectopic
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Pregnancy, post-term
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Preterm labor
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Premature rupture of membranes, preterm
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Premature rupture of membranes, term
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Preterm delivery
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Uterine atony
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Uterine inversion
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Uterine rupture
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Uterine scar dehiscence
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	

Diagnosis:	Group B streptococcal infection
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Cholestasis of pregnancy
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Pruritic urticarial papules and plaques of pregnancy (PUPPS)
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Uterine leiomyoma
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Pyelonephritis
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Urinary tract infection (lower tract)
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Any sexually transmitted infection (other than HIV)
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Bacterial vaginosis
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Significant trauma
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Gestational diabetes
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Chorioamnionitis
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Cervicitis

Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Fatty liver
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Cesarean wound infection
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	
Diagnosis:	Endometritis
Diagnosed?	☐
Number of completed gestational weeks at time of onset [nn].	

Last Menstrual Period Information:

Does the mother know the date of the first day of her last menstrual period? Yes ☐ No ☐

What is the date of the first day of the mother's last menstrual period? ~~A complete date is preferred for the last menstrual period date. If the day of the event is unknown, report the month and year: un/MMM/yyyy.~~

Is the mother certain about this date? Yes ☐ No ☐

Ultrasound Information: Complete this section using information from the earliest ultrasound available.

Date of scan: _____

Number of fetuses [n]: _____

Gestational age on date of this scan (completed weeks) [nn]: _____

Gestational age on date of this scan (completed days) [n]: _____

Estimated date of delivery based on this scan: _____

Fetus A ☐ B ☐ C ☐

Was fetal heart beat present? Present ☐ Absent ☐ Not evaluated ☐

Fetal weight (g) [nnnn] _____

Crown-rump length (cm) [nnn.nn] _____

Femur length (mm) [nnn.n] _____

Abdominal circumference (cm) [nnn.nn] _____

Biparietal diameter (mm) [nnn.n] _____

Head circumference (cm) [nnn.nn] _____

Were any fetal anomalies identified? Yes ☐ No ☐

If Yes, specify [200]: _____

Are there any comments regarding this obstetrical ultrasound? Yes ☐ No ☐

If Yes, specify [200]: _____

Number of fetuses/infants:

- 0 ☐
- 1 ☐
- 2 ☐
- 3 ☐

NOTE: If molar pregnancy or false positive, select '0'.

Infant PID Number:

If completing this log line for a subsequent pregnancy, leave "Infant PID" field blank.

Indicate outcome:

- Live birth ☐
- Stillbirth/Intrauterine fetal demise (IUFD ≥ 20 weeks) ☐
- Spontaneous abortion (< 20 weeks) ☐
- Induced abortion (therapeutic or elective) ☐
- Ectopic pregnancy ☐
- Molar pregnancy ☐
- False positive/No pregnancy ☐

Provide date of delivery/outcome: _____

Provide a brief narrative of circumstances [200]: _____

Estimated gestational age at time of pregnancy outcome (completed weeks) [nn]: _____

Estimated gestational age at time of pregnancy outcome (completed days) [n]: _____

When was stillbirth diagnosed?

- Prior to labor ☐
- During labor ☐
- At delivery ☐
- Unknown ☐

If stillborn, were macerated skin changes noted?

- Yes ☐
- No ☐
- Unknown ☐

Form: EVW10014: IMPAACT 2010 WHO Staging System for HIV Infection

INSTRUCTIONS: Refer to the WHO Case Definitions of HIV for Surveillance and Revised Clinical Staging and Immunological Classification of HIV-related Disease in Adults and Children (World Health Organization 2007).

Indicate the participant's WHO HIV clinical classification: `Indicate the worst classification.`	Stage 1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4 ☐
Does the participant know the date when they first reached the clinical stage? `For asymptomatic in Stage 1, indicate the date of HIV diagnosis`	Yes ☐ No ☐
How certain is the participant about this date?	Certain ☐ Uncertain ☐
If Certain, indicate the date when the study participant first reached the clinical stage:	_____
If Uncertain, estimate of when participant first reached the clinical stage:	Before ☐ During ☐ After ☐ Unknown ☐
Estimate year when participant first reached the clinical stage [YYYY]:	_____

1. - Number of fetuses:	1 ☐ 2 ☐ 3 ☐
2. - Was the mother in labor prior to delivery?	Yes ☐ No ☐ Unknown ☐
a. - Enter the date labor began:	_____
b. - Enter the time labor began:	_____
3. - How long prior to delivery did labor begin?	0-<4 hours ☐ 4-<6 hours ☐ 6-<12 hours ☐ 12-24 hours ☐ >24 hours ☐ Unknown ☐
4. - Did the membranes rupture prior to active labor?	Yes ☐ No ☐
5. - Was labor spontaneous or induced?	Spontaneous ☐ Induced ☐
a. - If Induced, what is the primary indication for induction?	Gestational hypertension (e.g., pre-eclampsia, eclampsia, HELLP) ☐ Worsening maternal chronic hypertension ☐ Chorioamnionitis ☐ Post-term pregnancy ☐ Fetal growth restriction ☐ Oligohydramnios ☐ Isoimmunization ☐ Abnormal fetal testing ☐ Multiple gestation ☐ Placental abruption ☐ Cholestasis of pregnancy ☐ Fetal death ☐ Prolonged rupture of membranes (PROM) ☐ Other maternal chronic disease (e.g. diabetes mellitus, renal disease, chronic pulmonary disease) ☐ Other maternal indication ☐ Other fetal indication ☐
b. - If Other, specify [70]:	_____
6. - Did the mother experience any adverse events during labor and delivery?	Yes ☐ No ☐ Unknown ☐

rotocol Section 7.2 and enter adverse events that meet protocol-specified reporting requirements into the ADE10002: Adverse Even

7. - Were any concomitant medications taken during labor and delivery? Yes ☐ No ☐ Unknown ☐

1 and enter concomitant medications that meet protocol-specified reporting requirements into the CMW10001: IMPAACT 2010 Concomit

8. - Were any corticosteroids given for preterm labor at any point during this pregnancy? Yes ☐ No ☐ Unknown ☐

es, go to the CMW10001: Concomitant Medications Log and enter any corticosteroids given for preterm labor

INSTRUCTIONS: Record only the vital signs and anthropometric measurements taken at birth on this form.

1. - Was a newborn exam performed? Yes / No

If No, specify reason not done [200]: _____

a. - Date of exam _____

2. - General Activity: Normal / Abnormal / Unknown

a. - If abnormal, specify [200]: _____

3. - Physical Exam: Normal / Abnormal / Unknown

a. - If abnormal, specify [200]: _____

4. - Are the infant's Apgar scores available? Yes / No

a. - At 1 minute? Yes / No

Score at 1 minute [nn]: _____

b. - At 5 minutes? Yes / No

Score at 5 minutes [nn]: _____

5. - Were any of the following anthropometric measurements collected at birth? Yes / No

uld be obtained at infant birth (from birth records). Measurements performed by study staff at the Delivery Visit should be reco

a. - Weight [nnnnnn.nn]: _____

Weight unit: Grams (g) / Kilograms (kg) / Pounds (lb)

b. - Length [nnn.n]: _____

Length unit: Centimeters (cm) / Inches (in)

c. - Head Circumference (cm) [nn.n]: Fixed Unit: cm

_____

d. - Was the status of fontanelle closure determined? Yes / No / Not Evaluated

Anterior Fontanelle: Open / Closed / Not Evaluated

Posterior Fontanelle: Open

Closed
Not Evaluated

1. - Is information available about the delivery?	Yes ☐ No ☐
2. - Infant PID Number:	_____
3. - What is the infant's date of birth?	_____
4. - What is the infant's time of birth?	_____
5. - What is the sex of the infant?	Male ☐ Female ☐ Ambiguous genitalia/Intersex ☐ Unknown ☐
6. - Type of delivery:	Spontaneous vaginal ☐ Assisted vaginal ☐ Elective cesarean ☐ Emergency cesarean ☐
a. - What was the primary indication for the cesarean section?	Protraction and/or arrest of labor ☐ Fetal distress ☐ Malpresentation ☐ Previous cesarean ☐ Placenta previa ☐ Placenta abruptio ☐ Reduction of MTCT risk (e.g. detectable maternal HIV RNA) ☐ Genital herpes simplex virus (HSV) ☐ Failed induction ☐ Prolonged rupture of membranes (PROM) ☐ Pre-eclampsia/Eclampsia ☐ Cord prolapse ☐ Multiple gestation ☐ Fetal anomaly ☐ Macrosomia ☐ Subject request/desire ☐ Other maternal indication ☐ Other fetal indication ☐
b. - If Other, specify [70]:	_____
7. - Presentation:	Vertex ☐ Breech ☐ Transverse ☐

Did you ever drink alcohol prior to this pregnancy?	Yes ☐ No ☐ Declined to answer ☐
Have you had at least one drink containing alcohol during this pregnancy?	Yes ☐ No ☐ Declined to answer ☐
Did you ever use tobacco products prior to this pregnancy?	Yes ☐ No ☐ Declined to answer ☐
Have you used any tobacco product at least one time during this pregnancy?	Yes ☐ No ☐ Declined to answer ☐
What type of tobacco product have you used?	Smoked only ☐ Smokeless only ☐ Both smoked and smokeless ☐

Form: LBW10000: HIV-1 Plasma Viral Load

1. - Was an HIV-1 RNA plasma viral load result obtained from the testing lab? Yes ☐ No ☐

a. - If No, reason viral load not obtained [200]: _____

2. - Result reported via the LDMS? Yes ☐ No ☐

`the results will be reported via the LDMS, answer 'Yes' and save. Do not complete the remainder of the form.`

3. - Specimen date: _____

4. - Enter the assay date; if assay date is not available, enter the report date: _____

5. - Date type: Assay date ☐ Report date ☐

6. - Assay type: bDNA (Versant HIV-1 RNA 3.0 3rd generation, Chiron/Bayer/Siemens) ☐ Roche COBAS TaqMan HIV-1 Test ☐ Abbott RealTime HIV-1 ☐ Roche COBAS TaqMan HIV-1 Test, V. 2.0 ☐ Other ☐

a. - If Other, specify [200]: _____

"Not Detected" results should be reported as less than the lower limit of quantification for the assay.

7. - HIV-1 RNA plasma viral load qualifier: Equal to (=) ☐ Greater than (>) ☐ Less than (<) ☐

a. - If qualifier is 'Less than (<)', indicate whether HIV-1 RNA was detected: Detected ☐ Not detected ☐ Unknown ☐

8. - HIV-1 RNA plasma viral load (copies/mL) [nnnnnnnnn]: Fixed Unit: copies/mL _____

Form: LBW10005: Pregnancy Test

1. - Was a pregnancy test performed?	Yes ☐ No ☐
a. - If No, specify reason not done [70]:	_____
2. - Specimen Type:	Serum ☐ Urine ☐
3. - Test Result:	Negative ☐ Positive ☐
4. - Specimen Date:	_____

Form: LBW10009: IMPAACT 2010 Laboratory Test Results (Chem/Hem)

INSTRUCTIONS: For IMPAACT 2010: Refer to Protocol Section 7.2 for laboratory test result reporting requirements. When any results are obtained that meet protocol-defined reporting requirements, enter "Yes" in item 1 and continue. For assistance when calculating creatinine clearance, use the appropriate calculator utility found on the Frontier Science Portal Website (www.frontierscience.org).

1. - Was the sample collected?	Yes ☐ No ☐
a. - If No, specify reason not collected [70]:	
2. - Collection date:	
12. - Are there any additional chemistry/hematology laboratory test results to report, obtained at an additional time point for this visit or since the last visit?	Yes ☐ No ☐
3. - Lab Test Name:	ALT - Alanine Amino Transferase (Serum Glutamic-Pyruvic Transaminase/SGPT)
a. - If Other, specify [70]:	
4. - Test performed?	Yes ☐ No ☐ Not Required ☐
a. - If No, specify reason not done [70]:	
5. - Result [nnnnnnn.nnn]:	
6. - Unit:	
7. - Normal Range Lower limit (Reference range) [nnnnnnn.nnn]:	
8. - Normal Range Upper limit (Reference range) [nnnnnnn.nnn]:	
9. - Toxicity grade:	0 - Grade 0 ☐ 1 - Grade 1 ☐ 2 - Grade 2 ☐ 3 - Grade 3 ☐ 4 - Grade 4 ☐ Not Gradable ☐
10. - Does test result meet protocol criteria for adverse event reporting?	Yes ☐ No ☐
11. - Select the corresponding adverse event term as reported on the AE Log.	
3. - Lab Test Name:	AST - Aspartate Amino Transferase (Serum Glutamic Oxaloacetic Transaminase/SGOT)
a. - If Other, specify [70]:	
4. - Test performed?	Yes ☐ No ☐ Not Required ☐
a. - If No, specify reason not done [70]:	
5. - Result [nnnnnnn.nnn]:	
6. - Unit:	
7. - Normal Range Lower limit (Reference range) [nnnnnnn.nnn]:	
8. - Normal Range Upper limit (Reference range) [nnnnnnn.nnn]:	

9. - Toxicity grade:	0 - Grade 0 ☐ 1 - Grade 1 ☐ 2 - Grade 2 ☐ 3 - Grade 3 ☐ 4 - Grade 4 ☐ Not Gradable ☐
10. - Does test result meet protocol criteria for adverse event reporting?	Yes ☐ No ☐
11. - Select the corresponding adverse event term as reported on the AE Log.	
3. - Lab Test Name:	ANC - Absolute Neutrophil Count (WBC x % Neutrophils Including Bands) ●
a. - If Other, specify [70]:	
4. - Test performed?	Yes ☐ No ☐ Not Required ☐
a. - If No, specify reason not done [70]:	
5. - Result [nnnnnnn.nnn]:	
6. - Unit:	
7. - Normal Range Lower limit (Reference range) [nnnnnnn.nnn]:	
8. - Normal Range Upper limit (Reference range) [nnnnnnn.nnn]:	
9. - Toxicity grade:	0 - Grade 0 ☐ 1 - Grade 1 ☐ 2 - Grade 2 ☐ 3 - Grade 3 ☐ 4 - Grade 4 ☐ Not Gradable ☐
10. - Does test result meet protocol criteria for adverse event reporting?	Yes ☐ No ☐
11. - Select the corresponding adverse event term as reported on the AE Log.	
3. - Lab Test Name:	CRCL - Creatinine Clearance - Calculated ●
a. - If Other, specify [70]:	
4. - Test performed?	Yes ☐ No ☐ Not Required ☐
a. - If No, specify reason not done [70]:	
5. - Result [nnnnnnn.nnn]:	
6. - Unit:	
7. - Normal Range Lower limit (Reference range) [nnnnnnn.nnn]:	
8. - Normal Range Upper limit (Reference range) [nnnnnnn.nnn]:	
9. - Toxicity grade:	0 - Grade 0 ☐

	1 - Grade 1 ☐
	2 - Grade 2 ☐
	3 - Grade 3 ☐
	4 - Grade 4 ☐
	Not Gradable ☐
10. - Does test result meet protocol criteria for adverse event reporting?	Yes ☐
	No ☐
11. - Select the corresponding adverse event term as reported on the AE Log.	
3. - Lab Test Name:	CRET - Creatinine ■
a. - If Other, specify [70]:	
4. - Test performed?	Yes ☐
	No ☐
	Not Required ☐
a. - If No, specify reason not done [70]:	
5. - Result [nnnnnnn.nnn]:	
6. - Unit:	
7. - Normal Range Lower limit (Reference range) [nnnnnnn.nnn]:	
8. - Normal Range Upper limit (Reference range) [nnnnnnn.nnn]:	
9. - Toxicity grade:	0 - Grade 0 ☐
	1 - Grade 1 ☐
	2 - Grade 2 ☐
	3 - Grade 3 ☐
	4 - Grade 4 ☐
	Not Gradable ☐
10. - Does test result meet protocol criteria for adverse event reporting?	Yes ☐
	No ☐
11. - Select the corresponding adverse event term as reported on the AE Log.	
3. - Lab Test Name:	HCT - Hematocrit ■
a. - If Other, specify [70]:	
4. - Test performed?	Yes ☐
	No ☐
	Not Required ☐
a. - If No, specify reason not done [70]:	
5. - Result [nnnnnnn.nnn]:	
6. - Unit:	
7. - Normal Range Lower limit (Reference range) [nnnnnnn.nnn]:	
8. - Normal Range Upper limit (Reference range) [nnnnnnn.nnn]:	
9. - Toxicity grade:	0 - Grade 0 ☐
	1 - Grade 1 ☐
	2 - Grade 2 ☐

	3 - Grade 3 ☐
	4 - Grade 4 ☐
	Not Gradable ☐
10. - Does test result meet protocol criteria for adverse event reporting?	Yes ☐
	No ☐
11. - Select the corresponding adverse event term as reported on the AE Log.	
3. - Lab Test Name:	HGB - Hemoglobin ■
a. - If Other, specify [70]:	
4. - Test performed?	Yes ☐
	No ☐
	Not Required ☐
a. - If No, specify reason not done [70]:	
5. - Result [nnnnnnn.nnn]:	
6. - Unit:	
7. - Normal Range Lower limit (Reference range) [nnnnnnn.nnn]:	
8. - Normal Range Upper limit (Reference range) [nnnnnnn.nnn]:	
9. - Toxicity grade:	0 - Grade 0 ☐
	1 - Grade 1 ☐
	2 - Grade 2 ☐
	3 - Grade 3 ☐
	4 - Grade 4 ☐
	Not Gradable ☐
10. - Does test result meet protocol criteria for adverse event reporting?	Yes ☐
	No ☐
11. - Select the corresponding adverse event term as reported on the AE Log.	
3. - Lab Test Name:	PLT - Platelets ■
a. - If Other, specify [70]:	
4. - Test performed?	Yes ☐
	No ☐
	Not Required ☐
a. - If No, specify reason not done [70]:	
5. - Result [nnnnnnn.nnn]:	
6. - Unit:	
7. - Normal Range Lower limit (Reference range) [nnnnnnn.nnn]:	
8. - Normal Range Upper limit (Reference range) [nnnnnnn.nnn]:	
9. - Toxicity grade:	0 - Grade 0 ☐
	1 - Grade 1 ☐
	2 - Grade 2 ☐
	3 - Grade 3 ☐
	4 - Grade 4 ☐

	Not Gradable ☐
10. - Does test result meet protocol criteria for adverse event reporting?	Yes ☐ No ☐
11. - Select the corresponding adverse event term as reported on the AE Log.	
3. - Lab Test Name:	RBC - Red Blood Cells ■
a. - If Other, specify [70]:	
4. - Test performed?	Yes ☐ No ☐ Not Required ☐
a. - If No, specify reason not done [70]:	
5. - Result [nnnnnnn.nnn]:	
6. - Unit:	
7. - Normal Range Lower limit (Reference range) [nnnnnnn.nnn]:	
8. - Normal Range Upper limit (Reference range) [nnnnnnn.nnn]:	
9. - Toxicity grade:	0 - Grade 0 ☐ 1 - Grade 1 ☐ 2 - Grade 2 ☐ 3 - Grade 3 ☐ 4 - Grade 4 ☐ Not Gradable ☐
10. - Does test result meet protocol criteria for adverse event reporting?	Yes ☐ No ☐
11. - Select the corresponding adverse event term as reported on the AE Log.	
3. - Lab Test Name:	WBC - White Blood Cells ■
a. - If Other, specify [70]:	
4. - Test performed?	Yes ☐ No ☐ Not Required ☐
a. - If No, specify reason not done [70]:	
5. - Result [nnnnnnn.nnn]:	
6. - Unit:	
7. - Normal Range Lower limit (Reference range) [nnnnnnn.nnn]:	
8. - Normal Range Upper limit (Reference range) [nnnnnnn.nnn]:	
9. - Toxicity grade:	0 - Grade 0 ☐ 1 - Grade 1 ☐ 2 - Grade 2 ☐ 3 - Grade 3 ☐ 4 - Grade 4 ☐ Not Gradable ☐

10. - Does test result meet protocol criteria for adverse event reporting? Yes ☐ No ☐

11. - Select the corresponding adverse event term as reported on the AE Log. _____

Form: LBW10010: IMPAACT 2010 Lymphocyte Subsets

INSTRUCTIONS: For IMPAACT 2010: Record only CD4+ counts for this study as per protocol.

1. - Were any lymphocyte subset results obtained at this visit or since the last visit?	Yes ☐ No ☐
a. - If No, specify reason not done [70]:	
2. - Laboratory specimen collection date	
[Edit Check Field]	
3. - Test name	CD4+ Absolute Count
a. - If Other, specify [70]:	
4. - Test performed?	Yes ☐ No ☐
a. - If No, specify the reason not done. [70]:	
5. - Result	

Form: LBW10011: IMPAACT 2010 Qualitative HIV-1 Results

Was a qualitative HIV-1 result obtained from the testing lab?	Yes ☐ No ☐
If No, specify reason not obtained [70]:	_____
Indicate the test type:	DNA PCR ☐ EIA ☐ Reverse transcriptase PCR ☐ Nucleic acid amplification test ☐ Fluorescent immunoassay ☐ Immunochemiluminometric assay ☐ ELISA ☐ Western blot ☐ ICD p24 ☐ p24 Antigen ☐ Rapid antibody antibody test ☐ Gen probe aptima ☐ Other ☐
Is this result being reported through the LDMS? If the results will be reported through the LDMS, answer 'Yes' and save. Do not complete the remainder of the form.	Yes ☐ No ☐
If No indicate the following:	
Specimen date:	_____
Enter the assay date; if assay date is not available, enter the report date:	_____
Date assay performed or report date?	Date assay performed ☐ Report date ☐
Test Result	Positive/Reactive ☐ Negative/Non-reactive ☐ Indeterminate ☐
Lab Code	_____

Indicate below which type(s) of consent form(s) have been provided or not provided.	Protocol Version 1.0 ☐ Protocol Version 2.0 ☐ Protocol Version 3.0 ☐ Protocol Version 4.0 ☐ Protocol Version 5.0 ☐ Letter of Amendment 1 ☐ Letter of Amendment 2 ☐ Letter of Amendment 3 ☐ Letter of Amendment 4 ☐ Letter of Amendment 5 ☐ Study drug use during subsequent pregnancy ☐ Other consent ☐
If Other, specify [70]:	_____
Status	Provided ☐ Not Provided ☐
Date of consent:	_____
Date of deconsent:	_____

Form: LGW10001: IMPAACT 2010 Prior Pregnancy Outcome Log

INSTRUCTIONS: Complete a log line for each prior pregnancy.

Is the outcome date known? Yes ☐ No ☐

If Yes, complete "Outcome date of prior pregnancy."
If No, provide the best estimate of the outcome date of the prior pregnancy.

Outcome date of prior pregnancy _____

Estimate of when prior pregnancy outcome occurred
- ☐ Before
- ☐ During
- ☐ After
- ☐ Unknown

Estimate year when prior pregnancy outcome occurred _____

Indicate outcome of prior pregnancy
- ☐ Live birth
- ☐ Stillbirth/Intrauterine fetal demise (IUFD ≥ 20 weeks)
- ☐ Spontaneous abortion (< 20 weeks)
- ☐ Induced abortion (therapeutic or elective)
- ☐ Ectopic pregnancy
- ☐ Molar pregnancy
- ☐ False positive/No pregnancy

Did neonatal death occur before 28 days of age? Yes ☐ No ☐

This question is only required when prior pregnancy outcome is "Live birth".

Form: MHW10001: IMPAACT 2010 Medical History Log

INSTRUCTIONS: For IMPAACT 2010:
• Refer to Protocol Sections 6.11, 6.12, and 7.2.

• Enter all pre-existing conditions occurring during the 28 days prior to enrollment (inclusive of the day of enrollment). For conditions that are ongoing at enrollment but resolve during follow-up, update entries as necessary to record the end date.
• At entry, report HIV as a medical condition. When reporting HIV, the date of diagnosis should be the participant's self-reported initial diagnosis date.
• Report any history of depression and/or suicidality.
• Report any history of bone fractures. When reporting any bone fractures, include a description of the location and type of fracture, and whether the fracture was traumatic or non-traumatic.
• Report any previous or new allergies or hypersensitivity to any medications on this form. Also report medications taken at or since enrollment that were associated with a medication allergy on the CMW10001: Concomitant Medications Log.

1. - Were any medical history conditions or events reported?
- Yes ☐
- No ☐

2. - What is the medical history condition or event [200]? _____

3. - What is the severity grade of the medical history condition/event?
- 1 - Grade 1 ☐
- 2 - Grade 2 ☐
- 3 - Grade 3 ☐
- 4 - Grade 4 ☐
- Not Gradable ☐

4. - What was the medical history condition or event start date? _____

5. - Start date unknown ☐

a. - Estimate of when condition/event started
- Before ☐
- During ☐
- After ☐
- Unknown ☐

b. - Estimate year condition or event started _____

6. - Is the medical history condition or event still ongoing?
- Yes ☐
- No ☐

7. - What was the medical history condition or event end date? _____

8. - End date unknown ☐

a. - Estimate of when condition or event ended
- Before ☐
- During ☐
- After ☐
- Unknown ☐

b. - Estimate year condition/event ended. _____

Is the participant's pre-pregnancy weight available?	Yes ☐ No ☐
If yes, enter the participant's pre-pregnancy weight [nnn.nn]	_____
Weight unit:	Grams (g) ☐ Kilograms (kg) ☐ Pounds (lb) ☐
Date of pre-pregnancy weight:	_____
How many pregnancies, including the current pregnancy, has this participant had? [nn]	_____

Obstetrical Exam:	
Date of exam:	
Fundal height (cm) [nnn.n]:	

Form: PKW10002: IMPAACT 2010 Pharmacokinetics Dosing Log

INSTRUCTIONS: For IMPAACT 2010: Please complete this form for any of the four possible study drug formulations listed below:

Dolutegravir (DTG)

Emtricitabine/tenofovir alafenamide (FTC/TAF)

Emtricitabine/tenofovir disoproxil fumarate (FTC/TDF)

Efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF)

Specify Drug [200]: _____

Dosing Time Point:
- ☐ Last dose
- ☐ 2nd last dose

Date Taken: _____

Time Taken: _____

Was this dose retained?
- ☐ Yes
- ☐ No

Was this dose re-administered?
- ☐ Yes
- ☐ No

Date of re-administration: _____

Time of re-administration: _____

Single Dose Amount Taken [nnnn.nnn]: _____

Dose Unit:
- ☐ mL
- ☐ mg
- ☐ mg/mL
- ☐ Other

If Other, specify [200]: _____

Formulation:
- ☐ Capsule
- ☐ Granule
- ☐ Injection
- ☐ Liquid
- ☐ Patch
- ☐ Pill
- ☐ Powder
- ☐ Ring
- ☐ Solution
- ☐ Suspension
- ☐ Tablet
- ☐ Other

If Other, specify [200]: _____

Was a meal taken within 1 hour of this dose?
- ☐ Yes
- ☐ No

Date of meal: _____

Time of meal: _____

Meal size:	Full Meal ☐
	Light Snack ☐
Fat content:	Low Fat ☐
	Moderate Fat ☐
	High Fat ☐
Was the meal retained?	Yes ☐
	No ☐

Was a sample collected for pharmacokinetic testing at this visit? Yes ☐ No ☐

If No, specify reason not collected [200]: _____

Indicate pharmacokinetic specimen type: BLD - Blood (Whole) ■

If Other, specify [70]: _____

Specimen obtained? Yes ☐ No ☐ Not Required ☐

If No, specify reason not obtained [200]: _____

Specimen Date: _____

Specimen Time: _____

Specimen sent to lab? Yes ☐ No ☐

Enter the first LDMS lab code where the specimen was sent.

NOTE: If the specimen was sent to a non-LDMS lab, enter '0-Unassigned'. _____

Indicate pharmacokinetic specimen type: BMK - Breast Milk ■

If Other, specify [70]: _____

Specimen obtained? Yes ☐ No ☐ Not Required ☐

If No, specify reason not obtained [200]: _____

Specimen Date: _____

Specimen Time: _____

Specimen sent to lab? Yes ☐ No ☐

Enter the first LDMS lab code where the specimen was sent.

NOTE: If the specimen was sent to a non-LDMS lab, enter '0-Unassigned'. _____

Indicate pharmacokinetic specimen type: HAR - Hair ■

If Other, specify [70]: _____

Specimen obtained? Yes ☐ No ☐ Not Required ☐

If No, specify reason not obtained [200]: _____

Specimen Date: _____

Specimen Time: _____

Specimen sent to lab? Yes ☐ No ☐

Enter the first LDMS lab code where the specimen was sent.

NOTE: If the specimen was sent to a non-LDMS lab, enter '0-Unassigned'.

Form: QLW10000: IMPAACT 2010 Edinburgh Postnatal Depression Scale

Was this questionnaire completed?	Yes ☐ No ☐
If No, specify reason not done [200]:	_____

We would like to know how you are feeling. Please select the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

1. - I have been able to laugh and see the funny side of things.	As much as I always could ☐ Not quite so much now ☐ Definitely not so much now ☐ Not at all ☐
2. - I have looked forward with enjoyment to things.	As much as I ever did ☐ Rather less than I used to ☐ Definitely less than I used to ☐ Hardly at all ☐
3. - I have blamed myself unnecessarily when things went wrong.	Yes, most of the time ☐ Yes, some of the time ☐ Not very often ☐ No, never ☐
4. - I have been anxious or worried for no good reason.	No, not at all ☐ Hardly ever ☐ Yes, sometimes ☐ Yes, very often ☐
5. - I have felt scared or panicky for no very good reason.	Yes, quite a lot ☐ Yes, sometimes ☐ No, not much ☐ No, not at all ☐
6. - Things have been getting on top of me.	Yes, most of the time I haven't been able to cope at all ☐ Yes, sometimes I haven't been coping as well as usual ☐ No, most of the time I have coped quite well ☐ No, I have been coping as well as ever ☐
7. - I have been so unhappy that I have had difficulty sleeping.	Yes, most of the time ☐ Yes, sometimes ☐ Not very often ☐ No, not at all ☐
8. - I have felt sad or miserable.	Yes, most of the time ☐ Yes, quite often ☐ Not very often ☐ No, never ☐
9. - I have been so unhappy that I have been crying.	Yes, most of the time ☐

	Yes, quite often ☐ Only occasionally ☐ No, never ☐
10. - The thought of harming myself has occurred to me.	Yes, quite often ☐ Sometimes ☐ Hardly ever ☐ Never ☐
Date Administered/Reviewed:	_____

[1] Source: Cox, J.L., Holden, J.M., and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. British Journal of Psychiatry 150:782-786

[2] Source: K. L. Wisner, B. L. Parry, C. M. Piontek, Postpartum Depression N Engl J Med vol. 347, No 3, July 18, 2002, 194-199

Following completion of this questionnaire, was the mother subsequently referred for further evaluation and/or management?	Yes ☐ No ☐

1 - Was this questionnaire completed?	Yes ☐ No ☐
If No, specify reason not done [200]:	

I am going to ask you some questions about taking your ARVs. We are collecting this information from all women in the study so we can get an idea of how everyone is doing with trying to take ARVs each day, which we know can be really challenging. I am happy to speak with you about any of these questions and answers after we complete the questions. I also want to be clear that the information you give me is private. Your answers will be combined with other women's answers, but will not otherwise be shared. My job is to ask these questions and collect your answers. Are you ready to begin? {confirm and then proceed}

2. - In the last 30 days, on how many days did you miss at least one dose of any of your ARVs? [nn]	
3. - In the last 30 days, how good a job did you do at taking your ARVs in the way you were supposed to?	Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐
4. - In the last 30 days, how often did you take your ARVs in the way you were supposed to?	Never ☐ Rarely ☐ Sometimes ☐ Usually ☐ Almost always ☐ Always ☐
5. - Point to the place on the line showing how much of your ARVs you have taken in the last 30 days.	Fixed Unit: %

---|
---|
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0
10
20
30
40
50
60
70
80
90
100

DID NOT TAKE ANY DOSES

TOOK EVERY DOSE

[1]Source: Wilson IB, Lee Y, Michaud J, Fowler FJ, Jr. Roger WH. Validation of a New Three-Item Self-Report Measure for Medication Adherence. AIDS and Behavior 2016.

[2]Source:Wilson IB, Folwer FJ, Jr., Cosenza CA, Michaud J, Bentkover J, Rana A, et al. Cognitive and field testing of a new set of medication aherence self-report items for HIV care. AIDS and Behavior 2014; 18(12):2349-2358

[3]Source: Finitsis DJ, Pellowski JA, Huedo-Medina TB, Fox MC, Kalichman SC. Visual analogue scale (VAS) measurement of antiretroviral adherence in people living with HIV (PLWH): a meta-analysis. Journal of Behavioral Medicine 2016.

[4]Source: Amico KR, Fisher WA, Cornman DH, Shuper PA, Redding CG, Konkle-Parker DJ, et al. Visual analog scale of ART adherence: association with 3-day self-report and adherence barriers. Journal of Acquired Immune Deficiency Syndromes (1999) 2006; 42(4):455-459.

1. - Was this questionnaire completed? Yes / No

If No, specify reason not done [200]: _____

Antepartum Week 8 Instructions

These questions are about experiences women have with trying to take their ARVs each day. Different things make taking ARVs every day difficult, while other things make it feel easier to do. First, I will go over a list of challenges women have reported to taking ARVs. Please tell me YES if what I say describes a challenge you have had with taking ARVs every day. Tell me NO if what I say has not been a challenge or has not created difficulty for you. I will not ask you about taking or missing doses during these challenges. The question is just whether or not you experienced the challenge at all since you entered the study, which was about 2 months ago. May we begin this section?

Postpartum Week 38 Instructions

These questions are about experiences women have with trying to take their ARVs each day. Different things make taking ARVs every day difficult, while other things make it feel easier to do. First, I will go over a list of challenges women have reported to taking ARVs. Please tell me YES if what I say describes a challenge you have had with taking ARVs every day. Tell me NO if what I say has not been a challenge or has not created difficulty for you. I will not ask you about taking or missing doses during these challenges. The question is just whether or not you experienced the challenge at all since you were pregnant, which was about 9 months ago. May we begin this section?

"Since you were pregnant" refers to the period since delivery or other pregnancy outcome.

2. - BARRIERS: Select "Yes", "No", or "Declined to answer" for each of the barriers to adherence listed below.

a. - I did not understand how to take my ARVs — Yes / No / Declined to answer

b. - I forget to take my ARVs — Yes / No / Declined to answer

c. - I ran out of ARVs — Yes / No / Declined to answer

d. - I could not get to clinic because of transportation problems — Yes / No / Declined to answer

e. - I was traveling away from home and did not take my ARVs with me or ran out of ARVs while I was away — Yes / No / Declined to answer

f. - I could not get to the clinic for refills due to work schedule — Yes / No / Declined to answer

g. - I could not get back to my ARVs until past my dosing time, and did not take that dose of ARVs — Yes / No / Declined to answer

h. - I had to share my ARVs with other people — Yes

	No ☐ Declined to answer ☐
i. - My ARVs were lost, damaged, or stolen	Yes ☐ No ☐ Declined to answer ☐
j. - I was around people who know my HIV status but don't know I am taking ARVs (I was trying to hide taking my ARVs)	Yes ☐ No ☐ Declined to answer ☐
k. - I was around people who don't know my HIV status (I was trying to hide taking my ARVs)	Yes ☐ No ☐ Declined to answer ☐
l. - I was around people who don't support taking ARVs	Yes ☐ No ☐ Declined to answer ☐
m. - I had side effects from the ARVs that made me feel sick	Yes ☐ No ☐ Declined to answer ☐
n. - I was worried about having side effects from the ARVs	Yes ☐ No ☐ Declined to answer ☐
o. - I was worried about the ARVs being safe for my baby	Yes ☐ No ☐ Declined to answer ☐
p. - I was worried about mixing the ARVs with other drugs or alcohol	Yes ☐ No ☐ Declined to answer ☐
q. - I was too drunk/high	Yes ☐ No ☐ Declined to answer ☐
r. - I just did not feel like taking my ARV medications	Yes ☐ No ☐ Declined to answer ☐
s. - I feel well so I did not take my ARV medications	Yes ☐ No ☐ Declined to answer ☐
t. - I did not feel that I needed the ARVs after my baby was born [only applies at postpartum visit]	Yes ☐ No ☐ Declined to answer ☐

u. - I do not like being reminded every day that I am infected with HIV, when I have to take the ARVs	Yes ☐ No ☐ Declined to answer ☐
v. - I do not think the ARVs work	Yes ☐ No ☐ Declined to answer ☐
w. - My religious beliefs	Yes ☐ No ☐ Declined to answer ☐
x. - Identify any other factors that made it more difficult [200]:	_____
3. - Of all choices above, what is the MAIN reason that made it more difficult to take your ARV medication(s) every day?	_____
a. - If Other, specify [200]:	_____

Form: QLW10005: IMPAACT 2010 Pittsburgh Sleep Quality Index (PSQI) Questionnaire

1. - Was this questionnaire completed? Yes / No

If No, specify reason not done [200]: _____

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

2. - During the past month, what time have you usually gone to bed at night? _____

3. - During the past month, how long (in minutes) has it usually taken you to fall asleep each night? [nnn] Fixed Unit: minutes _____

4. - During the past month, what time have you usually gotten up in the morning? _____

5. - During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.) [nn.n] Fixed Unit: hrs _____

6. - For each of the remaining questions, select the one best response. Please answer all questions.
During the past month, how often have you had trouble sleeping because you…

a. - Cannot get to sleep within 30 minutes
- Not during the past month
- Less than once a week
- Once or twice a week
- Three or more times a week

b. - Wake up in the middle of the night or early morning
- Not during the past month
- Less than once a week
- Once or twice a week
- Three or more times a week

c. - Have to get up to use the bathroom
- Not during the past month
- Less than once a week
- Once or twice a week
- Three or more times a week

d. - Cannot breathe comfortably
- Not during the past month
- Less than once a week
- Once or twice a week
- Three or more times a week

e. - Cough or snore loudly
- Not during the past month
- Less than once a week
- Once or twice a week
- Three or more times a week

f. - Feel too cold
- Not during the past month
- Less than once a week
- Once or twice a week
- Three or more times a week

g. - Feel too hot
- Not during the past month
- Less than once a week

	Once or twice a week ☐
	Three or more times a week ☐
h. - Had bad dreams	Not during the past month ☐
	Less than once a week ☐
	Once or twice a week ☐
	Three or more times a week ☐
i. - Have pain	Not during the past month ☐
	Less than once a week ☐
	Once or twice a week ☐
	Three or more times a week ☐
j. - Other	Not during the past month ☐
	Less than once a week ☐
	Once or twice a week ☐
	Three or more times a week ☐
Other reasons, please describe [200]:	_____
7. - During the past month, how would you rate your sleep quality overall?	Very good ☐
	Fairly good ☐
	Fairly bad ☐
	Very bad ☐
8. - During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?	Not during the past month ☐
	Less than once a week ☐
	Once or twice a week ☐
	Three or more times a week ☐
9. - During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?	Not during the past month ☐
	Less than once a week ☐
	Once or twice a week ☐
	Three or more times a week ☐
10. - During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?	No problem at all ☐
	Only a very slight problem ☐
	Somewhat of a problem ☐
	A very big problem ☐

Form: QLW10006: IMPAACT 2010 Generalized Anxiety Disorder 7-item (GAD-7) Scale

1. - Was this questionnaire completed?	Yes ☐ No ☐
If No, specify reason not done [200]:	_____
2. - Over the LAST 2 WEEKS, how often have you been bothered by the following problems?	
a. - Feeling nervous, anxious, or on edge.	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
b. - Not being able to stop or control worrying.	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
c. - Worrying too much about different things.	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
d. - Trouble relaxing.	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
e. - Being so restless that it is hard to sit still.	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
f. - Becoming easily annoyed or irritable.	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
g. - Feeling afraid as if something awful might happen.	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
3. - How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult ☐

[1]Source: Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006 May 22;166(10):1092-7. PubMed PMID: 16717171.

[2]Source: Chibanda D, Verhey R, Gibson LJ, Munetsi E, Machando D, Rusakaniko S, Munjoma R, Araya R, Weiss HA, Abas M. Validation of screening tools for depression and anxiety disorders in a primary care population with high HIV prevalence in Zimbabwe. J Affect Disord. 2016 Jul 1;198:50-5. doi: 10.1016/j.jad.2016.03.006. PubMed PMID: 27011359.

[3]Source: Simpson W, Glazer M, Michalski N, Steiner M, Frey BN. Comparative efficacy of the generalized anxiety disorder 7-item scale and the Edinburgh Postnatal Depression Scale as screening tools for generalized anxiety disorder in pregnancy and the postpartum period. Can J Psychiatry. 2014 Aug;59(8):434-40. PubMed PMID: 25161068; PubMed Central PMCID: PMC4143300.

4. - Following completion of this questionnaire, was the mother subsequently referred for further evaluation and/or management?

Yes ☐

No ☐

1. - Was this questionnaire completed? Yes / No

If No, specify reason not done [200]: _____

Antepartum Week 8 Instructions

Now I would like to ask you about things that may have made it easier for you to take your ARVs each day since you entered the study, which was about 2 months ago. Please think specifically about things that helped you or made you feel very confident about taking your ARVs. You may not have felt this way all the time, but if you felt this way at all in the last 2 months, please let me know. For each item I read to you, please tell me YES if what I say is something that was or is helpful to you; tell me NO if what I say has not been helpful to you. May we begin this section?

Postpartum Week 38 Instructions

Now I would like to ask you about things that may have made it easier for you to take your ARVs each day since you were pregnant, which was about 9 months ago. Please think specifically about things that helped you or made you feel very confident about taking your ARVs. You may not have felt this way all the time, but if you felt this way at all in the last 9 months, please let me know. For each item I read to you, please tell me YES if what I say is something that was or is helpful to you; tell me NO if what I say has not been helpful to you. May we begin this section?

"Since you were pregnant" refers to the period since delivery or other pregnancy outcome.

2. - FACILITATORS: Select "Yes", "No", or "Declined to answer" for each of the facilitators of adherence listed below.

a. - I thought about taking ARVs to stay healthy — Yes / No / Declined to answer

b. - I thought about taking ARVs to protect the health of my baby — Yes / No / Declined to answer

c. - I am used to taking my ARVs - it is habit — Yes / No / Declined to answer

d. - I was scared of what would happen if I didn't take my medications — Yes / No / Declined to answer

e. - I kept ARVs available/with me when I would need them — Yes / No / Declined to answer

f. - I took ARVs at the same time as something else I do every day — Yes / No / Declined to answer

g. - I had support from people close to me — Yes / No / Declined to answer

h. - I used a reminder (for example, phone alarm or person who reminded me) — Yes / No / Declined to answer

i. - I kept ARVs out where I could see them — Yes

	No ☐
	Declined to answer ☐
j. - I believed in the positive effects of the ARVs	Yes ☐
	No ☐
	Declined to answer ☐
k. - I focused on what I wanted to do for myself - not what others thought I should do	Yes ☐
	No ☐
	Declined to answer ☐
l. - I got helpful advice or support from study staff	Yes ☐
	No ☐
	Declined to answer ☐
m. - I got helpful advice or support from other study participants	Yes ☐
	No ☐
	Declined to answer ☐
n. - I wanted to avoid study staff getting mad or disappointed in me if I missed ARV doses	Yes ☐
	No ☐
	Declined to answer ☐
o. - I wanted to see (or continue to see) my suppressed viral load result	Yes ☐
	No ☐
	Declined to answer ☐
p. - I figured out a way to take my ARV medications in private	Yes ☐
	No ☐
	Declined to answer ☐
q. - I feel uncomfortable when I miss taking an ARV dose	Yes ☐
	No ☐
	Declined to answer ☐
r. - Identify any other factors that made it easier [200]:	_____
3. - Of all the choices above, what is the MAIN reason that made it easier for you to take your ARV medication(s) every day?	I thought about taking ARVs to stay healthy ☐
	I thought about taking ARVs to protect the health of my baby ☐
	I am used to taking my ARVs - it is habit ☐
	I was scared of what would happen if I didn't take my medications ☐
	I kept ARVs available/with me when I would need them ☐
	I took ARVs at the same time as something else I do every day ☐
	I had support from people close to me ☐
	I used a reminder (for example, phone alarm or person who reminded me) ☐
	I kept ARVs out where I could see them ☐

I believed in the positive effects of the ARVs	☐
I focused on what I wanted to do for myself - not what others thought I should do	☐
I got helpful advice or support from study staff	☐
I got helpful advice or support from other study participants	☐
I wanted to avoid study staff getting mad or disappointed in me if I missed ARV doses	☐
I wanted to see (or continue to see) my suppressed viral load result	☐
I figured out a way to take my ARV medications in private	☐
I feel uncomfortable when I miss taking an ARV dose	☐
Other facilitator	☐

a. - If Other, specify [200]: _____

1. - Since the last study visit, have any of the following feeding methods been used? Check all that apply.	At the Delivery visit, report any feeding methods use
a. - Breastfed by mother:	☐
b. - Breastfed by someone other than mother (e.g. wet nurse):	☐
c. - Formula fed:	☐
d. - Complementary food:	☐

Form: QLW10011: IMPAACT 2010 Breastfeeding, Formula, and Complementary Food Record

INSTRUCTIONS: For IMPAACT 2010:
• Complete this form with information related to never breastfeeding, initiation or discontinuation of breastfeeding, and introduction of formula and/or complementary foods.
• Breastfeeding questions refer to breastfeeding by only the infant's biological mother.
• Note in some instances, not all of the sections of this form will need to be completed. For example, if the infant's mother never breastfed her infant, the sections "Initial Breastfeeding Exposure" and "Breastfeeding Discontinuation" would never be completed. If the infant was breastfed by their biological mother, the section "Never Breastfed" would not be completed.
• Update this form as needed to report new information, for example breastfeeding discontinuation (weaning) or dates of introduction to formula and/or complementary foods.
• Modify this form as needed. For example if the date of "last exposure to breastmilk" changes (e.g. if a mother breastfeeds again after initially having been reported to have weaned), report the last date the infant was exposed to their biological mother's breastmilk.

NEVER BREASTFED

Instructions: Only complete this section if it is determined that the infant will never breastfeed.

1. - Since the last visit, has it been determined that the infant will never be breastfed?
Note: This question refers to breastfeeding by the infant's biological mother.
- Yes ☐
- No ☐

2. - What is the main reason the mother decided to never breastfeed her infant?
- Mother too sick to breastfeed ☐
- Infant too sick to breastfeed ☐
- Mother did not want to breastfeed ☐
- Infant did not want to breastfeed ☐
- Mother did not produce enough breastmilk ☐
- Fear of transmitting HIV to her infant ☐
- Advised by family member or spouse ☐
- Advised by health provider to avoid breastfeeding ☐
- Pregnancy ☐
- Mother returned to work/had to leave infant ☐
- Other ☐

a. - If Other, specify [200]: _____

INITIAL BREASTFEEDING EXPOSURE

Instructions: Only complete this section if the infant has ever been breastfed.

3. - Date of first breastfeeding by infant's biological mother: _____

4. - Did the mother breastfeed the infant within one hour of birth?
- Yes ☐
- No ☐
- Unknown ☐

BREASTFEEDING DISCONTINUATION (WEANING)

Instructions: Only complete this section if the infant has been completely weaned from breastmilk.

5. - Since the last visit, has the infant been completely weaned from breastmilk, defined as at least one week without breastmilk and no intention of restarting?
Note: This question refers to breastfeeding by the infant's biological mother.
- Yes ☐
- No ☐

6. - Date of last exposure to breastmilk: _____

INITIATION OF FORMULA

Instructions: Only complete this section when formula is first introduced.

7. - Date of first formula feeding: _____

INITIATION OF COMPLEMENTARY FOOD

Instructions: Only complete this section when complementary food is first introduced.

8. - Date of first complementary food: _____

2010_V1.0.0 Matrices: Print Matrix

Folder: PRINT

Form: SPW10001: IMPAACT 2010 Specimen Tracking

Participant ID:	
Study:	
Visit Week:	
SID:	
Site:	
1. - Were any specimens obtained at this visit for this study or will any specimens be shared from another study?	Yes ☐ No ☐
If No, specify reason not obtained [200]:	
10. - Were there any specimens to report, obtained at another date/time for this visit or since the last visit? (Selecting "Yes" will add an additional Specimen Tracking eCRF to this visit.)	Yes ☐ No ☐

Was a Hepatitis B surface antigen (HBsAg) result obtained?	Yes ☐ No ☐
If No, specify reason not obtained [70]:	_____
Date specimen obtained:	_____
What was the result?	Positive/Reactive ☐ Negative/Non-Reactive ☐ Indeterminate ☐

Form: SVW10000: IMPAACT 2010 Study Event Tracking - Infant

INSTRUCTIONS: This form will indicate if any events defined by the study have occurred since the last visit or at this visit. This includes new information about study status, informed consent status, specimen consent status, laboratory test results, adverse events (including signs and symptoms, diagnoses, and abnormal lab results), virology, and concomitant medications. Complete this form at each visit.

At this visit or since the last visit, was the infant taken off study (including lost to follow-up or death)?	Yes ☐ No ☐
At this visit or since the last visit, has the infant's informed consent status changed?	Yes ☐ No ☐
At this visit or since the last visit, has the infant's specimen consent status changed?	Yes ☐ No ☐
At this visit or since the last visit, are there any new adverse events (AEs) that are required to be reported per Protocol Section 7.2?	Yes ☐ No ☐
Are there any previously reported adverse events with new information to report, a change in previously reported information, or that have resolved since the last time the event was reported?	Yes ☐ No ☐
Were there any hematology tests, chemistry tests, or lymphocyte subsets results obtained at this visit that are required by the protocol to be reported, regardless of grade?	Yes ☐ No ☐
At this visit or since the last visit, have there been any changes in the concomitant medications that are required to be reported for this infant per Protocol Section 6.11?	Yes ☐ No ☐
At this visit or since the last visit, was an HIV NAT result obtained that requires an additional evaluation to confirm HIV infection?	Yes ☐ No ☐
If Yes, were the HIV Infection Confirmation evaluations completed? Refer to Protocol Section 6.8 for required evaluations.	Yes ☐ No ☐
Are there any new congenital anomalies that are required to be reported?	Yes ☐ No ☐

Form: SVW10001: IMPAACT 2010 Study Event Tracking - Maternal

INSTRUCTIONS: This form will indicate if any events defined by the study have occurred since the last visit or at this visit. This includes new information about study status, informed consent status, specimen consent status, laboratory test results, adverse events (including signs and symptoms, diagnoses, and abnormal lab results), medical history, virology, concomitant medications, and pregnancy information. Complete this form at each visit.

At this visit or since the last visit, was the mother taken off study (including lost to follow-up or death)?	Yes ☐ No ☐
At this visit or since the last visit, has the mother's informed consent status changed?	Yes ☐ No ☐
At this visit or since the last visit, has the mother's specimen consent status changed?	Yes ☐ No ☐
At this visit or since the last visit, have there been any changes in the mother's study drug regimen?	Yes ☐ No ☐
At this visit or since the last visit, have there been any changes in this mother's study drug regimen that require additional procedures for ARV switch per Protocol Section 6.6?	Yes ☐ No ☐
Was the Post ARV Switch Visit combined with a regularly scheduled visit?	Yes ☐ No ☐
At this visit or since the last visit, has this mother permanently discontinued all study drugs (including completion of protocol-specified follow-up, early discontinuation, lost-to-follow-up, or death)?	Yes ☐ No ☐
At this visit or since the last visit, has any new information become available regarding pre-existing conditions previously reported for this mother (including but not limited to identification of pre-existing conditions that were not previously reported, changes in previously-reported information, and resolution of previously-reported conditions)?	Yes ☐ No ☐
At this visit or since the last visit, have there been any changes in the concomitant medications that are required to be reported for this mother per Protocol Section 6.11?	Yes ☐ No ☐
At this visit or since the last visit, have any new adverse events meeting reporting criteria in Protocol Section 7.2 been identified for this mother?	Yes ☐ No ☐
At this visit or since the last visit, has any new information become available regarding adverse events previously-reported for this mother (including but not limited to changes in previously-reported information and resolution of the event)?	Yes ☐ No ☐
Were there any hematology tests, chemistry tests, lymphocyte subsets, or Hepatitis B surface antigen results obtained at this visit that are required by the protocol to be reported?	Yes ☐ No ☐
Was a specimen for HIV-1 RNA testing obtained at this visit?	Yes ☐ No ☐
At this visit or since the last visit, was an HIV-1 RNA test result obtained for this mother that requires additional procedures for confirmation of virologic failure per Protocol Sections 6.7 and 8.3?	Yes ☐ No ☐
If Yes, were the Confirmation of Virologic Failure Visit procedures completed?	Yes ☐ No ☐
At this visit or since the last visit, has the mother delivered or had another pregnancy outcome for the index pregnancy?	Yes ☐ No ☐

Since the last visit, has the mother become pregnant? `This question only pertains to subsequent pregnancies on-study`	Yes ☐ No ☐
At this visit or since the last visit, have there been any pregnancy diagnoses or congenital anomalies that have been identified during the subsequent pregnancy? `This question only pertains to subsequent pregnancies on-study`	Yes ☐ No ☐
At this visit or since the last visit, has the mother delivered or had another pregnancy outcome for the subsequent pregnancy? `This question only pertains to subsequent pregnancies on-study`	Yes ☐ No ☐

Form: TRK10000: Specimen Consent for Non-Protocol Defined Testing

INSTRUCTIONS: For IMPAACT 2010: This form records informed consent decisions for storage and future research use of specimens leftover (residual) after all protocol-specified testing has been completed. A separate form must be completed for each enrolled mother and each enrolled infant.

HUMAN GENETIC TESTING

1. - Does the study participant/guardian/caregiver consent to the use of his/her stored specimens for future non-protocol defined **human genetic testing**?

- Yes ☐
- No ☐
- Consent not specifically requested ☐

a. - Enter the date this decision takes effect: _____

SPECIMEN TESTING OTHER THAN HUMAN GENETIC TESTING

2. - Does the study participant/guardian/caregiver consent to use of his/her stored specimens for future, **other non-protocol defined testing?**

- Yes ☐
- No ☐
- Consent not specifically requested ☐

a. - Enter the date this decision takes effect: _____

Form: TXW10001: IMPAACT 2010 Treatment Log

INSTRUCTIONS: For IMPAACT 2010: Study drugs are defined as any of the four possible ARV formulations included in the maternal regimen and provided by the study as outlined in Protocol Section 5.1:
Dolutegravir (DTG)
Emtricitabine/tenofovir alafenamide (FTC/TAF)
Emtricitabine/tenofovir disoproxil fumarate (FTC/TDF)
Efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF)

[Edit Check Field] Links to AE log	
1. - Specify medication [100]:	
2. - Start date:	
3. - Single dose amount [nnnn.nnn]:	
4. - Frequency:	
a. - If Other, specify [70]:	
5. - Units:	mL ☐ mg ☐ mg/mL ☐ Other ☐
a. - If Other, specify [70]:	
6. - Formulation:	Capsule ☐ Granule ☐ Injection ☐ Liquid ☐ Patch ☐ Pill ☐ Powder ☐ Ring ☐ Solution ☐ Suspension ☐ Tablet ☐ Other ☐
a. - If Other, specify [70]:	
7. - Is this treatment still ongoing? If Yes, go to question 10. If No, continue	Yes ☐ No ☐
8. - End date:	
9. - Reason for modification:	
a. - Specify [200]:	
Associated Adverse Event [200]:	
10. - Date of initial report	

Form: VSW10000: Vital Signs

INSTRUCTIONS: For IMPAACT 2010: Complete this form only for mothers. Per Protocol Section 6.12, the following maternal evaluations are required: height (at screening only), weight, blood pressure. Answer "yes" to the first item on this form (were vital signs collected) if any of these required evaluations were performed.

Were vital signs collected?	Yes ☐ No ☐
If No, specify reason not done [200]:	
On what date were the measurements performed?	
Weight [nnnnnn.nn]:	
Weight unit:	Grams (g) ☐ Kilograms (kg) ☐ Pounds (lb) ☐
Height/Length [nnn.n]:	
Height/Length unit:	Centimeters (cm) ☐ Inches (in) ☐
Systolic Blood Pressure (mmHg) [nnn]:	Fixed Unit: mmHg
Diastolic Blood Pressure (mmHg) [nnn]:	Fixed Unit: mmHg
Indicate the method used to measure the blood pressure:	Single ☐ Standardized ☐

Form: VSW10001: Vital Signs - Infant

INSTRUCTIONS: Per Protocol Section 6.16, the following infant evaluations are required as part of each scheduled infant physical examination: length, weight, head circumference, fontanelle closure. Answer “yes” to the first item on this form (were vital signs collected) if any of these required evaluations were performed.

Were vital signs collected?
- Yes ☐
- No ☐

If No, specify reason not done [200]: _____

On what date were the measurements performed? _____

Weight [nnnnnn.nn]: _____

Weight unit:
- Grams (g) ☐
- Kilograms (kg) ☐
- Pounds (lb) ☐

Height/Length [nnn.n]: _____

Height/Length unit:
- Centimeters (cm) ☐
- Inches (in) ☐

Temperature [nnn.n]: _____

Temperature unit:
- Celsius (C) ☐
- Fahrenheit (F) ☐

Head Circumference (cm) [nn.n]: Fixed Unit: cm

_____

Was the status of fontanelle closure determined?
- Yes ☐
- No ☐
- Not Evaluated ☐

```
Choose "Not Evaluated" only after both Anterior and Posterior fontanelle have been identified as closed
```

Anterior Fontanelle:
- Open ☐
- Closed ☐
- Not Evaluated ☐

Posterior Fontanelle:
- Open ☐
- Closed ☐
- Not Evaluated ☐