**MATRIX-007/ CARE PrEP CRF Completion Guidelines (CCGs)**

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# Terms and Abbreviations

**MATRIX-007**: MATRIX-007 is a prospective observational cohort study of CATALYST study participants exposed to ARV-based HIV prevention methods: long-acting injectable cabotegravir (CAB-LA), dapivirine vaginal ring (DVR) or tenofovir-based oral pre-exposure prophylaxis (PrEP) – during pregnancy and their infants.

**Participant**: Refers to either the mother or the infant enrolled in MATRIX-007.

**Mother/Maternal Participant**: Refers specifically to the pregnant person participating (screened and/or enrolled) in MATRIX-007.

**Infant**: Refers specifically to the participant's infant that is enrolled in MATRIX-007.

**Minor**: An individual that is under the age of majority according to the laws of the country where data collection is taking place. Typically, that age of majority is 18 years of age.

**Emancipated Minor**: An individual that is under the age of majority but has legal status as an adult if the individual meets certain criteria established by the laws of the country where data collection is taking place.

**Case Report Form**: Abbreviated as CRF, it is a data collection form used to record information for an individual, sometimes referred to as a "case", that is enrolled in the study.

**Informed Consent**: Informed consent is a process in which a member of the research team educates a study candidate about the purpose of the research being conducted as well as the potential risk and benefits from participating in the study. The candidate must show understanding about the purpose of the study and be competent to make a voluntary decision about whether to participate or not. Children (usually anyone under the age of 17 years of age) cannot provide informed consent and the parent of legal guardian of the child must give permission for the child to participate.

# General CRF Instructions

### Overview of Question Types

REDCap allows data to be input several ways: numeric, multiple choice, and free response. Below outlines basic question types. The CRF specific instructions will include the basic question type as part of the directions.

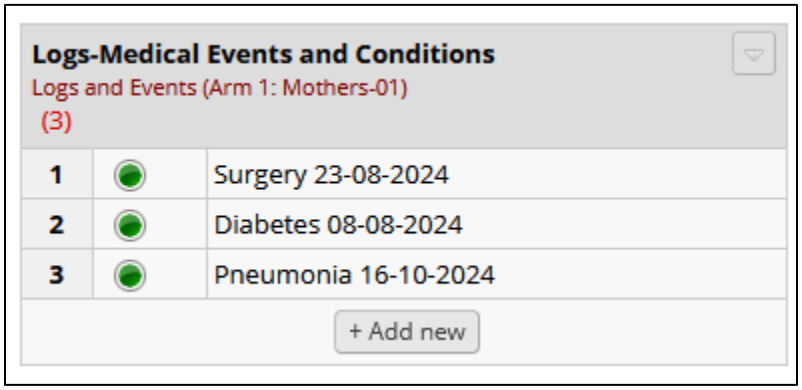
- **Multiple choice, single response**: These questions have multiple response options but only allow one option to be selected.
- **Select all that apply**: These questions have multiple response options and allow multiple options to be selected.
- **Date Entry**: Date entry field all follow the convention, DD-MM-YYYY. Take note that some study tools and aids are produced in the US. When using any aid, date calculator, or tool be conscious of the date format to ensure proper input into REDCap.
- **Free Text**: These fields allow any text as input. Frequently, questions with these fields ask for specifications, or elaborations.
- **Numeric Entry**: Only numbers are valid input. Sometimes the input can only be an integer (no decimals). The question will provide guidelines as to whether the input can have decimals or not. Use a period to enter a decimal; commas use will result in an error.
- **Yes/No**: These questions simply ask for a yes/no response.
- **Calculated Fields**: These fields will provide outputs. For example, Gestational Age as shown on multiple CRFs is the result of behind-the-scenes calculations.

### Constraints

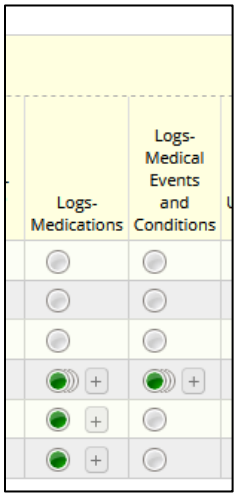
In order to ensure quality data questions will enforce constraints, meaning they will only allow certain types of data, specific values or value ranges. For example, when entering a participant's blood pressure, the field's constraint allows values of 0-300. If an entry outside of the constraint is entered, an alert will immediately pop up. The entry should be corrected before proceeding with the CRF.

### Repeatable Forms

Many of the CRFs are repeatable forms, meaning that several copies (called instances) of the CRF can be filled out. After an instance of the CRF is started it will display at the bottom of the participant's records dashboard as a log. The log will show a label for the instance that includes a name or description, often with the date that the CRF was started.



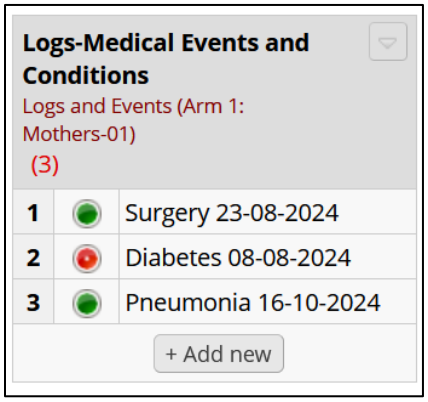

To fill out a new instance of the CRF, you can click the **+ Add new button** at the bottom of the log or click the plus button accessible in the dashboard.




On the dashboard, overlapping bubbles indicate that there are multiple instances of the CRF. Clicking the + button will also open a new instance


When the CRF is open, you will see a drop down menu at the top that allows you to view and select any instance of the CRF.

If there are medications, medical events, test results, etc. that you are continually monitoring and updating over time, it is recommended that you use the completion bubble to indicate that you need to follow up on that event.




In this example the instance for Diabetes is marked with the red bubble; this can serve as a reminder to follow-up on the condition if needed.

### CRFs that are Repeatable

The following CRFs are repeatable forms:

- PrEP Use CRF
- Medications CRF
- Medical Events and Conditions
- Ultrasound Results
- Test Results
- Vitals
- Study Visit
- EPDS
- Social Harms
- Protocol Deviation
- Participant Transfer

### Missing and Unknown Data

Many of the questions require a response or input, this will be indicated on the question as such "* must provide value." In cases where the question is required, but the information is missing or unknown, an input is still required for that question.

This section will define missing and unknown data and will then provide examples using different types of questions to show how to record that data is missing or unknown.

#### Definitions

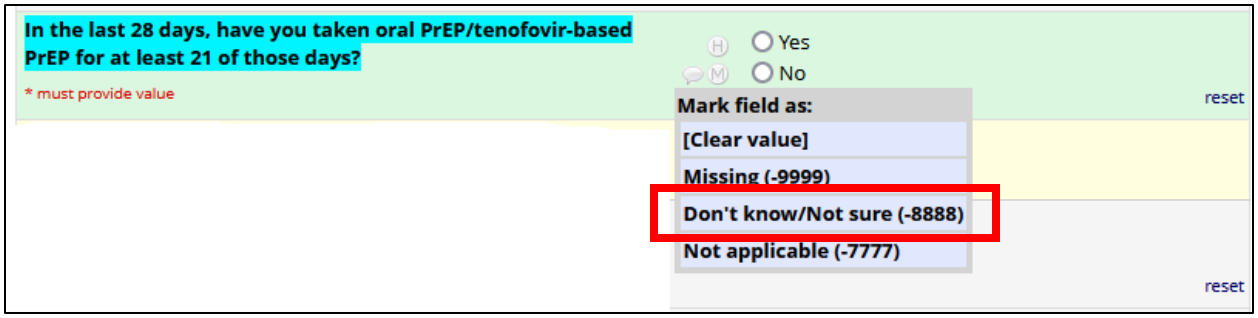
There are 4 codes/values that will be used as an input for missing or unknown data. When deciding how code the input, please consider the following definitions:

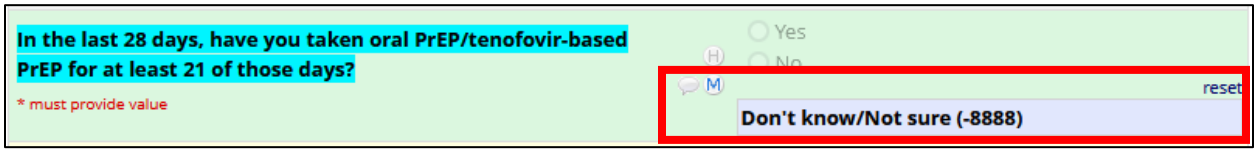
| Code | When and how to use | Examples |
|---|---|---|
| **Missing (-9999)** | • Data is missing/cannot be found<br>• Data is not available for abstraction<br>• Information is missing from a medical record | • Head circumference is not an appliable field in a birth record, thus missing to be recording in the Infant Outcome CRF<br>• Weight field is available in a birth record but is blank, thus missing to be recording in the Infant Outcome CRF |
| **Don't know/Not sure (-8888)** | • Participant reports that they do not know the answer to the question<br>• Participant reports that they do not have the information in order to answer the question<br>• CRA is unable to determine the requisite information | • Participant does not recall if medication was used during a past medical event recorded on the Medical Event/Conditions CRF<br>• Participant does not have information to confirm their rhesus status on the Obstetric Care and History CRF |

| | | |
|---|---|---|
| | | • Participant does not know biological father of the baby's past medical history |
| **Not applicable (-7777)** | • The question is not applicable to the participant<br>• The question is not applicable to the visit<br>• The question is not applicable to the context | • For a pregnancy loss, answering whether the infant received medication after birth on the Infant Outcome CRF<br>• Indicating growth chart percentile ranges on the Infant Physical Exam CRF<br>• Fetal heart tone (FHT) detection not done because participant is <16 wks GA on the Vitals CRF |
| **Not done/Not performed (-6666)** | • A procedure is not indicated (for REDCap fields that are required)<br>• A procedure was missed/could not be done and constitutes a protocol deviation<br>• Participant decline/refused procedure (protocol deviation) | • Blood pressure is not indicated (nor required) at the Pregnancy Outcome Visits on the Vital CRF<br>• Doppler was broken at visit when FHT detection is required and could not be performed on the vitals CRF (also a Protocol Deviation)<br>• Participant declines HIV testing at a visit and has no recent test on the Test Results CRF |

**Missing Data Examples**

Below is an example of a yes/no response question. Note that the question is required as indicated by: * must provide value. If the participant does not know or does not remember the information, you are able to provide a code by clicking on the "M" icon next to the response options. A pop-up box will appear with the options: Clear Value, and Missing/Unknown (-9999); Don't know/Not sure (-8888); and Not applicable (-7777), and not done (-6666). In this case, select Don't know/Not sure (-8888).



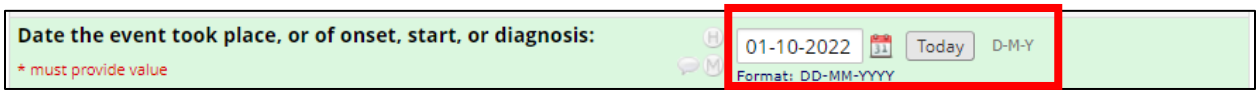

## Dates

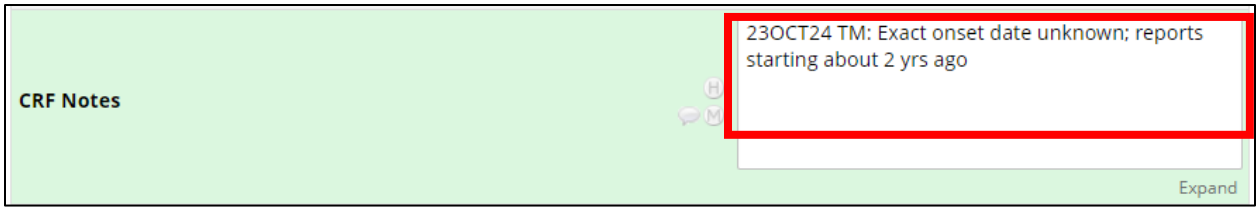
REDCap only allows dates to be entered using a complete format (DD-MM-YYYY). If the exact date is not known, enter the best estimated day, month and the year and indicate this uncertainty in CRF Notes field of the CRF. Only when a date is completely missing or unknown (the year, month, and day are <u>all</u> not known) should the field be marked as Missing/Unknown (-9999) or Don't know/Not sure (-8888).

Next is an example of when a participant might not remember a date, for instance when they first started taking medication in the distant past such albuterol. Again, click the "M" and select Don't know/Not sure (-8888) from the list of options.



The next example is where a participant started a having migraine about 2 yrs ago but does not remember the specific day/month. You should record the start date as 01-10-2022 in the date entry box on the Medical Events/Conditions CRF because this was approximately 2 years prior to the date of report. Include a CRF Note explaining the date estimation.

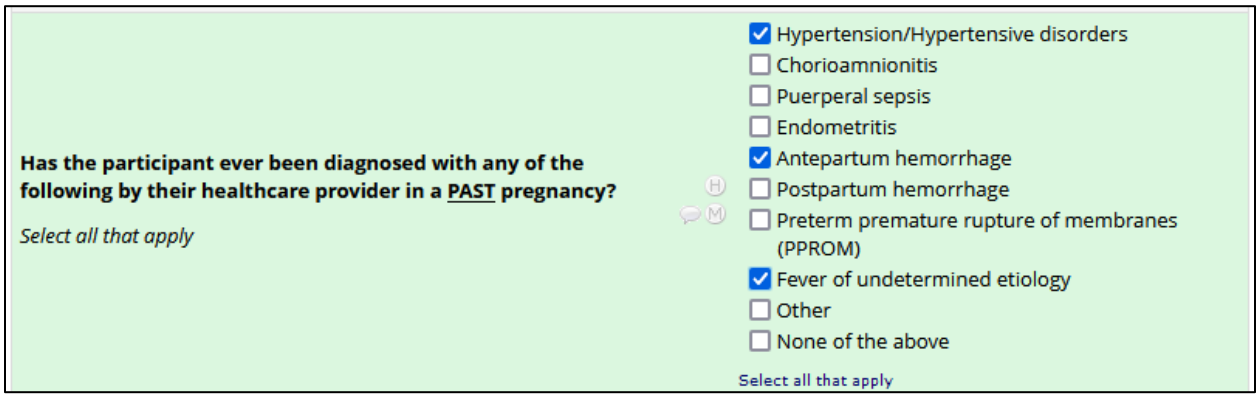


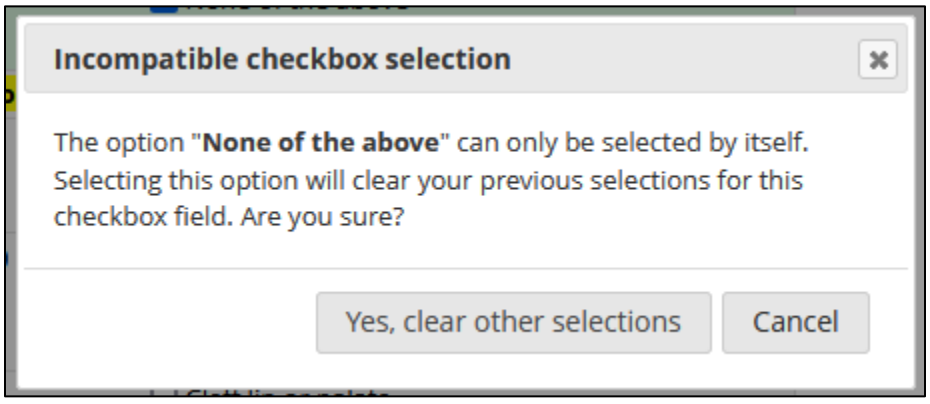


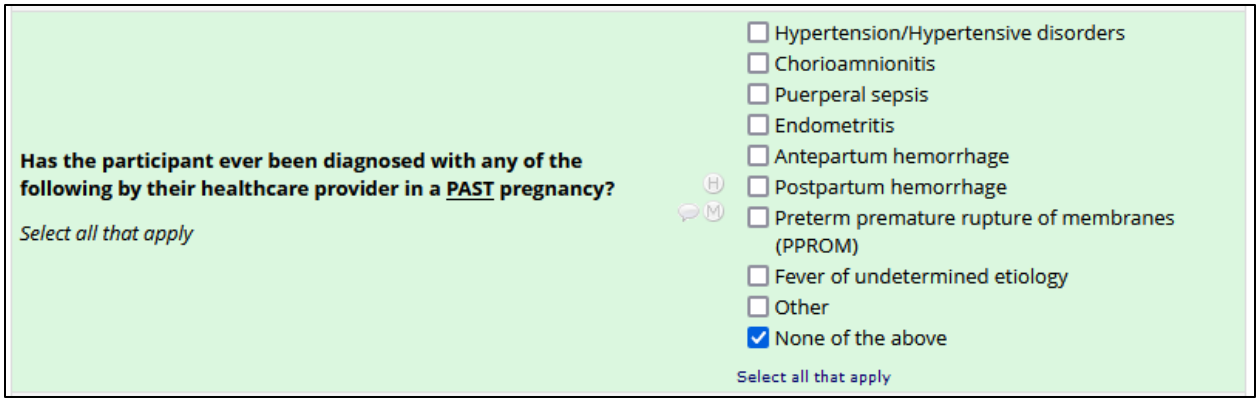

Many CRFs begin with an item of 'Enter today's date.' This field should always be the date the CRF was first started. Do not update this date if new information/changes are made at a later date.

### None of the Above

For questions that allow "Select all that apply" many will have an option for "None of the above." REDCap has a constraint that prevents "None of the above" from being selected with other response options. You will be notified if you try to select multiple options along with "None of the above."






## CRF Notes

Each MATRIX-007 CRF has a field at the end of the form called 'CRF Notes.' This is a free text field. Use CRF Notes to record pertinent information related to the CRF such as notation of an update made to a CRF at a different date than the CRF was first completed, explaining why a response was missing or procedure not done, indicating the type of medical records data on the CRF was abstracted from, or salient clinical or administrative information that would be useful for interpretation of entered responses. This field does not replace Chart Notes. Do NOT include any personally identifiable information. Any entry in CRF Notes should be accompanied by a date of the entry and initials of the study staff person who wrote the entry.


## CRF Completion Schedule

Below is an overview of CRFs organized by visit. As indicated, the CRF listed under the visit are to be completed for the visit. Some CRFs are optional, but must be completed at a later visit, other CRFs are required as indicated by the medical circumstances and history for the participant.

**Legend**

- ▪ CRF under maternal record
- ➢ CRF under infant record
- ❖ CRF under both mother and infant record

* Complete CRF as indicated

| Screening and Enrollment Visits (V101) |
|---|
| ▪ Eligibility CRF<br>▪ Demographics CRF<br>▪ Vitals CRF |

- Ultrasound Results CRF *
- Estimated Delivery Date CRF
- Obstetric Care and History CRF
- Medical Events/Conditions CRF *
- Medications CRF*
- PrEP Use CRF
- Study Visit CRF

## Antenatal Visits (V102-104)

- Ultrasound Results CRF*
- Vitals CRF
- Estimated Delivery Date CRF
- Test Results CRF
- Antenatal Obstetric Care CRF
- Medical Events/Conditions CRF *
- Medications CRF*
- PrEP Use CRF
- Study Visit CRF

## Pregnancy Outcome Visit (V201)

- Pregnancy Outcome CRF
- PrEP Use CRF
- Vitals CRF
- Test Results CRF
- EPDS
- Study Visit
- Infant Outcome CRF (complete under the maternal record for infants, even if enrolled)

  - Infant Physical Exam CRF
  - Infant Feeding Assessment CRF

  - Medical Events/Conditions CRF*
  - Medications CRF*
  - Study Exit*

## Postnatal and 3/6 Month Visits (V202/203)

- Postpartum Care CRF
- Vitals CRF
- Test Results CRF
- EPDS (required at V203, if indicated at V204)
- Study Visit

  - Infant Physical Exam CRF
  - Infant Feeding Assessment CRF

  - Medical Events/Conditions CRF *
  - Medications CRF*
  - Study Exit (required at V203) *

| Other CRFs – complete as needed |
| --- |
| ❖ Protocol Deviation CRF<br>❖ Social Harms CRF<br>❖ Participant Transfer CRF<br><br>➢ Congenital Anomalies Review CRF (complete under the maternal record for a non-enrolled infant) |

# CRF Specific Instructions

This section will provide specific instruction on how to fill it out each CRF and clarify the intent for CRF items that are potentially confusing.

## Antenatal Care

**Purpose**: The purpose of the Antenatal Care CRF is to confirm the maternal participant is receiving antenatal care, confirm gestational age, confirm delivery information, and see if there are any updates to her medical history, medication use, and care for the current pregnancy.

**General Instructions**: The Antenatal Care CRF is a repeatable CRF where an instance is completed at each Antenatal Quarterly Visit (V102-104).

Several questions will prompt to confirm information such as availability of ultrasound results, gestational age, pregnancy care, and delivery plans. Gather all available records the participant has available before starting this CRF. If Ultrasound results are available that will be used to determine the Final EDD, complete the Ultrasound Results CRF and EDD CRF *before* starting this CRF. Other questions will prompt updating medical history or healthcare provider information. Record this information immediately after completing the Antenatal Care CRF on the appropriate source documents.

Refer to the Study Procedures SSP section 5 and 6 for further information.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |
| Which visit is this? | Multiple choice, single response |
| Is the participant currently receiving antenatal care? | Yes/No question<br><br>Update paper Healthcare Provider Form with any new information. |
| Does the participant know where they plan to deliver? | Yes/No question<br><br>Update paper Healthcare Provider Form with any new information. |
| Are any medical records available for review?<br><br>Note: document records type in chart notes | Multiple choice, select all that apply<br><br>Select 'Yes, handheld along with participant report" if participant presented any type of record at the visit. Select 'Yes, abstracted from medical records' if study staff reviewed any type of medical record from a health facility, such as ultrasound reports, HIV testing logs or ANC registers. If these records were reviewed on a different date than the study visit, indicate this in the CRF notes. Specify any medical record types reviewed in the CRF Notes. |

| | |
|---|---|
| Are there any new ultrasound results available? | Yes/No question<br><br>Select 'yes' if any new ultrasound records are available, including a new paper Ultrasounds Results CRF. Enter the results into the Ultrasound Results CRF in REDCap and update the EDD CRF with a Final EDD, if applicable, *before* proceeding with the Antenatal Care CRF |
| Was there a new Hemoglobin test result available from ANC? | Yes/No question<br><br>Select 'yes' if a test result is available in a medical record to study staff at the time of this CRF completion |
| Date of Hemoglobin test | Date entry DD-MM-YYYY<br><br>Enter date from the test results report or other source medical record. |
| Hemoglobin result value (g/dL) | Numeric response.<br><br>Enter value from the test results report or other source medical record. |
| Do you have a new and final EDD to report?<br><br>Note: Document best estimated EDD after reviewing ultrasound result | Yes/No question<br><br>Select 'yes' if there is a new Ultrasound Results CRF that allows for the Final EDD to be determined. Complete the EDD CRF before proceeding with completion of the Antenatal CRF. The date entered on the EDD CRF will be used to calculate the gestational age at the time of the Antenatal CRF completion (item below). Note: The Final EDD is determined only once after the first ultrasound meeting dating criteria |
| Confirm gestational age: | REDCap will calculate the gestational age for the day of the visit. Confirm that the gestational age appears to be correct. If the gestational age does not appear to be correct, check the EDD on the Estimated Due Date CRF as well as the date of this CRF for data entry errors. |
| Has the participant been diagnosed with any of the following by their healthcare provider in this current pregnancy since their last visit? | This question is select all that apply.<br><br>Do not read out responses. Ascertain answer through discussion with participant and review of available medical records.<br><br>Only mark a new diagnosis not already documented at a previous visit. Document all selected events/conditions in a Medical Events/Conditions CRF. |
| Specify other complications: | Free text response<br><br>Provide a brief 1-3 word description, which should match to the description on the Medical Events/Conditions CRF |

| | |
|---|---|
| Have there been any additional or changes to existing medical event/conditions? | Yes/No question<br><br>Select 'yes' if any information about a medical events/conditions previously recorded on a medical events/conditions CRF has changed or there is a new event condition to report; if so complete a new Medical Events/Conditions CRF for each event. |
| Have there been any new medications or changes to existing medications? | Yes/No question<br><br>Select 'yes' if any information about a medication previously recorded on a Medications CRF has changed or there is a new medication to report; if so complete a new Medications CRF for each medication. |
| Has the participant used PEP since the last visit? | Yes/No question<br><br>If 'yes' document in a Medications CRF |
| CRF Notes | Free text field |

## Assign PID

**Purpose**: The purpose of the Assign PID CRF is to document that a PID that was pre-populated in REDCap is assigned to a participant.

**General Instructions**: Complete this CRF for each maternal participant at the Enrollment Visit that is screened for eligibility regardless of screening outcome. Complete this CRF for every enrolled infant at the visit when enrollment is verified (usually the Pregnancy Outcome Visit)

| Question | Notes \| Comments \| Question intent |
|---|---|
| PID: | This field will automatically populate the PID. |
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |
| Is PID assigned to the participant? | Yes/No question |

## Congenital Anomaly Review

**Purpose**: The purpose of the Congenital Anomaly Review CRF is to record the final determination made by the MATRIX-007 Congenital Anomaly Review for the congenital anomaly that was observed from the infant physical exam or medical records.

**General Instructions**: This CRF is completed after a reported congenital anomaly has undergone a MATRIX-007 Congenital Anomaly Review. Study staff are to complete this CRF by transcribing information provided in the final report provided by the Safety Sub-committee summarizing the review outcome. This CRF can be completed at any time; it does not need to be done at a study visit. In the case of multiple diagnoses/ICD-10 codes per case, complete a CRF instance for each distinct diagnosis/code.

| Question | Notes \| Comments \| Question intent |
|---|---|

| | |
|---|---|
| Enter date that MATRIX-007 Congenital Anomaly Review was completed: | This field will automatically populate with the date the CRF was initially started. |
| What type of congenital anomaly: | This question is select all that apply. |
| Specify other: | Free text response |
| Name of congenital anomaly | Free text response |
| What is the ICD-10 code | Free text response<br><br>Consult the Global Birth Defect Description and Coding (GBDDC) app to obtain the ICD-10 code. |
| Is this congenital anomaly major or minor | Multiple choice, single response |
| How certain is this diagnosis? | Multiple choice, single response |
| CRF Notes from MATRIX-007 CA review. | Free response |

## Demographics

**Purpose**: The purpose of the Demographics CRF is to record the maternal participant's basic demographic information such as age, relationship status, and education.

**CRF Instructions**: Complete this CRF at the enrollment visit (V101) for all participants who consent to screen for the study regardless of whether they enroll. Complete *after* assigning the PID and *before* starting the Eligibility CRF.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter today's date | This field will automatically populate with the date the CRF was initially started. |
| Age (years) | Numeric entry. Integer.<br><br>Enter current age of participant on date of CRF completion. Valid responses are between 15-100. Participants younger than 15 are not eligible. |
| Country | Once the country is selected it will skip to country specific sites and school options. |
| Site: | Site options are determined on the selected country.<br><br>Select site where the participant is undergoing screening |

| | |
|---|---|
| Preferred language: | Multiple choice, single response<br><br>Select language option offered by the site that the participant prefers to complete consent and interviewer administered CRF questions. |
| Highest level of schooling: | School options are determined by the selected country. Select highest level completed by the participant. |
| Relationship status: | Multiple choice, single response<br><br>Select current status for participant |
| Is the participant dependent on someone else for financial support? | Yes/No question<br><br>Select 'yes,' if the participant receives any financial support in addition to her own income she may have. |
| Does the participant have her own income? | Yes/No question<br><br>Select 'yes,' is the participant makes any income of her own, including from sex work or other non-reported work status. |

## Eligibility

**Purpose**: The purpose of the Eligibility CRF is to determine if a maternal candidate is eligible to enroll in the study based on meeting study inclusion and exclusion criteria per protocol.

**CRF Instructions**: Before filling out the Eligibility CRF, the maternal participant's consent should have been obtained to be screened for eligibility and participate in the study. The Eligibility CRF will ask you to confirm that the mother has provided informed consent. No study procedures other than assigning PID and completing the Demographics CRF can be completed prior to starting the Eligibility CRF.

There are 4 main sections to the CRF that determine eligibility: (1) Pregnancy, HIV, Syphilis status and testing, (2) Gestational age estimate, (3) PrEP exposure, and (4) Behavioral assessment. Local language version of the CRF is available for some questions that require verbatim reading to participants.

Participants that defer completion of eligibility criteria assessment have 35 days to complete the eligibility determination from the date of consent. When the participant returns to complete eligibly determination, the entire CRF should be reviewed again to confirm/update eligibility criteria. Responses can be overwritten as needed.

Refer to the Study Procedures SSP section 5 for further information.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Please record today's date: | This field will automatically populate with the date the CRF was initially started.<br><br>If the participant has a split visit to determine study eligibility, the form should be updated, including this date field to indicate the date the screening outcome was determined. |

| | |
|---|---|
| Did the participant provide written consent for this study prior to conduct of any study procedures? | ****REQUIRED FOR ELIGIBILITY****<br><br>Yes/No question<br><br>Select response that matches the response the participant marked in the study consent. If participant does NOT consent they are NOT eligible. |
| Enter date consent was given: | Date entry DD-MM-YYYY<br><br>Enter date participant signed the study consent form. |
| Did the participant consent to off-site visits? | Yes/No question<br><br>Select response that matches the response the participant marked in the study consent form. |
| Did the participant consent to photos/video for infant? | Yes/No question<br><br>Select response that matches the response the participant marked in the study consent form. |
| Has participant enrolled in MATRIX-007 for a previous pregnancy? | Yes/No question<br><br>Select 'yes' if the participant enrolled in the study for a previous pregnancy and is now screening to re-join the study for a subsequent (new) pregnancy. The participant should have received a new PID. |
| Enter the PID that was used for the mother previously: | Free text response<br><br>Only required for subsequent enrollments. Record the PID that was assigned to the participant for the past pregnancy. |
| **Pregnancy, HIV, and Syphilis Status and Testing** | The participant must meet the following conditions in this section to be eligible:<br>• Have a positive pregnancy test or show evidence of a viable pregnancy.<br>• Have a negative HIV test. |
| Does the participant report they are currently pregnant? | ****REQUIRED FOR ELIGIBILITY****<br>Yes/No question<br><br>Based on self-report. If the participant reports NOT pregnant she is NOT eligible; end screening. Select 'unsure' if the participant has any hesitation about her current pregnancy status, then proceed with pregnancy testing items below. |

| | |
|---|---|
| Has participant received an ultrasound in the last 5 days that confirmed the pregnancy? | Yes/No question<br><br>Select 'yes' if the participant self-reports or study staff can confirm through ANC providers. |
| Does participant have the results of the ultrasound with them today that includes an intrauterine pregnancy with a documented gestational age measured in weeks and days and/or the estimated date of delivery, and with fetal heart tones detected? | Yes/No question<br><br>Select 'yes' only if study staff can access/review the ultrasound record on the date of CRF completion and the report shows evidence of a viable pregnancy. See SSP section 6 for viable pregnancy guidance. File certified copies of ultrasound results in participant chart. |
| Date of Ultrasound | Date entry DD-MM-YYYY<br><br>Enter date ultrasound was performed |
| Has participant received a urine or serum human chorionic gonadotropin (hCG) (pregnancy) test within the last 5 days as part of antenatal care or other health services with the results available? | Yes/No question<br><br>Select 'yes' only if study staff can review/assess the test result on date of CRF completion and the test was performed in the previous 5 days. File certified copies of results in participant chart. |
| Date of **previous** test: | Date entry DD-MM-YYYY |
| Result of **previous** hCG test: | ****REQUIRED FOR ELIGIBILITY****<br><br>Multiple choice, single response<br><br>Select if the test result was 'positive' or 'negative.' If the test was quantitative, a value of ≥20 hCG indicates a 'positive' result. |
| Will hCG testing (urine pregnancy test) to confirm the pregnancy status be needed at this MATRIX-007 visit? | Yes/No question<br><br>If the participant does not have any adequate previous test or ultrasound results that confirm the pregnancy, then hCG testing must be done to determine eligibility. |
| Has the participant had **HIV testing** within the last 5 days as part of antenatal care or other health services with available results? | Yes/No question<br><br>Select 'yes' only if study staff can review/assess the test result on date of CRF completion and the test was performed in the previous 5 days. File certified copies of results in participant chart. |
| Enter date that HIV testing was performed: | Date entry DD-MM-YYYY<br><br>Enter date indicated on the test result. |

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| Enter the HIV testing outcome done within the last 5 days of today's visit: | ****REQUIRED FOR ELIGIBILITY****<br><br>Multiple choice, single response<br><br>If the participant has evidence for a positive HIV test where seroconversion is confirmed, the participant is NOT eligible.<br>If test results are currently inconclusive, meaning confirmatory testing is still ongoing, the participant is NOT eligible. |
| Does the participant have ART documentation for seroconversion? | Yes/No question<br><br>If the participant has evidence of seroconversion or ART documentation, the participant is NOT eligible |
| Will rapid HIV testing be <u>needed</u> at this MATRIX-007 visit?<br><br>*Note: If no, but syphilis testing is needed, HIV testing will be included in the combo rapid test*. | Yes/No question<br><br>If the participant does not have any adequate previous test results or ART documentation results, then HIV testing must be done to determine eligibility.<br><br>If syphilis testing is needed at this visit but HIV testing is not, select 'no' for this question. |
| Has the participant received a syphilis test within the last 3 months and during this pregnancy from a healthcare provider with the results available? | Yes/No question<br><br>Select 'yes' only if study staff can review/assess the test result on date of CRF completion and the test was performed during the current pregnancy and within the last 3 months. File certified copies of results in participant chart. |
| Enter date that syphilis testing was performed: | Date entry DD-MM-YYYY<br><br>Enter date indicated on the test result. |
| Type of **previous** syphilis testing: | Multiple choice, single response<br><br>Select the type of test performed and specify the test type/brand in CRF Notes. |
| Was there a positive test result? | Yes/No question |
| Has the participant received appropriate treatment (Penicillin G IM) | Yes/No question<br><br>If 'yes' and participant enrolls, end the treatment in the Medications CRF. |
| Will rapid syphilis/HIV (combo) testing be needed at this MATRIX-007 visit? | Yes/No question<br><br>If no adequate prior test result is available, testing is required at this visit. *Note for MATRIX-007, only prior testing with the MATRIX-007 approved rapid test (Standard Q Syphilis/HIV combo) is acceptable to omit syphilis testing by the study.* |

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| Result of urine hCG test performed today by MATRIX-007 study: | ****REQUIRED FOR ELIGIBILITY****<br>The participant must have a positive pregnancy test to be eligible.<br><br>Multiple choice, single response |
| Result of rapid HIV test done today by MATRIX-007 study: | ****REQUIRED FOR ELIGIBILITY****<br>Multiple choice, single response<br><br>The participant must have a negative HIV test to be eligible.<br><br>If participant received the Syphilis/HIV combo rapid test or a HIV only rapid test, enter the HIV test result here. |
| Results of syphilis testing done today by MATRIX-007 study: | Multiple choice, single response<br><br>Syphilis test outcome does not impact study eligibility. |
| **Pregnancy Dating** | The participant must provide adequate information to determine her gestational age. She must be less than 34 weeks gestation to be eligible. |
| What is the participant's best estimate of the first day of the last normal menstrual period (LMP)? | ****REQUIRED FOR ELIGIBILITY****<br><br>An LMP estimate is needed to determine gestational age. If the exact date is not known, enter the best estimated day, month and year. (e.g. if participant recalls it being in the middle of the month, enter 15th). The estimated gestational age may be calculated from this date so as providing as accurate as possible of a date is essential. |
| Is this LMP certain or uncertain? | Multiple choice, single response<br><br>If the participant is not certain of the date above or had to estimate, select 'uncertain.' |
| Follow this link to identify important dates in the pregnancy: https://perinatology.com/calculators/Due-Date.htm<br><br>*Enter best available input: LMP, EDD, or DoC* | Use the link to the perinatology calculator to input the LMP (Or date of conception or ultrasound due date, if available) to determine the participant's gestational age.<br><br>See SSP section 6 for pregnancy dating guidance. |

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| Using the calculator at the perinatology.com website or other study-approved calculator, what is the estimated date of conception? | Date entry DD-MM-YYYY<br><br>Taking the date directly from the output provided by the website, convert the date from MM-DD-YYY to DD-MM-YYYY when responding to this question. If date of conception was the input, record that date based on the data source (record or self-report). |
| Using the calculator at the perinatology.com website or other study-approved calculator, what is the estimated due date (EDD)? | Date entry DD-MM-YYYY<br><br>Taking the date directly from the output provided by the website, convert the date from MM-DD-YYY to DD-MM-YYYY when responding to this question. If EDD from ultrasound was the input, record that date based on the data source (record or self-report). |
| Using the calculator at the perinatology.com website or other study-approved calculator, what is the gestational age today? **Enter the WEEKS output of the GA** | Numeric response. Integer.<br><br>Enter the gestational age at the time of CRF completion. Note: if eligibility is reassessed at a later date of a split visit, update the GA to the current date of CRF completion.<br><br>Enter the weeks portion of the output. For example, if the output is 10 weeks and 4 days, enter '10' |
| Using the calculator at the perinatology.com website or other study-approved calculator, what is the gestational age today? **Enter the DAYS output of the GA** | Numeric response. Integer.<br><br>Enter the gestational age at the time of CRF completion. Note: if eligibility is reassessed at a later date of a split visit, update the GA to the current date of CRF completion<br><br>Enter the days portion of the output. For example if the output is 10 weeks and 4 days, enter '4' |
| Calculated gestational age (total days): | ****REQUIRED FOR ELIGIBILITY****<br><br>The participant must be less than 34 weeks gestation (238 days) to be eligible. |
| **Exposure Assessment** | The participant must have sufficient exposure to either CAB-LA, DVR, or oral PrEP and be currently or formerly enrolled in CATALYST to be eligible. |
| Has the participant ever been a cohort participant in CATALYST? | ****REQUIRED FOR ELIGIBILITY****<br>Yes/No question<br><br>Confirm based on site SOPs. Self-report by participant is not sufficient. The participant must have "ever been" a CATALYST participant to be eligible. |

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| Date of 180 days before estimated date of conception: | Calculated field.<br><br>Field is calculated based on the response for Date of Conception |
| Have you received a CAB PrEP injection since this date (insert date above)? | ****REQUIRED FOR ELIGIBILITY****<br><br>Yes/No question<br><br>Based on self-report. The participant must have sufficient exposure to either CAB-LA, DVR, or oral PrEP to be eligible. This would mean at least one injection of CAB-LA since 180 days (6 months) prior to date of conception. |
| In the last 28 days, have you used and had the PrEP ring inserted for at least 21 of those days? | ****REQUIRED FOR ELIGIBILITY****<br><br>Yes/No question<br><br>Based on self-report. The participant must have sufficient exposure to either CAB-LA, DVR, or oral PrEP to be eligible. This would mean she had the PrEP ring inserted for at least 21 days out of the last 28 (does not need to be consecutive). Probe with participant to determine approximate exposure.<br><br>If the response above is 'yes' but the participant is less than 4 weeks gestation, participant is NOT eligible until at least 4 weeks gestation. |
| In the last 28 days, have you taken oral PrEP/tenofovir-based PrEP for at least 21 of those days? | ****REQUIRED FOR ELIGIBILITY****<br><br>Yes/No question<br><br>Based on self-report. The participant must have sufficient exposure to either CAB-LA, DVR, or oral PrEP to be eligible. This would mean she had taken oral PrEP for at least 21 days out of the last 28 (does not need to be consecutive). Probe with participant to determine approximate exposure.<br><br>If the response above is 'yes' but the participant is less than 4 weeks gestation, participant is NOT eligible until at least 4 weeks gestation. |
| **Behavioral Assessment** | The participant must be receiving antenatal care by a healthcare provider, and not plan to permanently move away from, or be traveling for 3 or more consecutive months away from a CARE PrEP site, and have adequate locator information to be eligible. |

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| Are you currently receiving or do you plan to receive antenatal care? | ****REQUIRED FOR ELIGIBILITY****<br><br>Yes/No question<br><br>Read question verbatim to participant; available in study-designated local languages. Based on self-report or evidence of ANC hand-held records. The participant must be receiving or plan to receive antenatal care to be eligible. |
| Do you intend to relocate away from any of the study-linked CARE PrEP sites within time frame of the study (now up through 6 months postpartum)? | ****REQUIRED FOR ELIGIBILITY****<br><br>Yes/No question<br><br>Read question verbatim to participant; available in study-designated local languages. Based on self-report. The participant must reside within an area linked to a CARE PrEP site and not plan to relocate during estimated study participation to be eligible. |
| Do you intend to travel away from any of the study-linked CARE PrEP sites for three or more months? | ****REQUIRED FOR ELIGIBILITY****<br><br>Yes/No question<br><br>Read question verbatim to participant; available in study-designated local languages. Based on self-report. The participant cannot be away from an area linked to a CARE PrEP site for 3 or more months to be eligible. |
| Does the participant have adequate locator information? | ****REQUIRED FOR ELIGIBILITY****<br>Yes/No question<br><br>Collect and document locator information per SSP section 5 and site SOP. The participant must have adequate locator information documented to be eligible. |
| Screening Outcome | Based on eligibility criteria specified in the protocol, the participant is assessed for eligibility to enroll in the study. REDCap will notify study staff if the participant in NOT eligible. |
| Is there any other reason or condition to deem the participant ineligible for the study?<br><br>Such as that would preclude informed consent, make study participation unsafe for the participant, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives. | Yes/No question<br><br>Select 'Yes' if based on the eligibility criteria, other directives provided by the CARE PrEP management team, and the study staff's best judgement there is a legitimate and demonstrable reason why the participant should not be enrolled in the study given all other eligibility criteria are met . |

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| Please describe the reason/conditions why the participant is ineligible. | Free text response |
| Participant is NOT eligible.<br>DO NOT enroll the participant. | On REDCap, this field will display if the participant is NOT eligible to enroll in the study |
| Enrollment Status: | Select the outcome of screening the participant.<br><br>Multiple choice, single response<br><br>**Enrolled:** participant meets all eligibility criteria and then verbally agrees to be enrolled.<br>**Pending exposure status:** not all eligibility criteria is met at time of visit but will presumptively meet all eligibility criteria within the 35 day screening window: Examples are currently only 3 weeks pregnant, only 14 days of ring exposure in a current ring user, participant ran out of time today to complete screening.<br>**Failed – eligible but not interested:** participant meets all eligibility criteria but verbally indicate no desire to enroll<br>**Failed – not eligible:** fails to meet one or more eligibility criteria.<br>**Failed – declined to complete eligibility assessment:** stops eligibly assessment as any point, including not returning within the 35-day screening window. |
| Reason for screen fail:<br>Note: Look up code definition in participant tracker | Multiple choice, single response<br><br>If the participant is NOT eligible for enrollment, select the code for the screen fail reason. Codes map the eligibility criteria in the Protocol or to the reasons above for 'failed – eligible but not interested', 'failed – declined to complete eligibility assessment.' |

## EPDS Assessment

**Purpose**: The purpose of the EPDS is to screen the mother for possible postpartum depression. This is NOT a diagnostic tool. After the mother answers the questions, her EPDS score will be calculated by the CRF.

**General Instructions**: The EPDS CRF is required at the Pregnancy Outcome Visit (V201), Post-natal 3-Month Visit (V202), and if indicated at the Post-natal 6-Month Visit (V203). There are 10 questions to be read verbatim to the mother about how she has been feeling over the last 7 days leading up to the visit. Local language version of the CRF is available. Questions that are not well understood by the participant can be reframed as needed. Try to elicit a response instead of marking 'don't know/not sure.'

Refer to the Clinical Safety SSP section 6 for further information.

| Question | Notes \| Comments \| Question intent |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |
| "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." | Read the following aloud to participants as well as each question that is part of the EPDS. |
| I have been able to laugh and see the funny side of things. | Multiple choice, single response |
| I have looked forward with enjoyment to things. | Multiple choice, single response |
| I have blamed myself unnecessarily when things went wrong. | Multiple choice, single response |
| I have been anxious or worried for no good reason | Multiple choice, single response |
| I have felt scared or panicky for no very good reason | Multiple choice, single response |
| Things have been getting on top of me. | Multiple choice, single response |
| I have been so unhappy that I have had difficulty sleeping. | Multiple choice, single response |
| I have felt sad or miserable. | Multiple choice, single response |
| I have been so unhappy that I have been crying. | Multiple choice, single response |
| The thought of harming myself has occurred to me. | Multiple choice, single response<br><br>If participant responds 1, 2, or 3 refer participant to healthcare provider immediately. Document 'positive depression screening' in the Medications Events/Conditions CRF. |
| EPDS Score: | Total the score (sum across all questions) – automatically calculated by REDCap.<br><br>If EPDS score is 10 or greater, refer participant to healthcare provider. Document 'positive depression screening' in the Medications Events/Conditions CRF. |

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| Following completion of this questionnaire, was the mother subsequently referred for further evaluation and/or management? | Yes/No question<br><br>Response should be 'yes,' if the total score was 10 or higher or the self-harm question had a response other than 0 |
| CRF Notes | Free text response. |

## Estimated Due Date

**Purpose**: The purpose of the Estimated Due Date CRF is to record the estimated due date (EDD)of the pregnancy

**General Instructions**: The Estimated Due Date CRF is first completed at the Enrollment Visit (V101) with the Working EDD; unless the Final EDD is known at that visit based on a valid dating ultrasound. The same instance of the EDD CRF is then updated with the Final EDD at the visit where dating ultrasound results are available. Gestational age at the time of the pregnancy outcome is calculated based on the EDD on this CRF.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter today's date: | Date entry DD-MM-YYYY<br><br>Date should be the first time the CRF is completed; do not change the date when the CRF is later updated with the Final EDD. |
| Estimated Due Date: | Date entry DD-MM-YYYY<br><br>Enter the best known EDD at the time of CRF completion. Once the Final EDD is known, update the date field if the Final EDD differs from the Working EDD (re-dated). |
| Is the expected delivery date final (based on ultrasound results) or a working date? | Multiple choice, single response<br><br>Select 'working EDD – will be updated' if the dating ultrasound is not yet available to determine the Final EDD. Select 'Final EDD based on ultrasound results' once the dating ultrasound is available and the Final EDD has been determined. |
| What is the working date based on? | Multiple choice, single response<br><br>Make selection based on response about LMP certainty in the Eligibility CRF. |
| What is the final date based on? | Multiple choice, single response<br><br>Select 'ultrasound consistent with LMP' when the dating ultrasound confirms the Working EDD is accurate (no redating); Select 'Ultrasound not consistent with LMP' when the dating ultrasound determines that the Final EDD is different from the Working EDD (redate). |

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| CRF Notes | Free text response<br><br>When updating the CRF with the Final EDD, record the Working EDD in this field to retain reference of the Working EDD. |

## Infant Feeding Assessment

**Purpose**: The purpose of the Infant Feeding Assessment CRF is to record the food types/nutrition given to the infant over the course of the infant's follow-up.

**CRF Instructions**: Complete this CRF at the Pregnancy Outcome, Post-natal 3-month and 6-month visits (V201-203) for all enrolled infants; mother can still report on feeding without the infant present.

| Question | Notes \| Comments \| Question intent |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |
| What type of visit is this? | Multiple choice, single response |
| What has the infant been fed since birth or last visit (whichever was most recent)? | This question is select all that apply.<br><br>Do not read out responses. Check the applicable responses from the participant. |
| Please specify what the infant has been fed: | Free text response<br><br>Use the text box to describe any 'other' responses. |
| Has the infant completely weaned from breast milk?<br>*(Defined as at least one week without breast milk and no intention of restarting)* | Yes/No question |
| CRF Notes: | Free text response |

## Infant Outcome

**Purpose**: The purpose of the Infant Outcome CRF is to record outcomes for each fetus/infant from the pregnancy.

**CRF Instructions**: This CRF must be completed after the Pregnancy Outcome CRF because the Infant Outcome CRF relies on the outcome date from the Pregnancy Outcome CRF to generate the type of pregnancy outcome. It is important to note that the data collected for this CRF relates specifically to the pregnancy outcome, and clinical information, measurements or events that occurred during the outcome/birth to the fetus/infant. For a multigestational pregnancy, complete one CRF per fetus/infant. Record the CRF under the maternal record, even for enrolled infants.

| Question | Notes \| Comments \| Question intent |
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| Outcome: | Non-living/Living<br><br>Select 'living' if the infant was born alive. Select 'non-living' if the pregnancy ended in a miscarriage, still birth, or elective termination. NOTE: Do not record any mention of an abortion/termination in any open text fields of a CRF; simply consider it a pregnancy loss. |
| Is the infant enrolled in the study? | Yes/No question<br><br>Select 'yes' for an infant born alive that had consent to participant in the study on file at the time of birth.<br><br>Select 'no' if the infant was not born alive or consent for the infant's participation was withdrawn prior to birth. For a non-enrolled infant/fetus, the remainder of this CRF can still be completed to the extent possible based on the maternal delivery record or self-reported information from the maternal participant. |
| Date of enrollment (i.e., DOB): | Date entry DD-MM-YYYY<br><br>Date should match the infant date of birth. |
| Why did infant not enroll in the study? | Multiple choice, single response<br><br>Select reason why no enrolled infant. 'Other' should be rarely selected. |
| Please specify why infant was not enrolled in the study: | Free text response<br><br>Explain why 'other' was selected for above item. |
| Fetus ID assigned from ultrasound results: | Dropdown selection<br><br>If Ultrasound results identified multiple fetuses, each was assigned an ID of A, B, C, D, etc. in the Ultrasound results CRF. This ID allows linkage between pre-natal records and delivery/post-natal records for fetuses/infants regardless of enrollment status. |
| GA on date of outcome | This is a calculated field based on the EDD recorded on the Estimated Due Date CRF and the date of the pregnancy outcome from the Pregnancy Outcome CRF. The output ins provided in total weeks (14.43); to record the weeks and days (14 weeks 3 days) use the table to covert the number behind the decimal to days (.43 = 3 days). Confirm that the gestational age appears to be correct. If not, then correct any data entry errors for the EDD or the pregnancy outcome in the respective CRFs |
| Type of outcome: | This is a calculated field that will automatically populate one of 4 outcomes below. Confirm that the outcome appears correct. If an error is suspected check the EDD, the date of the pregnancy outcome, and if the outcome was correctly marked as "Living" or "Non-living" above. |

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| Is there a medical record that provides a different outcome from the above calculated outcome? | Yes/No question<br><br>Select 'yes' if there is a discrepancy between the outcome as calculated by REDCap in the item above and medical records for the infant/fetus.<br><br>Note: If 'yes' complete remaining portions of the CRF based on the REDCap-calculated outcome to the extent possible |
| How does the medical record categorize this outcome? | Multiple choice, single response<br><br>Determine the classification of the outcome based on the medical records that are discrepant with the outcome calculated by REDCap. |
| Explain the discrepancy, including what data was provided on the record | Free text response<br><br>Provide rationale for why the outcome determined by the study and the medical records were different. For example, an Apgar score of 3 was recorded but the medical record referenced a stillborn. |
| Delivery method: | Multiple choice, single response<br><br>Select 'no deliver/pregnancy loss' for early losses. If the loss was a delivered stillbirth, record the applicable vaginal or cesarean method. Select the response that best matches the final method of delivery. Select 'Cesarean delivery (emergency)' for an unplanned cesarean delivery. Select Cesarean delivery (elective) for a planned/scheduled cesarean delivery. |
| If vaginal, was it a breech delivery for this particular infant? | Yes/No question<br><br>Select 'yes' if the baby was in breeched position during labor |
| Type of fetal demise/stillbirth: | Multiple choice, single response<br>Select 'macerated' ff the medical record indicates a macerated fetus |
| Was this a spontaneous preterm delivery? | Yes/No question<br>This item appears only if the outcome type is 'premature live birth (<37 weeks)<br>If this delivery resulted from an induction of labor, check no.<br>A spontaneous preterm delivery suggests that the participant presented in labor and proceeded to delivery her infant |
| What was the reason for delivery? | Free text response<br>If the delivery was medically indicated, specify the indication. |
| Fetal/infant sex | Multiple choice, single response<br><br>Select response based on medical record. |
| Were any fetal/infant congenital anomalies identified prior to this visit? | This question is select all that apply. |

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| Specify the 'other' congenital anomalies that were identified: | Free text response |
| Did the infant receive any resuscitation efforts at birth? | Yes/No question<br><br>This might include chest compressions or oxygen. |
| Please describe the resuscitation efforts: | Free text response |
| Did infant require any additional special care after delivery (for example antibiotics, NICU stay, respiratory support)? | Yes/No question |
| Please describe the special care that the infant received after delivery: | Free text response |
| Infant birth weight (g): | Numeric response. Valid response 0-5000<br><br>If not recorded in the delivery record, select as 'missing.' If only participant self-report is available, indicate the measure and record it was self-reported in CRF Notes. If the recorded measure and the mother's recollection differs, record the measure noted in the medical record. |
| Infant birth length (cm): | Numeric response. Valid response 0-60<br><br>If not recorded in the delivery record, select as 'missing.' If only participant self-report is available, indicate the measure and record it was self-reported in CRF Notes. If the recorded measure and the mother's recollection differs, record the measure noted in the medical record. |
| Infant head circumference (cm): | Numeric response. Valid response 0-45<br><br>If not recorded in the delivery record, select as 'missing.' If only participant self-report is available, indicate the measure and record it was self-reported in CRF Notes. If the recorded measure and the mother's recollection differs, record the measure noted in the medical record. |
| Infant body temperature (C): | Numeric response. Valid response 0-40<br><br>If not recorded in the delivery record, select as 'not done/not performed.' If no record is available and the mother does not know, select 'don't know/not sure.' |

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| Route of temperature: | Multiple choice, single response<br><br>If not recorded in the delivery record, select as 'missing.' If no record is available and the mother does not know, select 'don't know/not sure.' |
| Infant pulse (beats/min): | Numeric response. Valid response 0-200<br><br>If not recorded in the delivery record, select as 'missing.' If no record is available and the mother does not know, select 'don't know/not sure.' |
| Infant rate of respiration (breaths/min): | Numeric response. Valid response 0-65<br><br>If not recorded in the delivery record, select as 'missing.' If no record is available and the mother does not know, select 'don't know/not sure.' |
| Apgar score 1 minute | Numeric response. Valid response 0-10<br><br>If not recorded in the delivery record, select as 'missing.' If no record is available and the mother does not know, select 'don't know/not sure.' |
| Apgar score 5 minutes | Numeric response. Valid response 0-10<br><br>If not recorded in the delivery record, select as 'missing.' If no record is available and the mother does not know, select 'don't know/not sure.' |
| Does the infant have any medical events/conditions to report since birth? | Yes/No question<br><br>If 'yes,' document in a Medical Events/Conditions CRF - under the infant record for enrolled infants and maternal record for non-enrolled infants.<br><br>If not a live birth, select 'not applicable.' |
| Has the infant participant been given any medications since birth? | Yes/No question<br><br>If 'yes,' document in a Medications CRF under infant record<br><br>If not a live birth, select 'not applicable.' |
| Has the infant had any other contact with the health system since birth, e.g., hospitalization, specialist care, diagnostic testing, etc.? | Yes/No question<br><br>Select 'yes' if the infant participant(s) has received any care in addition to the routine delivery from a health care provider.<br><br>Select 'plans to obtain care' if the infant is scheduled for a visit with a care provider or the mother is planning to schedule a visit.<br><br>Update Healthcare Provider Form as needed<br><br>If not a live birth, select 'not applicable.' |

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| Where any medical records reviewed?<br><br>Note: document record type in chart notes | Yes/No question<br><br>Select 'Yes, handheld along with participant report" if participant presented any type of record at the visit. Select 'Yes, abstracted from medical records' if study staff reviewed any type of medical record from a health facility. Specify any medical record types reviewed in the CRF Notes. |
| CRF Notes | Free text response<br><br>For enrolled infants, record the infant PID.<br><br>Indicate date and type of records where medical information was abstracted for entry in this CRF; if any information was per participant self-report only. |

## Infant Physical Exam

**Purpose**: The purpose of the Infant Physical Exam CRF is to record growth measurements and findings from the comprehensive surface exam.

**CRF Instructions**: Complete the CRF at the Pregnancy Outcome, postnatal 3-month and 6-month follow-up visits (V201-203) for all enrolled infants present at the visit. The first part of the CRF records growth measurements. The second part of the CRF records findings by body group from the surface exam which should be completed with the assistance of GBD App.

See SSP section 6 for detailed guidance on conducting the infant physical exam.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |
| What type of visit is this? | Multiple choice, single response |
| Were any medical records reviewed?<br><br>Note: document records type in chart notes | Yes/No question<br><br>Indicate the type of records available in CRF Notes |
| Infant sex: | Multiple choice, single response<br><br>Select sex based on study staff clinical assessment of the infant. |
| Infant weight (g): | Numeric response. Integer. Valid response 0-1500<br><br>Enter weight in grams if measurement taken during the study visit. |

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| Assess weight-for-age using appropriate infant chart: | Multiple choice, single response.<br><br>MARK AS NOT APPLICABLE; field will be removed with next CRF update. |
| Infant length (cm): | Numeric response. Integer. Valid response 0-100<br><br>Enter length in centimeters if measurement taken during the study visit. |
| Assess length-for-age using appropriate infant chart: | Multiple choice, single response<br><br>MARK AS NOT APPLICABLE; field will be removed with next CRF update. |
| Infant head circumference (cm): | Numeric response. Integer. Valid response 0-55<br><br>Enter head circumference in centimeters if measurement taken during the study visit. |
| Assess head circumference-for-age using appropriate infant chart: | Multiple choice, single response<br><br>MARK AS NOT APPLICABLE; field will be removed with next CRF update. |
| Was a surface examination completed? | Yes/No question<br><br>Select 'yes' if any portion of the surface exam was done at the study visit. The remaining items on the CRF will only appear if 'yes' selected. |
| Is the abnormality an extra digit? | Yes/No question |
| Where are the extra digits? | This question is select all that apply. |
| Where on the left hand is the extra digit located? | Multiple choice, single response |
| Does the extra digit appear as: | Multiple choice, single response |
| Where on the right hand is the extra digit located? | Multiple choice, single response |
| Does the extra digit appear as: | Multiple choice, single response |
| Where on the right foot is the extra digit located? | Multiple choice, single response |
| Does the extra digit appear as: | Multiple choice, single response |
| Where on the left foot is the extra digit located? | Multiple choice, single response |

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| Does the extra digit appear as: | Multiple choice, single response |
| Description of abnormality: (please include as much detail as possible) | Free text response |
| Are the fingers and toes NORMAL? (including nails, number, dangling fused, shape or parts missing, abnormally large or small) | Yes/No question |
| Description of abnormality: (please include as much detail as possible) | Yes/No question |
| Is the head and neck exam NORMAL? (includes skull, fontanelles, eyes, ears, nose, jaw) | Yes/No question |
| Description of abnormality: (please include as much detail as possible) | Free text response |
| Is there evidence of hydrocephalus (swollen head)? | Yes/No question |
| Is there a defect in the skull? | Yes/No question |
| If there is a defect in the skull, is it: | Multiple choice, single response |
| Is the mouth, lip and palate exam NORMAL? (cleft lip or palate) | Yes/No question |
| Description of abnormality: (please include as much detail as possible) | Free text response |
| Is the chest exam NORMAL? (shape and respiratory movements) | Yes/No question |
| Description of abnormality: (please include as much detail as possible) | Free text response |

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| Are the Abdominal and Anal exam NORMAL? (masses/anal closure defect) | Yes/No question |
| Description of abnormality: (please include as much detail as possible) | Free text response |
| Are the arms and legs (including hands and feet) NORMAL? (length, shape, missing parts) | Yes/No question |
| Description of abnormality: (please include as much detail as possible) | Free text response |
| Is the spine exam NORMAL? (lumps or cysts or bulging in the back including the neck, thorax or lumbar area) | Yes/No question |
| Description of abnormality: (please include as much detail as possible) | Free text response |
| Where in the spine is the defect located? | This question is select all that apply. |
| Is the spinal defect: | Multiple choice, single response |
| Are the hips and genitalia NORMAL? (including urethra, testes, penile shaft, vagina, labia) | Yes/No question |
| Description of abnormality: (please include as much detail as possible) | Free text response |
| Is the skin exam NORMAL? (pale, blue, birth marks, or any large very red areas) | Yes/No question |
| Description of abnormality: (please include as much detail as possible) | Free text response |
| Describe any other abnormality, unusual finding or make any comment about abnormality: | Free text response<br><br>Only response if applicable; field is not required |

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| Did the examination show a suspected anomaly? | Yes/No question<br>Only select 'yes' if an abnormal finding above is suspected to be a CA. If a finding indicated in the above field(s) is abnormal for another reason, select 'no' for this field.<br><br>If 'yes' submit query to SSC after the CRF is completed. |
| Was a diagnosis determined? | Yes/No question |
| Specify diagnosis (or diagnoses) | Free text response<br><br>Provide diagnosis based on the GBP App categorization |
| What is the ICD-10 code?<br>*Reference the GBD App* | Free text response<br><br>Consult the Global Birth Defect Description and Coding (GBDDC) app to obtain the ICD-10 code.<br><br>Enter the name of the suspected congenital anomaly along with the ICD-10 code.<br><br>Note: if a response is entered in this field, a new one will automatically populate below in case there are multiple CAs to report. Leave subsequent response fields blank if not needed.Notify the data manager if additional ICD-10 codes are needed. |
| How certain is this diagnosis? | Multiple choice, single response<br><br>Select certainly based on clinical judgement. If more than one CA is recorded and the certainty of the diagnosis is different, select the response that corresponds to the least certain response of any of the reported CAs. |
| CRF Notes | free response field. |

## Medical Events and Conditions

**Purpose**: The purpose of the Medical Events and Conditions CRF is to record important and pertinent medical history of the participant, any relevant ongoing medical events or conditions that started before study enrollment, and any clinically significant events or conditions that arise during study participation. This CRF is available under the maternal and infant record arms.

**General Instructions**: This a repeatable log-style CRF for a participant. Complete a CRF instance for each new medical event/condition.

See Medical and Medications Guide and SSP Section 6 for further guidance on relevant medical events to record for maternal and infant participants.

Whenever possible, report a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as separate CRF log entries as applicable. If a cluster of symptoms reported on separate CRF log entries is later attributed to a single diagnosis, change/update the earliest reported CRF to the diagnosis. In the study database, these other symptoms can be deleted by clicking "Delete data for THIS FORM only" at the bottom of the CRF log entry.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter date event/condition was reported to site staff: | Date entry DD-MM-YYYY. |
| Is the event/condition related to: | Multiple choice, single response.<br><br>Events/conditions related to 'Maternal participants' and 'fetus/unenrolled infants' are reported under the Maternal record; 'Enrolled Infant' are reported under the Infant record. |
| Type of visit that the event/condition was first reported: | Multiple choice, single response |
| Brief 1-3 word description of the event/condition: | Free text response.<br>Use 1-3 words such as 'upper respiratory infection' or 'endometritis.' Use medical terminology to describe the event/condition. Record a diagnosis if available. Include the anatomical location if applicable. For lab abnormalities, record the lab name with the direction (i.e., increased or decreased). For example, "increased hemoglobin". |
| Description of the event/condition: | Free text response.<br><br>Provide a full description of the event/condition, including underlying cause if known, how diagnosis was confirmed, details about the frequency (if a recurring chronic condition such as a herpes flare) or severity as perceived by the participant. |
| Affected body system: | Multiple choice, single response.<br><br>Select the most appropriate body system.<br>Select 'mental health' for disorders such as substance use disorder, alcohol, or tobacco use disorder.<br>Select 'infection' for any type of infection, even if occurring in another body system, such as syphilis, respiratory infection, endometritis, etc.<br>Select' neurological' for headaches and migraines<br>Select 'obstetric' for preeclampsia, chorioamnionitis, preterm labor |
| Specify the 'other' body system effected by medical event: | Free text response<br><br>Item appears if 'other' selected in item above. |

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| Date the event took place, or date of onset, start, or diagnosis: | Date entry DD-MM-YYYY<br><br>Record one of the following, as appropriate: the date on which the participant reports first experiencing the event/condition (onset of first symptom if diagnosis has multiple associated symptoms); date of the study visit/study exam (for vitals, testing, clinical screenings, or infant physical exam findings); specimen collection date (for lab abnormality). |
| Were medications prescribed as part of the treatment for the event/condition? | Yes/No question<br>Answer this question for any reportable medications including OTCs if taken for more than 2 weeks.<br><br>If the event was treated with a medication, select 'Yes.' A corresponding Medication CRF should be recorded. |
| Were there any hospitalizations, prolongation of hospitalizations or deaths associated with the event. | Yes/No question<br><br>Routine hospitalization for deliver/birth is not considered a hospitalization unless it was prolonged due an event/condition. Note: If the response is yes and the event was related to study participation, evaluate criteria for an SAE. |
| Describe any relevant information from the participant's medical history that could explain the event (past occurrences, medications use or risk factors)? | Free text response<br><br>Record any additional details that might add clarity to the medical event. For example, if a participant is admitted to the hospital with pancreatitis and record any known history of alcohol misuse. |

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| What is the current status of the event/condition? | Multiple choice, single response<br><br>***Not recovered/resolved or ongoing****:* Select this option if the event is continuing at the same severity at the time of the study visit when the event is recorded/reviewed, including at participant exit from the study.<br><br>***In the process of recovering/resolving***: event is continuing but improving and has not yet resolved or returned to baseline severity/frequency.<br><br>***Fully recovered/resolved:*** Event is no longer present. Note that if a participant started taking medication to control an event/condition, it is not considered resolved while the medication is still indicated.<br><br>***Fully recovered/resolved with sequelae:*** Participant has recovered from the event/conditions, but with remaining effects or impairment. These remaining effects can be temporary, but are still present at the time of the report/review.<br><br>***Resulted in Death:*** Select only if the event is fatal to the participant. Any other events/conditions continuing at the time of death should be changed to "not recovered/resolved". |
| Please describe the sequelae associated with the event/condition: | Free text response |
| Date when the event/condition ended or was resolved: | Date entry DD-MM-YYYY<br><br>If the event/condition is not ongoing record the date on which the participant reports no longer experiencing the event/condition or associated symptoms. Provide approximate date if exact date unknown. |
| Are any medical records available for review?<br><br>Note: document records type in chart notes | This question is select all that apply.<br><br>Select the type of record. Update this response if medical record abstraction following initial recording of the event/condition led to any information updated in the record. |

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| Is the event due to study participation and meets SAE criteria? | Yes/No question<br><br>SAE criteria includes the event/conditions being related to study participation AND any of the following criteria met: Results in death, Is life-threatening, Requires in-patient hospitalization or prolongs an existing hospitalization, Results in persistent or significant disability/incapacity, Is Important medical event that may not be immediately life-threatening or result in death, or hospitalization but may jeopardize the participant or may require intervention to prevent one of the outcomes listed above. |
| CRF Notes | Free text response |

## Medications

**Purpose**: The purpose of the Medications CRF is to document any medications that the maternal participant has taken during the pregnancy and during study participation, and any medications that the infant takes from birth during study participation. This CRF is available under the maternal and infant record arms.

**General Instructions**: This is a repeatable log-style CRF for a participant. Complete a CRF instance for each new medication. Do not record PrEP use in this CRF; see instructions for PrEP Use CRF instead. Refer to Medical and Medications Guide and SSP Section 6 for further guidance on relevant medications to record for maternal and infant participants.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter date event/condition was reported to site staff: | Date entry DD-MM-YYYY. |
| Medication name: | Free text response<br><br>Record either the generic or brand name of the medication. A combination medication can be recorded as one entry using the generic name. If a combination medication does not have a generic name or the generic name is unknown, each active ingredient must be reported as a separate entry. |
| Indication/reason for taking medication: | Free text response<br><br>For health supplements, such as multivitamins, record 'general health'. For preventive medications, record 'prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza"). In most instances (excluding nutritional supplements and/or prophylactic treatments), the indication should correspond to an item on Medical Events/Conditions CRF(s). |

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| Date started medication: | Date entry DD-MM-YYYY<br><br>**Injections:** record each injection as a separate entry, with the same date used for start and stop date. (ex: DMPA, vaccines, penicillin, etc.)<br><br>**Oral contraceptive birth control pills**: Record each pill pack confirmed by the participant to have been taken on a new log line. Indicate the start date as the date the first pill of the pack was taken.<br><br>**Implants/IUD**: Record each implant/IUD on a new log line. The start date should be the date of implant or insertion. |
| Is medication ongoing? | Yes/No<br><br>Select 'yes' if the participant is still using/taking the medication. Select 'no' if participant is no longer using the medication; a recorded stop date will be expected. |
| Date stopped medication: | Date entry DD-MM-YYYY<br><br>This item appears if medication is not indicated as ongoing above.<br><br>If the exact date is not known, enter the best estimated day, month and the year and indicate this uncertainty in CRF Notes.<br><br>This item can be completed at any time during study participation when the stop date is known.<br><br>**Injections:** record each injection as a separate entry, with the same date used for start and stop date. ex: DMPA, vaccines, penicillin, etc.)<br><br>**Oral contraceptive birth control pills**: Indicate the stop date as the date the last pill of the pack was taken.<br><br>**Implants/IUD**: The stop date should be the date the implant/IUD is removed. |

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| Dose: | Text response<br><br>Record the numeric value of the dose. If the participant does not know the exact dose units (e.g., “250 mg”), record an estimate (e.g., “1 tablet”).<br><br>For combination drugs, use the ‘/’ or ‘-’ to distinguish the different doses (i.e., hydrocodone/acetaminophen 5/500). For multivitamin tablets or liquids, record the number of tablets or liquid measurement (e.g. “1” pill or “1” tablespoon”) if the exact dosage is unknown.<br><br>When documenting medical devices with no active medication, such as an IUCD, enter the dose as “1”, the dose unit as “Other”, and indicate “device” in the text field. |
| Dosing units: | Multiple choice, single response.<br><br>Select/record the applicable dose units provided in the drop-down list. For the example, 100 mg is taken daily. Select **Milligrams** from list of options. If the participant does not know the exact dose units (e.g., “100 mg”), record an estimate (e.g., “1 tablet”).<br><br>For combination drugs with different units (e.g. 300mg/3ml), select ‘other.’<br><br>If no information on units is known, select the ‘Unknown’ option.<br>When documenting medical devices with no active medication, such as an IUCD, mark the Dose Unit as ‘Other’ and specify “device” in the “If other dose units, specify” text field provided. . |
| Specify “Other” dosing units: | Free text response<br><br>For combination drugs with different units, provide the unit that matches the dose recoded in the Dose field (i.e., mg/ml or mg/kg). |
| Frequency: | Multiple choice, single response<br><br>Select how frequently dosing occurs. Fore example, if 100 mg is taken daily, select **Daily** from the list of options. |

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| Specify “Other” frequency”: | Free text response<br><br>If ‘Other’ is selected above, specify in the corresponding “If other frequency, specify” text field provided.<br>**Implants/IUD**: Indicate the frequency as “Other” and write “continuous” in the text field. |
| Route/Mode: | Multiple choice, single response<br><br>Select how the medication is taken. |
| Specify “Other” route/mode: | Free text response<br><br>If ‘Other’ is selected above, specify in the corresponding “If other route, specify” text field provided.<br>**Implants/IUD**: For IUD route, select “Other” and write “intrauterine” in the text field. For Implant route, select “Other’ and write “sub-dermal” in the text field |
| Taken for reported Medical Event/Condition? | Yes/No question.<br><br>If the medication was administered to treat a reported medical event/condition, select ‘Yes.’ A corresponding Medical Event/Condition CRF should be recorded. |
| CRF Notes | Free text response<br><br>Include entry to document any updates to medication such as a stop date or change in dose/frequency. |

## Obstetric Care and History

**Purpose**: The purpose of the Obstetric Care and History CRF is to record important information about the mother’s current and past obstetric and gynecologic health.

**CRF Instructions**: Complete the Obstetric History CRF at the Enrollment Visit (V101). The CRF will ask a series of questions about if the mother has previously been pregnant or given birth, if she has had any complications with previous pregnancies or her reproductive health, and her plans for delivery for the current pregnancy. The CRF will prompt entry of pertinent information about previous medical events or complications in the Medical Events and Conditions CRF and Medications CRF, and prompt entry of pertinent information about her healthcare providers on the appropriate forms. Complete/update any Medical Events and Conditions CRF, Medications CRF, and healthcare provider forms immediately after completing the Obstetric Care and History CRF if prompted.

Refer to the Clinical Safety SSP section 6 for further information.

| **Question** | **Notes \| Comments \| Question intent** |
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| Enter today’s date: | This field will automatically populate with the date the CRF was initially started. |

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| Has the participant previously been pregnant? | Yes/No question<br><br>Based on self-report or availability of medical records. |
| Has the participant previously had a full-term birth (≥37 weeks gestation)? | Yes/No question<br><br>Based on self-report or availability of medical records. Probe with participant to ascertain the approximate GA at time of outcome for previous births. |
| Number of full-term births: | Numeric response. Integer. |
| Has the participant ever experienced preterm/premature births (<37 0/7 weeks)? | Yes/No question<br><br>Based on self-report or availability of medical records. Probe with participant to ascertain the approximate GA at time of outcome for previous births. |
| Number of preterm/premature births: | Numeric response. Integer.<br><br>Based on self-report or availability of medical records. |
| Has the participant ever experienced pregnancy loss before 20 weeks gestation? | Yes/No question<br><br>Based on self-report or availability of medical records. Probe with participant to ascertain the approximate GA at time of outcome for previous births. |
| Number of pregnancy losses before 20 weeks gestation: | Numeric response. Integer.<br><br>Based on self-report or availability of medical records. |
| Has the participant ever experienced pregnancy loss at or after 20 weeks gestation? | Yes/No question<br><br>Based on self-report or availability of medical records. Probe with participant to ascertain the approximate GA at time of outcome for previous births. |
| Number of pregnancy losses at or after 20 weeks gestation: | Numeric response. Integer.<br><br>Based on self-report or availability of medical records. |
| Has the participant ever experienced neonatal loss (loss of infant within first 28 days of life)? | Yes/No question<br><br>Based on self-report or availability of medical records. Probe with participant to ascertain the date of birth and approximate date of death |
| Number of neonatal losses (loss of infant within first 28 days of life): | Numeric response. Integer.<br><br>Based on self-report or availability of medical records. |

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| Has the participant ever been diagnosed with any of the following by their healthcare provider in a ***past*** pregnancy? | This question is select all that apply.<br><br>Do not read out responses. Ascertain answer through discussion with participant and review of available medical records.<br><br>If participant has chronic hypertension that overlapped with the pregnancy, select the hypertension response.<br><br>Document all selected events/conditions in a Medical Events/Conditions CRF |
| Please specify the 'other' complications: | Free text response<br><br>Provide a brief 1-3 word description, which should match to the description on the Medical Events/Conditions CRF |
| What is the participant's rhesus status? | Multiple choice, single response<br><br>If negative, document condition in a Medical Events/Conditions CRF |
| Did the participant receive the Rho(D) immune globulin (RhIg) shot (e.g., RhoGAM) with ***all past*** pregnancies? | Yes/No question<br><br>Select 'yes' only if the shot was received in all past pregnancies. If the participant is not sure, select 'don't know/not sure' instead of no. |
| Has the participant, or members of her family, ever been diagnosed with any of the following conditions? | Multiple choice, select all that apply.<br><br>Do not read out responses. Ascertain answer through discussion with participant and review of available medical records.<br>This pertains to conditions of the maternal participant or her family. |
| Please specify other diagnosis/condition: | Free text response |
| Has the biological father, or members of his family, ever been diagnosed with any of the following conditions? | This question is select all that apply.<br><br>Do not read out responses. Ascertain answer through discussion with participant and review of available medical records.<br>This pertains to conditions of the paternal side of the pregnancy (baby's biological father and his family). |
| Please specify other diagnosis/condition: | Free text response<br><br>Provide a brief 1-3 word description |

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| Has the participant been diagnosed with any of the following by their healthcare provider in this ***current*** pregnancy? | This question is select all that apply.<br><br>Document all selected events/conditions in a Medical Events/Conditions CRF |
| Please specify the 'other' pregnancy complications: | Free text response<br><br>Provide a brief 1-3 word description, which should match to the description on the Medical Events/Conditions CRF |
| Does the participant have a history of any of the following? | This question is select all that apply.<br><br>Do not read out responses. Ascertain answer through discussion with participant and review of available medical records.<br><br>Document all selected events/conditions in a Medical Events/Conditions CRF |
| Does the participant have a history of smoking? | Yes/No question<br><br>Select 'yes' if a participant reports that she has a history of smoking regularly. If the participant notes that she has tried cigarettes but would not consider herself a smoker, mselect 'yes' if participant reports having smoked at least five cigarettes in her life. |
| Does the participant currently smoke cigarettes? | Yes/No question<br><br>Document as 'tobacco use disorder' in a Medical Events/Conditions CRF |
| Has the participant ever consumed alcoholic beverages regularly (three or more drinks each week)? | Yes/No question |
| During this pregnancy has the participant consumed or currently consume alcoholic beverages? | Yes/No question<br><br>Select 'yes' if any alcoholic beverage has been consumed during the pregnancy<br><br>Document as 'alcohol use disorder' in a Medical Events/Conditions CRF |
| During this pregnancy, how often did/does the participant drink alcoholic beverages? (less than once a month, once a month, weekly, daily) | Multiple choice, single response |

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| During this pregnancy or within the year leading up to this pregnancy does the participant report any exposures to toxic chemicals, substances, or materials such as work pollutants, contaminated water, pesticides, fertilizers, environmental toxins, cleaning agents? | Yes/No question<br><br>Document in a Medical Events/Conditions CRF |
| Specify if participant reports exposure | Free text response<br><br>Provide a brief 1-3 word description, which should match the description on the Medical Events/Conditions CRF |
| During this pregnancy has the participant ever used recreational or illicit drugs? | Yes/No question<br><br>Types of drugs could include marijuana/cannabis, MDMA, amphetamines, prescription opioids, cocaine, heroin, psychedelics, etc.<br><br>Document as 'substance abuse disorder' in a Medical Events/Conditions CRF |
| Specify drug use: | Free text response<br><br>Such as the examples listed above |
| Does the participant have any medications used during the pregnancy so far to report? | Yes/No question<br><br>Select 'yes' only if the medication is reportable for the study. See Medical and Medications Guide.<br><br>If 'yes' document in a Medications CRF |
| Has the participant used PEP during this pregnancy? | Yes/No question<br><br>If 'yes' document in a Medications CRF |
| Is the participant currently receiving antenatal care? | Yes/No question |
| Does the participant know where they plan to deliver? | Yes/No question<br><br>Update healthcare provider form as needed |

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| Were any medical records reviewed? | Multiple choice, select all that apply<br><br>Select 'Yes, handheld along with participant report" if participant presented any type of record at the visit. Select 'Yes, abstracted from medical records' if study staff reviewed any type of medical record from a health facility, such as HIV testing logs or ANC registers. If these records were reviewed on a different date than the study visit, indicate this in the CRF notes. Specify any medical record types reviewed in the CRF Notes. |
| CRF Notes | Free text field |

## Participant Transfer

**Purpose**: The purpose of the Participant Transfer CRF is to record if a participant (maternal and/infant) moves locations to another CARE PrEP study site.

**General Instructions**: Participant transfers can occur within a country or outside of a country. A transferred participant should have two instances of this CRF in their record – one completed by the transferring site confirming the transfer and one completed by the receiving site upon receipt. CRF can be done outside of a study visit. The transferring site should complete the CRF *after* participant records have been sent to the receiving site. The receiving site should complete this CRF *after* receiving the participant records from the transferring site. Refer to the Study Procedures SSP Section 5 for further instructions on participant site transfers.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |
| Is this the transferring or receiving site? | Multiple choice, single response<br><br>Select the based on if the site completing the CRF is transferring or receiving a participant |
| Is this transfer within or outside of the transferring (original) country? | Multiple choice, single response<br><br>Select if the participant is transferring to a site within the same country they are currently enrolled in or transferring to a different MATRIX-007 country. |
| Name of transferring site: | Multiple choice, single response<br><br>Select the name of the site the participant is transferring out of. |
| Name of receiving site | Multiple choice, single response<br><br>Select the name of the sit the participant is being received by. |

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| Last completed visit: | Multiple choice, single response<br><br>Only the transferring site answers this item. The receiving site will not see this question. |
| If “interim”, specify visit code: *E.G. 102.1* | If interim visit, enter the corresponding code. |
| Date participant’s records were sent to receiving site (date records left the site if shipping) | Date entry DD-MM-YYYY<br><br>Only the transferring site answers this item. The receiving site will not see this question. |
| Date participant’s records were received at receiving site | Date entry DD-MM-YYYY<br><br>Only the site receiving the participant answers this item. The transferring site will not see this question. |
| CRF Notes | Free text response |

## PrEP Use

**Purpose**: The purpose of the PrEP Use CRF is to record information on the maternal participant’s self-reported use of the following products: CAB-LA (CAB PrEP), dapivirine vaginal ring (PrEP Ring), and tenofovir-based oral daily pills (oral PrEP) used for the prevention of HIV.

**General Instructions**: The PrEP Use CRF is a repeatable CRF where multiple instances of the CRF can be filled out. A PrEP Use CRF instance should be completed for each month starting from the month of conception through the end of maternal study follow-up. The CRF is expected to be completed at each study visit through study exit. CRFs instances should be in chronological order by month. The first completed instance of the CRF will record information about exposure to CAB-LA before the pregnancy and information about monthly PrEP use from time of conception through time of the study visit. At each subsequent visits, complete instances of the CRF for each month of time since the prior visit. Local language versions of the CR are available for questions that mut be read verbatim

Refer to the SSP section 6 for more information.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter today’s date: | This field will automatically populate with the date the CRF was initially started. |
| Is this the first time filling out this CRF for this participant?<br><br>For the first time completing an instance of this CRF, assess | Yes/No question<br><br>Select ‘yes’ if the <u>first time</u> the CRF is completed at the Enrollment Visit. |

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| CAB-LA exposure for the year before the date of conception. | |
| READ ALOUD TO PARTICIPANT<br><br>In the year before you became pregnant, about how many injections of CAB-LA/injectable PrEP did you receive prior to [DATE OF CONCEPTION]? | numeric response. Integer<br><br>Read question aloud. REDCAP will autogenerate the Date on conception based on the date provided in the Eligibility CRF.<br><br>Probe with participant to ascertain number of CAB injections received prior to the date of conception. Enter '0' if none. If participant is unsure, enter the best estimate. |
| READ ALOUD TO PARTICIPANT<br><br>Which month/year did you most recently receive an injection of CAB-LA/injectable PrEP before becoming pregnant on [DATE OF CONCEPTION]?<br><br>Select the MONTH | Multiple choice, single response<br><br>Item will appear if any number greater than '0' is entered in the above item.<br><br>Read question aloud. Probe with participant to determine the date of the most recent injection prior to conception. This can be the same month as the month of conception.<br><br>Enter the month in this field |
| Select the YEAR for the month that the most recent injection was received prior to becoming pregnant: | Multiple choice, single response<br><br>Enter the year for the response to the item above in this field. |
| Complete an instance of this CRF for each month starting from the month of conception through the month of maternal study exit.<br><br>Select the month: | Multiple choice, single response<br><br>Select the month this CRF instance is being administered for.<br><br>Note: Start with the month of conception for the pregnancy. Each instance of the CRF should be the subsequent month to the previously completed instance |
| Select the year: | Multiple choice, single response<br><br>Select the year corresponding to the month indicated above that this CRF instance is being administered for. |

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| READ ALOUD TO PARTICIPANT (Remember to insert the month and year)<br><br>During [MONTH] [YEAR], did you receive an injection of CAB-LA/injectable PrEP? | Yes/No question<br><br>Read question aloud. REDCap will auto populate the month and year indicated in the items above. If participant is unsure, probe using visual tool (calendar) or discussing key events in the participant's life to help estimate. |
| READ ALOUD TO PARTICIPANT (Remember to insert the month and year<br><br>During [MONTH] [YEAR], how often did you have the dapivirine/PrEP ring inserted? | Multiple choice, single response<br><br>Read question aloud. REDCap will auto populate the month and year indicated in the items above. If participant is unsure, probe using visual tool (calendar) or discussing key events in the participant's life to help estimate.<br><br>Select 'did not have to use' if the participant was not prescribed the PrEP ring or no longer had supply of the ring to use.<br><br>Select 'Have it but didn't use it' if the participant was given ring but never inserted it<br><br>Determining use for responses for most, about or less than half of the time, does not need to be based on consecutive days; approximate the total the participant used ring that month (through the reporting date) and select the best response. |
| READ ALOUD TO PARTICIPANT (Remember to insert the month and year<br><br>During [MONTH][YEAR], how often did you take tenofovir-based/oral PrEP? | Multiple choice, single response<br><br>Read question aloud. REDCap will auto populate the month and year indicated in the items above. If participant is unsure, probe using visual tool (calendar) or discussing key events in the participant's life to help estimate.<br><br>Select 'did not have to use' if the participant was not prescribed the oral PrEP or no longer had supply of oral PrEP to use.<br><br>Select 'Have it but didn't use it' if the participant was given oral PrEP but never ingested any pills<br><br>Determining use for responses for most, about or less than half of the time, does not need to be based on consecutive days; approximate the total the participant used oral PrEP that month (through the reporting date) and select the best response. |
| CRF Notes | Free text response<br><br>Provide any salient details about use during the month such known dates of stopping/starting. Also, indicate if the month |

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|---|---|
| | was partially assessed if the visit date was within the month and if the month was reassessed at the next study visit. |

## Postpartum Care

**Purpose**: The purpose of the Postpartum Care CRF is to record if the maternal or infant participant has received any care or services since experiencing the outcome, and prompt for updates to medical events and healthcare provider information as needed.

**General Instructions**: Complete the CRF at the Post-natal Visits (V202 & 203). Most questions ask if the mother has any information that needs to be updated about health or medical history since experiencing the outcome. The CRF will prompt completion/updates to other CRFs such as the Medical Events CRF as needed, which should be done immediately following completion of the Postpartum CRF.

Refer to the Study Procedures SSP section 5 for further information.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |
| Which visit is this? | Multiple choice, single response |
| Are any medical records available for review?<br><br>Note: document record type in chart notes | Yes/No question<br><br>Indicate the type of records available in CRF Notes |
| Has the participant received any <u>new</u> health care since the last visit or experiencing the outcome for the index pregnancy (e.g., postnatal care, postpartum family planning, or follow-up for pregnancy loss)? | Yes/No question<br><br>This question relates to the maternal participant only.<br>Select 'plans to obtain care' if the mother is scheduled for a visit with a care provider or is planning to schedule a visit.<br><br>Update Healthcare Provider Form as needed |
| Have there been any new or changes to existing medical events/conditions related to this birth for the <u>maternal</u> participant? | Yes/No question<br><br>Select 'yes' if any information about a medical events/conditions previously recorded on a medical events/conditions CRF has changed or there is a new event condition to report; if so complete a new Medical Events/Conditions CRF for each event. |

| | |
|---|---|
| Have there been any new or changes to existing medications related to this birth for the maternal participant? | Yes/No question<br><br>This question relates to the maternal participant only.<br>Select 'yes' if any information about a medication previously recorded on a Medications CRF has changed or there is a new medication to report; if so, complete a new Medications CRF for each medication. |
| Has the infant had any new contact with the health system since the last visit or birth, e.g., well-baby/routine immunization, hospitalization, specialist care, diagnostic testing, etc.? | Yes/No question<br><br>This question relates to the infant participant(s) only. Select 'yes' if the infant participant(s) has received any care in addition to the routine delivery from a health care provider.<br><br>Update Healthcare Provider Form as needed |
| Have there been any new or changes to existing medical events/conditions related to this birth for the infant participant? | Yes/No question<br><br>This question relates to the infant participant(s) only. Select 'yes' if any information about a medical events/conditions previously recorded on a medical events/conditions CRF has changed or there is a new event condition to report; if so complete a new Medical Events/Conditions CRF for each event. |
| Have there been any new or changes to existing medications related to this birth for the infant participant? | Yes/No question<br><br>This question relates to the infant participant(s) only.<br>Select 'yes' if any information about a medication previously recorded on a Medications CRF has changed or there is a new medication to report; if so, complete a new Medications CRF for each medication. |
| CRF notes | Free text response |

## Pregnancy Outcome

**Purpose**: The purpose of the Pregnancy Outcome CRF is to record the date of the outcome, any complications surrounding the outcome that the mother experienced, and the general care that was provide for the mother.

**General Instructions**: This CRF is expected at eh Pregnancy Outcome Visit (V201). Complete this CRF before the Infant Outcome CRF because the Infant Outcome CRF relies on the outcome date from this CRF to generate the type of pregnancy outcome. Several questions ask about specific complications that may have occurred. It is important to note that the data collected for this CRF relates specifically to the pregnancy outcome, and clinical information, measurements or events that occurred during the outcome or shortly after the outcome.

Refer to the Study Procedures SSP section 5.4.3 for further information.

| Question | Notes \| Comments \| Question intent |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |
| What type of visit is this? | Multiple choice, single response |
| Where did the delivery/outcome occur? | Multiple choice, single response<br><br>Select the location where the birth took place. Select 'health facility' if the outcome occurred at a health facility with ANC/delivery services, as appliable. If the birth took place at home, in transit to a health facility, or another place that was not a maternity ward, select 'at home/other location.' Even if the baby was taken afterward to a health facility for registration and evaluation, still select this option. |
| Did the participant seek follow-up care for themselves or the baby after the outcome? | Yes/No question<br><br>Appears if item above response was 'at home/other location.'<br><br>Select 'yes' if the baby was brought to a health facility soon after birth for evaluation and registration. Indicate the health facility on the Healthcare Provider Form. |
| Please specify the facility: | Free text response<br><br>Do not enter the name of the facility where the outcome occurred. Instead, the valid options are:<br><br>Enter **Site-based facility** if the outcome occurred at the expected, CARE PrEP associated facility.<br><br>Enter **Non-site-based facility** if the outcome occurred at another facility not associated with the CARE PrEP Site.<br><br>If not at home or a health facility, enter the description such as 'in car in transit to hospital' 'at church,' etc. |
| Date of pregnancy outcome | Date entry DD-MM-YYYY<br><br>If the exact date is not known, enter the best estimated day, month and the year. |
| Is date certain? | Yes/No question<br><br>Select 'no' if the pregnancy outcome date was estimated or there was any uncertainty to the date indicated in the item above. |

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| Were there any complications associated with the mother? | This question is select all that apply.<br><br>Do not read out responses. Ascertain answer through discussion with participant and review of available medical records.<br><br>Document all selected events/conditions in a Medical Events/Conditions CRF |
| Specify the complications related to the outcome: | Free text response<br><br>Provide a brief 1-3 word description, which should match to the description on the Medical Events/Conditions CRF |
| Where any medical records reviewed?<br><br>Note: document record type in chart notes | Yes/No question<br><br>Select 'Yes, handheld along with participant report" if participant presented any type of record at the visit. Select 'Yes, abstracted from medical records' if study staff reviewed any type of medical record from a health facility. Specify any medical record types reviewed in the CRF Notes. |
| Are there any new ultrasound results available? | Yes/No question<br><br>Select 'yes' if results were from a study-directed or clinical provider direct ultrasound. Enter results on the Ultrasound results CRF in REDCap; update EDD CRF if used for determining the final EDD. |
| Have there been any new or changes to existing maternal medical events/conditions related to this pregnancy and/or outcome? | Yes/No question<br><br>Select 'yes' if any information about a medical events/conditions previously recorded on a medical events/conditions CRF has changed or there is a new event condition to report; if so complete a new Medical Events/Conditions CRF for each event. |
| Have there been any new or changes to existing medications for the maternal participant? | Yes/No question<br><br>Select 'yes' if any information about a medication previously recorded on a Medications CRF has changed or there is a new medication to report; if so, complete a new Medications CRF for each medication. |
| Has the participant used PEP during the pregnancy since the last visit? | Yes/No question<br><br>If 'yes' document in a Medications CRF |

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|---|---|
| Has the participant received any health care since experiencing the outcome for the index pregnancy (e.g., postnatal care, postpartum family planning, or follow-up for pregnancy loss)? | Yes/No question<br><br>Select 'yes' if the participant or infant has received any care in addition to the routine delivery from a health care provider. Update the HealthCare Provider Form as applicable. |
| How many of fetus/infants came from this pregnancy? | Numeric response. Integer.<br><br>Enter the total number of fetus/infants from the pregnancy, regardless of outcome status.<br><br>Please notify the Data Manager if more than 3 infants resulted from the pregnancy. |
| CRF Notes | free text field<br><br>Indicate date and type of records where medical information was abstracted for entry in this CRF. |

## Protocol Deviation

**Purpose**: The purpose of the Protocol Deviation CRF is to document when deviations from the protocol occur, reasons for the deviation, and what was done to rectify or prevent the same deviation from occurring again.

**General Instructions**: This is a repeatable log-style CRF for a participant. Complete a CRF instance for each new protocol deviation associated with a participant during study participation (including the screening period). CRF can be done outside of a study visit. Please be as specific as possible when describing the deviation, and actions taking to address it and prevent it from occurring again. If a protocol deviation impacts more than one participant, complete an instance of the CRF under each impacted participant record. Refer to the Study Procedures SSP Section 1 for further instructions on protocol deviation reporting.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter today's date | This field will automatically populate with the date the CRF was initially started. |
| Date that site became aware of deviation: | Date entry DD-MM-YYYY<br>Record the date any study staff first became aware of the deviation. |
| Date that deviation occurred: | Date entry DD-MM-YYYY<br>Record the date the deviation occurred on or first started. |
| Type of deviation: | Multiple choice, single response<br>Record the applicable deviation by selecting from the drop-down menu.<br><br>*Please see table below for the types of deviations.* |

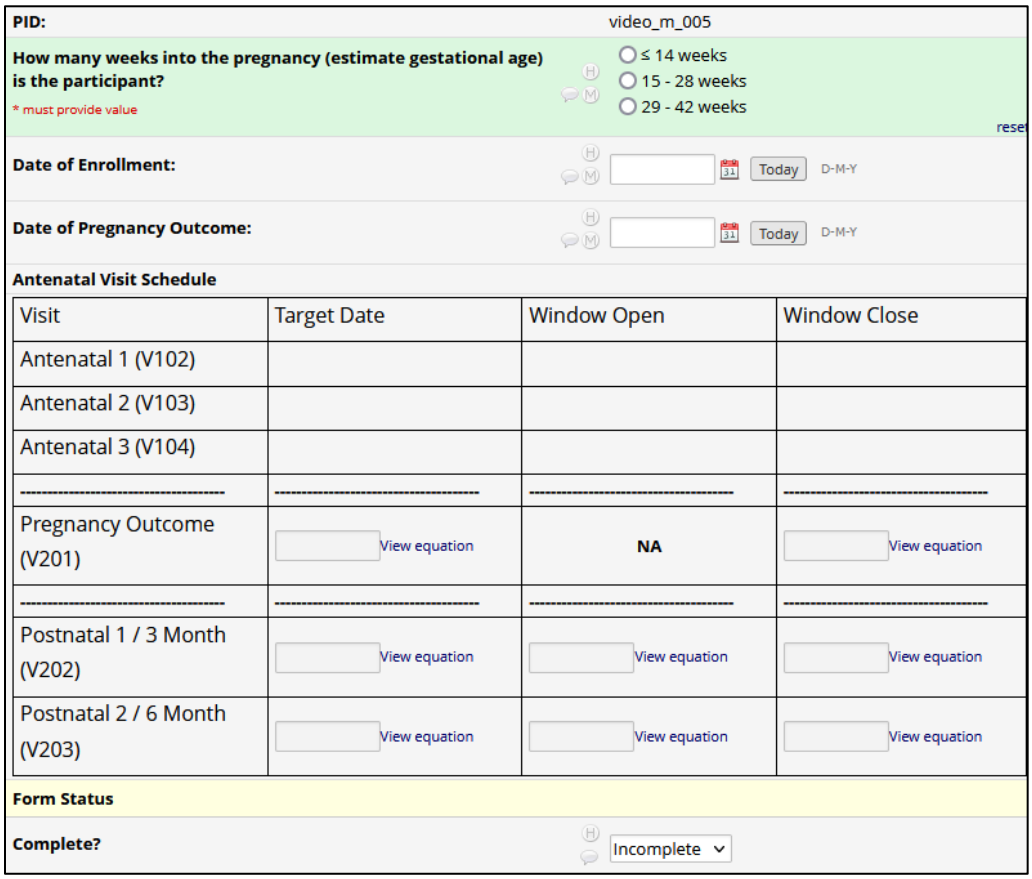
| | |
|---|---|
| | Record “other” if none of the listed categories match. |
| Please describe the deviation: | Free text response<br>Use the text field to briefly describe the specific details of the deviation |
| Plans or action taken to address the deviation: | Free text response<br>Use the text field to provide a brief description of the plans to address the deviation. |
| Plans or action taken to prevent future occurrences of the deviation: | Free text response<br>Use the text field to provide a brief description of the plans to address future occurrence of the deviation. |
| CRF Notes | Free text response |

| **PROTOCOL DEVIATION TYPES** |
|---|
| **Enrollment of an ineligible participant:** The participant enrolled and not all eligibility requirements were met. |
| **Informed Consent deviations:** Examples include<br>failure to accurately execute and/or document any part of the informed consent process, consenting a minor who does not meet emancipated status per protocol |
| **Conduct of non-protocol procedure:** A clinical or administrative procedure was performed that was not specified in the protocol and was not covered under local standard of care practice. |
| **Use on non-approved IRB/IEC materials:** Include use of ANY study-related material that requires IRB or EC approval for use per site requirements. |
| **Breach of participant confidentiality:** Include potential and actual cases where participant confidentiality is breached. For example, a staff member put a participant’s name on a case report form. |
| **Unreported or significantly delay in reporting SAE and/or Social harms:** site staff become aware of an SAE and/or social harm, but do not report it per protocol requirements |
| **Study procedure deviation (i.e., missed or incomplete procedures):** Any missed or incomplete procedures required per protocol for a study visit, includes for reasons of participant decline, error by study staff and logistical constraints<br><br>Also, any instance when any study procedure, including clinical and administrative procedures, is completed by a staff member who is not adequately qualified AND delegated to perform the procedure. |
| **Visit completed outside of window:** Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. For example, if visit 201 procedures are done in the visit 202 window. |
| **Other:** any other violation, divergence or departure from the MATRIX-007 protocol that is reportable to local IRB/IEC. |

## Scheduling Tool

**Purpose**: The Scheduling Tool is an optional CRF that helps you create a schedule of study visits for the participant.

**CRF Instructions**: There are 3 requisite inputs to creating a schedule. The first is to select the gestational age range for the participant; this determines how many Antenatal Visits the participant would ideally come in for. The second is the date of enrollment which populates the target dates and visit windows for the antenatal visits. The third input is the pregnancy outcome from which the postnatal visits and visit windows are calculated.



**PID:** video_m_005

**How many weeks into the pregnancy (estimate gestational age) is the participant?**
* must provide value

- ≤ 14 weeks
- 15 - 28 weeks
- 29 - 42 weeks

reset

**Date of Enrollment:** Today D-M-Y

**Date of Pregnancy Outcome:** Today D-M-Y

**Antenatal Visit Schedule**

| Visit | Target Date | Window Open | Window Close |
|---|---|---|---|
| Antenatal 1 (V102) | | | |
| Antenatal 2 (V103) | | | |
| Antenatal 3 (V104) | | | |
| ---------- | ---------- | ---------- | ---------- |
| Pregnancy Outcome (V201) | View equation | NA | View equation |
| ---------- | ---------- | ---------- | ---------- |
| Postnatal 1 / 3 Month (V202) | View equation | View equation | View equation |
| Postnatal 2 / 6 Month (V203) | View equation | View equation | View equation |

**Form Status**

**Complete?** Incomplete

## Social Harms

**Purpose**: The purpose of the Social Harms CRF is to document when the participant experiences any social harm as a result of study participation.

**General Instructions**: This is a repeatable log-style CRF for a participant. Complete a CRF instance for each new social harm reported. Please be as specific as possible when describing the social harm and the context surrounding it, specifically how study participation led to the harm occurring. If the social harm qualifies as a Serious Adverse Event (SAE), document it under the Medical Events/Conditions CRF as well. See SSP section 6 for SAE criteria and reporting guidance. Refer to Clinical Safety SSP section 6 for further information in Social Harms.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|

| | |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started |
| Date of event was initially brought to team's awareness: | Date entry DD-MM-YYYY<br><br>This date will usually be the same as the date the CRF was completed (above date), unless there was a delay in when the site was aware and a directive to complete the event as a social harm |
| Description of event:<br>*Event details, cause, including relation to study participation and what happened since the event* | Free text response |
| Type of social harm: | This question is select all that apply.<br><br>***Education*** *- Been turned down by an educational program, told to leave an educational program, study visits interfering with school attendance/performance, or experienced other problems at school*<br>***Employment*** *- Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work*<br>***Housing*** *- Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing*<br>***Medical/Dental*** *- Been refused medical or dental treatment, or treated negatively by a health care provider*<br>***Family Relationships*** *– Had negative experiences with family (excluding partner)*<br>***Partner Relationships*** *– Had negative experiences with significant other, spouse, or sex partner*<br>***Friend/community Relationships (Other)*** *- Had negative experiences with friends, neighbors or other community members*<br>***Travel/Immigration*** *– Had problems obtaining formal permission to travel or enter another country, such as being denied a visa, or had a problem with immigration/naturalization*<br>***Other*** *- Had other problems not covered in the list above* |
| Specify other type of social harm: | Free text response<br><br>Provide event details including rationale for the event being study related and what happened since the event. |
| Event start date: | Date entry DD-MM-YYYY<br><br>Record the date/approximate date the negative experience first started. |
| Did the event involve physical harm? | Multiple choice, single response |

| | |
|---|---|
| Event's impact on quality of life: | Multiple choice, single response<br><br>Select the most appropriate category based on the participant's assessment of impact on quality of life.<br>***Mild:*** *causing no or minimal impact on usual social & functional activities*<br>***Moderate:*** *causing greater than minimal impact with usual social & functional activities*<br>***Major:*** *causing inability to perform usual social & functional activities* |
| Is event ongoing? | Yes/No question |
| Event end date: | Date entry DD-MM-YYYY<br>Record the date/ approximate date the negative experience ended. |
| Event outcome: | Multiple choice, single response<br><br>Select the most appropriate category based on the participant's assessment:<br>***Unresolved:*** *Mark if the participant reports the impact of the social harm on their life is continuing*<br>***Resolved:*** *Mark if the participant reports the event no longer impacts their daily life* |
| Is follow-up from study staff needed? | Multiple choice, single response<br><br>Indicate whether the event requires follow-up from staff at future visits:<br>***Yes, continue to follow-up:*** *Mark if follow-up required at the next visit. For example, if staff need to check in on the outcome of any referrals provided in response to the social harm, or the participant requests ongoing assistance from study staff.*<br>***No further action needed:*** *Mark if no further action is needed from staff to address the issue. For example, the participant reports the event is resolved or does not require further assistance from study staff* |
| Actions taken to address social harm: | Free text response<br><br>Provide any actions the participant or the study team took to address the event including any referrals or changes to study procedures/participation, support with study disclosure, etc. |
| Is this social harm reportable as a Social Adverse Event (SAE)? | Yes/No question<br><br>If the was relate to a SAE, select 'Yes.' A corresponding Medical Event/Condition CRF should be recorded. |
| CRF Notes | Free text response |

## Study Exit

**Purpose**: The purpose of the Study Exit CRF is to document that the participant has exited the study and the reason for the exit.

**General Instructions**: This is the very last CRF to be completed for the participant. Record study exit for the maternal participant should under the maternal record; record study exit for the infant participant should under the infant record. This CRF can be completed at any visit, including an interim visit, or in absentia if the participant is not present at the time of study exit.

| Question | Notes \| Comments \| Question intent |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |
| Which participant is this for? | Multiple choice, single response |
| Primary reason for completion/discontinuation: | Multiple choice, single response<br><br>**Scheduled exit visit/end of study:** Select or maternal participant if the participant completed the Visit 203 or exited earlier due to a pregnancy loss or infant loss. Select for infant participant if the participant completed Visit 203.<br>**Death:** Select if the event the participant dies.<br>**Participant is unwilling or unable to comply with required study procedures:** Requires investigator decision to terminate study participation.<br>**Lost to follow-up:** Requires investigator decision to terminate study participation.<br>**Investigator decision:** Investigator decides to terminate the participant from the study prior to scheduled exit. Select this option if the decision was not one of the above 2 options.<br>**Early study closure:** Select in the event the entire study is ended prior to participant completing their expected study schedule.<br>**Withdrawal of consent by participant:** select for the maternal participant if the mother withdraws consent for herself; select for the infant participant if the mother withdraws consent for her infant<br>**Study terminated by sponsor:** Select in the event the entire study is ended by the study sponsor prior to participant completing their expected study schedule.<br>**Other:** Select if exiting for a reason not specified above. (This response is expected to be rare.) |
| Specify other | Free text response<br>Specify reason if 'other' is selected for study exit. |
| Please provide any pertinent additional information for participant's study exit: | Free text response<br><br>For example, explain that the maternal participant exited at the Pregnancy Outcome Visit because of a pregnancy loss and no further follow-up was needed. |

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|---|---|
| CRF Notes | Free text response |

## Study Visit

**Purpose**: The purpose of the Study Visit CRF is to provide general documentation for the study visit such as date, location, completion of the visit and procedures, and if infants were present (when pertinent). This CRF is available under the maternal record arm.

**General Instructions**: This is a repeatable log-style CRF for a participant. Complete a CRF instance for each new visit/contact with a participant where data is entered into a CRF (new or updates). The CRF is under the Maternal record and should be completed on behalf of the maternal and infant participant, if applicable. The CRF will ask for the PID(s) of the infant(s), if applicable.

Every time a portion of a visit is completed, a new Study Visit CRF should be completed. For example, if the Pregnancy Outcome Visit was started over a phone contact, complete a Study Visit CRF marking 'Pregnancy Outcome Visit,' 'Over the Phone,' and 'Incomplete.' Then when the participant comes to complete the visit at the site as part of a split visit (must be within the pregnancy outcome visit window), complete a new Study Visit CRF as 'Pregnancy Outcome Visit,' 'onsite,' and 'complete.'

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter date for today's visit (or date of form completion for a missed visit): | This field will automatically populate with the date the CRF was initially started. |
| What type of visit is this? | Multiple choice, single response |
| If 'Interim visit,' enter visit code: | If interim visit, enter the corresponding code. See SSP section 5 for interim visit code format. |
| Was an infant(s) present | Yes/No question.<br>If an enrolled infant is not present for a visit, respond 'no' even if information about the infant recorded was provided by the maternal participant. |
| Explain why infant was not present for the visit: | Free text response |
| Infant PID: | Enter PID for each enrolled infant present for visit. The CRF allows up to 3 PIDs to be entered. Contact the Study Data Manager if more than 3 fields are required. |
| Infant PID: | |
| Infant PID: | |
| Site: | Site options are determined on the selected country on the Demographics CRF |

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| Was the visit completed on this date? | Yes/No question<br><br>Completion of a visit means that all procedures intended to be completed were completed. Select 'no, incomplete visit' when a participant was unable to complete all procedures on that visit date.<br><br>If the CRF is being completed at a second date of a split visit where the remaining study procedures are completed, select 'yes'<br><br>Select 'no, missed visit' when the window has closed for scheduled visit and the participant did not start the visit.<br>Note: A visit is still missed even if procedures were made up at an interim or other scheduled visit. |
| Please specify why the visit was not completed or other reason: | Free text response |
| Visit location: | Multiple choice, single response |
| Please specify location of off-site visit: | Free text response<br><br>This question will appear if the visit location of 'off-site, other' was selected above.<br><br>Do not enter the name of the facility where the visit occurred. Instead, enter: **non-site based location**. |
| Was an SAE or Social Harm (SH) reported during this visit? | Multiple choice, select all that apply.<br><br>If SAE is marked, a Medical Events/Condition CRF with SAE indicated should have been completed at this visit<br>If SH is marked, an SH CRF should have been completed at this visit. |
| Where any procedures missed? | Yes/No question<br><br>Select 'Yes' if a*ny required* study procedure for the visit type was not done. |
| Indicate what procedures were missed and why. | Free text response.<br><br>Indicate all missed procedures and explain if procedures were missed such as because participant declines, they were missed by mistake, or could not be completed due to logistical constraints.<br>Also, record missed procedures in a Protocol Deviation CRF |

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|---|---|
| CRF Notes | Free text response.<br><br>Record reasons for miss or incomplete visits, including any plans to make-up or complete the visit. |

## Test Results

**Purpose**: The purpose of the Test Results CRF is to document study-performed testing or documentation from other health services for testing for pregnancy, HIV, and syphilis.

**General Instructions**: Complete this CRF at all study visit except for the Enrollment Visit. HIV rapid testing will be done per local standard of testing; participants with a positive rapid HIV test will be referred back to the CATALYST study site or public sector clinic for confirmatory testing per the national testing algorithm in each study country; HIV rapid testing and pre- and post-test counseling may be omitted from study visits if HIV occurred as part of PrEP or ANC visit within 5 days of the study visit and MATRIX-007 study staff can verify the test results or if participant has initiated ART and MATRIX-007 study staff can verify the ART documentation, as outlined in the MATRIX-007 SSP sections 6.

Syphilis rapid testing will be done per local standard of testing; participants with a positive rapid syphilis test will be referred outside the MATRIX-007 study site for additional testing if needed and for treatment per local standard of care; syphilis testing may be omitted from this study visit if MATRIX-007 study staff can verify a documented result performed with a MATRIX-approved test during pregnancy and in the prior 3 months, as outlined in the MATRIX-007 SSP section 6.

Pregnancy testing will be done per local standard of testing; pregnancy testing may be omitted from study visits if pregnancy testing or ultrasound confirming pregnancy occurred as part of PrEP or ANC visit within 5 days of the study visit and MATRIX-007 study staff can verify the test results as outlined in the MATRIX-007 SSP Section 6.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |
| What type of visit is this? | Multiple choice, single response |
| Has the participant received an HIV test within the last 5 days of today's visit? | Yes/No question<br><br>Select 'yes' if a test result is available to study staff that clearly shows the test type, date performed, and outcome of the test. Create a certified copy and file in the participant's chart. |
| Enter date previous HIV testing was performed: | Date entry DD-MM-YYYY<br><br>Enter date on recorded on test record. Do not rely in self-report. |

| | |
|---|---|
| Enter the outcome of the HIV testing done within the last 5 days of today's visit: | Multiple choice, single response<br><br>Enter outcome on recorded on test record. Do not rely in self-report. |
| Does the participant have ART documentation for seroconversion?<br><br>Note: chart note type of documentation | Yes/No question<br><br>Select 'HIV positive (seroconversion confirmed)' only if documentation is available that confirms the participant's status.<br><br>Select 'inconclusive' if the participant is awaiting results of confirmatory testing following at least one positive rapid test. |
| Enter date of ART initiation: | Date entry DD-MM-YYYY<br><br>Enter date ART was first prescribed per documentation (prescription on bottle, hand-held record, etc.) |
| Will rapid HIV testing be needed at this MATRIX-007 visit?<br><br>*Note: If no, but syphilis testing is needed, HIV testing will be included in the combo rapid test.* | Yes/No question<br><br>Select 'yes' if no documentation meeting criteria to omit the test is available.<br><br>Select 'no' if documentation is available to omit the test or seroconversion was confirmed at a previous study visit. |
| Since the last visit, has the participant received a new syphilis test from a healthcare provider with the results available? | Yes/No question<br><br>Select 'yes' if documentation is available to study staff of a syphilis test during pregnancy and in the prior 3 months.<br><br>Select 'no/unsure' if no documentation is available that meets the above criteria. |
| Enter date that syphilis testing was performed: | Date entry DD-MM-YYYY<br><br>Enter date on recorded on test record. Do not rely in self-report. |
| What type of test was done? | Multiple choice, single response<br><br>Select the test type based on what is recorded in the medical record/test result. |
| Result of **previous** syphilis testing: | Multiple choice, single response |

| | |
|---|---|
| Will rapid syphilis testing be needed at this MATRIX-007 visit?<br><br>*Note: perform only if indicated* | Yes/No question<br><br>Syphilis testing is only performed if indicated at follow-up visits. Refer to site SOP. |
| Will urine hCG testing be needed at this visit?<br><br>*Note: perform only if indicated* | Multiple choice, single response<br><br>Pregnancy testing is only performed during following up if indicated at Post-natal Visits (V202 & 203). Refer to site SOP. |
| Enter **HIV test** result | Multiple choice, single response<br><br>Enter outcome of study-performed test done at the present study visit. Outcome should be the same as on the Testing Log. |
| Enter **syphilis test** result | Multiple choice, single response<br><br>Enter outcome of study-performed test done at the present study visit. Outcome should be the same as on the Testing Log. |
| Enter **urine HCG** test result | Multiple choice, single response<br><br>Enter outcome of study-performed test done at the present study visit. Outcome should be the same as on the Testing Log. |
| CRF Notes | Free test response<br><br>Indicate any type of test results documentation used to omit testing. Provide rationale for any clinically indicated testing (i.e. for syphilis and pregnancy) |

## Ultrasound Results

**Purpose**: The purpose of the Ultrasound Results CRF is to document available results ultrasound performed on the index pregnancy.

**General Instructions**: Per protocol, all maternal participants will have a study-directed ultrasound performed, ideally between 8-24 weeks gestation, for purposes of pregnancy dating. In addition, any ultrasound performed for clinical indications through their clinical provider or directed by the study are to be documented on this CRF. Any ultrasound performed at the request of the study should be first documented by the ultrasonographer on a paper-based CRF, then site staff will transcribe the data onto an Ultrasound Results CRF in the participant's record in REDCap. If the source data is from a non-study report/record, also transcribe the information into the Ultrasound Results CRF in REDCap. Complete this CRF at any study visit when ultrasound results are available.

The CRF has 3 sections. The first section is general pregnancy and gestational age information. The second section is completed only if the participant is in the first trimester. The third section is completed only if the participant is in the second or third trimester.

Refer to the SSP section 6 for more information.

| Question | Notes \| Comments \| Question intent |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |
| Date ultrasound was performed: | Date entry DD-MM-YYYY<br><br>Record date matching the paper source document. |
| First day of last normal menstrual period (LMP): | Date entry DD-MM-YYYY<br><br>Date should match previously reported LMP recorded in the Eligibility CRF. . |
| Is participant estimated to be in first, or second/third trimester? | Multiple choice, single response<br><br>Record assumed trimester at time of ultrasound (based on Working EDD). |
| Number of sacs/embryos/fetuses: | Numeric response. Integer. |
| Fetus ID: | Multiple choice, single response drop down menu.<br><br>Assign 'A' to a singleton pregnancy; assign 'B' and so forth to fetuses of a multigestational pregnancy. |
| **Section: First Trimester** | |
| Type of ultrasound: | Multiple choice, single response |
| Was gestational sac visualized? | Yes/No question |
| Gestational sac diameter (mm): Mean if possible | Numeric response |
| Yolk sac present? | Yes/No question |
| Presence of embryo documented? | Yes/No question |
| Cardiac activity detected: | Multiple choice, single response |
| Crown Rump Length: | Numeric response |
| Pregnancy is intrauterine (IUP)? | Yes/No question |
| Pregnancy is viable? | Yes/No question |
| Estimated Gestational Age based on ultrasound (enter weeks component): | Numeric response. Integer. |

| | |
|---|---|
| Estimated Gestational Age based on ultrasound (enter days component): | Numeric response. Integer. |
| Estimated due date based on ultrasound: | Date entry DD-MM-YYYY |
| **Section: Second/Third Trimester** | |
| Placental location: | Multiple choice, single response |
| Amniotic fluid index: | Numeric response |
| Deepest vertical pocket: | Numeric response |
| Cardiac activity detected: | Multiple choice, single response |
| Biparietal Diameter, BPD (mm): | Numeric response |
| Abdominal circumference, AC (mm): | Numeric response |
| Femur length, FL (mm): | Numeric response |
| Estimated Gestational Age based on BPD, AC, FL (weeks) | Numeric response. Integer. |
| Estimated Gestational Age based on BPD, AC, FL (days): | Numeric response. Integer. |
| Estimated due date based on ultrasound: | Date entry DD-MM-YYYY |
| CRF Notes: | free text response |

## Vitals

**Purpose**: The purpose of the Vitals CRF is to record basic vitals and metrics for the maternal participant.

**General Instructions**: The Vitals CRF is a repeatable CRF and expected to have an instance completed at every scheduled study visit for the maternal participant. The Vitals CRF is only expected to be completed at the Enrollment and Antenatal Visits; the CRF should only be completed at other visits if there is an indication to perform a vital.

| **Question** | **Notes \| Comments \| Question intent** |
|---|---|
| Enter today's date: | This field will automatically populate with the date the CRF was initially started. |

| | |
|---|---|
| Which visit is this? | Multiple choice, single response |
| Systolic blood pressure: | Numeric response. Integer.<br>Valid response: 0-300<br><br>Required at Enrollment and Antenatal Quarterly Visits (V101-104); if indicated at all other visits. If not done at visits where BP is not indicated, select 'not done'<br><br>If multiple recordings were taken at a visit, record the highest value. |
| Diastolic blood pressure: | Numeric response. Integer.<br>Valid response: 0-300<br><br>Required at Enrollment and Antenatal Quarterly Visits (V101-104); if indicated at all other visits. If not done at visits where BP is not indicated, select 'not done'<br><br>If multiple recordings were taken at a visit, record the highest value. |
| Height (cm): | Numeric response.<br>Valid response: 0-250<br><br>Only measured at enrollment visit (V101). |
| Weight (kg): | Numeric response.<br>Valid response: 0-250<br><br>Only measured at Enrollment and Antenatal Quarterly Visits (V101-104). |
| Fetal heart tone detected: | Yes/No question<br><br>Only measured at Enrollment and Antenatal Quarterly Visits (V101-104). If fetal heart tone is abnormal, indicate in CRF Notes below. |
| CRF Notes | Free text response.<br><br>Indicate reason for any required vital was not taken or clinical indication for blood pressure obtained when not required. |