

CRF – Eligibility Screener		
No.	Question	Response
001	Did the participant provide written consent for this study prior to conduct of any study procedures?	0 = No End form 1 = Yes
002	Enter date consent was given:	_ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
003	Did the participant consent to off-site visits?	0 = No 1 = Yes
004	Did the participant consent to photos/video for infant?	0 = No 1 = Yes
005	Has participant enrolled in MATRIX-007 for a previous pregnancy?	0 = No 1 = Yes
006	Enter the PID that was used for the mother previously:	Respond only if [005 = 1]
Pregnancy, HIV, and Syphilis Status		
007	Does the participant report they are currently pregnant?	0 = No End form 1 = Yes 2 = Not sure
008	Has participant received an ultrasound in the last 5 days that confirmed the pregnancy?	0 = No Skip to 011 1 = Yes
009	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?	0 = No Skip to 011 1 = Yes (viable pregnancy)

010	Date of Ultrasound	Respond only if [009 = 1] Date should not exceed 5 days before today's date. _ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
011	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?	0 = No Skip to 014 1 = Yes
012	Date of previous test:	Date should not exceed 5 days before today's date. _ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
013	Result of previous hCG test:	0 = Negative End form 1 = Positive Skip to 015
014	Will hCG testing (urine pregnancy test) to confirm the pregnancy status be needed at this MATRIX-007 visit?	0 = No 1 = Yes
015	Has the participant had HIV testing within the last 5 days as part of antenatal care or other health services with available results?	0 = No Skip to 019 1 = Yes
016	Enter date that HIV testing was performed:	Date should not exceed 5 days before today's date. _ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y

017	Enter the HIV testing outcome done within the last 5 days of today's visit:	0 = HIV negative Skip to 020 1 = HIV positive (seroconversion confirmed) Skip to 018 then end form 2 = Inconclusive End form
018	Does the participant have ART documentation for seroconversion?	0 = No 1 = Yes (seroconversion confirmed) END screening after responding, participant is ineligible.
019	Will rapid HIV testing be <u>needed</u> at this MATRIX-007 visit? <i>Note: If no, but syphilis testing is needed, HIV testing will be included in the combo rapid test.</i>	0 = No End form 1 = Yes
020	Has the participant received a syphilis test within the last 3 months and during this pregnancy from a healthcare provider with the results available?	0 = No/Not sure Skip to 025 1 = Yes
021	Enter date that syphilis testing was performed:	Date should not exceed 3 months before today's date _ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
022	Type of previous syphilis testing:	0 = RPR or VDRL 1 = Treponemal antibody 2 = Rapid (with or without HIV testing) Specific rapid test type/brand if known in CRF Notes
023	Was there a positive test result?	0 = No Skip to 025 1 = Yes Submit a SSC query and add to Medical Conditions/Events CRF once enrolled.
024	Has the participant received appropriate treatment?	Respond only if [023 = 1] 0 = No 1 = Yes 2 = Don't know/Uncertain

025	Will rapid syphilis/HIV (combo) testing be needed at this MATRIX-007 visit?	0 = No 1 = Yes
HCG, HIV, syphilis Test Results Perform any needed pregnancy, HIV and/ syphilis testing and document results below		
026	Result of urine hCG test performed today by MATRIX-007 study:	Respond only if [014 = 1] 0 = Negative End form 1 = Positive 2 = Not done
027	Result of rapid HIV test done today by MATRIX-007 study:	Respond only if [019 = 1] 0 = HIV negative 1 = HIV positive End form 2 = Not done
028	Results of syphilis testing done today by MATRIX-007 study:	Respond only if [025 = 1] 0 = Negative 1 = Positive 2 = Not done Submit a SSC query and add to Medical Conditions/Events CRF once enrolled.
Pregnancy Dating		
029	What is the participant's best estimate of the first day of the last normal menstrual period (LMP)?	— — / — — / — — — — D D / M M / Y Y Y Y
030	Is this LMP certain or uncertain?	0 = Uncertain 1 = Certain
031	Follow this link to identify important dates in the pregnancy Convert Pregnancy Calculator dates from MM-DD-YYYY format to DD-MM-YYYY format <i>Enter best available input: LMP, EDD, or DoC</i>	https://perinatology.com/calculators/Due-Date.htm

032	Using the calculator at the perinatology.com website or other study-approved source, what is the estimated date of conception? Convert Pregnancy Calculator dates from MM-DD-YYYY format to DD-MM-YYYY format	<pre> -- / -- / ----- D D / M M / Y Y Y Y </pre>
033	Using the calculator at the perinatology.com website or other study-approved source, what is the estimated due date (EDD)? Convert Pregnancy Calculator dates from MM-DD-YYYY format to DD-MM-YYYY format	<pre> -- / -- / ----- D D / M M / Y Y Y Y </pre>
034	Using the calculator at the perinatology.com website or other study-approved source, what is the gestational age today? Enter the WEEKS output of the GA	
035	Using the calculator at the perinatology.com website or other study-approved source, what is the gestational age today? Enter the DAYS output of the GA	
036	(REDCap field) Calculated gestational age (total days):	If [≥34 weeks] then END
Exposure Assessment		
037	Has the participant ever been a cohort participant in CATALYST?	0 = No End form 1 = Yes
038	Date of 180 days before estimated date of conception:	<pre> -- / -- / ----- D D / M M / Y Y Y Y </pre>

039	Read aloud to participant: Have you received a CAB PrEP injection since this date (insert date above)?	0 = No 1 = Yes
040	Read aloud to participant: In the last 28 days, have you used and had the PrEP ring inserted for at least 21 of those days?	0 = No 1 = Yes
041	Read aloud to participant: In the last 28 days, have you taken oral PrEP/tenofovir-based PrEP for at least 21 of those days?	0 = No End form 1 = Yes
Behavioral Assessment		
042	Read aloud to participant: Are you currently receiving or do you plan to receive antenatal care?	0 = No End form 1 = Yes
043	Read aloud to participant: 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)?	0 = No 1 = Yes End form
044	Read aloud to participant: Do you intend to travel away from any of the study-linked CARE PrEP sites for three or more months?	0 = No 1 = Yes End form
045	Does the participant have adequate locator information? Record participant locator information per site SOP	0 = No End form 1 = Yes

Screening Outcome		
046	<p>Is there any other reason or condition to deem the participant ineligible for the study?</p> <p>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.</p>	<p>0 = No Skip to 047 then end form. 1 = Yes</p>
047	<p>Please describe the reason/conditions why the participant is ineligible.</p>	<p>Respond only if [046 = 1] then END</p>
048	<p>Participant Eligibility:</p>	<p>0 = "Eligible" 1 = "Not Eligible"</p> <p>If participant is exposed ONLY to PrEP ring or oral PrEP and the gestational age is less than 4 weeks, wait until participant is at least 4 weeks gestation to resume screening.</p>
049	<p>Enrollment Status:</p>	<p>0 = Enrolled 1 = Pending exposure status/form completion 2 = Failed - eligible but not interested 3 = Failed - not eligible 4 = Failed - declined to complete eligibility assessment</p>
050	<p>Enter date of enrollment:</p>	<p>Respond only if [049 = 0]</p> <p>__ / __ / ____ D D / M M / Y Y Y Y</p>

051	Enter date of screen-fail:	<p>Respond only if [049 = 2, 3, 4]</p> <p>__ __ / __ __ / __ __ __ __ D D / M M / Y Y Y Y</p>
052	Reason for screen fail: Note: Look up code definition in participant tracker	<p>Respond only if [049 = 2, 3, 4]</p> <p>0 = I-1 Not 18 yr + or emancipated minor 1 = I-2a No informed consent for self and/or baby 2 = I-2b Inadequate locator info 3 = I-2c Not willing to comply with study 4 = I-2d Inadequate antenatal care intention 5 = I-9e No permission to contact care providers/obtain records 6 = I-9f No permission to access CATALYST data 7 = I-2e Inadequate locator info 8 = I-3 Estimated 34wks GA or over 9 = I-4 HIV infected 10 = I-5 No CATALYST participation 11 = I-6 Not currently pregnant 12 = I-7 Inadequate PrEP exposure 13 = E-1a Intends to relocate 14 = E-1b Intends to travel away 15 = E-2 Positive HIV rapid 16 = E-3 Less than 28 days pregnant, with only oral PrEP and/or ring exposure 17 = E-4 Any other condition (IoR/designee)</p>
053	Explain other reason for screen fail:	<p>Respond only if 050 = 17</p>

054 END	Participant must meet all eligibility requirements in order to enroll.	
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