Clinical Research Site (CRS) Capacity Questionnaire: Site Selection

MATRIX-[*XXX*]

[*Insert Study Title*]

Instructions: If you wish to apply for your site to participate in MATRIX-[*XXX*], complete this questionnaire, print the completed questionnaire, hand sign and date it, **scan the completed, signed, dated questionnaire and email it to [*XXX*]** by the date noted in the solicitation email.

1. Name and physical address of your Clinical Research Site (CRS):

    a. Please provide specifics about your CRS's hours of operation during MATRIX-[XXX] (i.e., [*expected dates of study duration*]). Please specify evening/weekend hours, days of the week, etc.

2. Name(s), email(s), phone number(s) and current biosketch(es) (within 2 years; please attach to questionnaire) of CRS Lead Investigator(s):

3. Names, emails, phone numbers and current biosketches (within 2 years; please attach to questionnaire) of CRS clinician(s) and coordinator(s) who will have a leadership role in MATRIX-[XXX], if different from above:

4. Why do you want to participate in MATRIX-[XXX]? (Maximum 100 words)

5. Do you have access to the study population described in MATRIX-[XXX] (i.e., [*description of target study population*])?

6. Study participants must be [*compliant with or willing to comply with key study inclusion/exclusion criteria, e.g., use contraception, remain sexually abstinent, etc., and/or willing to be randomized to placebo product*]. What challenges, if any, do you foresee regarding recruiting participants who [*are already compliant with and/or would be willing to comply with criteria, e.g., initiate contraception, remain sexually abstinent, be randomized to placebo, etc.*]? Please describe how you would address these challenges.

7. Please characterize the contraceptive use profile of the MATRIX-[XXX] target population (i.e., [*description of target study population*]) in your area. This could include contraceptive prevalence, methods available and methods used.

Clinical Trial and Investigator-Driven Research Experience/Capacity

[*Include questions #8-15 as applicable depending on study population and type of study*]

8. Do you have previous experience conducting first-in-human (FIH) or Phase 1 acceptability/tolerability studies?

YES **NO** If "Yes", please list below:

Study Number and Full Name/Descriptor	**Product**	**No. of participants screened/enrolled**

For the studies listed above, please describe strategies used for recruiting and retaining participants and note which strategies were most successful.

9. Do you have previous experience conducting pharmacokinetic (PK) studies?

YES **NO** If "Yes", please list below:

Study Number and Full Name/Descriptor	**Product**	**No. of participants screened/enrolled**

For the studies listed above, please describe strategies used for recruiting and retaining participants (if different from those described previously) and note which strategies were most successful.

10. The schedule for PK sample collection requires participants to be seen on [*PK sample collection visit schedule for study*]. Would you be able to see participants on that schedule? Please provide specifics on how your CRS would accommodate participants on that visit schedule.

11. Does your clinic have the ability to collect cervicovaginal tissue biopsies? If yes, please describe; if no, please describe what you would need in terms of training, equipment, etc. for your clinic to have this ability.

    a. Do you have access to a laboratory that can conduct the following tissue sample analyses planned for MATRIX-[XXX]? Check all that apply:

       □ [*Tissue sample study endpoint #1*]
       □ [*Tissue sample study endpoint #2*]
       □ [*Tissue sample study endpoint #3…]*

12. Do you have previous experience conducting clinical studies evaluating only placebo products?

    YES **NO** If "Yes", please list below:

Study Number and Full Name/Descriptor	**Product**	**No. of participants screened/enrolled**

For the studies listed above, please describe strategies used for recruiting and retaining participants (if different from those described previously) and note which strategies were most successful.

13. Do you have previous experience conducting [*vaginal/rectal/multicompartment*] microbicide studies?

    YES **NO** If "Yes", please list below:

Study Number and Full Name/Descriptor	**Product**	**No. of participants screened/enrolled**

For the studies listed above, please describe strategies used for recruiting and retaining participants (if different from those described previously) and note which strategies were most successful.

14. Do you have previous experience conducting clinical trials of investigational contraceptive products/drugs?

YES **NO** If "Yes", please list below:

Study Number and Full Name/Descriptor	**Product**	**No. of participants screened/enrolled**

For the studies listed above, please describe strategies used for recruiting and retaining participants (if different from those described previously) and note which strategies were most successful.

15. Do you have previous experience conducting clinical studies with adolescent girls and young women (AGYW)?

YES **NO** If "Yes", please list below:

Study Number and Full Name/Descriptor	**Age Range of Study Participants**	**Product**	**No. of participants screened/enrolled**

For the studies listed above, please describe strategies used for recruiting and retaining participants (if different from those described previously) and note which strategies were most successful.

Social and Behavioral Research (SBR) Experience/Capacity

[*Include questions #16-18 as applicable depending on study objectives/endpoints and planned behavioral assessments*]

16. Do you have previous experience conducting early phase clinical studies that incorporate [*planned quantitative behavioral assessments, e.g., questionnaires re: drug/product acceptability, preferences, etc.*]? List most recent three.

YES **NO** If "Yes", please list below:

Study Number and Full Name/Descriptor	**Method(s) Utilized**	**No. of participants screened/enrolled**

17. Do you currently have the ability to administer [*planned quantitative behavioral assessments*] using any of the following tools? Check all that apply; if yes, please describe; if no, please describe what you would need in terms of training, equipment, etc. for you to have this ability:

□ Web/cloud-based applications (e.g., REDCap)

□ Audio / Computer-assisted survey instruments (A/CASI)

□ Text messaging (SMS) or other remote applications (e.g., WhatsApp)

18. Do you have previous experience conducting early phase clinical studies that incorporate [*planned qualitative behavioral assessments, e.g., in-depth interviews [IDI], focus group discussions [FGD], key informant interview [KII], discrete choice experiments [DCE], participant-centered counseling, etc.)*]? List most recent three.

YES **NO** If "Yes", please list below:

Study Number and Full Name/Descriptor	**Method(s) Utilized**	**No. of participants screened/enrolled**

Community Engagement Capacity

19. Describe your community advisory board (CAB) composition in terms of [*demographic and/or other characteristic(s) relevant to target study population*].

20. How do you plan to engage the local community(ies) and stakeholders in preparation for MATRIX-[XXX], during implementation and at results dissemination?

Participant Recruitment/Retainment Capacity

21. What other studies do you expect would run concurrently with MATRIX-[XXX] at your site during [*study implementation year(s)*]? Would any of those studies be drawing from a similar population as MATRIX-[XXX]?

Study Number and Name	**Intervention /Product**	**Anticipated total enrolled from your site**	**How is the population similar?**	**Expected dates your site:** • **Begins screening** • **Completes enrollment** • **Completes follow-up**

22. Please comment on recruitment strategies you would likely employ for MATRIX-[XXX] (e.g., radio, SMS, community-based events, clinic-based advertisements, etc.) and specify by name the places and/or venues from which you might target potential participants for recruitment.

23. Please describe plans to engage and retain MATRIX-[XXX] participants, including possible services offered within the clinic, how staff might engage with them, what activities the participants might do while at the clinic, etc.

24. Please describe possible barriers to MATRIX-[XXX] participants attending clinic visits, such as schedules and transport, and how you would address these.

25. Please state the monthly enrollment rate you anticipate at your site (a range is acceptable).

Regulatory Experience and Capacity

26. Please list the regulatory approvals (including product importation and specimen transfer) required for MATRIX-[XXX] at your site (i.e., regulatory bodies, Ethics Committees, Drug Authorities, etc.).

27. How long do you anticipate it might take to obtain regulatory approval(s) (including product importation and specimen transfer) for MATRIX-[XXX]? What challenges, if any, would you anticipate in obtaining regulatory approval(s)?

28. What additional challenges would you anticipate in implementing MATRIX-[XXX] at your site? Identify any mitigation strategies you envision.

29. Briefly describe any recent (i.e., in the previous year) updates to risk mitigation procedures and/or disaster management plans at your site.

30. Does your site have any additional experience or expertise that you believe will contribute to conducting MATRIX-[XXX] successfully? (Maximum 100 words)

    This question is designed to provide you a place to add information not specifically requested already and/or explain what process(es) you plan to put in place for any response(s) you marked "No" above.

Signature Section

Please print your name and sign and date on the lines provided below.

_____
Printed Name of Person Completing this Questionnaire

_____ _____
Signature Date of Signature