Clinical Research Site Capacity Questionnaire: Baseline Assessment

Instructions: Complete this questionnaire, print the completed questionnaire, hand sign and date it, **scan the completed, signed, dated questionnaire and email it to the MATRIX Prime and Clinical Trials Hub** by the date noted in the solicitation email.

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

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. Name of CRS clinician(s) and coordinator(s) who will have a leadership role in MATRIX studies, if different from above:

4. Do you have access to the following study population(s) of healthy, HIV-uninfected women? If yes, please describe:

    a. Adults between the ages of 18-45

    b. Adolescent girls and young women (AGYW) between the ages of 16-17

    c. Pregnant and/or breastfeeding women (PBFW)

    d. Female sex workers (FSW)

5. Please provide a brief description of your CRS, i.e., describe the number/layout of clinical rooms, counselling rooms, waiting area, pharmacy, etc.

6. Please provide an organogram of your study team with job titles listed.

Clinical and Laboratory Capacity

7. Are you currently able to perform the following activities/procedures on-site? Please check all that apply:

   - □ HIV testing (rapid and confirmatory)
   - □ Phlebotomy
   - □ STI testing using NAAT
   - □ Rapid pregnancy testing
   - □ Physical exam
   - □ Pelvic exam
   - □ Cervicovaginal fluid (CVF) and cervicovaginal lavage (CVL) collection
   - □ Cervical tissue biopsy collection
   - □ Systemic counseling
   - □ Essential documents storage
   - □ Direct data entry and management (if applicable, please list below any electronic data capture systems you are familiar with, e.g., RedCap, Medidata, InForm, etc.)

8. Are you currently able to process and store the following laboratory specimens at your site? Please check all that apply:

   - □ Whole blood, serum and plasma
   - □ Dried blood spots (DBS)
   - □ Urine
   - □ CVF
   - □ PAP smears
   - □ Cervical tissue biopsies
   - □ Other samples (please define based on your experience)

   a. Which tests are you currently able to do on-site (i.e., HIV, STI, pregnancy, microscopy) and which would be performed off-site at a commercial laboratory?

   b. If samples are sent off-site, which laboratory(ies) do you use?

9. Please describe the method for specimen tracking at your site, from collection, processing, and storage to shipping.

10. Describe your processes related to shipping biological specimens outside your country, including time to obtain IRB/IEC approvals and import/export permits, and any challenges related to these processes.

11. Are you currently able to store and/or ship specimens requiring cold chain conditions? If yes, please describe.

    a. Are requisite personnel trained and currently certified in IATA compliant shipping and Good Clinical Laboratory Practice?

12. Describe the investigational pharmacy facility at your site in terms of:

    a. Pharmacy personnel

    b. Infrastructure: space, pharmacy equipment (e.g., biosafety cabinets, clean rooms, electronic temperature monitoring systems and backup plans for temperature monitoring, after hours call out for temperature deviations)

    c. Study product/drug storage and accountability management

    d. Study product/drug destruction process

Clinical Trial and Investigator-Driven Research Experience

13. Do you have previous experience conducting early phase (i.e., first-in-human [FIH], Phase 1) acceptability/tolerability studies?

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

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

14. 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 enrolled

15. Do you have the capacity to collect multiple PK samples from the same participant over a period of 6 hours or longer (i.e., 12 or 24 hours)? If yes, please describe your CRS infrastructure and security measures in place to do so without risk to staff or participants, e.g., should overnight clinic stays be necessary.

    a. Please describe sample transport logistics at your site, including distance/time between clinic and processing laboratory(ies).

16. 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 enrolled

17. Do you have recent (i.e., in last 3 years) experience conducting Investigational New Drug (IND) and/or Investigational Device Exemption (IDE) studies for HIV prevention products/drugs?

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

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

18. 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 enrolled

Social and Behavioral Research (SBR) Capacity

MATRIX will assess biomedical HIV prevention product acceptability, end user experience and preferences, and key influencer perceptions during clinical trials and through non-clinical research activities.

19. Do you have previous experience conducting studies that incorporate qualitative data collection (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 enrolled

20. Do you have previous experience conducting studies that utilize text messaging (SMS), computer-assisted survey instruments (CASI) and/or audio computer-assisted survey instruments (ACASI) as a data collection tool? List most recent three.

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

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

Regulatory Experience and Capacity

21. What is the age of research consent in your country?

    a. Does the age of research consent differ for married and unmarried young people?

    b. Does the age of research consent differ for minors with and without children?

    c. Please describe IRB/IEC process(es) for soliciting parental consent and/or minor participant assent.

22. Please describe how long it typically takes to acquire all IRB/IEC and drug regulatory authority approvals and product importation permits required to conduct biomedical clinical trials at your site.

    a. If available, please share your IRB/IEC and drug regulatory authority meeting dates for 2022/2023.

Community Engagement Capacity

23. Does your CRS or institution have one or more community advisory boards (CAB)? If yes, please describe.

24. How do you plan to engage the local community(ies) and stakeholders in preparation for a study, during implementation and at results dissemination?

25. Please describe possible barriers to study participants attending clinic visits, such as schedules and transport, and how you would address these.

26. Briefly describe any risk mitigation procedures and/or disaster management plans you may have at your site. If available, please attach a copy of your risk mitigation plan.

27. Does your site have any additional experience or expertise that you believe will contribute to conducting biomedical clinical trials 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