**To confirm eligibility for the study, ask the participant the following questions and mark his/her responses accordingly. Questions may be read verbatim or reworded if necessary to adequately evaluate all criteria.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | If you were to join this research study, would you be willing to use of an effective method of contraception by your Enrollment visit and continue use of this same method for the duration of the study, which is expected to be about 3 to 5 months? *Note: Effective methods included hormonal methods excluding vaginal ring, IUD inserted at least 42 days prior to Enrollment, sterilization of participant or partner at least 42 days prior to Enrollment, or self-identify as having sex with women exclusively.* | Yes 🞎 | No 🞎 |
|  | Have you had at least one episode of consensual receptive anal intercourse in your lifetime? | Yes 🞎 | No 🞎 |
|  | Do you agree not to take part in any other research studies involving drugs, medical devices, genital or rectal products, or vaccines after this Screening visit and for the duration of your study participation? | Yes 🞎 | No 🞎 |
|  | Are you available for all visits and willing and able to comply with all study procedural requirements? | Yes 🞎 | No 🞎 |
|  | Are you willing to abstain from non-study products, medications, and sexual practices as required by the study, for the duration of your study participation? | Yes 🞎 | No 🞎 |
|  | Are you willing to abstain from using anticoagulant and rectally-administered medications during study participation? | Yes 🞎 | No 🞎 |
|  | Are you willing to abstain from using PrEP for HIV prevention for one month prior to your enrollment visit and for the during your study participation? | Yes 🞎 | No 🞎 |
|  | In the past month, have you used pre-exposure prophylaxis (PrEP) (Truvada®) for HIV prevention? | Yes\*\* 🞎 | No 🞎 |
|  | In the past 3 months, have you used post-exposure prophylaxis (PEP) for HIV exposure? | Yes\*\* 🞎 | No 🞎 |
|  | Are you pregnant and/or breastfeeding now or plan to become pregnant or begin breastfeeding during your study participation? | Yes 🞎 | No 🞎 |
|  | Have you been pregnant within the last 90 days (3 months)? | Yes\*\* 🞎 | No 🞎 |
|  | Have you ever had an adverse or bad reaction to any of the study product components? | Yes 🞎 | No 🞎 |
|  | Have you ever had an adverse or bad reaction to latex or polyurethane? | Yes 🞎 | No 🞎 |
|  | Have you had condomless receptive anal intercourse and/or penile-vaginal intercourse with a partner known to be HIV-positive or whose status is unknown in the last 6 months? | Yes\*\* 🞎 | No 🞎 |
|  | In the past 12 months, have you used a needle to inject drugs that were not prescribed to you by a medical professional? | Yes\*\* 🞎 | No 🞎 |
|  | In the past 30 days (4 weeks) have you participated in any other research study involving drugs, medical devices, genital or rectal products or vaccines? | Yes\*\*🞎 | No 🞎 |
|  | Have you been diagnosed or treated for any anogenital STIs in the past 3 months? | Yes\*\*🞎 | No 🞎 |
|  | Have you had a gynecologic, genital, or rectal procedure (e.g., tubal ligation, dilation and curettage, piercing, hemorrhoidal resection, polyp removal) in the last 60 days, or rectal biopsy within the last 7 days? | Yes\*\*🞎 | No 🞎 |

**For the participant to be eligible, the responses to items 1-7 above must be “Yes.”**

**For the participant to be eligible, the responses to items 8-18 above must be “No.”**

**\*\*If the response to item 8-9, 11, and 14-18 are “Yes,” assess likelihood of eligibility by Enrollment Visit and proceed accordingly.**