

MTN-027 Screening Behavioral Eligibility Worksheet (Page 1 of 2)

PTID: _____ - _____ - _____

VISIT CODE: 1. 0

VISIT DATE: _____

To confirm eligibility for the study, ask the participant the following questions and mark her responses accordingly.

1	If you were to join this research study, would you be willing to abstain from receptive sexual activity for the 5 days prior to Enrollment and for the duration of study participation? This includes: penile-vaginal intercourse, anal intercourse, receptive oral intercourse, finger stimulation, and the use of sex toys.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2	If you were to join this research study, would you be willing to use an effective method of contraception at Enrollment and continue the use of an effective method for the duration of study participation? Effective methods include: hormonal methods other than vaginal rings, IUD inserted at least 28 days (4 weeks) before Enrollment, sterilization of you or partner, you self-identify as a woman who has sex with women exclusively, or you have been sexually abstinent (no sex) for at least 90 days before enrollment.	Yes <input type="checkbox"/>	No <input type="checkbox"/> *
3	Are you willing to not insert any non-study vaginal products or objects into the vagina for the 5 days prior to Enrollment and for the duration of study participation? This includes, but is not limited to: spermicides, female condoms, diaphragms, contraceptive vaginal rings, vaginal medications, menstrual cups, cervical caps (or any other vaginal barrier method), douches, lubricants, and sex toys (vibrators, dildos, etc.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4	Do you agree that you will not take part in other research studies involving drugs, medical devices, or vaginal products for the duration of study participation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5	Do you have a regular menstrual cycle with at least 21 days between menses?	Yes <input type="checkbox"/>	No <input type="checkbox"/> †

In order for the participant to be eligible, the responses to items 1, 3 and 4 above must be 'YES' at Screening.

*If the response to item 2 is "NO", assess likelihood of eligibility by enrollment visit and proceed accordingly.

†This criterion is not applicable for participants that report use of a progestin-only method of contraception, e.g. Depo-Provera or levonorgestrel-releasing IUD, nor to participants using continuous oral contraceptive pills.

Staff Initials/Date: _____

Version 1.0 dated 23 February 2015

MTN-027 Screening Behavioral Eligibility Worksheet (Page 2 of 2)

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To confirm eligibility for the study, ask the participant the following questions and mark her responses accordingly.

6	Have you ever had a known adverse or bad reaction to Vicriviroc or MK-2048 (the study drugs)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
7	Have you ever had a hypersensitivity or allergy to either the NuvaRing or Implanon/Nexplanon? These products contain ethylene vinyl acetate (EVA) copolymer 28, which is also contained in the study vaginal rings.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
8	In the past 12 months, have you used a needle to inject drugs that were not prescribed to you by a medical professional?	Yes <input type="checkbox"/> *	No <input type="checkbox"/>	
9	In the past 6 months, have you used Post-exposure prophylaxis (PEP) for HIV exposure or Pre-exposure prophylaxis (PrEP) for HIV prevention?	Yes <input type="checkbox"/> *	No <input type="checkbox"/>	
10	Do you regularly use or do you anticipate using CYP3A inducer(s) and/or inhibitor(s) during study participation? <i>[Note to interviewer: ensure list of CYP3A inducers/inhibitors is reviewed with participant]</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
11	Are you using or do you plan to use female-to-male transition therapy during the period of study participation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
12	In the past year (12 months), have you had four or more yeast infections?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
13	In the past 6 months, have you been diagnosed with gonorrhea, chlamydia or syphilis?	Yes <input type="checkbox"/> *	No <input type="checkbox"/>	
14	In the past 3 months (90 days), have you been pregnant, given birth (including stillbirth) or had a pregnancy terminated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
15	Are you breastfeeding now?	Yes <input type="checkbox"/> *	No <input type="checkbox"/>	
16	Have you had a hysterectomy?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
17	Do you intend to become pregnant in the next 3 months?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
18	Do you plan to move away from the study site area in the next 3 months?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
19	In the past 60 days (8 weeks) have you participated in any other research study involving drugs, medical devices, or vaginal products?	Yes <input type="checkbox"/> *	No <input type="checkbox"/>	
20	If you currently have a sexual partner, is your partner known to be HIV-positive?	NA <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

In order for the participant to be eligible, the responses to items 6-7, 10-12, 14, 16-18, and 20 above must be 'NO' or "NA".

*If the responses to any of items 8-9, 13, 15 and 19 are "YES", assess likelihood of eligibility by enrollment visit and proceed accordingly.

Staff Initials/Date: _____

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