Updated Medical and Menstrual History [V2, V3, V4, V5, V6, V7, V8, V9 and PRN at Interim]

01	Date of assessment:	__ __ / __ __ / __ __ __ __ (dd/mm/yyyy)
02	Have there been any changes to your medical history since your last visit/contact? (Including changes with medical problems previously reported). *Update Pre-existing Conditions Log as needed.*	☐ Yes ☐ No
03	Have there been any changes to your concomitant medications (including dose) since your last visit/contact? (Including any changes with oral, vaginal, herbal, over the counter or prescription medications) *Update Con Med Log as needed.*	☐ Yes ☐ No
04	Notes related to updated medical history:	

The following three protocol adherence questions are only applicable after Visit 2 Enrollment.

05	Have you used PrEP or PEP since study enrollment? *If yes, discontinue per protocol.*	☐ Yes ☐ No ☐ N/A
06	Have you used any non-therapeutic injection drugs since study enrollment? *If yes, discontinue per protocol.*	☐ Yes ☐ No ☐ N/A
07	Are you participating in any other studies (includes studies involving drugs, medical devices, vaginal products or vaccines). *If yes, complete a protocol deviation, update Con Med Log as applicable, and consult with PSRT.*	☐ Yes ☐ No ☐ N/A

The following two social impact questions are only to be asked at specific visits.

08	Ask at V2, V4, V5, V6, V8, V9: Have you experienced a negative change, event, or experience in your life related to your study participation? *If yes, complete an entry on the Social Harms and Benefits Assessment Log.*	☐ Yes ☐ No ☐ Not Done (V3 and V7)
09	Ask at V5 and V9: Have you experienced a positive change, event, or experience in your life related to your study participation? *If yes, complete an entry on the Social Harms and Benefits Assessment Log.*	☐ Yes ☐ No ☐ Not Done (V2,3,4,6,7,8)

10	Have you had a menstrual period since your last visit/contact?	☐ Yes *(answer 10a)* ☐ No ☐ N/A

10a. Complete only if had a period since their last visit/contact:

First day of last menstrual period: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy)

REQUIRED CRF | Updated Medical and Menstrual History (continued)

11	Have you changed your birth control/contraception method since your last visit?	☐ Yes *(answer 11a)* ☐ No

11a. Complete only if you have changed your birth control/contraception method since your last visit:

What acceptable contraception method(s) are you using to prevent pregnancy? *Choose all that apply. document hormonal methods on Con Med Log.*	☐ Oral contraceptives → *Document hormonal methods on Con Med Log.* ☐ Injectable contraceptives (Depo) → *Document hormonal methods on Con Med Log.* ☐ Implant → *Document hormonal methods on Con Med Log.* ☐ IUD (non-copper) → *Document hormonal methods on Con Med Log.* ☐ Copper IUD → Date of copper IUD insertion: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy) ☐ Sterilization of participant → Date of sterilization: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy) ☐ Condoms (for US sites only) → Date you began using condoms: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy) ☐ Other, specify: ______________________________ ↓ Date you began using other contraception: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy)

12	Have you experienced any vaginal symptoms or concerns (including vaginal bleeding) since your last visit?	☐ Yes *(answer 12a)* ☐ No

12a. Complete only if you have experienced any vaginal symptoms or concerns (including vaginal bleeding) since your last visit:

Mark all vaginal symptoms that apply: *Update Pre-existing Conditions Log or Adverse Event Log as applicable.*	☐ Itching or irritation ☐ Abnormal discharge (different than normal fluctuations in discharge) ☐ Abnormal odor (outside of normal) ☐ Discomfort or pain ☐ Unexpected vaginal bleeding (or breakthrough bleeding) ☐ Other *(answer 12b)*

12b. Complete only if you have experienced other vaginal symptoms or concerns (including vaginal bleeding) since your last visit:

Other vaginal symptom(s), specify: ______________________________

13	Have you experienced any urinary symptoms or concerns since your last visit?	☐ Yes *(answer 13a)* ☐ No

13a. Complete only if you have experienced any urinary symptoms or concerns since your last visit:

Mark all urinary symptoms that apply: *Update Pre-existing Conditions Log or Adverse Event Log as applicable.*	☐ Burning with urination ☐ Increased frequency of urination ☐ Urgency (feeling the urge or need to urinate but not being able to go) ☐ Other *(answer 13b)*

13b. Complete only if you have experienced other urinary symptoms or concerns since your last visit:

Other urinary symptom(s), specify: ______________________________

CRF Completed By: ________ (initials)

CRF Completion Date: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy)