

**Updated Medical and Menstrual History**

<b>01</b>	Date of assessment:	___ / ___ / _____ (dd/mm/yyyy)
<b>02</b>	Have there been any changes to your medical history since your last visit/contact? ⓘ <i>Update Pre-existing Conditions Log as needed.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>03</b>	Have there been any changes to your concomitant medications since your last visit/contact? (Including any changes with oral, vaginal, herbal, other-the-counter or prescription medications) ⓘ <i>Update Concomitant Medications Log as needed.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>04</b>	Notes related to updated medical history:	

ⓘ **The following three protocol adherence questions are only visible in REDCap after Visit 2 Enrollment. Skip this section during V2 Enrollment/Randomization visit.**

<b>05</b>	Have you used PrEP or PEP since study enrollment? ⓘ <i>If yes, discontinue per protocol.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>06</b>	Have you used any non-therapeutic injection drugs since study enrollment? ⓘ <i>If yes, discontinue per protocol.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>07</b>	Are you participating in any other studies (includes studies involving drugs, medical devices, vaginal products or vaccines). ⓘ <i>If yes, complete a protocol deviation, update ConMeds as applicable, and consult with PSRT.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

ⓘ **The following two Social Impact questions are only visible in REDCap at Visit 9. If this is not Visit 9, Skip this section and go to question 10 below.**

<b>08</b>	Have you experienced a negative change, event, or experience in your life related to your study participation? ⓘ <i>If yes, complete an entry on the Social Harms and Benefits Assessment Log.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>09</b>	Have you experienced a positive change, event, or experience in your life related to your study participation? ⓘ <i>If yes, complete an entry on the Social Harms and Benefits Assessment Log.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

<b>10</b>	Have you had a period since your last visit/contact?	<input type="checkbox"/> Yes (answer 10a) <input type="checkbox"/> No <input type="checkbox"/> N/A (Amenorrhea)
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ⓘ *10a. Complete only if had a period since their last visit/contact:*

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

**Updated Medical and Menstrual History (continued)**

<b>11</b>	Have you changed your birth control/contraception method since your last visit?	<input type="checkbox"/> Yes (answer 11a) <input type="checkbox"/> No
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**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?  <b>!</b> Choose all that apply; document hormonal methods on Con Med Log.	<input type="checkbox"/> Oral contraceptives → Document hormonal methods on Con Med Log. <input type="checkbox"/> Injectable contraceptives (Depo) → Document hormonal methods on Con Med Log. <input type="checkbox"/> Implant → Document hormonal methods on Con Med Log. <input type="checkbox"/> IUD (non-copper) → Document hormonal methods on Con Med Log. <input type="checkbox"/> Copper IUD → Date of copper IUD insertion: ___ / ___ / _____ (dd/mm/yyyy) <input type="checkbox"/> Sterilization of participant → Date of sterilization: ___ / ___ / _____ (dd/mm/yyyy) <input type="checkbox"/> Condoms (for US sites only) → Date you began using condoms: ___ / ___ / _____ (dd/mm/yyyy) <input type="checkbox"/> Abstinence from penile-vaginal intercourse → Date began using abstinence: ___ / ___ / _____ (dd/mm/yyyy)  <input type="checkbox"/> Other, specify: _____ ↓ Date you began using other contraception: ___ / ___ / _____ (dd/mm/yyyy)
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<b>12</b>	Have you experienced any vaginal symptoms or concerns (including vaginal bleeding) since your last visit?	<input type="checkbox"/> Yes (answer 12a) <input type="checkbox"/> No
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**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:  <b>!</b> Update Pre-existing Conditions Log or Adverse Event Log as applicable.	<input type="checkbox"/> Itching or irritation <input type="checkbox"/> Abnormal discharge (different than fluctuations in discharge with participant's menstrual cycle or contraception) <input type="checkbox"/> Abnormal odor (outside of normal) <input type="checkbox"/> Discomfort or Pain <input type="checkbox"/> Unexpected vaginal bleeding <input type="checkbox"/> Other (answer 12b)
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**12b. Complete only if you have experienced other vaginal symptoms or concerns (including vaginal bleeding) since your last visit:**

Other vaginal symptom(s), specify: \_\_\_\_\_

<b>13</b>	Have you experienced any urinary symptoms or concerns since your last visit?	<input type="checkbox"/> Yes (answer 13a) <input type="checkbox"/> No
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**13a. Complete only if you have experienced any urinary symptoms or concerns since your last visit:**

Mark all urinary symptoms that apply:  <b>!</b> Update Pre-existing Conditions Log or Adverse Event Log as applicable.	<input type="checkbox"/> Burning with urination <input type="checkbox"/> Frequency (urinating more than normal and not explained for instance by increased water intake) <input type="checkbox"/> Urgency (feeling the urge or need to urinate but not being able to go) <input type="checkbox"/> Other (answer 13b)
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**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)