Brief acceptability 1 (FU2) CRF [Visit 3, 7]

Note: To be used when contacting the participant via SMS or phone (or in-person, if preferred) approximately 7 days after the insertion of each IVR.

These questions are intended to ask participants about their experience with the ring after insertion and to offer support/guidance to address any challenges or concerns they have identified.

1. Have you noticed, been aware of, or felt the ring since you left the clinic? *Noticed can include if the participant felt, saw, or was aware of the ring.*	☐ 1 Yes, describe: _____ ☐ 2 No
2. Have you noticed any changes to your vagina since using the ring?	☐ 1 Yes, describe: _____ ☐ 2 No
3. Has the ring bothered you or caused any type of discomfort? *If one is needed (such as significant discomfort), complete an AE form.*	☐ 1 Not at all → ***skip to Q5*** ☐ 2 A little ☐ 3 A lot
4. In what ways has the ring bothered you or caused discomfort?	*Specify:* _____ _____ ___ _____
5. Have you inserted any of the following into your vagina since your last visit? *Read list and select each that apply*	☐ 1 Condom (male or female) ☐ 2 Tampons ☐ 3 Lubricants ☐ 4 Douches ☐ 5 Sex toys ☐ 6 Water (alone or with soap) ☐ 7 Vaginal medications ☐ 8 Vaginal moisturizers ☐ 9 Vaginal products, to make the vagina dry or tight ☐ 10 Materials such as paper, cloth, sponges or cotton wool ☐ 11 Other, *specify:* _____ ☐ 12 *None of the above*
6. Has the vaginal ring been removed or come out since it was inserted during your study visit? *Check all that apply*	☐ 1 Yes, the ring was removed intentionally ☐ 2 Yes, the ring came out unintentionally or accidentally ☐ 3 No, the ring has not come out, either accidentally or intentionally → ***skip to Q12***

7. *[If Q6 = 1]* How many times has the ring been removed intentionally since you inserted it?	___ times intentionally
8. *[If Q6 = 1]* Why was the vaginal ring removed? *Check all that apply*	☐ 1 *It was uncomfortable* ☐ 2 *It felt like it was falling out* ☐ 3 *I wanted to show my partner/ my partner wanted to see it* ☐ 4 *My partner asked me not to wear it* ☐ 5 *I wanted to clean it* ☐ 6 *I was menstruating* ☐ 7 *I wanted to have sex without it* ☐ 8 *I was sick (e.g. diarrhea) and worried that it would be expelled* ☐ 9 *Other (specify):* _____
9. *[If Q6 = 2]* How many times has the vaginal ring come out unintentionally or accidentally since you inserted it?	___ times unintentionally
10. *[If Q6 = 2]* Do you know what caused the ring to come out? [*Probes: when did this happen? What were you doing when this happened?*]	Describe: _____ _____
11. *[If Q6 = 1 or 2]* Of the times that you mentioned before, what was the longest time that the ring was out?	☐ 1 Less than 1 hour ☐ 2 More than 1 hour but less than 3 hours ☐ 3 More than 3 hours but less than 24 hours ☐ 4 24 hours or more ☐ 5 Not sure
12. What do you like about the ring so far?	_____ _____
13. What do you dislike about the ring so far?	_____ _____
14. Do you have any concerns about the ring at this time?	☐ 1 Yes, *describe the concerns:* _____ _____ ☐ 2 No
15. Do you have any questions for me?	☐ 1 Yes, *describe the question the participant has, and any follow-up needed or counseling to be offered:* _____ _____ ☐ 2 No

END OF CRF

CRF Completed By: _____ (initials) CRF Completion Date: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy)