

Brief acceptability (FU2) CRF [Visit 3, 4, 5, 7, 8]

*Note: Information in italics is for the interviewer and will not be read aloud to the participant.*

*To be used when contacting the participant via SMS or phone (or in-person, if preferred) between 24-72 hours after Visit 2 and Visit 6, as well as when contacting the participant via SMS or phone at 1 and 2 weeks after Visit 2, and 2 weeks after Visit 6.*

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

<p>1. Have you noticed the film since your last visit/contact? <i>Noticed can include if the participant felt, saw, or was aware of the film.</i></p> <p><i>If the participant describes any film expulsion, notate this in questions 8-16 below.</i></p>	<p><input type="checkbox"/> <sub>1</sub> Yes, describe: _____</p> <p><input type="checkbox"/> <sub>2</sub> No</p>
<p>2. Has the film bothered you or caused any discomfort? <i>If one is needed (such as significant discomfort), complete an AE form.</i></p>	<p><input type="checkbox"/> <sub>1</sub> Not at all → <b>skip to Q4</b></p> <p><input type="checkbox"/> <sub>2</sub> Some</p> <p><input type="checkbox"/> <sub>3</sub> Quite a bit</p>
<p>3. In what ways has the film bothered you or caused discomfort?</p>	<p>Specify: _____</p>
<p>4. Have you noticed any changes to your vagina since using the film?</p>	<p><input type="checkbox"/> <sub>1</sub> Yes, describe: _____</p> <p><input type="checkbox"/> <sub>2</sub> No</p>
<p>5. Do you have any concerns about using the film right now?</p>	<p><input type="checkbox"/> <sub>1</sub> Yes, <i>Specify</i>: _____</p> <p><input type="checkbox"/> <sub>2</sub> No</p>
<p><i>Asked only at Visits 4, 5, and 8 (one or two weeks after V2/V6)</i></p> <p>6. Have you inserted anything other than the film into your vagina since your last visit? <i>Read list and select each that apply.</i></p>	<p><input type="checkbox"/> <sub>1</sub> Condom (male or female)</p> <p><input type="checkbox"/> <sub>2</sub> Tampons</p> <p><input type="checkbox"/> <sub>3</sub> Lubricants</p> <p><input type="checkbox"/> <sub>4</sub> Douches</p> <p><input type="checkbox"/> <sub>5</sub> Sex toys</p> <p><input type="checkbox"/> <sub>6</sub> Water (alone or with soap)</p> <p><input type="checkbox"/> <sub>7</sub> Vaginal medications</p> <p><input type="checkbox"/> <sub>8</sub> Vaginal moisturizers</p> <p><input type="checkbox"/> <sub>9</sub> Vaginal desiccants, to make the vagina dry or tight</p> <p><input type="checkbox"/> <sub>10</sub> Materials such as paper, cloth, or cotton wool</p> <p><input type="checkbox"/> <sub>11</sub> Other, <i>specify</i>: _____</p>
<p>7. <i>[At Visits 4 &amp; 5 only: I know you were counseled to abstain from sex during the first month of film use, but I know sometimes sex doesn't only happen when we plan it].</i> <i>All visits: Have you had vaginal sex since we last contacted you?</i></p>	<p><input type="checkbox"/> <sub>1</sub> Yes</p> <p><input type="checkbox"/> <sub>2</sub> No</p>

<p>8. Since your last contact, have you noticed the film coming out of your vagina, partially or fully?</p>	<p><input type="checkbox"/> 1 Yes, partially  <input type="checkbox"/> 2 Yes, fully  <input type="checkbox"/> 3 Not sure, <i>specify:</i> _____  <input type="checkbox"/> 4 No, not at all → <i>skip to Q17</i></p>
<p><b>We are interested in knowing as many details as possible about the circumstances surrounding the film coming out. I have some specific questions for you to answer, and then you can tell me anything else you'd like to share about the film coming out.</b></p> <p><b>Can you describe what happened when the film came out?</b></p>	
<p>9. <i>[If 8 = 1,2,3]</i> Where did you see the film?</p>	<p><input type="checkbox"/> 1 In the toilet  <input type="checkbox"/> 2 On toilet paper  <input type="checkbox"/> 3 In underwear  <input type="checkbox"/> 4 Other, describe: _____</p>
<p>10. <i>[If 8 = 1,2,3]</i> What were you doing when you saw the film?</p>	<p><input type="checkbox"/> 1 Urinating  <input type="checkbox"/> 2 Having a bowel movement  <input type="checkbox"/> 3 Having sex  <input type="checkbox"/> 4 Changing clothes  <input type="checkbox"/> 5 Showering  <input type="checkbox"/> 6 Other, describe: _____</p>
<p>11. <i>[If 8 = 1,2,3]</i> Did you feel the film come out?</p>	<p><input type="checkbox"/> 1 Yes  <input type="checkbox"/> 2 No (just saw the film)</p>
<p>12. <i>[If 8 = 1,2,3]</i> Describe what you saw when the film came out?  <i>Prompt participant about size, shape, color, texture, etc.</i></p>	<p>_____          _____          _____          _____</p>
<p>13. <i>[If 8 = 1,2,3]</i> What day did you <b>first</b> notice the film came out?</p>	<p>Date: _____          [DD] [MM] [YYYY]</p>
<p>14. <i>[If 8 = 1,2,3]</i> Approximately what time of day was it when you noticed that the film had come out?</p>	<p><input type="checkbox"/> 1 Morning (5am – 11:59am)  <input type="checkbox"/> 2 Afternoon (12pm – 4:59pm)  <input type="checkbox"/> 3 Evening (5pm – 9:59pm)  <input type="checkbox"/> 4 Night (10pm – 4:59am)</p>
<p>15. <i>[If 8 = 1,2,3]</i> In the six hours before you noticed the film coming out, had you been doing any of the following activities?</p>	<p><input type="checkbox"/> 1 Exercise or physical activity, describe: _____  <input type="checkbox"/> 2 Having sex  <input type="checkbox"/> 3 Other, describe: _____</p>
<p>16. <i>[If 8 = 1,2,3]</i> Is there anything else you'd like to share or that you think I should know about your film coming out?  <i>Please note any further details surrounding the film expulsion.</i></p>	<p>_____          _____          _____          _____</p>
<p>17. Is there anything you found positive or beneficial about the film so far?</p>	<p><input type="checkbox"/> 1 Yes, describe: _____  <input type="checkbox"/> 2 No</p>

18. Do you have any questions for me?	<input type="checkbox"/> <sub>1</sub> Yes, <i>describe the question the participant has, and any follow-up needed or counseling to be offered:</i> _____ _____ <input type="checkbox"/> <sub>2</sub> No
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END OF CRF

CRF Completed By: \_\_\_\_\_ (initials)

CRF Completion Date: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ (dd/mm/yyyy)