

Clinician Observations for Removal (COR) CRF [Visits 5, 9]

Note: To be clinician-completed at every in-clinic visit with product removal (product initiation and follow-up visit, per protocol). Clinician will be present (behind a curtain) to address questions and concerns. Privacy should be offered to participants.

1.	Was the vaginal ring removed?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No [END FORM]
2.	Was the vaginal ring removed in the presence of a clinician?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No → skip to Q4
3.	Were you:	<input type="checkbox"/> ₁ In the same room as participant but behind a curtain or separation <input type="checkbox"/> ₂ In the same room as participant not behind a curtain or separation <input type="checkbox"/> ₃ Other, specify: _____
4.	Did the participant require assistance with removal of the vaginal ring?	<input type="checkbox"/> ₁ Yes, specify type of assistance needed: _____ <input type="checkbox"/> ₂ No
5.	(If Q2 = Yes) Based on your perception or observation, how difficult or easy was it for the participant to remove the vaginal ring?	<input type="checkbox"/> ₁ Very difficult <input type="checkbox"/> ₂ Difficult <input type="checkbox"/> ₃ Neither difficult nor easy → skip to Q7 <input type="checkbox"/> ₄ Easy → skip to Q7 <input type="checkbox"/> ₅ Very easy → skip to Q7
6.	Explain why it was difficult for the participant to remove the vaginal ring? (mark all that apply)	<input type="checkbox"/> ₁ Reluctance to remove the ring herself <input type="checkbox"/> ₂ Physical discomfort or pain while removing the ring <input type="checkbox"/> ₃ Discomfort with touching the vagina <input type="checkbox"/> ₄ Concern that she could not “find” the ring <input type="checkbox"/> ₅ Discomfort with removing in the presence of clinician <input type="checkbox"/> ₆ Difficulty with grasping the ring <input type="checkbox"/> ₇ Other, specify: _____ _____

7.	(If Q2 = Yes) Based on your perception or observation, did the participant remove the vaginal ring as per the provided instructions?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No If no, explain: _____ _____ _____
8.	(If Q2 = Yes) Based on your perception or observation, how confident did the participant seem removing the vaginal ring today?	<input type="checkbox"/> ₁ Very confident <input type="checkbox"/> ₂ Confident <input type="checkbox"/> ₃ Not confident
9.	Were there any concerns with ring inspection following removal?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
10.	If Q9 = Yes) What was the concern(s)?	<input type="checkbox"/> ₁ Missing cassette <input type="checkbox"/> ₂ Ring discoloration <input type="checkbox"/> ₃ Ring deformity <input type="checkbox"/> ₄ Other, describe: _____ _____ _____
11.	Notes:	

END OF CRF

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