Clinician Observations for Insertion (COI) CRF [Visits 2, 6]

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

1.	Was the vaginal ring inserted?	☐₁ Yes ☐₂ No [*END FORM*]
2.	Was the vaginal ring inserted in the presence of a clinician?	☐₁ Yes ☐₂ No → *skip to Q4*
3.	Were you:	☐₁ In the same room as participant but behind a curtain or separation ☐₂ In the same room as participant not behind a curtain or separation ☐₃ Other, specify: _____
4.	Did the participant require assistance with insertion of the vaginal ring?	☐₁ Yes, specify type of assistance needed, including any adjustments made to placement of the ring: _____ ☐₂ No
5.	Did you check placement of the ring?	☐₁ Yes ☐₂ No
6.	*(If Q2 = Yes)* Based on your perception or observation, how difficult or easy was it for the participant to insert the vaginal ring?	☐₁ Very difficult ☐₂ Difficult ☐₃ Neither difficult nor easy → *skip to Q8* ☐₄ Easy → *skip to Q8* ☐₅ Very easy → *skip to Q8*
7.	Explain why it was difficult for the participant to insert the vaginal ring?	_____ _____
8.	*(If Q2 = Yes)* Based on your observation, did the participant insert the vaginal ring as per the provided instructions?	☐₁ Yes ☐₂ No If no, explain: _____ _____
9.	After the insertion, did the participant remove and reinsert the ring?	☐₁ Yes ☐₂ No → *skip to Q11*
10.	Please note any challenges or notable circumstances with the removal and reinsertion: _____ _____ _____	

11.	*(If Q2 = Yes)* Based on your observation, how confident did the participant seem inserting the vaginal ring today?	☐₁ Very confident ☐₂ Confident ☐₃ Not confident
12.	Notes:	

END OF CRF

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