

Clinician Observations (CO) 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). Clinician will be present (behind a curtain) to address questions and concerns. Privacy should be offered to participants.

1.	Was the vaginal film inserted?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No [END FORM]
2.	Was the vaginal film inserted in the presence of a clinician?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
3.	Did the participant require assistance with self-insertion of the vaginal film?	<input type="checkbox"/> ₁ Yes, <i>specify type of assistance needed:</i> _____ <input type="checkbox"/> ₂ No
4.	How many attempts did the participant need to successfully insert the vaginal film?	<input type="checkbox"/> ₁ 1 attempt <input type="checkbox"/> ₂ 2 attempts <input type="checkbox"/> ₃ Unsuccessful at self-insertion
5.	Based on your presence in the room, how difficult or easy was it for the participant to insert the vaginal film?	<input type="checkbox"/> ₁ Very difficult <input type="checkbox"/> ₂ Difficult <input type="checkbox"/> ₃ Neither difficult nor easy <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 insert the vaginal film?	<hr/> <i>(Open ended response)</i>
7.	Based on your observation, did the participant insert the vaginal film as per the provided instructions?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No If no, explain: <hr/>
8.	What percentage (or amount/centimeters?) of the film was visible outside the vagina at clinical assessment?	<input type="checkbox"/> ₁ Most of the film (>50%) <input type="checkbox"/> ₂ About half of the film (50%) <input type="checkbox"/> ₃ Very little of the film (<50%) <input type="checkbox"/> ₄ None of the film
9.	Was the participant instructed to “tuck in” any visible film following the initial external exam?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No → skip to Q12
10.	Did the participant successfully “tuck in” visible film after the second external exam?	<input type="checkbox"/> ₁ Yes → skip to Q12 <input type="checkbox"/> ₂ No
11.	Did you (the clinician) “tuck in” any remaining visible film?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
12.	Based on your observation, how confident did the participant seem inserting the vaginal film?	<input type="checkbox"/> ₁ Very confident <input type="checkbox"/> ₂ Confident <input type="checkbox"/> ₃ Not confident
	Notes:	

END OF CRF

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