Adverse Events Log

DATE SENSITIVE DATA ENTRY. Please enter the data from the paper CRF into REDCap ASAP. Adverse Event (AE) should be recorded in REDCap within 3 days of date site was informed of AE.

01	REDCap entry Date: *You will be prompted to click the "Today" button when entering this AE in REDCap.*	__ __ / __ __ / __ __ __ __ (dd/mm/yyyy)
02	Date site was informed of AE: *AE should be recorded in REDCap within 3 days of date site was informed of AE.*	__ __ / __ __ / __ __ __ __ (dd/mm/yyyy)
03	Adverse Event Description:	_____

04	AE onset date:	__ __ / __ __ / __ __ __ __ (dd/mm/yyyy)
05	Body system:	☐ Constitutional ☐ Cardiovascular ☐ Digestive ☐ Endocrine ☐ Hemic/Lymphatic ☐ Metabolic/Nutritional ☐ Musculoskeletal ☐ Nervous ☐ Respiratory ☐ Skin/Appendages ☐ Special Senses (5 senses + equilibrium) ☐ Urogenital ☐ Infection ☐ HEENT ☐ Other *(answer 05a)*

05a. Complete only if other body system:

Other body system: _____

06	Severity:	☐ Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Life threatening ☐ Grade 5 - Death
07	Was this AE a worsening of a pre-existing condition?	☐ Yes ☐ No
08	Study Product Administration:	☐ No change ☐ Held (2nd film not administered) ☐ Permanently discontinued ☐ Not applicable
09	Status:	☐ Continuing ☐ Continuing at end of study participation ☐ Death *(answer 10a)* ☐ Severity/frequency increased ☐ Resolved/Stabilized *(answer 09a)*

09a. Complete only if status marked "Death" or "Resolved/Stabilized":

Status/Outcome Date: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy)

Adverse Events Log (continued)

10	Treatment: Mark 'none' or all that apply:	☐ None ☐ Visible film removed ☐ Medications *(answer 10a)* ☐ New/Prolonged hospitalization *(answer 10b)* ☐ Procedure/Surgery *(answer 10c)* ☐ Other *(answer 10d)*

10a. Complete only if treatment marked "medications" at question 10:

Medications, specify: _____

10b. Complete only if treatment marked "new/prolonged hospitalization" at question 10:

New/Prolonged hospitalization, specify: _____

Brief details.

10c. Complete only if treatment marked "procedure/surgery" at question 10:

Procedure or surgery, specify: _____

10d. Complete only if treatment marked "other" at question 10:

Other treatment, specify: _____

11	This AE was first reported at:	☐ Visit 2 (enrollment) ☐ Visit 3 (phone call) ☐ Visit 4 (phone call) ☐ Visit 5 (phone call) ☐ Visit 6 (clinic visit) ☐ Visit 7 (phone call) ☐ Visit 8 (phone call) ☐ Visit 9 (clinic visit) ☐ Visit 10 (final phone call) ☐ Interim Visit ☐ Unscheduled phone contact ☐ Other *(answer 11a)*

11a. Complete only if AE first reported at was marked "other":

Other, specify: _____

12	Is this AE serious according to ICH guidelines?	☐ Yes *(answer 12a)* ☐ No

12a. Complete only if this AE is serious according to ICH guidelines:

SAE Category:	☐ Death ☐ Life-threatening (immediate risk of death) ☐ Hospitalization/Prolongation of existing hospitalization *(answer 12b)* ☐ Important Medical Event ☐ Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions ☐ Other *(answer 12c)*

Adverse Events Log (continued)

12b. Complete only if SAE category was marked "hospitalization/prolongation of existing hospitalization":

Hospitalization admission date:	__ __ / __ __ / __ __ __ __ (dd/mm/yyyy)
Hospitalization discharge date:	__ __ / __ __ / __ __ __ __ (dd/mm/yyyy)

12c. Complete only if SAE category was marked "other":

Other SAE category: _____

12a. Continued. Complete only if this AE is serious according to ICH guidelines:

Has the participant had any diagnostic testing or labs done related to this SAE?	☐ Yes *(answer 12d)* ☐ No

12d. Complete only if the participant had any diagnostic testing or labs done related to this SAE:

Indicate diagnostic tests and labs done, including results if known:

Update as needed. Additional space for notes if needed are available below).

12d. Complete only if the participant had any diagnostic testing or labs done related to this SAE:

(Additional space for notes if needed) Indicate diagnostic tests and labs done, including results if known: *Update as needed.*

Adverse Events Log (continued)

13	Date participant had first vaginal film study product inserted?	__ __ / __ __ / __ __ __ __ (dd/mm/yyyy)
14	Has participant had 2nd vaginal film study product inserted?	☐ Yes ☐ No *(answer 14a)*

14a. Complete only if participant had 2nd vaginal film study product inserted:

Date participant had second vaginal film study product inserted?	__ __ / __ __ / __ __ __ __ (dd/mm/yyyy)

Relatedness

15	Relatedness to Study Product/Procedure: *Relatedness to be determined by a study clinician.*	☐ Not related ☐ Related

16	Justification of relatedness (for both related and not related):	
17	Name of Clinician determining relatedness:	_____

Adverse Events Log (continued)

Please include a narrative documenting any additional treatment, hospitalization, or outcomes for this AE/SAE. Add additional notes as needed. End each note with your name or initials and the date.

18	Comment (1):
19	Comment (2):

Adverse Events Log (continued)

20	Comment (3):

21	Comment (4):

CRF Completed By: _____ (initials)

CRF Completion Date: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy)