

**Adverse Events Log [Ongoing Logs]**



**DATE SENSITIVE DATA ENTRY. Please enter the data from the paper CRF into REDCap ASAP.**

<b>01</b>	REDCap entry Date:	You do not need to enter a date on this paper CRF, but you will be prompted to click the "Today" button when entering this AE in REDCap
<b>02</b>	Date site was informed of AE:	___ / ___ / ____ (dd/mm/yyyy)
<b>03</b>	Adverse Event Description:	_____

<b>04</b>	AE onset date:	___ / ___ / ____ (dd/mm/yyyy)
<b>05</b>	Body system:	<input type="checkbox"/> Constitutional <input type="checkbox"/> Cardiovascular <input type="checkbox"/> Digestive <input type="checkbox"/> Endocrine <input type="checkbox"/> Hemic/Lymphatic <input type="checkbox"/> Metabolic/Nutritional <input type="checkbox"/> Musculoskeletal <input type="checkbox"/> Nervous <input type="checkbox"/> Respiratory <input type="checkbox"/> Skin/Appendages <input type="checkbox"/> Special Senses (5 senses + equilibrium) <input type="checkbox"/> Urogenital <input type="checkbox"/> Infection <input type="checkbox"/> HEENT <input type="checkbox"/> Other (answer 05a)

05a. Complete only if other body system:

Other body system: \_\_\_\_\_

<b>06</b>	Severity:	<input type="checkbox"/> Grade 1 - Mild <input type="checkbox"/> Grade 2 - Moderate <input type="checkbox"/> Grade 3 - Severe <input type="checkbox"/> Grade 4 - Life threatening <input type="checkbox"/> Grade 5 - Death
<b>07</b>	Was this AE a worsening of a pre-existing condition?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>08</b>	Study Product Administration:	<input type="checkbox"/> No change <input type="checkbox"/> Held (2nd ring not administered) <input type="checkbox"/> Permanently discontinued <input type="checkbox"/> Not applicable
<b>09</b>	Status:	<input type="checkbox"/> Continuing <input type="checkbox"/> Continuing at end of study participation <input type="checkbox"/> Death (answer 9a) <input type="checkbox"/> Severity/frequency increased <input type="checkbox"/> Resolved/Stabilized (answer 09a)

**Adverse Events Log (continued)**

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

Status/Outcome Date: \_\_\_ / \_\_\_ / \_\_\_\_\_ (dd/mm/yyyy)

<b>10</b>	Treatment: Mark 'none' or all that apply:	<input type="checkbox"/> None <input type="checkbox"/> Ring removed <input type="checkbox"/> Medications (answer 10a) <input type="checkbox"/> New/Prolonged hospitalization (answer 10b) <input type="checkbox"/> Procedure/Surgery (answer 10c) <input type="checkbox"/> Other (answer 10d)
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! 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: \_\_\_\_\_

<b>11</b>	This AE was first reported at:	<input type="checkbox"/> Visit 2 (enrollment) <input type="checkbox"/> Visit 3 (phone call) <input type="checkbox"/> Visit 4 (clinic visit) <input type="checkbox"/> Visit 5 (clinic visit) <input type="checkbox"/> Visit 6 (clinic visit) <input type="checkbox"/> Visit 7 (phone call) <input type="checkbox"/> Visit 8 (clinic visit) <input type="checkbox"/> Visit 9 (clinic visit/IDI) <input type="checkbox"/> Interim Visit <input type="checkbox"/> Unscheduled phone contact <input type="checkbox"/> Other (answer 11a)
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! 11a. Complete only if AE first reported at was marked "other":

Other, specify: \_\_\_\_\_

<b>12</b>	Is this AE serious according to ICH guidelines?	<input type="checkbox"/> Yes (answer 12a) <input type="checkbox"/> No
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**Adverse Events Log (continued)**

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

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

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?	<input type="checkbox"/> Yes (answer 12d)
	<input type="checkbox"/> 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.

**Adverse Events Log (continued)**

<b>13</b>	Date participant had first intravaginal ring study product inserted?	____ / ____ / _____ (dd/mm/yyyy)
<b>14</b>	Has participant had 2nd intravaginal ring study product inserted?	<input type="checkbox"/> Yes (answer 14a) <input type="checkbox"/> No

*14a. Complete only if participant had 2<sup>nd</sup> intravaginal ring study product inserted:*

Date participant had second intravaginal ring study product inserted?	____ / ____ / _____ (dd/mm/yyyy)
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**Relatedness**

<b>15</b>	Relatedness to Study Product/Procedure: <i>Relatedness to be determined by a study clinician.</i>	<input type="checkbox"/> Not related <input type="checkbox"/> Related
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<b>16</b>	Justification of relatedness (for both related and not related): <div style="border: 1px solid black; border-radius: 25px; height: 450px; margin-top: 10px;"></div>
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<b>17</b>	Name of Clinician determining relatedness:	
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**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.

<b>18</b>	Comment (1): <div style="border: 1px solid black; border-radius: 15px; height: 300px; margin-top: 5px;"></div>
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<b>19</b>	Comment (2): <div style="border: 1px solid black; border-radius: 15px; height: 300px; margin-top: 5px;"></div>
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**Adverse Events Log (continued)**

<b>20</b>	Comment (3): <div style="border: 1px solid black; border-radius: 15px; height: 300px; margin-top: 5px;"></div>
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<b>21</b>	Comment (4): <div style="border: 1px solid black; border-radius: 15px; height: 300px; margin-top: 5px;"></div>
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CRF Completed By: \_\_\_\_\_ (initials)

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