MTN-020 Data Communiqué #9

August 6, 2013



Updated Ring Adherence (RA-1) CRF Version 1.0 – 30Jul13

SAMPLE, DO NOT FAX MTN-020 ASPIRE (192) RA-1 (133)	Visit 1
Participant ID Site Number Participant Number Chik	Visit Date dd MMM yy
Ring Adherence	
Did the participant have access to a vaginal ring during the past month?	yes no ☐ If no, end of form.
How many times in the past month has the participant had the vaginal ring out, in total?	times → If 00, end of form.
How many of these times was the vaginal ring out for more than 12 hours continuously?	times — If 00, go to item 5.
In the past month, what is the longest number of days in a row the vaginal ring was out?	days
In the past month, why was the vaginal ring out? Record all codes that apply. See L Reason Code	back of form for code listing.
5a	
5c.	
5d	
5e	
50.	
If there is a reason that is not represented in the Reason Code list, mark item 51, on the adjacent specify lines. Otherwise, leave items 51 and 51 blank.	n or 5i, as applicable, and record the reason
5h. Other reason ring removed by participant or clinician, specify:	
Si. Other reason ring came out on its own, specify:	
Comments:	

Form instructions:

- □ Item 4 text "in the past month" added to clarify that the longest number of days in a row the vaginal ring has been out applies to the past month only (maximum 31 days).
- ☐ The previous Item 5 response boxes have been replaced with Reason Code boxes.



Updated Ring Adherence (RA-1) CRF Version 1.0 – 30Jul13

	Purpose: This form is used to document the participant's self-reported study ring use during follow-up.				
Genera Information Instructions	early termination visit, as applicable. Complete at these visits even if the	he	particip	ant has been on product hold or has been permanently	
	monthly visit.				
tem-specific	Instructions:				
Item 1	: Mark 'no' if the participant did not have a ring in her possession during vaginal ring, regardless of how long ago the ring was dispensed, and r example, a participant is dispensed a ring at the Morth 1 Visit. In Month 3 Visit, mark 'yes' since the participant had in her possession fit	reg isse	ardless es her N	of whether or not the participant used the ring. For North 2 Visit, but returns for her Month 3 Visit. At her	
Item 2	The purpose of this question is to capture all instances in the past mor regularly scheduled study visits. Do not count instances when the ring				
Item 4	: When determining the longest number of days in a row, include partial the ring on a Wednesday and re-inserted it on a Friday, count this as 3 over-estimate rather than an exact or under-estimate.				
Item 5	Refer to the list of Reason Codes below. Record the two-digit code tha past month (because the participant or dirinion removed the ring, or recorded (firm 50-5g). A Reson Code is required for item 50. Record items blank. For example, if three Reason Codes apply, record the cord REASONS RING REMOVED BY PARTICIP	ing d a des	expulsi my add in item	on occurred). Up to seven Reason Codes may be itional reason codes in items 5b-5g; leave any unused is 5a-5c and leave items 5d-5g blank.	
Hygienic or	Physical Reasons	7		al or Sexual Reasons	
	cription	Н	Code	Description	
10 Disc	comfort/symptoms: Ring caused discomfort/ participant experienced genital or other ploms	1	20	Partner ring knowledge: Did not want husband or primary sex partner to know about ring	
11 Ring	ploms falling out: Ring was partially falling out		21	Partner concerns/objections: Husband or any sex pertner did not like the ring and/or wanted her to remove/stop using the ring	
11 Ring 12 Ring 13 Ring	ptoms			partner to know about ring Partner concerns/objections: Husband or any sex partner did	
11 Ring 12 Ring 13 Ring 14 Men 15 Clea	ploms 1 failing out: Ring was parlially failing out 1 placement: Didn't feel the ring was correctly placed presentce: Wanted to look at leng or use of the ring was still in place sessBleedling: Had or was expecting menses' any type of genital bleeding or spotting med ring: Removed ring to clean it		21	partner to know about ring Partner concernsiobjections: Husband or any sex partner did not like the ring and/or wanted her to removel slop using the ring Family concernsiobjections: Family member (other than husband/pinnary sex partner) did not like the ring and/or wanted	
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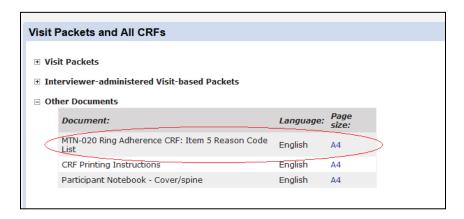
Form instructions:

- General information/Instructions, Items 1 & 2 updated to clarify intent of questions
- Reason Codes added to Item 5 instructions with bolded lead-in text for easy identification
- Reasons for ring removals grouped into new categories
- Reason codes 10 & 14 text amended per Data Communique #8
- Additional reasons added based on data review of site responses to date

with a Ring for Extended Use

Updated Ring Adherence (RA-1) CRF Version 1.0 – 30Jul13

- □ Atlas Visit Packets have been updated to include new RA-1 CRF
- □ A separate document, "MTN020 Ring Adherence CRF: Item 5 Reason Code List" is available under 'Other documents' on Atlas as a reference to aid staff in completing item 5.



- ☐ Sites can begin transitioning to this new form immediately
- □ The previous RA-1 CRF may continue to be used until <u>August 12</u>. <u>2013</u>. Starting on this date, all sites are expected to use the new version exclusively.

A Study to Prevent Infection

with a Ring for Extended Use

Ring Worries (RW-1), Item 3

2	ΔΝ	Do NOT FAX Visit Month
ľ		
	Par	ticipant ID Sle Number Pertiopant Number On Visit Date dd MMM yy
	Rin	ng Worries
	1.	How worried are you about having a vaginal ring inside of you every day for very worried somewhat worlied not at all worried at least a year?
	2.	Some women may have worries or concerns about the vaginal ring. I am going to ask you a series of questions that can be answered with yes or no regarding all the worries you may have today about using the vaginal ring. Are you worried about yes no
		2a. the ring being dirty?
		2b. the ring coming out by accident?
		2c. the ring not staying correctly in place?
		2d. the ring getting stuck inside your body?
		2e. the ring coming out during sex?
\prod		2f. the ring feeling uncomfortable or painful during sex?
$\ \ $		2g. primary sex partner or other sex partner feeling the ring during sex?
		2h. wearing the ring during menses?
		2i. difficulty inserting the ring?
		2j. difficulty removing the ring?
		2k. the ring feeling uncomfortable or painful during normal daily activities?
		2I. primary sex partner or other sex partners not liking or approving of you wearing the ring?
		2m. a family member not liking or approving of you wearing the ring?
		2n. the ring causing infection, infertility or other health problems?
		2o. feeling sick from wearing the ring?
		2pasyltring erse? Specify:
T	Co	mplete item 3 only at PUEV or early Termination visit.
	3.	As you know, none of the women in this study know if they were given a ring with Dapivirine inside it or a ring with placebo inside. Now that you have finished using the study ring, I would like you to say which ring you think you were using, Dapivirine or placebo?

If a participant permanently discontinues from study product prior to her scheduled PUEV, complete all items on the RW-1 CRF, including Item 3, at the permanent discontinuation visit *instead* of the PUEV.

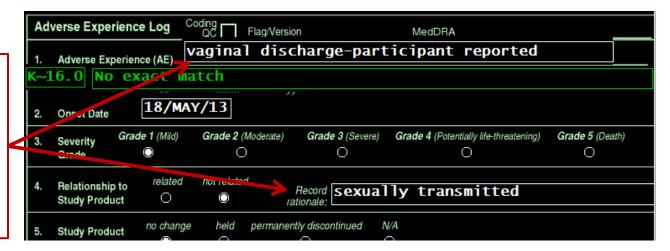


AE-1/GAE-1 Log CRFs – Item 4 Rationale

- ☐ If a previously completed GAE-1/AE-1 Log CRF page is updated with new information (for ex. a change to product relatedness or a medication taken for the AE), review other items on the page for consistency and update as needed.
 - ➤ If AE relationship to the vaginal ring changes due to test results confirming a diagnosis, **update both Item 1 and Item 4.**

Example 1:

To resolve CQC, AE
Text (Item 1) should be
updated to specify the
STI to be consistent
with the rationale in
Item 4.



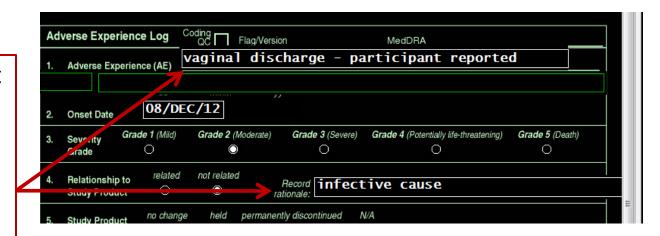


AE-1/GAE-1 Log CRFs – Item 4 Rationale

- ☐ If a previously completed GAE-1/AE-1 Log CRF page is updated with new information (for ex. A change to product relatedness or a medication taken for the AE), review other items on the page for consistency and update as needed.
 - ➤ If AE relationship to the vaginal ring changes due to test results confirming a diagnosis, **update both Item 1 and Item 4.**

Example 2:

To resolve CQC, AE Text (Item 1) should be updated to report 'vaginal infection' or 'vulvovaginitis' unless more specific dx is known to be consistent with the rationale in Item 4.





AE-1/GAE-1 Log CRFs – Item 4 Rationale

- ☐ If a previously completed GAE-1/AE-1 Log CRF page is updated with new information (for ex. A change to product relatedness or a medication taken for the AE), review other items on the page for consistency and update as needed.
 - ➤ If AE relationship to the vaginal ring changes due to test results confirming a diagnosis, **update both Item 1 and Item 4.**

Example 3:

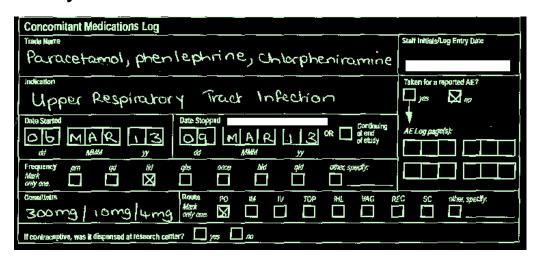
To resolve CQC, AE Text (Item 1) should be updated to report "vulval infection" or 'vulvovaginitis' unless a more specific dx is known to be consistent with the rationale in Item 4.





- ☐ If a trade name is not available/ or not reportable per national guidelines, record the generic name of the medication.
- ☐ A combination medication with a known generic name, can be recorded as one entry on the CM-1.

For example:



with a Ring for Extended Use

□ If a combination medication does have a known generic name, each active ingredient must be reported as a separate entry in order to be accurately coded at SCHARP.

Example 1:

```
Trade Name

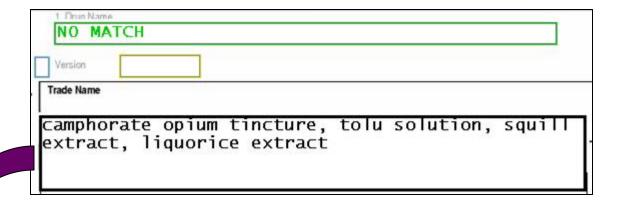
Chloramphenicol 1% / dexamethasone 0.1%
```

This item should be recorded as 2 separate entries on CM-1:

- 1. Chloramphenicol
- 2. Dexamethason



Example 2:



This item should be recorded as 4 separate entries on CM-1:

- 1. Camphorated tincture of opium
- 2. Tolu
- 3. Squill
- 4. Liquorice liquid extract



Example 3:

NO MATCH	
Version	
Concomitant Medications Log	
Trade Name	
vitamin A, Thiamin,	Riboflavin
Indication	

This item should be recorded as 3 separate entries on CM-1:

- 1. Vitamin A
- 2. Thiamin
- 3. Riboflavin



Minor spelling differences can affect the coding of medications. Please ensure the correct and consistent spelling of medications throughout the study.

Ex. 1: Aluminium Hydroxide vs. Aluminum Hydroxide

ALUMINIUM HYDROXIDE	00057401001
ALUMINIUM HYDROXID KENT PHARM	00057401024
ALUMINUM HYDROXIDE	00057401038
ALUMINIUM HYDROXID	00057401043

Ex. 2: Hydroxyzine vs. Hydroxizine

HYDROXYZINE	00058402009
HYDROXYZINUM	00058402015
NOVO-HYDROXYZIN	00058402018
HYDROXIZINE	00058402023

Ex. 3: Azithromycin Mylan vs. Azithromycine Mylan

searchstring	drugcode
AZITHROMYCIN MYLAN	00944301450
AZITHROMYCINE MYLAN	00944304008



Ring Collection/Insertion (RCI-1) CRF – item 4a

Item 4a:

- If a new ring is not dispensed, mark 'participant declined the study ring' if the participant herself declined the study ring **OR** if the participant declined study ring due to family or partners' wishes.
- Provide details on the adjacent specify line.

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	Statistical Center for HIV/AIDS Research & Prevention (SCHARP) Ring	Collection/Insertion (RCI-1)
	SAMPLE: DO NOT FAX MTN-020 ASPIRE (192) RCI-1 (135)	1 Page 1 of 1
	Participant ID Site Number Participant Number Chik Visit Date dd	MMM yy
	Ring Collection/Insertion	
	1. Did the participant have a ring in place at the start of the visit?	o to item 2.
	1a. When was the ring last in place? dd MMM yy OF	not applicable (ring not in place since last visit)
	2. Number of used rings collected none 1 2 3	If "1," go to item 3.
	2a. If none, 2, or 3, specify reason:	
	3. Number of unused (never inserted) rings collected none 1 2 3	
	4. Number of new rings dispensed to participant:	— Go to item 5.
	4a. Reason ring not dispensed	
	participant on clinical hold	
	participant has been permanently discontinued from product	
	participant declined study ring, specify:	→ Go to item 7.
	scheduled PUEV	
	early termination	
	other, specify:	
- 1		



Product Hold/Discontinuation (PH-1) CRF – item 4

Pro	oduct Hold/Discontinuation Log
1.	Date and visit month when study product hold was initiated dd MMM yy visit month
2.	Why is study product being held? Mark only one per page. pregnancy positive rapid HIV test result adverse experience breastfeeding allergic reaction to the study product report of PEP use for HIV exposure other, specify:
3.	Date of last study product use dd MMM yy
4.	Was the participant instructed to resume study product use? dd MMM YY
	no – hold continuing for another reason Date:
	no – early termination Date:
	no – hold continuing at scheduled PUEV Date: Complete
	no – permanently discontinued Date: Follow-up ACASI Tracking form.

<u>Item 4: "no - early</u> termination" response

Mark "no-early termination" for Item 4 if a participant terminates early while the product hold is still in place and enter the date of the early termination visit.



Questions?

 Please contact Jen Berthiaume and Karen Patterson with any questions you have about this slide presentation or the Data Communiqué.

Email us at:
jberthia@scharp.org
karenp@scharp.org

