

# **MTN-020**

## **Data Communiqué #8**

---

May 10, 2013

# AE and GAE Log CRF Revisions

- ❑ The AE-1 and GAE-1 Log CRF have been revised for sites to include a rationale for adverse events **related** to study product.
- ❑ SCHARP will follow-up for needed form additions to already reported AEs via email.
- ❑ Updated versions of these Log forms are available in the “As Needed” PDF packets on the MTN020 ATLAS webpage.

Adverse Experience Log					
1. Adverse Experience (AE)	_____				
	<i>Record diagnosis, if available. Include anatomical location, if applicable.</i>				
2. Onset Date	dd	MMM	yy		
	<input type="text"/>	<input type="text"/>	<input type="text"/>		
3. Severity Grade	Grade 1 (Mild)	Grade 2 (Moderate)	Grade 3 (Severe)	Grade 4 (Potentially life-threatening)	Grade 5 (Death)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Relationship to Study Product	related	not related	Record rationale: _____		
	<input type="checkbox"/>	<input type="checkbox"/>			

**Item 4:**  
Provide rational if 'related' or 'not related' box is marked

# HIV Confirmatory Results (HCR-1) CRF Revisions

- The original GP40 Western Blot band has been corrected to P40
- No actions required for previously submitted HCR-1 forms
- An updated version of this form is available in the “As Needed” PDF packets on the MTN020 ATLAS webpage.

Western Blot Band	Band Interpretation			
	(-) Negative	(+/-) Indeterminate	(+) Positive	(++) High Positive
GP160	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GP120	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P65	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P55/51	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GP41	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P40	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P31	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P24	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P18	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

# NEW CRF: Prevention Study Experiences (PSE-1)

New, interviewer-administered form to assess participants' perception of product efficacy and product assignment and understanding of the study randomization process

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) Prevention Study Experiences (PSE-1)

MTN-020 ASPIRE (192) PSE-1 (163) Visit Month     Page 1 of 1

Participant ID -- Visit Date

Site Number Participant Number CRF dd MMM yy

### Prevention Study Experiences

The next several questions ask about your thoughts and experiences as a participant in this study.

- Participating in the ASPIRE study involves many things. One of those things is using a vaginal ring. How confident are you that the vaginal ring you are using in this study will prevent you from getting HIV? Please respond with a number from 0 to 100, with 0 meaning not at all confident, and 100 being very confident that the ring will prevent you from getting HIV.
- Participants in this study are in one of the following groups. Which group do you think you are in? *Read responses aloud.*
  - vaginal ring containing dapivirine
  - vaginal ring containing placebo
  - don't know/not sure
- How was it decided which study group you are in? *Read responses aloud.*
  - a study doctor chose the group that would be best for me
  - randomly (by chance)
  - other, specify: \_\_\_\_\_
  - don't know/not sure
- Will either of the vaginal rings in the ASPIRE study reduce people's chances of getting HIV? *yes no maybe don't know/not sure*
  - 
  - If no, end of form.*
  - Imagine 100 people who are using the dapivirine ring in this study. About how many of them will have their chances of getting HIV reduced?    OR  don't know/not sure
  - Imagine 100 people who are using the placebo ring in this study. About how many of them will have their chances of getting HIV reduced?    OR  don't know/not sure

- Required at Month 3 and Month 12
- The English version is available in the “Interviewer-administered forms - English” PDF packet on the MTN020 ATLAS webpage.
- SCHARP to follow-up with sites to produce translated form.

# Ring Adherence (RA-1) Clarifications: Item 5

---

When completing item 5- reasons vaginal ring was out (mark all that apply), please keep in mind the following:

- For 5a, “ring caused discomfort”, mark this box (and not 5m) if the participant reports experiencing genital or other symptoms that caused her to remove the ring.
- For 5d, “had or was expecting menses”, mark this response if the participant removed the ring due to any type of genital bleeding or spotting (not just menses).
- Only mark 5m “other, specify” if the reason the participant removed the ring is not already listed.
- Only mark 5t “other, specify” if the reason the ring came out on its own is not already listed.
- If you wish to provide additional details on an item that is marked among 5a-5l and 5n-5s, use the Comments field at the bottom of the page (comments are not required, however).

# 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](mailto:jberthia@scharp.org)

[karenp@scharp.org](mailto:karenp@scharp.org)

