MTN Reginal Meeting

Pharmacy Break-out Session

October 2, 2012

Pharmacy Session Overview

- Dapivirine Clinical Pharmacology
- Product Complaint Process
- Shipping, to VAT or not to VAT
- Pharmacists Role in ASPIRE
- Used Ring Destruction Process
- Protocol Deviation Reporting
- Off-Site Visits
- IVRs
- Wrap up

Tuesday October 2nd

12:30 PM to 1:30 PM	**LUNCH (Restaurant Thirty7)**			
1:30 PM to 2:00 PM	**Welcome and Objectives**			
2:00 PM to 2:30 PM	Dapivirine Clinical Pharmacology		Cindy Jacobson	
2:30 PM to 3:00 PM	How to Handle Product Complaints		Tracie DiPasquale	
3:00 PM to 3:30 PM	**BREAK (Old Harbour Lobby)**			
3:30 PM to 4:00 PM	Pharmacists		Site	
4:00 PM to 4:30 PM	Role in ASPIRE		Presentations	
4:30 PM to 5:00 PM	Product Destruction		Site Presentations	
5 : 0 0 P M	**Meeting adjourned**			

Dapivirine Clincial Pharmacology

- Data complied by IPM
- Not for duplication, for training only
- Mechanism of action
- pK data

Tracie DiPasquale

- International Partnership for Microbicides (IPM)
- Materials Planning and Supply Chain Lead
- Extensive experience in the pharmaceutical industry in packaging and supply chain management

Tracie DiPasquale

- Currently manages drug supply chain from drug substance, manufacturing and drug product through packaging and distribution.
- Clinical drug supply management and oversight.

Tracie DiPasquale

- Works with internal Regulatory and QA to obtain QP Declaration and release for clinical Supplies
- Develop drug supply forecasts and budgets
- Manage inventory at vendors

Tracie DiPasquale

- Product Complaints

Pharmacists Role in ASPIRE

- Site presentations
- Communication from the site
- Discussion

Pharmacists Role in ASPIRE

Uganda

Participants will be referred to pharmacists by clinic staff when questions arise that could be best answered by pharmacy staff.

Pharmacists will educate participants about relevant issues, such as results from other related studies, during any participant meetings held on site.

Pharmacists Role in ASPIRE

MRC

Pharmacists may be involved in the counseling of participants for whom a second ring is dispensed (e.g. how to store the second ring or what to do with the used ring until the participant returns to the clinic).

Pharmacists could also be involved in counseling and providing information regarding damaged rings and procedure to be followed.

Pharmacists Role in ASPIRE

Cape Town

Pharmacists provide adherence counseling and information on side effects related to contraception and STI treatments.

Pharmacists may also revisit procedures for ring insertion with the participant, ensure participant understanding of what to expect and when the next ring will be inserted, what to do if the ring comes out, ring use during menstruation, and why it is important to return used rings to the clinic.

The pharmacist may accompany the participant to see the clinician during ring dispensation.

Pharmacists Role in ASPIRE

eThekwini

Pharmacists will provide counseling and information to participants during group education sessions in the clinic waiting room.

Pharmacists Role in ASPIRE

Zimbabwe

Pharmacists will provide information to participants about the provision of any prescribed primary care drugs.

Pharmacists Role in ASPIRE

WRHI

The pharmacist may provide counselling about the administration, storage, and side effects of any concomitant medications issued during the study.

The pharmacists will be available at follow-up visits for counseling sessions should the participant have any specific questions around the ring (its formulation, possible discomforts) or at the request of the clinician or nurse.

Pharmacists Role in ASPIRE

Zambia

If the study nurse is unable to answer participant questions or provide adequate counseling to a participant for any reason, the pharmacist may leave the pharmacy to provide this counseling or invite the participant into the pharmacy counseling room to discuss this important information.

Pharmacists will counsel participants about all non-study products dispensed from the pharmacy.

Pharmacists Role in ASPIRE

Lilongwe

Pharmacists may meet with participants to discuss drug dispensation and adherence issues that may come up related to the study product.

Pharmacists Role in ASPIRE

Blantyre

Pharmacists will not take on additional roles to increase interaction with participants as clinic staff will be able to provide sufficient information and adherence counseling.

Pharmacists Role in ASPIRE

Education

Provide information/education during participant meetings or group education sessions in the waiting room.

Meet with participants whenever a second ring is dispensed to discuss proper storage used and unused rings.

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Pharmacists Role in ASPIRE

Education

Provide information to participants about non-study products dispensed from the pharmacy and other concomitant medications.

Review important information and/or product use instructions with participants throughout the study.

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Pharmacists Role in ASPIRE

Counseling

Provide ring adherence counseling.

Conduct counseling and provide information regarding contraception and/or STI treatments.

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Pharmacists Role in ASPIRE

Participant Questions

If the study nurse or other clinical staff is unable to answer a particular participant question, she may be referred to the pharmacist.

Pharmacists may not routinely provide ring adherence counseling, but will be available to step in if participant has specific questions about the study product.

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Pharmacists Role in ASPIRE

Other

Participant may accompany clinic staff to pharmacy or pharmacist may accompany participant to clinic staff when study product is dispensed.

Reminder calls to participants between Enrollment and Month 1 (and/or other study visits) to answer questions, gather information, and remind of nex appointment.

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Pharmacists Role in ASPIRE

Other Cont.

Periodic check-ins with pharmacists during specified follow-up visits to maintain relationship.

Pharmacists Role in Product Destruction

- Site Presentations
- How are used rings disposed of in the clinic?
- What do your containers look like?
- Are the inaccessible to ppts?
- How are they managed?
- What is the pharmacy role in the process?

CLINIC STUDY PRODUCT ACCOUNTABILITY LOG COVER PAGE

Clinic Study Product Accountability Log Cover Page

Name of Site:		**DAIDS Site Number:**	
Protocol Title:	**MTN-020: A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase 3 Safety and Effectiveness Trial of a Vaginal Matrix Ring Containing Dapivirine for the Prevention of HIV-1 Infection in Women (ASPIRE)**		
Site Investigator:		**Phone Number:**	

Destruction Container Code	Date Sent for Destruction	Clinic Staff Initials	Date of Destruction	Clinic Staff Initials	Comments

Version 1.0; 9 July 12

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MTN Reginal Meeting

Pharmacy Break-out Session

October 3, 2012

Wednesday October 3rd

12:30 PM to 1:30 PM	LUNCH (Restaurant Thirty7)			
1:30 PM to 2:00 PM	Welcome and Objectives			
2:00 PM to 2:30 PM	Protocol Deviations		Cindy Jacobson	
2:30 PM to 3:00 PM	Off-Site Visits		Group Discussion	
3:00 PM to 3:30 PM	BREAK (Old Harbour Lobby)			
3:30 PM to 4:00 PM	Off-Site Visits		Site Presentations	
4:00 PM to 4:30 PM	IVRs		Tracie DiPasquale	
4:30 PM to 5:00 PM	Wrap-up		Cindy Jacobson	
5:00 PM	Meeting adjourned			

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) MTN-020 Protocol Deviation Log (PDL-1)

SAMPLE: DO NOT FAX TO DATAFAX

MTN (000) PDL-1 (499)

Note: Number pages sequentially (01, 02, 03) for each participant. Page ☐☐

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Site Number – Participant Number – Chk)

Form Completion Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

MTN-020 Protocol Deviation Log

1. Site awareness date: ☐☐ dd ☐☐☐ MMM ☐☐ yy

2. Deviation date: ☐☐ dd ☐☐☐ MMM ☐☐ yy

3. Has or will this deviation be reported to local IRB/EC? ☐ yes ☐ no ☐ not required

4. Has or will this deviation be reported to DAIDS as a critical event? ☐ yes ☐ no ☐ not applicable

5. Type of deviation:

- ☐ 5a. Inappropriate enrollment
- ☐ 5b. Failure to follow trial randomization or blinding procedures
- ☐ 5c. Study product management deviation
- ☐ 5d. Study product dispensing error
- ☐ 5e. Conduct of non-trial related procedure
- ☐ 5f. Improper AE/EAE follow-up
- ☐ 5g. Unreported AE
- ☐ 5h. Unreported EAE
- ☐ 5i. Breach of confidentiality
- ☐ 5j. Physical assessment deviation
- ☐ 5k. Laboratory evaluation deviation
- ☐ 5l. Mishandled laboratory sample(s)
- ☐ 5m. Staff performing duties that they are not qualified to perform
- ☐ 5n. Questionnaire administration deviation
- ☐ 5o. Counseling deviation
- ☐ 5p. Use of non-IRB/EC-approved materials
- ☐ 5q. Use of excluded concomitant medications or other products
- ☐ 5r. Informed consent process deviation
- ☐ 5s. Visit completed outside of window
- ☐ 5t. other, describe: _____

6. Description of deviation: _____

7. Steps taken to address the deviation: _____

8. Steps taken to prevent future occurrences of the deviation: _____

9. Deviation reported by: ☐☐ staff code

Purpose:	This form is used to document and report protocol deviations identified for a participant while enrolled in the MTN-020 study.
General Information/ Instructions:	Complete this form each time a protocol deviation is identified. Consult the Study Management Team if you are unsure if an event requires reporting as a deviation.
Item-specific Instructions:	
Page:	Number pages sequentially for each participant, starting with 01. Do no re-use page numbers if a form is marked for delete.
Item 2:	Record the date the event occurred (start date).
Item 4:	Mark the "not applicable" box if, at the time of form completion, the DAIDS Critical Event Policy is not in effect.
Item 5:	Mark the category that describes the deviation. Mark only one category per form (complete one form per deviation type/category if multiple deviations occur on the same day). Examples for some of the categories are listed below: • **Inappropriate enrollment:** Participant did not meet all study inclusion and exclusion criteria on day enrolled. • **Failure to follow trial randomization or blinding procedures:** For example, randomization procedures not followed by site or product blinding procedures not followed by pharmacy staff. • **Study product management deviation:** Use when study product is not held, or permanently discontinued, or resumed per protocol requirements. • **Study product dispensing error:** Examples include dispensing the wrong study product to a participant or dispensing product to a participant on product hold. Do not include any information related to study product assignment (product codes) on this form. Pharmacy staff to follow-up with MTN Pharmacist separately. • **Conduct of non-trial related procedure:** Use when a clinical or administrative procedure is performed that is not included/required by protocol. • **Improper AE/EAE follow-up:** Use when an AE or EAE is not followed per protocol. • **Unreported AE:** Use when an AE is not reported as required. • **Unreported EAE:** Use when an EAE is not reported as required. • **Breach of confidentiality:** Use this for potential or actual instances where confidentiality is breached. An example may include a staff member putting a participant's name instead of the PTID on a case report form. • **Physical assessment deviation:** This includes missed, incorrect, or incomplete physical or pelvic exam assessments. • **Laboratory evaluation deviation:** Includes missed, incorrect, or incomplete laboratory evaluations/testing. • **Mishandled laboratory sample(s):** Includes errors in the labeling, physical handling, processing, or shipment of laboratory specimens. • **Staff performing duties that they are not qualified to perform:** Use for any instance when a study procedure is completed by a staff member who is not adequately qualified **AND** delegated to perform the study procedure. Includes both clinical and administrative study procedures. • **Questionnaire administration deviation:** Includes cases where a required questionnaire was not completed. • **Counseling deviation:** Use when the required counseling is not done and/or not documented correctly. • **Use of non-IRB/EC-approved materials:** Includes use of **ANY** study-related material that requires IRB or EC approval per site requirements. • **Informed consent:** Examples include failure to accurately execute and/or document any part of the informed consent process.
Item 6:	Use this area to include details about the deviation.
Item 9:	Record staff code of the site staff person who completed the form. Sites will need to assign a two-digit staff code to each site staff person who will be completing this form. This list is created, maintained, and kept at the study site.

Protocol Deviations

- New form and procedure
- 5C and 5D refer to study product
- 5C refers to action by clinic
- 5D refers to action by pharmacy
- #9 Staff code?

Off Site Visits

- SSP section 6.4.3 Off-site Visit Procedures (overall guidance)
- SSP section 9.10 Study Product Considerations for Off-Site Visits
- Purpose of retention/tracing or collect product
- Will these be conducted by your site?
- Sites need IRB approval and an SOP

Off Site Visits

Pharmacy considerations should include:

- Specifications on product supply procedures for off-site visits. *NOTE: All pharmacy procedures outlined in the MTN-020 off-site visit SOP should be reviewed and approved by the MTN Director of Pharmacy prior to implementation.*

Off Site Visits

- MTN-020 Study Product Request Slip must indicate if product is for off-site visit
- Ensuring proper chain of custody of participant-specific study product from time of receipt from the pharmacy to time of delivery to the participant, including ensuring that participant-specific study product is delivered to the correct participant

Off Site Visits

- Transporting participant-specific study product at appropriate temperatures from time of receipt to time of delivery to the participant
- Document temperature recordings (max/min thermometer)
- Site SOPs should outline steps that will be taken to document that the temperature during transport was maintained at 15º-30º.

Off Site Visits

- Brief temperature excursions between 5º-40º are permissible. If a temperature excursion occurs in this range the ring may be used, however, the site pharmacist and MTN pharmacist must be notified.
- Temperatures experienced during transport must be documented on the Off-site Visit Log.

Off Site Visits

- Handling/returning participant-specific study product when the participant cannot be located or refuses to receive the product dispensed for her
- Handling of used and unused study product, including procedures for collection and transportation back to clinic for disposal
- Unused product to the pharmacy for quarintine

Off Site Visits

- Procedures and timeframes for this process and completing the documentation should be agreed upon by pharmacy and clinic staff and specified in SOPs
- One MTN-020 Off-site visit log should be completed for each trip away from study site to document product delivery/return
- Return log to the pharmacy same day

Off Site Visits

- Documenting all of the above, and appropriately storing all documentation in either the study clinic and/or pharmacy (as per site SOP)

IVRS – IPM027

Presented by Tracie DiPasquale:

- What is an IVRS?
- How does an IVRS work?
- What are the advantages of an IVRS?
- How does an IVRS manage drug supply?
- What do the screens look like?
- Technical support?

Wrap-up

- Issues for MTN follow-up
- Issues for site follow-up
- Meeting feedback
- Any questions