Review of Study Product
Re-Supply and Re-Issue

MTN Annual Meeting
Washington DC
March 16th, 2010
Definitions

- What is the definition of product re-supply?
  - Dispensing new supplies of study product

- What is the definition of product re-issue?
  - Refers to providing participants with their own previously returned study product
Study Product Return

- Participants instructed to bring all unused product to all visits
- Pharmacy staff count returned product and determine quantity:
  - Expected to be returned
  - Actually returned
  - Available for re-issue
Product Eligible for Re-Issue

- Pharmacy staff will determine based on factors such as:
  - Physical condition
  - Expiry Dates
    - Oral: 30 days after bottle is opened
    - Gel: 60 days after dispensed
    - Indicated by “do not use after” date

Key counseling message:
Use re-issued product first
Only four of each tablet are available for re-issue before the “do not use after” date (20 MAR 2010). Remind participant to take re-issued product first, then open new bottles.
Clinic staff use information recorded on the Unused Product Returns Form to

- Guide adherence counseling
- Guide the ordering of study product to be re-supplied and re-issued
Study Product Re-Issue

- For participants eligible to continue product use, authorized clinic staff determine quantity of product needed until next visit.
- Total amount = re-supply + re-issue.
- To determine total amount, consider:
  - Number of days until next visit
  - Standard re-supply quantities (30 tablets/bottle; 10 gels/carton)
  - Quantity available for re-issue
Ideal Quantity

- Unless specific concerns are identified by the IoR or designee, aim to provide the larger of these two quantities:
  - Quantity needed for daily use through the next scheduled visit date, plus 7 days
  - Quantity needed for daily use through the next target visit date, plus 7 days
Minimum Quantity

- **At a minimum**, participants must be provided with enough study product for daily use until their next scheduled study visit.

- **Ideal** is ideal, **minimum** is required.
Study Product Re-Supply

- For example, if next visit is targeted to take place in 28 days, but is scheduled to take place in 29 days, aim to provide a 36-day supply (29+7=36)

- That is, *ideally* re-supply 30 and re-issue 6 if available from the participant’s returns

- At a *minimum*, a 29-day supply is required

- Remember Expiry: Instruct and counsel participant to use re-issued product first
MTN-003 Study Product Request Slip – VAGINAL GEL

Participant ID: ____________________________  Clinic Randomization Envelope #: ____________________________

Clinic Staff Instructions: Mark RE-SUPPLY, HOLD, PERMANENTLY DISCONTINUE, or RESUME. If re-supply, mark RE-ISSUE if applicable. If re-supply or resume, record the number of cartons to be dispensed. If re-issue, record the number of applicators to be re-issued. If hold or permanently discontinue, record the reason. Sign and date at the bottom. Deliver white original to pharmacy. File yellow copy in participant study notebook.

☐ RE-SUPPLY
Dispense ______ cartons of study gel (10 applicators/carton) to participant as directed in protocol.

☐ HOLD  Reason: ________________________________________________________________

Pharmacy Staff Instructions: Do not dispense any further study gel unless/until another MTN-003 Study Product Request Slip – VAGINAL GEL marked “RESUME” is received.

☐ PERMANENTLY DISCONTINUE  Reason: ______________________________________________

Pharmacy Staff Instructions: Do not dispense any further study gel.

☐ RESUME
Dispense ______ cartons of study gel (10 applicators/carton) to participant as directed in protocol.
Comments: _________________________________________________________________

Clinic Staff Instructions: For product resumptions, this slip must be signed by an authorized prescriber.

☐ RE-ISSUE
Re-issue ______ applicators of study gel to participant.
Comments: _________________________________________________________________

Clinic Staff Name (please print): ____________________________________________________
Clinic Staff Signature: ____________________________________________________________
Date completed: __________ MMDD ______  Participant’s next visit date: __________ MMDD ______

Pharmacy
Example

- Unused Product Returns slip indicates 4 TDF and 4 TDF/FTC tablets available for re-issue
- **Target Date** is in 28 days
- **Scheduled Date** is in 37 days

What is the **ideal** and **minimum** quantity to supply?

**Ideal = 44**

**Minimum = 37**
Example

- Ideal 44, Minimum 37
- Four of each tablet available for re-issue

- How might you handle this situation?
  - Reschedule the participant
  - Up to 60-day supply permitted at IoR discretion
    - Remember that more than 60-day supply requires approval of DAIDS Medical Officer
  - Can always consult the PSRT
Print 2 copies:
- File one in participant binder
- Send one to pharmacy with study product request slip

<table>
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<th>Target date of next scheduled visit:</th>
<th>20-Feb-10</th>
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<table>
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<th>Scheduled date of next scheduled visit:</th>
<th>17-Feb-10</th>
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<th>Minimum quantity of study product needed until next scheduled visit date:</th>
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<table>
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<th>Date used for ideal quantity calculation:</th>
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<table>
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<tr>
<th>Ideal quantity of study product to provide:</th>
<th>40</th>
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Staff Initials and Date: ________________

Worksheet version date = 15 September 2010
Re-Supply/Re-Issue at Early Study Visits

- Most participants will **not** have enough available to supply **ideal** quantity at early study visits
  - Example: M1 visit, scheduled on target date (28 days), perfect adherence
    - Available for Re-Issue = 2
    - Ideal quantity = 28 + 7 = 35
    - Actual quantity provided = 32

- **Ideal** is ideal, **minimum** is required

- Expect supply available for re-issue to build over time
### Overtime, Supply Will Build

<table>
<thead>
<tr>
<th>Visit</th>
<th>Target Date</th>
<th>Actual Date</th>
<th>Actual Return (perfect adherence)</th>
<th>Ideal</th>
<th>Re-Supply</th>
<th>Re-Issue</th>
<th>Total Dispensed</th>
<th>New Bottle Opened</th>
<th>New Bottle Expiry</th>
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<td>23-Jul</td>
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Visit Scheduling Considerations

- Should you schedule early in visit window to build re-issue supply faster?
  - No - Every effort should be made to schedule on the target visit date
  - If not possible to schedule on target, recommended to schedule earlier rather than later in the visit window
  - Extreme deviation from 28-day intervals should be avoided
Questions?