

# Review of Study Product Re-Supply and Re-Issue

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MTN Annual Meeting

Washington DC

March 16<sup>th</sup>, 2010



# Definitions

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- 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

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- 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

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- 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**

## MTN-003 Unused Product Returns

PTID: --      --  
dd      MMM      yy

	<u>TDF or Placebo</u>	and	<u>FTC/TDF or Placebo</u>	or	<u>Tenofovir 1% Gel or Placebo</u>
Quantity of product expected to be returned	<input type="text" value="4"/>		<input type="text" value="4"/>		<input type="text"/>
Quantity of product actually returned	<input type="text" value="6"/>		<input type="text" value="6"/>		<input type="text"/>
Quantity of product available for reissue	<input type="text" value="4"/>		<input type="text" value="4"/>		<input type="text"/>

Pharmacy staff comments:

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.

RPh Initials: \_\_\_\_\_

Pharmacy

# Study Product Return

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- 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

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- 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

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- 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

or

- Quantity needed for daily use through the next **target** visit date, plus 7 days





# Minimum Quantity

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- 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

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- 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: [ ] [ ] - [ ] [ ] [ ] [ ] - [ ] [ ] Participant's next visit date: [ ] [ ] - [ ] [ ] [ ] [ ] - [ ] [ ]  
dd MMM yy dd MMM yy

**Pharmacy**

# Example

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- 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

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- 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

**MTN-003 STUDY PRODUCT ORDERING TOOL**

**Print 2 copies:**

- File one in participant binder
- Send one to pharmacy with study product request slip

**Target date of next scheduled visit:**

**20-Feb-10**  
(dd-MMM-yy)

**Scheduled date of next scheduled visit:**

**17-Feb-10**  
(dd-MMM-yy)

**Scheduled**

**Minimum quantity of study product needed until next scheduled visit date:**

**30**

**Minimum**

**Date used for ideal quantity calculation:**  
(this is the later of the target and scheduled visit dates)

**20-Feb-10**

**Ideal quantity of study product to provide:**

**40**

**Ideal**

**Staff Initials and Date:** \_\_\_\_\_

# Re-Supply/Re-Issue at Early Study Visits

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- 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

Visit	Target Date	Actual Date	Actual Return (perfect adherence)	Ideal	Re-Supply	Re-Issue	Total Dispensed	New Bottle Opened	New Bottle Expiry
Enrollment	1-Jan		-	-	30	-	-	1-Jan	31-Jan
M1	29-Jan	29-Jan	2	35	30	2	32	31-Jan	2-Mar
M2	26-Feb	26-Feb	4	35	30	4	34	2-Mar	1-Apr
M3	26-Mar	26-Mar	6	35	30	5	35	31-Mar	30-Apr
M4	23-Apr	23-Apr	7	35	30	5	35	28-Apr	28-May
M5	21-May	21-May	7	35	30	5	35	26-May	25-Jun
M6	18-Jun	18-Jun	7	35	30	5	35	23-Jun	23-Jul





# Visit Scheduling Considerations

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- 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



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Questions?