

# Pharmacy Breakout Session

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# Pharmacy Breakout Session: Objectives

- Understand the role of the pharmacy team (MTN and PAB)
- Understand upcoming changes being made to the DAIDS Pharmacy Guidelines and Instruction Manual
- Learn from the HPTN 035 experience
- Understand the rationale and design for MTN-003
- Outline study product guidelines to effectively implement MTN-003
- Determine study product methodology for MTN-003 to enhance design
- Identify issues associated with randomization
- Identify action items



# Pharmacy Guidelines

- Revised DAIDS Pharmacy Guidelines will be available electronically
- Hyperlink to relevant DAIDS Pharmaceutical Affairs Branch Forms

## ACTION ITEMS

- Once the document is available sites may need to update IT capabilities in the pharmacies.



# HPTN 035 Experience

- Pharmacy dispensing and storage space for study product
- Study product preparation area
- Study product documentation storage area
- Temperature monitoring and control and back-up systems
- Stability of study product outside recommended temperature range



# HPTN 035 Experience cont'd

- Study product applicator and carton size
- Participant sharing, mixing, abandonment of study product
- Adherence issues
- Counseling of participant by pharmacy and clinic staff
- Appropriate staffing



# Action Items

- Support pharmacy staff for additional space requirements for upcoming trials
- IoR and clinic staff at new clinical research sites need to understand the pharmacy requirements e.g. generator, continuous temperature monitor etc
- Pharmacists involvement with study product adherence counseling, consider pharmacy sub-study to evaluate
- Plan for adequate pharmacy staff



# MTN 003 design discussion

Understand the rationale and design for MTN-003

- Discussed consideration of the “double dummy” option

Pro's

- Sharing of study products is current problem at sites
- Prevent the possible swapping concerns
- Require less intense counseling

Con's

- Possible activity of the Placebo gel

Other

- Adherence to 2 products and condom was not viewed as a major concern



# MTN 003 Discussion Conclusions

- Support proposed protocol design
- Recommend HPTN 035 randomization methodology

## Points to consider:

- Possible swapping
- Size and appearance of the tablets
- Blister packs preferred
- Smaller pre-filled applicators recommended
- 1 month supply in smallest container possible
- Reliable contraception





Did you know??

284,730

