Implementing MTN Protocols
Laboratory Evaluations at the MU-JHU Core Lab – a review

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Cape Town, SA
About MU-JHU Core Lab

• Makerere University – Johns Hopkins University (MU-JHU) Core clinical & research lab is located at the Infectious Diseases Institute (IDI), New Mulago Hospital, Kampala.
• Began operation in 1989, acquired CAP accreditation 2003, fully complies to GCLP standards & US CLIA-88 requirements
• Supported lab evaluations for over 60 clinical trials since inception 20 years ago
• Handles approx. 16,000 test requests monthly
• Some past achievements/ recognitions
  – MLO Lab of the year 2nd runner up, April 2008
  – Zero deficiencies…CAP inspection, 2009
  – MLO Lab of the year 1st runner up, April 2010
Background

• MTN is dedicated to research in the prevention of HIV transmission by use of topically applied (rectal & vaginal) antimicrobial agents.
• Developed several protocols for the study of safety, PK, efficacy, effectiveness, application, acceptability of topical agents.
• A few of the studies have been completed, some ongoing, and others in pipeline.
• As a site laboratory we’re charged with performance of protocol laboratory evaluations as per guidelines & to highest possible quality expectations.
Progress track

• In 2008, we commenced performance of lab evaluations for MTN-001.
• In 2009 we commenced MTN-003
• In 2010 we commenced MTN-016
• We’re getting ready to start on MTN-015
• Expect more…
‘09 challenges & Implication at studies commencement

• New SOP’s
• New purchases
  – Reagents
  – ELISA equipment
• New partnerships/arrangements
  – MU-Walter Reed Laboratory – CD38, HepB.
  – MU/MOH STI clinic – BD Probe tech
• New validations
• New space allocations
• New training, staff orientations
• Pre-activation PPD inspection
‘09 challenges & Implication at studies commencement cont’d

- Enumerate all study specific testing tasks & plans to achieve quality testing
- Extra time/ attention in view of many other always demanding studies (>60)
- Creating many new documents, logs.
- Study specific training for staff
- Clear communications lines with clinic & NL to ensure appropriateness of lab plans/ decisions
‘09 challenges & Implication at studies commencement cont’d

- PK- PBMC processing time lines
- Sample volumes
Over the past year...

- We’ve gained more experience
- We’ve been audited & we’ve audited ourselves
  - Validation records
  - Rapid tests QC
  - Safety issues at our offsite clinic lab
- Made significant steps in closing gaps
  - Knowledge from continual practice
  - Communication lines
  - Inventory management. Closing in on BV supplies
  - HIV testing & review at offsite clinic
By now...

• Moved from implementation struggles to...
• Attaining, maintaining & superseding quality expectations as per respective protocols.
• Is that so? ...may be!!!
• Continuous monitoring of quality benchmarks
• Daily QC, TAT, PIR, CSC, Un-acceptable specimens, equipment maintenance
### 2009 CSC Reports Analysis

#### SUMMARY OF EXTERNAL QUALITY ASSURANCE REPORTS (CSC) FOR 2009

<table>
<thead>
<tr>
<th>Category</th>
<th>Item</th>
<th>Total</th>
<th>% of Cat</th>
<th>Cat. Total</th>
<th>Per% of Total</th>
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<td>Unacceptable/Rejected Specimen not called to Clinic</td>
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<td>Results Error Suspected</td>
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<tr>
<td></td>
<td>Tests Not Performed</td>
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<td></td>
<td>Analytical-Other</td>
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<tr>
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<td>Results not delivered within expected TAT</td>
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MTN Protocols

• Proper use of quality benchmarks:-
  – Helpful at error detection – sensitive/specific
    • Quality goals
    • Error definitions
    • Error detection mechanisms
  – Error prevention
  – Corrective action resolution of problems
  – Learning from errors
  – Policy/procedure improvements
  – Continual monitoring
Presently…

- Streamlining our shipments processes
- Made improvements in LDMS repository reports. Nevertheless we still receive about 4-15 errors monthly.
- Training more techs in MTN specific procedures
- Continual monitoring - e.g. proteinuria over reporting.
Future…

• Less than 3% error rates in all lab processes and procedures.
• Attainment of study objectives in MTN protocols owing to quality laboratory generated from Kampala site.
• We are already making it…!!!!!
Thank you!

• Any Questions!