

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

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# 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
  - MTN best PT performance, May 2008
  - MLO Lab of the year 2<sup>nd</sup> runner up, April 2008
  - Zero deficiencies...CAP inspection, 2009
  - MLO Lab of the year 1<sup>st</sup> 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

Category	Item	Total	% of C at	Cat. Total	Per% of Total
Pre-Analytical	Delay in Specimen pick-up/Processing	0	0.0	53	77%
	Data Entry Error	35	66.0		
	Specimen Processing Error	7	13.2		
	Unacceptable/Rejected Specimen not called to Clinic	0	0.0		
	Pre-Other	11	20.8		
Analytical	Wrong Tests Performed	0	0.0	6	9%
	Results Error Suspected	4	4.0		
	Tests Not Performed	1	16.7		
	Analytical-Other	1	16.7		
Post - Analytical	Critical results not Called	4	40.0	10	14%
	Results not delivered within expected TAT	0	0.0		
	Results Transcription Errors	1	10.0		
	Data Download Error	0	0.0		
	Yellow Form missing	0	0.0		
	Storage Status error	4	40.0		
	Post-Other	1	10.0		
<b>Total Per Month</b>		<b>69</b>			

# 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!