

MTN-001 Menu Lessons Learned

Patrick Karugaba
MU-JHU Core Lab,
Kampala Uganda

Objectives

- Introduction
- Identifying strength & resources at our disposal.
- Enumeration of challenges/tasks
- Lessons learned
- Conclusion

Introduction

- MTN-001 a phase 2 adherence & pharmacokinetic study
- 24 participants at this site
- SSP in place
- Expectations from the lab: support to study through
 - Timely & accurate results provisions for assessment of safety, study end points.
 - Doing it well...first time &...always

Strengths/ Resources we had

- Currently support over 60 clinical trials
- MTN-001 SSP, Lab Considerations publications
- Introductory workshops/ break out sessions-
MTN regional meetings
- MTN & IMPAACT network lab support
- pSMILE support
- On-site visits by network lab personnel, FHI,
MTN executive head,
- On-site training

New testing activities

- SDA for CT & GC – BD Probe Tech
- Phosphorous
- CD 38 & HLA-DR
- Hep.B sAg & Hep.B sAb
- CVL processing
- Unique PK-PBMC protocol
- Unique/new test methods
 - Siemens Uristics , - Syphilis RPR, - OSOM Trich
 - Quick Vue hCG, - OSOM BVBLUE

Implications

- New SOP's
- New purchases
 - Reagents
 - ELISA equipment
- New partnerships/arrangements
 - MU-Walter Reed Laboratory – CD38/HLA-DR, HepB.
 - MU/MOH STI clinic – BD Probe tech
- New validations
- New space allocations
- New training, staff orientations
- Pre-activation PPD inspection

Challenges/ Tasks

- 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

More specific challenges

- PK- PBMC processing time lines
- Sample volumes
 - Informed consent provisions
 - Natural variations
- Increased documentation burden
 - LDMS tracking sheets
 - More Logs

Going over the challenges/tasks

- Proper review & understanding of study specific lab considerations
- Setting targets in line with general study activation time lines
- Regular review of progress
- Consultation with clinic & NL
- Identification & addressing of weak processes points/limiting factors

Going over the challenges/tasks

- Keeping communication lines clear
- Don't waste time
- Aggressive follow up
- Streamlining processes & teamwork activities
- Partnerships
- Innovations

Conclusion

- The following were found to be key to successful preparation for MTN-001
 - Planning
 - Communication & consultation (above & below)
 - Aggressive implementation
 - Constant review

Acknowledgements

- All staff at MU-JHU Core Lab
- Network Lab Staff
- Clinic Staff
- MWRP management

Thank You

- Any Questions???