MTN-001 Menu
Lessons Learned

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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
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• Any Questions???