Implementation of New HIV Tests

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Phase 1

- MTN Leadership and DAIDS agreements on plan
  - Scientific/Medical Considerations
  - Cost implications
- Discussions with sites
Acquisition of required equipment and reagents

- Can all required items be purchased locally?
- How long will this take? In many cases, vendors can be the rate limiting step
- Determining initial purchase and ongoing purchase schedule
Phase 3

- Installation
- Training
  - Do local vendors have capacity to train on these platforms
  - Possibility of centralized trainings
- Local SOP development
  - MTN will review
Phase 4

- Validations
  - Prior validation evaluation
  - Identification of samples to be used for validation
  - Creation of blinded panels
  - Approval or troubleshooting
  - Validation report
Phase 5

- Establishment of EQA
  - General rule of 2 panels before testing DAIDS samples
  - In some cases, external validation samples can be used for EQA proxy
Phase 6

- Approval process
  - MTN can approve for MTN studies only
  - SMILE notification
  - Validation reports can be presented to other DAIDS or Non-DAIDS research groups but MTN cannot approve for them