



# Implementation of New HIV Tests

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# Phase 1

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- MTN Leadership and DAIDS agreements on plan
  - Scientific/Medical Considerations
  - Cost implications
- Discussions with sites



# Phase 2

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- 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

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



# Phase 4

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



# Phase 5

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- 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

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- 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