



EDCTP

European & Developing Countries  
Clinical Trials Partnership



# Anticipated Challenges & Mitigation Strategies

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- **Robust formation**
  - World class research institutions
  - Institutions that directly interface study population
  - Multi disciplinarily
  - History of collaboration
- **Project Design**
  - strong capacity building component
- **Timing**
- **Funding**
  - Source and nature
  - Technical support

# Challenge: infrastructure e.g poor internet connectivity

- Communication
- Data management



**Mitigation: Budget for internet  
connectivity**

# Challenge: Staff Turnover

- **Adequate incentives** – training, commensurate financial remuneration
- Opening up training to many people esp those that are affiliated to the trial
- Carefully and well structured recruitment of staff
- Acceptable **human resource practices**

# Unexpected clinical care Costs – Over the budget

- Complications
- Unrelated disease conditions
- Related d'ses that attract costs higher than anticipated

## Mitigation strategy

- Considerable budget allocation
- Flexibility in attached budget
- Indirect costs

# Little Understanding of research funding

- Host Institution
- Other institutional structure
  - ❑ Taxes policies
  - ❑ Institutional overheads
  - ❑ Participant insurance cover
- Continuous engagements



# Loss to follow and withdrawals

- Evaluate for **compliance to the project** at recruitment
- Reminders for compliance,
- Ensuring a good knowledge of participant **contacts**
- Home visits
- **Adherence counselling**
- Take advantage **tracking systems** currently used



# DTG safety signals

- Dynamic policy/ guidelines
- Varying opinions on use of contraceptives
- Potential effect on **participant recruitment**

# Mitigation

## Recruitment

- Inclusive yet scientifically robust eligibility criteria
- Proper counselling
- Project aim and concepts are well understood

## Ensure safety of participants

- Keep an ear to findings from on-going studies
- Rigorous safety monitoring – with frequent safety monitoring reports
- Competent DSMB

# Financial and political instability

## Financial

- Maintain a significant amount of money in more stable currencies Euro /US\$

## Political

- Careful selection of data collection sites
- Alternative sites – by having a big number in Ethiopia, programs that have multiple sites

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