

PREGART: Anticipated Challenges And Mitigation Strategies

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The PREGART Consortium



MAKERERE UNIVERSITY



**Karolinska
Institutet**



■ **Robust formation**

- World class research institution
- Institutions that directly interface study population
- Multi disciplinarily
- History of collaboration

■ **Project Design**

- strong capacity building component

■ **Timing**

■ **Funding**

- Source and nature
- Technical support

Anticipated challenges mitigation strategies

Challenge: Poor Internet & other key infrastructure

- 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**

Additional clinical care Costs

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

Mitigation strategy

- Considerable budget allocation
- Flexibility in attached budget

Loss to follow and withdrawals

- Evaluate for **compliance to the project** at recruitment
- Reminders for compliance,
- Ensuring a good knowledge of participant **contacts**- GPS coordinates
- 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

Acknowledgment

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