

PREGART: PREGART Overview II

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Project Coordinator

September 14-16, 2019
Elilly International Hotel
Addis Ababa, Ethiopia

The PREGART Consortium



**Karolinska
Institutet**



MAKERERE UNIVERSITY



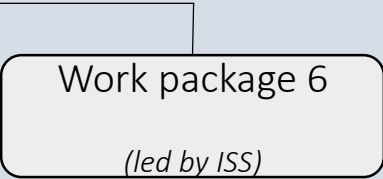
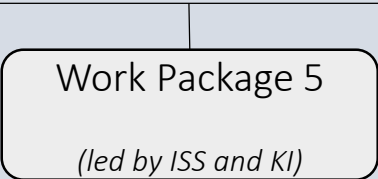
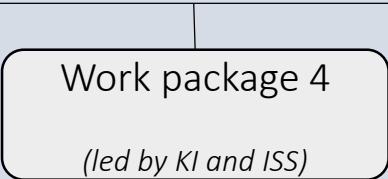
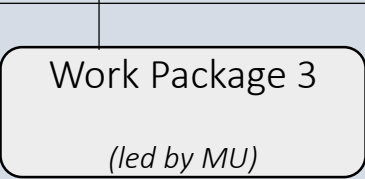
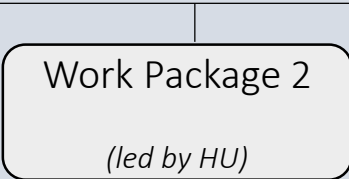
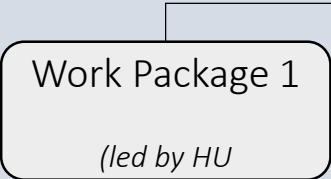
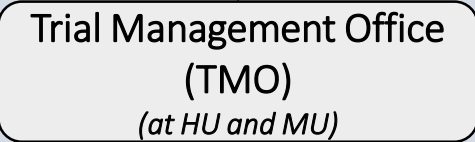
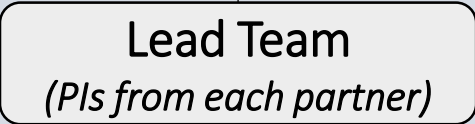
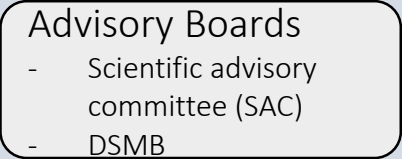
Collaborative Project: Implementation Strategy

Important stakeholders during implementation

- Universities in the four countries
- National and regional ministries of health
- Hospitals/research sites
- Ethics and regulatory agencies
- Other regional/national stakeholders

Work packages

- **Work Package1** – Coordination and Support of PREGART
- **Work Package 2** – Trial Management – Ethiopia
- **Work Package 3** – Trial Management – Uganda
- **Work Package 4** – Data Management and Statistical Analysis
- **Work Package 5** – Capacity Building
- **Work Package 6** – Communication and Dissemination



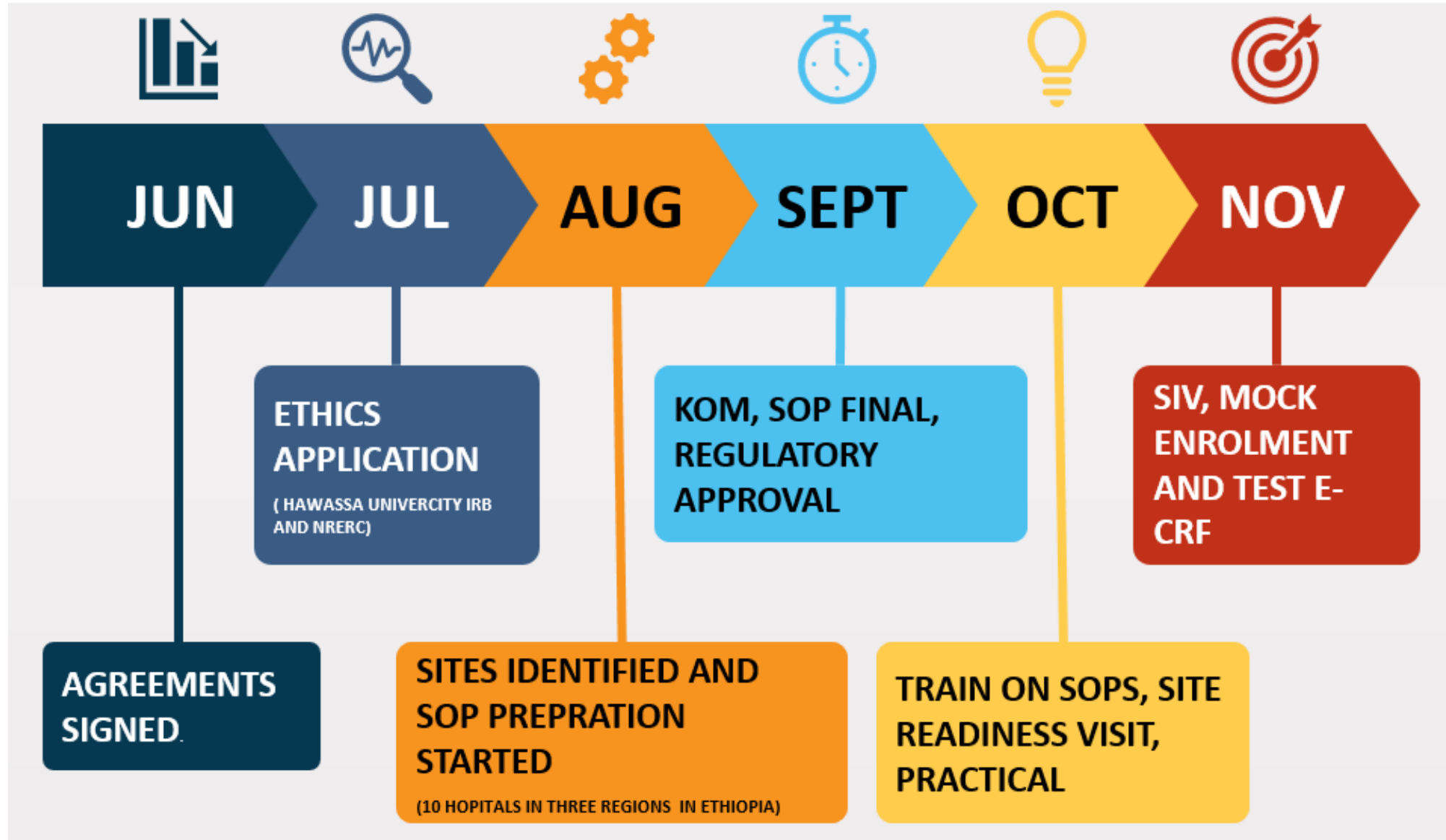
Current status and ethics/regulatory approvals

- PREGART official start date: June 1, 2019
- KOM – September 2019
- SOPs ready and tested – November 2019
- Site Initiation Visit – December 2019
- First patient approvals package – End of December 2019

Current status and ethics/regulatory approvals

- Ethical and regulatory approvals:
 - Submitted documents to NRERC – May 2019
 - First revisions received in June 2019
 - Revised protocol with responses re submitted
 - Awaiting approval
 - Issues related to insurance need to be resolved
 - Once approvals from NRERC, submission to EFDA will follow
 - Around one month required to secure approval

Achievements and plan timeline



Thank you!

Questions!