

## **PREGART Ethiopia Core Investigators Conducted Trial Implementation Progress Monitoring Meeting in Hawassa**

**Hawassa, Ethiopia — [October 2025]**

The **PREGART Ethiopia core investigators** convened a four-day **trial implementation progress monitoring meeting** from **August 25–28, 2025**, at **Rori International Hotel, Hawassa**, to review ongoing clinical trial activities, assess interim results, and provide strategic guidance for enhancing trial implementation. The meeting brought together key investigators and management team members, including **Prof. Eleni Aklilu (Karolinska Institute, Sweden)**, **Prof. Yifru Berhan (Independent Consultant)**, **Prof. Eyasu Makonnen (Addis Ababa University)**, **Dr. Birkneh Tilahun (International Vaccine Institute & joined online)**, and the **PREGART trial management group at the coordination office—Dr. Abel Gedefaw, Dr. Dejene Hailu, and Dr. Meron Hassessen**, and others.

During the meeting, participants **reviewed trial progress**, including recruitment performance, interim **safety and efficacy analysis**, and PhD students' progress were evaluated. The identified key challenges were discussed in detail and provided recommendations to accelerate trial implementation. While the trial performance in terms of recruitment and **GCP/regulatory compliance** was encouraging, the team recommended finalizing recruitment by **2026**. The key strategic recommendations included:

- **Trial site expansion** with comprehensive preparation for new sites, including regulatory and ethics amendment submissions.
- Employment of **full-time study clinicians**, laboratory quality monitoring officers, and IMP accountability officers.
- Conducting **site selection feasibility assessments** and identifying qualified trial site staff.
- Providing **GCP training** for all staff at new sites.
- Implementing **frequent monitoring by clinical trial monitors** to ensure adequate oversight of new sites.
- **Reorganizing the data management team** to strengthen data quality and integrity.
- Preparing **interim analyses** for upcoming **Data Safety Monitoring Board (DSMB)** meetings.

The meeting concluded with a **brief discussion with Hawassa University leadership**, including **President Prof. Chirotaw Ayle** and **Vice President for Research and Collaboration, Dr. Tafesse Mathewos**, regarding ongoing trial implementation and university support to enhance trial success. University leadership reaffirmed their **commitment to supporting the trial**. The investigators also held a site visit at one of the trial sites found in Hawassa & initiated the CTU renovation with the college's higher officials.

The **PREGART project expresses its gratitude** to the project consortium partners—**Hawassa University (Ethiopia)**, **Karolinska Institute (Sweden)**, **Makerere University (Uganda)**, **ISS (Italy)**—and to the funder **EDCTP2** for their continued support in building Ethiopia's clinical trial capacity.



Pictures taken during the meeting at RORI hotel, Hawassa, August 25-28 /2025.









The above pictures were taken during the site visit of Hawassa University Clinical trial unit renovation initiation and PREGART Hawassa University hospital trial site visit, August 25-28/2025.







**Photo Caption: PREGART Trial Implementation Progress Meeting, Hawassa, August 2025**

Key participants at the front seated line (left to right): **Dr. Tafesse Mathewos**, Vice President for Research and Collaboration, **Prof. Chirotaw Ayle**, President of Hawassa University, and **Prof. Eleni Aklilu**, Consortium Principal Investigator at Karolinska Institute. The photos were taken during the discussion with university leadership and at the conclusion of the meeting.