

PREGART Supports EFDA in Achieving WHO Level III Regulatory Maturity for Clinical Trials

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The PREGART Clinical Trial is proud to have contributed to the Ethiopian Food and Drug Authority's (EFDA) achievement of **WHO Level III regulatory maturity** for clinical trial oversight—an important milestone demonstrating that Ethiopia now meets advanced international standards for clinical trial authorization, inspection, and regulatory governance.

Although fewer than 20 clinical trials are currently authorized nationally, PREGART—funded by EDCTP2 and EDCTP3—operates across **more than 16 trial sites** and implements an **adaptive trial design**, requiring continuous regulatory review, approval, and ongoing safety monitoring. Through frequent engagement with EFDA on protocol evaluations, **GCP inspections across more than 10 sites in 2024/2025**, real-time adverse event reporting, regular communication on progress updates, CAPA responses, and clarification of regulatory queries, the trial has substantially strengthened EFDA's technical capacity and operational experience. This collaboration played a key role in EFDA's progress toward achieving WHO Level III maturity, an essential foundation for a reliable and trusted national research environment.

“Reaching WHO Level III is a remarkable national achievement,” said **Prof. Eleni Aklilu**, PREGART Consortium Principal Investigator at Karolinska Institute. “The continued support from research partners like PREGART ensures Ethiopia is well-positioned to advance into more complex clinical research.”

Over the past four years, PREGART has also contributed to building Ethiopia's clinical research workforce. The trial has trained **over 300 healthcare professionals** in GCP/GCLP and trial operations, with nearly **150 gaining hands-on experience** in trial implementation as investigators, study nurses, pharmacists, adherence supporters, and laboratory personnel. Its multi-site governance structure has strengthened national capacity in data quality, safety reporting, and investigational product accountability—all critical components of high-quality clinical research.

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

EFDA Attains WHO Maturity Level 3 in Medicine Regulation



Photo taken from the EFDA official website



Picture taken from the PREGART team and EFDA GCP inspection experts at the end of the GCP inspection in two different trial sites.



Picture taken during the final GCP inspection findings discussion at one of the trial site GCP inspections