



PREGART WORK PACKAGES

The PREGART project foresees a work plan structured on six integrated work packages: three of them are devoted to the clinical trial and data analysis, two of them to extend the scope of the project beyond the trial, through capacity building and communication activities and the first one to coordinate them.

Work Package 1: Coordination and Support of PREGART

Lead: Hawassa University (HU), Ethiopia

The main objective of WP1 is to implement the trial strictly adhering to timelines and budget of the project, and to establish a reliable and smooth communication between the participant institutes. Dedicated project coordinating offices will be established at the trial implementation sites in Ethiopia and Uganda with clear operating procedures and processes and will coordinate activities of the rest of the work packages.

Work Package 2: Trial Management – Ethiopia

Lead: Hawassa University (HU), Ethiopia

The main objective of WP2 is to ensure the successful start-up, execution and completion of the PREGART clinical trial: developing standard operating procedures for each activity (patient recruitment, follow up and laboratory procedures, and work flows for the different work stations); establishing reliable and effective trial management structures to ensure that the trial is conducted rigorously to a high standard and in compliance with protocol and Good Clinical Practice; implementing study participants recruitment and follow up. The local principal investigator will ensure that both the study participant, study clinician and the investigator are blinded to the study drug regimens. All partners PREGART participating institution will be responsible for the design and planning of the trial.

Work Package 3: Trial Management – Uganda

Lead: Makerere University, Uganda

This work package is similar to WP2 but will be coordinated in Uganda. This work package will help to standardize the procedures employed in the trial. One data collector for each study site will be recruited as a data collection supervisor to continuously monitor the quality of data collected on daily basis and follow adherence to standard operating procedures and study protocol.

Work Package 4: Data Management and Statistical Analysis

Lead: Karolinska Institutet, Sweden

The main aim of WP4 is to evaluate and ensure the quality of the data that will be collected following the European Commission, Clinical Trials – [Directive 2001/20/EC](#) Article 15 (5). A data management team who will regularly report to the trial management office and trial steering committee will be established at the trial implementation sites in Ethiopia and Uganda.

Work Package 5: Capacity Building

Lead: Karolinska Institutet, Sweden

The main aim of WP5 is to strengthen clinical trials capacity within a wider research capacity building programme that is sustained beyond and above the PREGART trial. This activity will be led by co-investigators from Karolinska Institutet, Sweden and ISS in Italy. Trainings will be cascaded both to support the implementation of PREGART and to build capacity in the two countries. Postdoc and PhD level trainings will be provided as medium and long-term courses.

Work Package 6: Communication and Dissemination

Lead: Istituto Superiore di Sanità (ISS), Italy

The main aim of WP6 is to communicate and disseminate project information and results. PREGART trial will produce data that would be of interest to a wide range of audiences, including researchers, patients, health care providers, community members, international organizations and policy and decisionmakers. Through the communicative activity, this work package aims also to promote the use of results of PREGART in developing and revising HIV treatment guidelines for pregnant and breast feeding.



protecting mother and baby



EDCTP



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