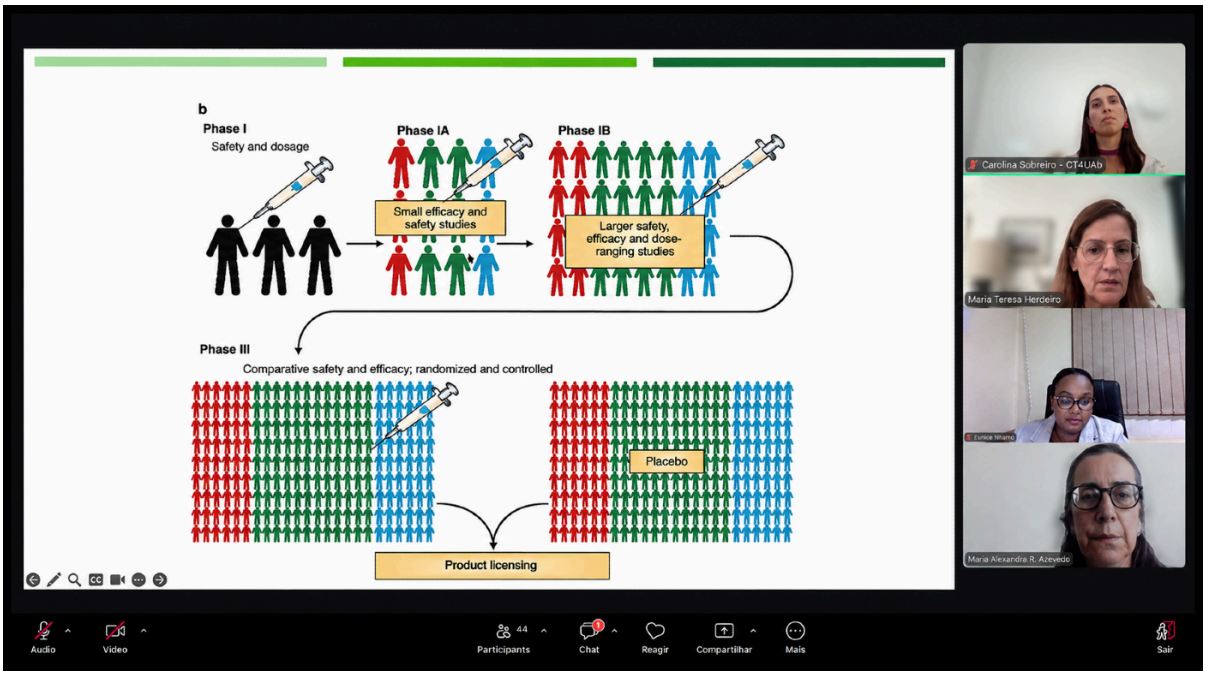


Webinar: Regulatory Affairs and Clinical Trials

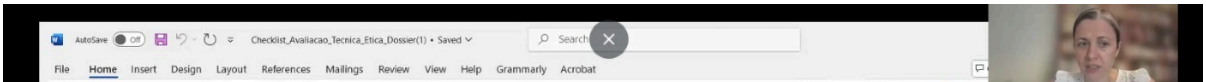
As part of the CT-Luso project's webinar series, a session dedicated to the theme **"Regulatory Affairs and Clinical Trials"** was held on May 28th , bringing together over 40 participants from various Portuguese-speaking countries to reflect on the challenges and opportunities of regulatory harmonization in clinical research.

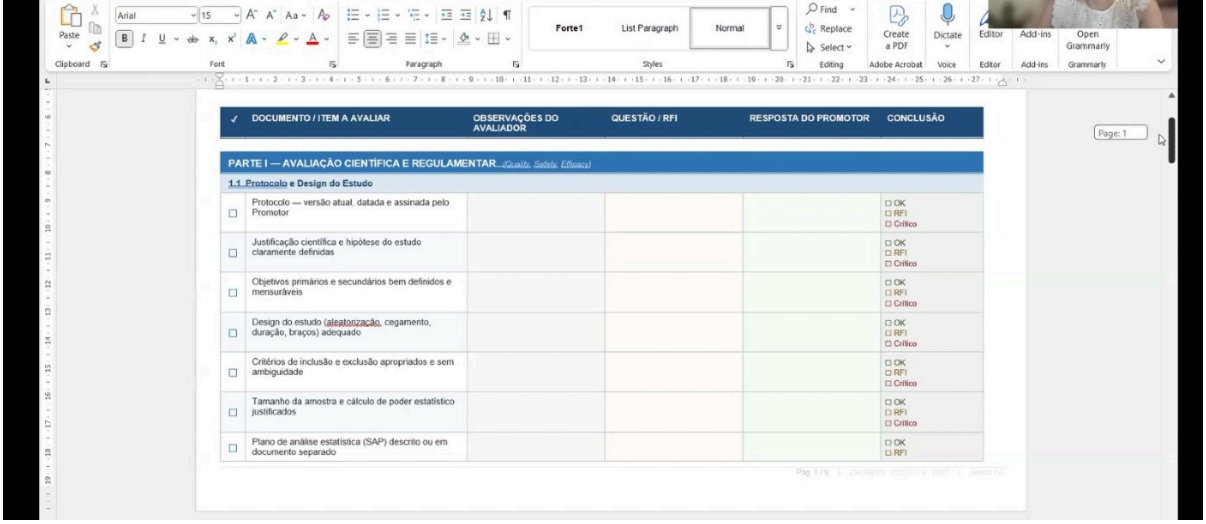
The session featured a presentation by **Maria Teresa Herdeiro** , Professor in the Department of Medical Sciences and researcher at the Institute of Biomedical Research of the University of Aveiro, and was moderated by **Lígia Tembe** , Executive Administrator for the Technical-Scientific Area of the National Regulatory Authority for Medicines of Mozambique (ANARME).

The speaker emphasized that clinical trials constitute a fundamental stage in the drug lifecycle, allowing for the evaluation of its quality, safety, and efficacy before marketing authorization. However, he warned of some limitations inherent in these studies, such as the small number of participants, age restrictions, and the limited duration of exposure to the medications, factors that can make it difficult to detect rare or late adverse reactions.

The next CT Luso Webinar is scheduled for June 25th (6:00 PM in Portugal) with the theme "Equity in Access to Innovation in Health" .

Read more...



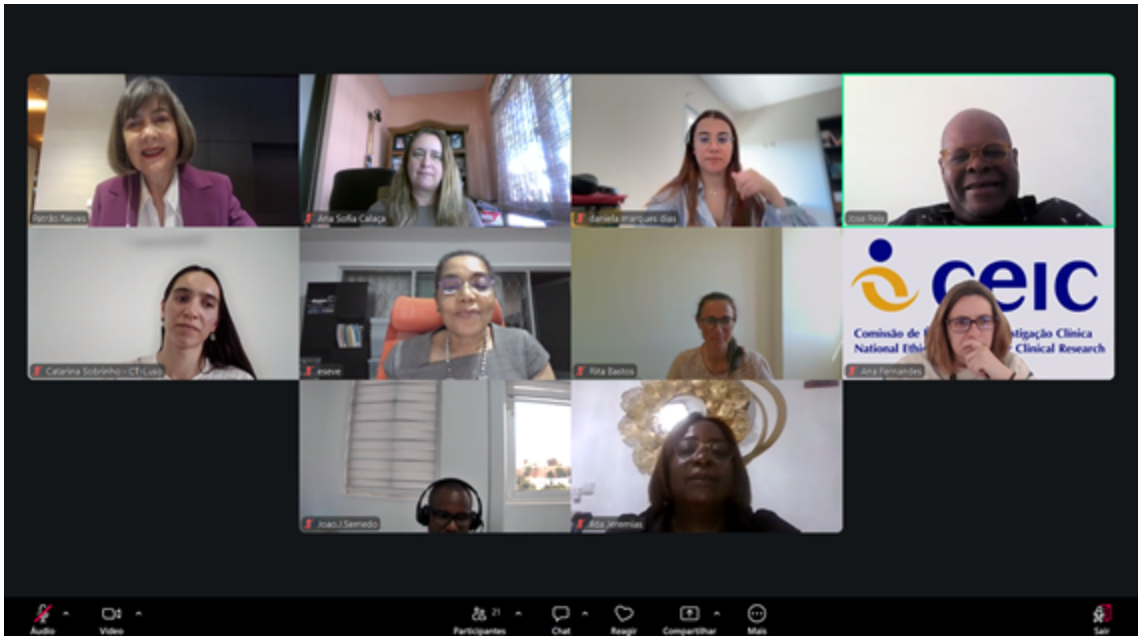


New phase of CT Luso promotes harmonization of practices in clinical trials.

Within the scope of the Advanced Training dedicated to the ICH-GCP Good Clinical Practice Guidelines (R3), integrated into the CT Luso project, sessions are underway dedicated to the creation of **Standard Operating Procedures** (SOPs) and **form templates** harmonized with international standards applicable to clinical trials.

These sessions aim to build harmonized documents that can be used by the Drug Regulatory Authorities, Ethics Committees and Research Centers of the Portuguese-speaking African Countries (PALOP), for greater convergence of practices among Portuguese-speaking countries.

Developed based on the ICH-GCP International Guidelines for Good Clinical Practice, these procedures and form templates will be subsequently adapted to the specific realities and needs of each partner country. They are intended to serve as tools to support institutional strengthening, technical capacity building, and harmonization of procedures, contributing to greater efficiency and streamlining of processes related to clinical research.



CT-Luso partners define priorities for the next stage of the

project.

The partners of the CT-Luso project met for their **20th coordination meeting** on May 6th to review the activities carried out and outline the next phases of implementation. Key topics included the conclusion of the case study discussion phase, the planning of new training activities, and the strengthening of institutional cooperation among the participating countries.

Read more...

CT Luso Video: Shared knowledge for common challenges in the Portuguese-speaking world.

Esperança Sevene, Scientific Coordinator of the CT Luso project and President of the National Bioethics Committee for Health of Mozambique, emphasizes the strategic importance of cooperation between Portuguese-speaking African countries in strengthening ethical and regulatory capacities related to clinical trials, highlighting the role of knowledge sharing, training, and international integration in this field.

WATCH THE VIDEO HERE

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Este projeto faz parte do programa EDCTP3 e tem o apoio da União Europeia