CT-Luso – Ethics and Regulatory Capacity Building Partnership for Clinical Trials in Portuguese-speaking African Countries

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BACKGROUND AND PROJECT APPROACH

CT-Luso (2024-2027) is an ethical and regulatory capacity building project focused on Clinical Trials (CT) in the Portuguese-speaking African Countries (PSAC): Angola, Cape Verde, Guinea-Bissau, Mozambique, and São Tomé and Príncipe, partnering with Portugal. This initiative involves 24 institutions engaged in biomedical research across six countries, including National Regulatory Authorities (NRA), Research Ethics Committees (REC), Research Centers, and Universities.

It aims to strengthen and harmonize the ethical and legal framework for conducting CT and enhance the functioning of competent institutions, with 3 goals:

- **Short-term:** Strengthen and harmonize the ethical-legal framework for conducting clinical trials.
- **Medium-term:** Establish a community of practice by engaging various stakeholders to promote scientific research in each country.
- **Long-term:** Create the foundations of a Lusophone cluster for clinical trials that will enable the submission of research protocols for implementation across the five PSAC.

CT-Luso is structured into eight work packages (WP): coordination and management (WP1), scientific leadership (WP2), analysis of legislative gaps and recommendations (WP3), training programs (covering WP 4, 5, 6, and 7), and communication (WP8). The project addresses three complementary domains: legislative, institutional and professional. The work packages are designed to respond to these areas in an integrated manner.

LEGISLATIVE
Strengthening and harmonizing national ethical and legal frameworks for clinical trials.

INSTITUCIONAL
Strengthening competent institutions and promoting more coordinated ethical and regulatory processes.

PROFESSIONAL
Developing a progressive and certified training pathway for professionals involved in clinical research.

RESULTS

• LEGISLATIVE STRENGHTENING

A comprehensive assessment of the ethical, legal and institutional frameworks for clinical trials across the five PSAC resulted in **three complementary outputs**, providing a basis for strengthening national frameworks and promoting greater regulatory and ethical coordination.

1. **Analysis of national legislation:** Country-level analysis of legislation in force and under development applicable to biomedical research and clinical trials, identifying regulatory gaps and different levels of framework maturity;
2. **Institutional mapping of NRA & REC:** Mapping of the competent NRA and REC, including their structures, responsibilities and the relationship between ethical review and regulatory assessment of clinical trials;
3. **Country-specific recommendations:** Recommendations addressing the gaps identified in each country, with priority actions to strengthen ethical and regulatory frameworks, improve NRA–REC coordination and support progressive harmonisation with international standards.

1. The legislative survey resulted in a detailed analysis of current national legislation and the rules that are in the legislative process in the field of biomedical research, with a particular focus on clinical trials.

Angola has already approved a significant number of laws, reflecting important advances in its biomedical research regulation. Key legislation such as the **Clinical and Biomedical Research Law is under discussion** and will be essential for structuring scientific research in the country.

Cape Verde has approved legislation mainly focused on the entities responsible for regulating research. However, **key legal texts, including the Biomedical Research Law, are still under revision or pending approval.**

Guinea-Bissau is still developing its legislative framework. **All relevant laws remain in the approval phase**, reflecting the country's early stage in regulating scientific and biomedical research.

Mozambique presents a **solid and well-structured legislative framework**, with approved laws aligned with international best practices. This provides a strong legal foundation for conducting and supervising research.

São Tomé and Príncipe is in a transitional stage, with several laws in the process of being promulgated. **The Basic Law of the National Health System** is particularly relevant in this context.

2. The institutional landscape across the PSAC also reveals different levels of regulatory maturity. While most countries have already formalised their **National Regulatory Authorities**, São Tomé and Príncipe remains the only country still drafting the legislation to officially establish its authority.

Regarding **National Research Ethics Committees**, the scenario is more diverse. **Cape Verde, Angola, Guinea-Bissau, and Mozambique** are engaged in **ongoing legislative processes** — either initiating or revising the legal framework. In contrast, **Angola and São Tomé and Príncipe** already have ethics legislation formally **approved and in effect**.

Relationship between the National Research Ethics Committees and the National Regulatory Authorities in each of the PSAC

In **Angola,** National Institute for Health Research (INIS) is the coordinating institution for health research. The CEMS (Ethics Committee for Medicine and Health) carries out its work on INIS premises, unless it is necessary to carry it out elsewhere. Documents **do not reveal a clear definition of the relationship between CEMS and ARMED (Regulatory Agency for Medicines and Health Technologies)**, as the country's medicines regulator.

In **Cape Verde** there is **no explicit definition of the relationship** between the National Ethics Commission for Health (CNES) and Independent Health Regulatory Authority (ERIS).

In **Guinea-Bissau**, the relationship between the National Ethics Commission for Health Research (CNEPS) and Regulatory Authority for Pharmacy, Laboratory, Medicines and Other Health Products (ARFAME, IP) is not clearly defined in the current regulations, leaving open the guidelines on how these two entities should coordinate regarding the regulation and supervision of clinical trials and medicines.

In **Mozambique**, although it is not explicit, the relationship is revealed by the fact that ANARME, IP. (National Regulatory Authority for Medicines) has the power to "authorise the carrying out of clinical trials, subject to the opinion of the Bioethics Committee" (article 10, b) and insofar as the Board of Directors is responsible for "deciding on the carrying out of clinical and therapeutic trials, after hearing the ethics committee" (article 9(2)(s) of ANARME's Organic Statute (Decree no. 115/2020, of 31 December).

In **São Tomé and Príncipe**, it is possible to affirm the existence of a relationship between ARFAMED (National Regulatory Authority for Pharmacies and Medicines) and CESIC (Health Ethics Committee for Scientific Research), because of the competences of each body and this collaboration is mentioned in the Clinical Trials Regulation Section of the Regulation and Legal Department (Article 28(2)(b) of the aforementioned Proposal).

3. Country-specific recommendations

Recommendations reflected the **different regulatory maturity and priorities of each country**:

Angola - Further strengthen the existing framework, particularly regarding data protection, vulnerable participants, conflicts of interest, clinical trial registration, safety monitoring and post-trial follow-up.

Cape Verde - Strengthen the proposed health research legislation by clarifying key concepts, risk–benefit assessment, data protection and oversight mechanisms, including clinical trial registration.

Guinea-Bissau - Develop a more comprehensive regulatory framework covering informed consent, data protection, GCP (Good Clinical Pratice), authorisation procedures, safety monitoring and clinical trial registration.

Mozambique - Refine the existing framework by strengthening provisions on informed consent, post-trial follow-up, urgent safety measures, monitoring and inspection.

São Tomé and Príncipe - Develop dedicated clinical research legislation, consolidating ethical principles, informed consent, data protection, safety, authorisation procedures and institutional responsibilities.

• INSTITUCIONAL STRENGHTENING

Strengthening NRA–REC coordination – Institutional mapping revealed different levels of formalisation of NRA–REC coordination across the five PSAC, highlighting opportunities for clearer roles and more coordinated ethical and regulatory review of clinical trials.

Templates and supporting materials were developed to help competent institutions standardise and harmonise ethical and regulatory procedures and facilitate more coordinated processes.

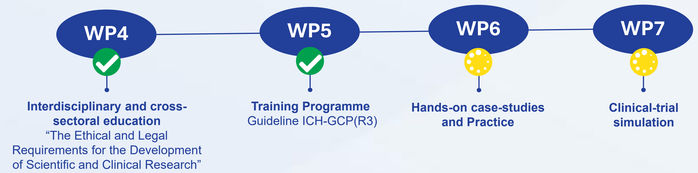
• PROFESSIONAL CAPACITY BUILDING

CT-Luso implements a **progressive training pathway**, moving from foundational interdisciplinary training to advanced training and practical application.The first training level, **WP4 – Interdisciplinary and cross-sectoral education** "The Ethical and Legal Requirements for the Development of Scientific and Clinical Research", was successfully completed, substantially exceeding its initial target:

Participants included **ethics committee members**, **regulatory authorities**, **researchers**, **project managers and academics** from across the five PSAC, who reported a positive impact of the training on their professional activities.

Following WP4, **advanced ICH-GCP(R3) training (WP5) has also been completed**, marking the second level of the CT-Luso professional capacity-building pathway. The programme will now progress to its practical stages:

- **WP6 – Hands-on case-studies and Practice:** In-person practical training in Portugal, providing exposure to clinical-trial assessment, implementation and oversight.
- **WP7 – Clinical-trial simulation :** Application and integration of competencies acquired throughout the training pathway.



CONCLUSIONS

CT-Luso demonstrates the value of an integrated approach combining legislative strengthening, institutional development and progressive professional capacity building.

Country-specific regulatory analysis and recommendations provide a basis for stronger and more harmonised clinical-trial frameworks, while institutional tools support more coordinated ethical and regulatory processes. The completed WP4 and WP5 training programmes demonstrate substantial reach, high academic achievement and perceived professional impact across the five PSAC.

Together, these actions contribute to creating more sustainable conditions for high-quality, ethical and internationally aligned clinical research.

REFERENCES

To perform the legislative study, publicly accessible legislation was consulted, as well as draft legislation in the areas of human research, biomedical research, bioethics, and ethics.

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