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

André Dias Pereira[1], Carla Barbosa [1], Ana Elisabete Ferreira[1], Daniela Marques Dias[1], Walter Van-Trier [2], João Semedo[3], Miguel Pereira[4], Virgílio Uamba[5], Bernardett Santos [6], Catarina Sobrinho[7], Maria Alexandra Ribeiro[7], Helder Mota Filipe[7,10], Maria Patrão Neves[7]

[1]Lawyers and Researchers, Center for Biomedical Law, Faculty of Law of the University of Coimbra, Coimbra, Portugal; [2]Lawyer, Ministry of Health, Luanda, Angola; [3]Lawyer, ERIS, Praia, Cape Verde; [4]Lawyer, Ministry of Health, Bissau, Guinea-Bisau; [5]Lawyer, ANARME, Maputo, Mozambique; [6]Lawyer, Ministry of Health, São Tomé, São Tomé and Príncipe; [7]CT-Luso Project, Portuguese Pharmaceutical Society, Lisbon, Portugal; [10] President, Portuguese Pharmaceutical Society, Lisbon, Portugal

Background

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, Ethics Committees, Research Centers, and Universities **(figure 1)**.

It aims to strengthen and harmonize the ethical and legal framework for conducting CTs 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.

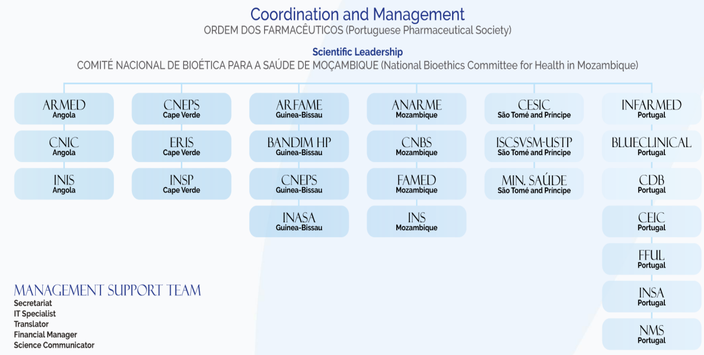

Figure 1 – Organisational Chart

Methods

CT-Luso is organized into **eight work packages** (WP).

Its main goal will be achieved through a review of the national ethical and legal framework **(WP3)** and the establishment of a training program at various levels:

- The first level will be interdisciplinary and thematically comprehensive, based on internationally agreed ethical and legal principles **(WP4)**.
- The second level will focus specifically on the ethical, legal, and procedural requirements of clinical research **(WP5)**.
- The third level will emphasize effective practices, particularly in monitoring the entire process of submission, approval, and oversight of clinical trials **(WP6)**.
- The fourth level will involve simulating scenarios to apply the skills and knowledge acquired from the previous training levels **(WP7)**.

Additionally, coordination will ensure the smooth operation of the project **(WP1)**, alongside scientific supervision **(WP2)**. A dissemination plan for the results will also be developed, tailored to various target audiences **(WP8)**.

Results

CT-Luso has conducted a **comprehensive study of (1) existing biomedical research legislation** and the **(2) regulatory frameworks of the competent bodies in the PSAC** in close collaboration with legal experts from each country.

(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.

Overall**, Angola, Cape Verde, and Mozambique** demonstrate more advanced and regulated frameworks, while **Guinea-Bissau and São Tomé and Príncipe** remain in development phases. Despite this variability, all countries show growing concern for ethical principles essential to research quality and safety.

Despite these disparities, all the countries surveyed are showing **increasing concern for fundamental ethical principles**, which are essential for guaranteeing the quality and safety of research.

The analysis revealed that several essential ethical aspects, in line with international best practices, have already been included in the legislation and/or draft legislation of all the countries. These include the **primacy of human dignity** and the **protection of the human being**, which underpin the ethical standards governing clinical trials, as well as **the requirement for ethical approval** prior to conducting studies **(table 1)**.

In addition, other fundamental requirements, such as **obtaining informed consent** in a clear and transparent manner, the confidentiality of participants' personal data and a rigorous assessment of the risks and benefits involved in trials, are also covered by current or draft legislation in all the countries analysed.

Ethical requirements	Primacy of the human being / dignity	Regulatory approval	Ethical opinion	Requirements for obtaining informed consent	Consent from people without the ability to consent (minors and incapacitated adults)	Data confidentiality	Conflict of interest	Risk assessmen t/ benefits	Security and control	Responsibilities of the promoter, investigator, monitor and auditor	Authorisation procedures	Clinical Trials Database	Insurance / indemnity / damage repair	Supervision of good clinical and manufacturing practices for experimental medicines	Post-test monitoring of participants	Urgent security measures	Publicising clinical studies	Non-discrimination	Good clinical practice
Angola	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	-	✓	✓	-	-	✓	✓	✓
Cape Verde	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	✓	✓
Guinea-Bissau	✓	✓	✓	✓	✓	✓	-	✓	-	-	-	-	✓	-	-	-	-	✓	-
Mozambique	✓	✓	✓	✓	-	✓	✓	✓	-	✓	✓	-	✓	✓	-	-	-	✓	-
São Tomé and Príncipe	✓	-	✓	✓	-	✓	✓	✓	✓	-	-	-	-	-	-	-	-	-	-

Table 1 - Checklist of ethical and regulatory requirements laid down in current legislation or internal regulations
Caption: In white the requirements that are currently in effect, in blue those that are in the legislative process, and in green the requirements that have not yet been established. The color coding of each cell allows for a quick identification of the implementation stages for each requirement

(2) The institutional landscape across the PSAC also reveals different levels of regulatory maturity **(Table 2).**

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**.

Country	National Regulatory Authority	Legislation	National Research Ethics Committees	Legislation
Angola	Regulatory Agency for Medicines and Health Technologies (ARMED)	Presidential Decree no. 136/21, of 1st June	National Institute for Health Research (INIS)	Presidential Decree no. 177/19, of 22nd May
			Ethics Committee of the Ministry of Health (CEMS)	Order no. 2378/GAB.MIN/MS/2019 Internal Regulations (final version)
Cape Verde	Independent Health Regulatory Authority (ERIS)	Decree-Law no. 3/2019, of 10th January (Creates ERIS)	National Health Ethics Council (CNES)	(preliminary draft)
Guinea-Bissau	Regulatory Authority for Pharmacy, Laboratory, Medicines and Other Health Products, IP (ARFAME, IP)	Decree no. 13/2023 (Creation)	National Health Research Ethics Committee (CNEPS)	(proposal for a decree)
Mozambique	National Regulatory Authority for Medicines, IP (ANARME)	Decree no. 115/2020, of 31st December (Statute Organic) Ministerial Diploma no. 20/2022, of 9th February (Internal Regulations)	National Bioethics Committee for Health (CNBS)	Order no. 58/2017 (Creation) (proposed Organic Statute of the CNBS) CNBS Internal Regulations
São Tomé and Principe	Regulatory Authority for Pharmacy, Medicines and Health Technologies and approval of its Statute (ARFAMED)	Decree-Law no. .../2024 (Proposed Decree-Law for creation)	National Ethics Commission of the Ministry of Health	Order no. 01/GMS/2022 (Team) Resolution no. 02 of 21stJune 2024 (approves CESIC's internal regulations) Order no. 59/2024 (Creation of CESIC)

Table 2 - Overview of National Regulatory Authorities and National Research Ethics Committees in the PSAC and their legal Frameworks
Caption: Blue-shaded cells indicate institutions whose legislation is currently undergoing the legislative process, whereas white-shaded cells correspond to institutions with legislation that has already been approved.

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

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**, 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 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 and CESIC**, 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).

Conclusions

The analysis of the current legal and institutional frameworks across the PSAC, together with the identified gaps, demonstrates that while the construction and full implementation of a comprehensive and effective regulatory system for clinical trials still requires specific adjustments, significant progress has already been made. The groundwork for a robust, internationally aligned legislative framework is well underway in several countries, with others actively developing the necessary structures. This evolution is essential for reinforcing national and institutional capacities, ensuring that clinical research conducted in these countries meets internationally recognised standards of quality, safety, and ethical integrity.

By addressing the remaining challenges, the PSAC are steadily positioning themselves as credible and trustworthy partners on the global biomedical research stage.

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.

This project is part of the EDCTP3 program, supported by the European Union.

ct-luso@ordemfarmaceuticos.pt | Rua da Sociedade Farmacêutica, n.º18 | 1169-075 Lisboa, Portugal