CT·LUSO CLINICAL TRIALS IN PORTUGUESE-SPEAKING AFRICAN COUNTRIES

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

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Background

CT-Luso 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)**. The project is funded by the Global Health EDCTP3, with support from the European Union, and will run for 40 months, beginning in September 2024.

CT-Luso aims to strengthen and harmonize the ethical and legal framework for conducting CTs and to enhance the functioning of competent institutions, with three main 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

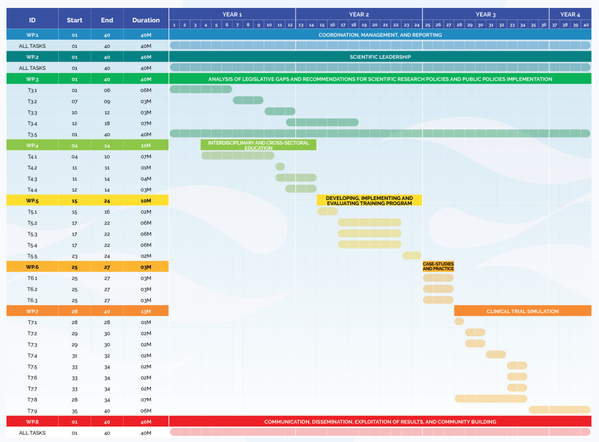

Figure 2 – Timeline of Project's work packages and mains tasks

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 existing biomedical research legislation and the regulatory frameworks of the competent bodies in the PSAC in close collaboration with legal experts from each country.

The legislative survey carried out as part of WP3 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 **(tables 1 and 2)**.

The survey reveals a diverse and complex scenario regarding the regulation of biomedical research in the countries involved. Some countries, such as Guinea-Bissau and São Tomé and Príncipe, still lack a formal legal framework or have draft legislation that is not yet approved, like Cape Verde; others, namely Angola and Mozambique have established and regulated legal frameworks for biomedical research, including clinical trials. Nevertheless, all the countries surveyed show increasing awareness of the fundamental ethical principles essential for ensuring the quality and safety of research.

COUNTRY	LEGISLATION	NAME
Angola	Presidential Decree no. 136/21, of 1st June	Organic statute of the Regulatory Agency for Medicines and Health Technologies (ARMED)
	Presidential Decree no. 177/19, of 22nd May	Organic Statute of the National Institute for Health Research (INIS)
	Presidential Decree no. 191/10, of 1st September	Regulations governing the exercise of pharmaceutical activity
	Presidential Decree no. 180/10, of 18th August	Law on the General Basis of National Pharmaceutical Policy
	Law no. 21-B/92, of 28th August	Basic Law of the National Health System
	(draft law)	Law on Clinical and Biomedical Research
	(final version)	Internal Regulations of the Ethics Committee of the Ministry of Health (CEMS)
Cape Verde	Regulatory Decree no. 12/2024 of 27th September	Approves the New Statutes of the National Institute of Public Health (INSP)
	Decree-Law no. 3/2019, of 10th January	Independent Health Regulatory Authority (ERIS)
	Resolution no. 83/2018 of 16th August	Approves the National Pharmaceutical Policy 2018-2028
	Regulatory Decree no. 23/2014, of 10th June	Approves the statutes of the National Institute of Public Health
	Resolution no. 5/2008, of 18th February	Approves the National Health Policy (2007)
	Decree-Law no. 26/2007, of 30th July	National Research Ethics Committee for Health (CNEPS)
	Law no. 41/IV/2004, of 5th April (under review)	Basic Law of the National Health Service
	(project dispatch)	Objects of insignificant value and value for mandatory reporting
	(project dispatch)	Access for sales representatives to healthcare establishments and services
	(in project)	Medical devices
	(in project)	Creation of the National Health Ethics Council (CNES) - repeal of Decree-Law 26/2007 of 30th July
	-	Biomedical Research Bill
Guinea-Bissau	-	National Regulatory Authority for Medicines and Health Products
	(in project)	Statute of the National Committee for Ethics in Health Research (CNEPS)
	(in project)	Code of Ethics
	(in project)	Decree creating the CNEPS

Table 1 - Legislative overview of Angola, Cape Verde and Guinea-Bissau
Caption: The shading (blue) indicates the documents that are still in the legislative circuit

COUNTRY	LEGISLATION	NAME
Mozambique	Decree no. 53/2024, of 18th July	Approves the Regulation of the Research Law at Human Health
	Decree no. 65/2023, of 4th December	Approves the Regulation of the Law Establishing Mechanisms for Health Protection and Promotion, Disease Prevention and Control, and Public Health Threats and Risks
	Resolution no. 4/2023, of 8th November	Approves the Guideline for the Preparation and Submission of Periodic Safety Reports by AIM Titles (RPS)
	Law no. 6/2023, of 8th June	Human Health Research Act
	Decree no. 17/2023 of 27th April	Conducting Clinical Trials on Medicines, Vaccines and Other Biological and Health Products for Human Use
	Ministerial Diploma no. 2/2023, of 4th January	Prescription and Dispensing Rules for Medicines, Vaccines and other Biological Products
	Decree no. 34/2022, of 19th July	Redefines the nature, attributions and competences of the Medicines and Medical Articles Centre, created by Decree no. 13/75, of 6th September
	Ministerial Diploma no. 20/2022, of 9th February	Internal Regulations of the National Medicines Regulatory Authority, IP
	Resolution no. 13/2021, of 16th April	Approves the Health Policy and its Strategy
	Decree no. 115/2020, of 31st December	Approves the Organic Statute of the National Medicines Regulatory Authority, IP (ANARME)
	Decree no. 29/2019, of 18th April	Approves the Regulation on Good Manufacturing Practices for Medicines for Human Use
	Law no. 12/2017, of 8th September	Law on Medicines, Vaccines and Other Biological Products for Human Use
	Order no. 58/2017, of 31st August	Creation of the National Bioethics Committee for Health (CNBS)
	Resolution no. 4/2017 of 26th May	Organic Statute of the Ministry of Health
São Tomé and Príncipe	Order no. 01/GMS/2022	Creation of the National Ethics Commission Team for the Ministry of Health
	Law no. 9/2018 (under approval)	Basic Law of the National Health System
	Decree-Law no. .../2024 (pending enactment)	Proposed Decree-Law on the Statute of Medicines and Health Technologies, Introduction, Marketing and Manufacture of Medicines and Health Technologies
	(pending enactment)	Internal Regulations of the Health Ethics Committee for Scientific Research (CESIC)
	(pending enactment)	Proposed Decree-Law for the creation of the Central Supply Centre for Medicines and Health Products (CAME) and approval of its Statutes
	(pending enactment)	Proposal for a Legal Framework for Out-of-Store Pharmacies and Drug Stores
	Decree-Law no.../2024 (pending enactment)	Proposed Decree-Law for the creation of the Pharmacy, Medicines and Health Technologies Regulatory Authority and approval of its respective Statute

Table 2 - Legislative overview of Mozambique and São Tomé and Príncipe
Caption: The shading (blue) indicates the documents that are still in the legislative circuit

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 3)**.

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 assessment/ 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 3 - 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

Conclusions

This legislative survey provides a solid basis for the formulation of recommendations aimed at closing regulatory gaps and promoting the harmonization of ethical and regulatory practices. A detailed analysis of the legislative framework and the identified gaps reveals that, although the construction and implementation of a strong and effective national and institutional legislative system still requires the integration of some additional aspects, the level of implementation already achieved indicates that this goal is getting closer to being materialised. Creating a robust legislative framework, which not only effectively regulates clinical trials in the countries involved, but is also internationally recognised and accepted, is already underway and could be achieved with the final adjustments needed. This progress is fundamental to ensuring that countries can be recognised on the global biomedical research stage, promoting confidence and safety in the clinical trials carried out in these countries, both nationally and internationally.

References

To perform the legislative study, the public-accessible legislation was consulted, as well as ready-to-approve legislation in the area of human research, biomedical research, bioethics and ethics.

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