



## **CT-Luso**

Ethics and Regulatory Capacity Building Partnership for Clinical Trials in Portuguese-speaking African Countries (PALOP)

Project 101145790

WP3 - Analysis of legislative gaps and recommendations for scientific research policies and public policies implementation

### **Deliverable 3.1 - Legislative dossier**

28/02/2025



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## 1. Contextualising introduction

### 1.1. General context

CT-Luso is an ethical and regulatory training project in the area of clinical trials, which is being carried out in five Portuguese-speaking African countries (PALOPs): Angola, Cape Verde, Guinea-Bissau, Mozambique and São Tomé and Príncipe. Approved under the "European and Developing Countries Clinical Trials Partnership Programme (EDCTP3)" and funded by the European Commission, CT-Luso has a duration of 40 months and is developed through 8 Work Packages (WP), structured as a continuance of the BERG-Luso Project, which ran from 2018 to 2022.

The main goals are to establish and/or strengthen an ethical and legal framework for conducting clinical trials, to strengthen the operating structure of the institutions involved in biomedical research, articulating and streamlining their relationship, and to invest in the construction of a broad scientific community.

The first stage, which is now underway, aims to promote the harmonisation of national legislative frameworks in line with good international practice in the field of biomedical research, especially regarding clinical trials, thereby improving the quality and safety of research processes. To this end, an international team of lawyers was formed, consisting of Walter Van-Trier (Angola), João Semedo (Cape Verde), Miguel Pereira (Guinea-Bissau), Virgílio Uamba (Mozambique) and Bernardett Santos (São Tomé and Príncipe)<sup>1</sup>, all appointed by their respective Ministries for Health, under the leadership of the Biomedical Law Centre of the University of Coimbra, through André Dias Pereira, Ana Elisabete Ferreira, Carla Barbosa and Daniela Dias.

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<sup>1</sup> <https://ct-luso.com/mod/page/view.php?id=21>

In this context, WP3 plays a crucial role, focusing on analysing legislation and regulations in partner countries and identifying any gaps, with reference to international best practice. Its mission is to signal challenges and opportunities in the existing regulatory framework, formulating recommendations to fill any gaps identified and thus ensure the creation and implementation of a robust legislative and institutional framework. This work contributes to promoting a harmonised regulatory environment in line with international best practice, allowing for safer and more effective development of biomedical research and clinical trials in the PALOP countries.

The impact of CT-Luso goes far beyond technical training, bringing profound benefits for the modernisation and structuring of health and research policies in the PALOP countries. This project aims to make a significant contribution to increasing quality and confidence in conducting clinical trials, both locally and internationally. By strengthening the regulatory and ethical frameworks for biomedical research, CT-Luso not only boosts the scientific capacity of these countries, but also promotes greater transparency and security in clinical trial processes, bringing them into line with international best practice. This impact thus results in a solid foundation that favours the continued development of clinical research and ensures that trials carried out in these countries are conducted to high ethical and scientific standards.

## **1.2. Specific objectives**

This dossier was developed as part of WP3 and its main objective is to carry out a thorough legal survey in order to provide a comprehensive understanding of the current legislative landscape in the PALOPs in the field of clinical research, with particular emphasis on clinical trials.

Therefore, the methodology adopted first required an exhaustive survey of the legislation in force or being processed in the PALOP countries, a task carried out by the lawyers of each of these five partner countries. This was followed by a rigorous and detailed analysis of these laws by lawyers from the Biomedical Law Centre, always accompanied by lawyers from the PALOP countries. The work carried out systematised the laws in force and those in the legislative process, as well as highlighting the central issues which need to be addressed, in order to create an integrated

and easily accessible vision of the legal bases governing biomedical research. Only through this careful approach was it possible to identify the gaps in the current regulatory framework and then propose appropriate solutions.

The following is a presentation of:

- Legislative survey (legislation in force and in progress)
- Identification and control of ethical and regulatory requirements

The analysis was carried out in a structured, collaborative and continuous manner, with the active participation of the international team of lawyers, ensuring a comprehensive and contextualised view of legal and legislative needs. The methodology employed, based on close collaboration between the parties involved, guarantees the robustness and effectiveness of the survey, allowing gaps and opportunities to be properly identified and addressed. This collaborative process was essential for drawing up an accurate diagnosis of regulatory needs, which will serve as the basis for future actions to strengthen the legal framework in the PALOPs.

## **2. Legislative survey (legislation in force or in progress)**

The legislative survey carried out as part of WP3, in close collaboration with PALOP legal experts, 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. This process involved meticulous work, as it was necessary to map out the different pieces of legislation in force, as well as to identify legislative projects in the process of being published which could have an impact on the regulation of clinical trials. To ensure that the survey was complete and up-to-date, direct contact between Portuguese lawyers and lawyers from each of the PALOP countries was essential. This intense and continuous collaboration was crucial to speed up the obtaining of relevant documents and to ensure that all legal diplomas, as well as draft laws, were duly analysed and included in the process.

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The exchange of information between Portuguese lawyers and the national lawyers of the partner countries played a fundamental role in validating the sources and ensuring that the survey was as exhaustive as possible. Each jurisdiction had specificities which required a contextualised approach to ensure that all the regulatory aspects of biomedical research were duly taken into account. This collaborative process not only facilitated access to the documents, but will also ensure that, at a later stage in the development of the deliverable, all the diplomas and legislative projects are carefully scrutinised, allowing for an in-depth analysis of existing gaps and opportunities for improvement.

In addition, the direct involvement of national lawyers ensured that the legal and cultural realities of each country were respected during the process, promoting greater precision and relevance in the legislative analysis. This joint work also made it possible to identify common ground between the legal systems of the different countries, which will facilitate, in the long term, the harmonisation of legislative practices and the construction of a more integrated and efficient regulatory framework for clinical trials.

This legislative survey, which is an essential component of WP3, as already mentioned, serves as a solid basis for the following stages of the project, allowing the analysis of gaps and the formulation of recommendations to be done in an informed and contextualised manner. By precisely identifying the areas in which legislation still needs to be developed or improved, the process contributes to strengthen the legal framework governing biomedical research in the PALOPs, creating a more favourable environment for conducting safe, ethical and high-quality clinical trials.

The following tables clearly and visually reflect the legislative survey carried out under WP3 for each of the countries, providing a detailed representation of the legislation in force and the legislative projects underway. These tables highlight the legislation which regulates clinical research practices, providing a comprehensive overview of the current legislative landscape in each of the participating countries.

As well as illustrating the rules that are already established, the tables also show the documents which are in the legislative process, signalling the changes and developments that are being worked on to strengthen the regulation of clinical trials. This graphic representation makes it easier to understand where each country stands in terms of regulating biomedical research, making it possible to quickly identify the areas which already have consolidated regulations and those that are still in the development or revision phase.

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To summarise, for each partner country named in the left-hand column, the corresponding legislation is identified in the middle column and its name in the right-hand column, distinguishing between those in force (in white) and those in progress (shaded in blue).

This way, the tables are an analysis tool for the legal experts involved in the process, but they also provide a clear and accessible overview for all interested parties, including researchers, regulators and legislators. It is therefore an essential piece for understanding legislative progress in the various countries, providing a solid basis for subsequent actions aimed at filling the gaps identified and promoting the harmonisation of legislation between the countries involved in the project.

Table 1 - Angola's legislative landscape

Country	Legislation	Name
Angola	Presidential Decree no. 136/21, of 1 <sup>st</sup> June	Organic statute of the Regulatory Agency for Medicines and Health Technologies (ARMED)
	Presidential Decree no. 177/19, of 22 <sup>nd</sup> May	Organic Statute of the National Institute for Health Research (INIS)
	Presidential Decree no. 191/10, of 1 <sup>st</sup> September	Regulations governing the exercise of pharmaceutical activity
	Presidential Decree no. 180/10, of 18 <sup>th</sup> August	Law on the General Basis of National Pharmaceutical Policy
	Law no. 21-B/92, of 28 <sup>th</sup> August	Basic Law of the National Health System
	<b>(draft law)</b>	<b>Law on Clinical and Biomedical Research</b>

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Country	Legislation	Name
	(final version)	Internal Regulations of the Ethics Committee of the Ministry of Health (CEMS)

**Caption:** The shading (blue) in the documents indicates the standards that are still in the legislative process.

Angola's legislative landscape is dynamic, with a significant number of laws already approved, reflecting important advances in the regulatory framework. There are also important pieces of legislation in the process of being approved, such as the Clinical and Biomedical Research Law, whose impact will be fundamental for structuring and regulating scientific research in the country.

Table 2 - Cape Verde's legislative landscape

Country	Legislation	Name
Cape Verde	Regulatory Decree no. 12/2024 of 27 <sup>th</sup> September	Approves the New Statutes of the National Institute of Public Health (INSP)
	Decree-Law no. 3/2019, of 10 <sup>th</sup> January	Independent Health Regulatory Authority (ERIS)
	Resolution no. 83/2018 of 16 <sup>th</sup> August	Approves the National Pharmaceutical Policy 2018-2028
	Regulatory Decree no. 23/2014, of 10 <sup>th</sup> June	Approves the statutes of the National Institute of Public Health

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Country	Legislation	Name
	Resolution no. 5/2008, of 18 <sup>th</sup> February	Approves the National Health Policy (2007)
	Decree-Law no. 26/2007, of 30 <sup>th</sup> July	National Research Ethics Committee for Health (CNEPS)
	Law no. 41/IV/2004, of 5 <sup>th</sup> April <b>(under review)</b>	Basic Law of the National Health Service
	<b>(project dispatch)</b>	Objects of insignificant value and value for mandatory reporting
	<b>(project dispatch)</b>	Access for sales representatives to healthcare establishments and services
	<b>(in project)</b>	Medical devices
	<b>(in project)</b>	Creation of the National Health Ethics Council (CNES) - repeal of Decree-Law 26/2007 of 30 <sup>th</sup> July
	-	Biomedical Research Bill

**Caption:** The shading (blue) in the documents indicates the diplomas which remain in the legislative circuit.

Cape Verde's legislative landscape is constantly evolving, reflecting a continuous effort to adapt and strengthen its regulations in the area of scientific research. Most of the already approved legislation is directly related to the entities involved in analysing and regulating scientific research

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in the country. However, it should be noted that there are several pieces of legislation still in the approval or revision phase and, as it is the case in Angola, the Biomedical Research Law is of great importance in this context.

Table 3 - Legislative overview of Guinea-Bissau

Country	Legislation	Name
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

**Caption:** The shading (blue) in the documents indicates the diplomas that remain in the legislative circuit.

Guinea-Bissau's legislative landscape is at a stage of development in terms of regulating scientific and biomedical research, with all the legislation currently in the phase of approval. The various pieces of legislation shaded (blue), as an indication that they are still in the legislative process, bear witness to the country's commitment to consolidating an appropriate legal framework for regulating and monitoring scientific research.

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Table 4 - Mozambique's legislative landscape

Country	Legislation	Name
<b>Mozambique</b>	Decree no. 53/2024, of 18 <sup>th</sup> July	Approves the Regulation of the Research Law at Human Health
	Decree no. 65/2023, of 4 <sup>th</sup> 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 8 <sup>th</sup> November	Approves the Guideline for the Preparation and Submission of Periodic Safety Reports by AIM Titles (RPS)
	Law no. 6/2023, of 8 <sup>th</sup> June	Human Health Research Act
	Decree no. 17/2023 of 27 <sup>th</sup> April	Conducting Clinical Trials on Medicines, Vaccines and Other Biological and Health Products for Human Use
	Ministerial Diploma no. 2/2023, of 4 <sup>th</sup> January	Prescription and Dispensing Rules for Medicines, Vaccines and other Biological Products

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Country	Legislation	Name
	Decree no. 34/2022, of 19 <sup>th</sup> July	Redefines the nature, attributions and competences of the Medicines and Medical Articles Centre, created by Decree no. 13/75, of 6 <sup>th</sup> September
	Ministerial Diploma no. 20/2022, of 9 <sup>th</sup> February	Internal Regulations of the National Medicines Regulatory Authority, IP
	Resolution no. 13/2021, of 16 <sup>th</sup> April	Approves the Health Policy and its Strategy
	Decree no. 115/2020, of 31 <sup>st</sup> December	Approves the Organic Statute of the National Medicines Regulatory Authority, IP (ANARME)
	Decree no. 29/2019, of 18 <sup>th</sup> April	Approves the Regulation on Good Manufacturing Practices for Medicines for Human Use
	Law no. 12/2017, of 8 <sup>th</sup> September	Law on Medicines, Vaccines and Other Biological Products for Human Use
	Order no. 58/2017, of 31 <sup>st</sup> August	Creation of the National Bioethics Committee for Health (CNBS)
	Resolution no. 4/2017 of 26 <sup>th</sup> May	Organic Statute of the Ministry of Health

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Mozambique has a solid and well-structured legislative framework, made up of legislation which has already been approved, reflecting the country's significant progress in regulating scientific and biomedical research. This shows that Mozambique is making great strides towards a robust legislative system in line with international best practice, guaranteeing a firm legal basis for carrying out and supervising scientific research in the country.

Table 5 - Legislative overview of São Tomé and Príncipe

Country	Legislation	Name
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 <b>(under approval)</b>	Basic Law of the National Health System
	Decree-Law no. .../2024 <b>(pending enactment)</b>	Proposed Decree-Law on the Statute of Medicines and Health Technologies, Introduction, Marketing and Manufacture of Medicines and Health Technologies
	<b>(pending enactment)</b>	Internal Regulations of the Health Ethics Committee for Scientific Research (CESIC)
	<b>(pending enactment)</b>	Proposed Decree-Law for the creation of the Central Supply Centre for Medicines and

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Country	Legislation	Name
		Health Products (CAME) and approval of its Statutes
	<b>(pending enactment)</b>	Proposal for a Legal Framework for Out-of-Store Pharmacies and Drug Stores
	Decree-Law no.../2024 <b>(pending enactment)</b>	Proposed Decree-Law for the creation of the Pharmacy, Medicines and Health Technologies Regulatory Authority and approval of its respective Statute

**Caption:** The shading (blue) in the documents indicates the diplomas that remain in the legislative circuit.

São Tomé and Príncipe's legislative landscape is evolving, with several pieces of legislation in the process of being promulgated. Of particular note is the Basic Law of the National Health System.

### 3. Identification and control of ethical and regulatory requirements

Following the process described above, WP3 conducted a thorough legislative survey of the ethical and regulatory requirements that underpin biomedical research, carrying out a detailed analysis of the documents and legal diplomas obtained from each of the PALOP countries. This survey is extremely important, as it makes it possible to precisely identify the gaps in current legislation. By mapping these gaps, WP3 will be able to draw up specific and targeted recommendations aimed not only at making up for regulatory deficiencies, but also at promoting the harmonisation of the regulatory framework between the various participating countries. The ultimate goal is to ensure a more robust regulatory landscape, in line with international best practice and capable of fostering safe, ethical and efficient biomedical research in the countries involved.

The following is a schematic presentation of the work carried out on the ethical requirements to be contemplated in the legislation:

- positively identified requirements (✓) for each partner country are distinguished from their absence (-);
- a distinction is made between those which are in force (in white), in progress (in blue), and those not yet provided for either in approved legislation or in the legislative circuit (in green).

Table 6 - Checklist of ethical and regulatory requirements laid down in current legislation or internal regulations

Ethical requirements	Angola	Cape Verde	Guinea-Bissau	Mozambique	São Tomé and Príncipe
Primacy of the human being / dignity	✓	✓	✓	✓	✓
Regulatory approval	✓	✓	✓	✓	-

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<b>Ethical requirements</b>	<b>Angola</b>	<b>Cape Verde</b>	<b>Guinea-Bissau</b>	<b>Mozambique</b>	<b>São Tomé and Príncipe</b>
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	✓	✓	✓	✓	-

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Ethical requirements	Angola	Cape Verde	Guinea-Bissau	Mozambique	São Tomé and Príncipe
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	✓	✓	-	-	-

**Caption:** In white we find that which is already in force; in blue that which is in the legislative process; and in green the requirements which are not yet foreseen. The colour of each cell allows you to quickly identify the stages of implementation of each requirement.

#### **4. General Appreciation**

From the survey and detailed analysis carried out, it is possible to observe a diverse and complex scenario regarding the regulation of biomedical research in the countries involved. This panorama varies significantly between countries, with some nations still lacking a formal legal framework or with draft legislation in the development phase and not yet approved, such as Guinea-Bissau and São Tomé and Príncipe. On the other hand, there are countries, such as Angola, Cape Verde and Mozambique, where there is already an established and regulated legal framework for biomedical research, including clinical trials.

However, it is important to emphasise that, despite these disparities, all the countries in the survey show a growing 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 opinions prior to conducting studies.

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. These elements are crucial to ensuring that clinical trials are conducted according to the highest ethical and safety standards, respecting the rights and well-being of participants.

This legislative survey, by identifying the ethical aspects already addressed in existing and draft legislation, provides a solid basis for the formulation of recommendations aimed not only at closing regulatory gaps, but also at promoting the harmonisation of ethical and regulatory practices. This way, WP3 contributes to significant progress in building a robust regulatory framework which meets local needs and, at the same time, is aligned with international best practice in biomedical research.

## 5. Observations

The legal study carried out in this record shows substantial regulatory developments in recent years in all the countries analysed, reflecting a growing concern and commitment to creating a more solid regulatory framework in line with international best practices. This progress is clearly visible, not only in the significant number of documents being drafted, but also in the revision of existing standards, as illustrated in the tables relating to the legislative survey. Analysing the legislative processes underway shows that the countries involved are increasingly adapting their legislation to international best practice and adapting it to meet the contemporary challenges of biomedical research, including clinical trials, with a broader and more integrated vision.

The table on the ethical requirements covered by legislation, after a careful reading, offers a detailed overview of the matters already covered in the legislation in force or in the process of being approved, as well as those that have not yet been duly regulated but which, according to the analysis of the legal team, are essential and should be covered. The distinction between that which has been approved and is in force and that which is in the pipeline awaiting approval is fundamental, as it allows us not only to understand the current state of legislation, but also to identify the gaps that need to be filled in order to guarantee a robust and harmonised legal system capable of responding to the ethical and scientific demands of clinical research.

A detailed analysis of the legislative framework and the gaps identified leads to the conclusion 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. The creation of 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.