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Article

CT-Luso: towards ethical and regulatory harmonisation of clinical trials in Portuguese-speaking african countries

CT-Luso: para uma harmonização ética e regulatória dos ensaios clínicos nos países africanos de língua portuguesa

CT-Luso: hacia una armonización ética y normativa de los ensayos clínicos en los países africanos de lengua portuguesa

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Abstract

Objective: to conduct a survey and comparative analysis of current and/or pending legislation in the field of biomedical research, particularly clinical trials, in the five Portuguese-speaking african countries, within the framework of the CT-Luso project. **Methodology:** documentary analysis based on the systematic survey and examination of 52 legislative instruments, complemented by a technical comparison with international requirements applicable to clinical research, namely Regulation (European Union) No. 536/2014 and the Declaration of Helsinki. **Results:** significant heterogeneity was found in the legal frameworks for biomedical research in the Portuguese-speaking african countries. Only some of the countries have specific legislation for clinical trials; the rest are governed by general health or research standards. Weaknesses were identified in regulatory authorities and ethics committees with uneven powers, affecting ethical evaluation and participant protection. A lack of alignment with international standards was observed, especially regarding informed consent, data sharing and transparency. However, there was political will for regulatory convergence, expressed in ongoing legislative initiatives and the strengthening of inter-institutional cooperation. **Conclusion:** the approach adopted by CT-Luso confirms that international legal cooperation is an effective tool for diagnosing vulnerabilities and guiding legislative reforms in clinical research. However, challenges remain in terms of ethical and regulatory harmonisation, which must be overcome in order to consolidate robust legal frameworks, ensure the protection of participants and strengthen the integration of portuguese-speaking african countries into international good scientific practice. The creation of regional coordination mechanisms and the progressive adoption of common ethical and legal benchmarks are decisive steps towards strengthening research governance and its sustainable integration into the global scientific arena.

Keywords: Biomedical Research; Clinical Trials; Comparative Study.

Resumo

Objetivo: proceder ao levantamento e análise comparativa da legislação em vigor e/ou em tramitação no domínio da investigação biomédica, em especial dos ensaios clínicos, nos cinco países africanos de língua oficial portuguesa, por meio do projeto CT-Luso. **Metodologia:** análise documental baseada no levantamento e exame sistemático de 52 instrumentos legislativos, complementada por comparação técnica com exigências internacionais aplicáveis à investigação clínica, nomeadamente o Regulamento n.º 536/2014 do Parlamento Europeu e do Conselho e a Declaração de Helsínquia. **Resultados:** verificaram-se heterogeneidades significativas nos enquadramentos jurídicos da investigação biomédica nos países africanos de língua oficial portuguesa. Apenas parte dos países dispõe de legislação específica para ensaios clínicos; os restantes regem-se por normas gerais de saúde ou investigação. Identificaram-se fragilidades nas autoridades reguladoras e comités de ética com competências desiguais, afetando a avaliação ética e a proteção dos participantes. Observou-se desalinhamento face aos padrões internacionais, especialmente quanto ao consentimento informado, partilha de dados e transparência. Contudo, constatou-se vontade política de convergência normativa, expressa em iniciativas legislativas em curso e fortalecimento da cooperação interinstitucional. **Conclusão:** a abordagem adotada pelo CT-Luso confirma que a cooperação jurídica internacional é instrumento eficaz para diagnosticar vulnerabilidades e orientar reformas legislativas na investigação clínica. Persistem desafios de harmonização ética e regulatória, cuja superação é essencial para consolidar quadros jurídicos robustos, garantir proteção dos participantes e reforçar a integração dos países africanos de língua oficial portuguesa nas boas práticas científicas internacionais. A criação de mecanismos regionais de coordenação e a adoção progressiva de referenciais ético-jurídicos comuns são passos decisivos para fortalecer a governança da investigação e a sua inserção sustentável no espaço científico global.

Palavras-chave: Pesquisa Biomédica; Ensaios Clínicos; Estudo Comparativo.

Resumen

Objetivo: realizar un estudio y análisis comparativo de la legislación vigente y/o en trámite en el ámbito de la investigación biomédica, en particular de los ensayos clínicos, en los cinco países africanos de lengua oficial portuguesa, en el marco del proyecto CT-Luso. **Metodología:** análisis documental basado en el levantamiento y examen sistemático de 52 instrumentos legislativos, complementado con una comparación técnica con los requisitos internacionales aplicables a la investigación clínica, en particular el Reglamento (Unión Europea) n.º 536/2014 y la Declaración de Helsinki. **Resultados:** se observaron importantes heterogeneidades en los marcos jurídicos de la investigación biomédica en los países africanos de habla portuguesa. Solo algunos de estos países cuentan con legislación específica para los ensayos clínicos; los demás se rigen por normas generales de salud o investigación. Se identificaron deficiencias en las autoridades reguladoras y los comités de ética, con competencias desiguales, lo que afecta a la evaluación ética y la protección de los participantes. Se observó un desajuste con respecto a las normas internacionales, especialmente en lo que se refiere al consentimiento informado, el intercambio de datos y la transparencia. Sin embargo, se constató la voluntad política de convergencia normativa, expresada en iniciativas legislativas en curso y en el fortalecimiento de la cooperación interinstitucional. **Conclusión:** el enfoque adoptado por el CT-Luso confirma que la cooperación jurídica internacional es un instrumento eficaz para diagnosticar vulnerabilidades y orientar las reformas legislativas en la investigación clínica. Sin embargo, persisten los retos de armonización ética y normativa, cuya superación es esencial para consolidar marcos jurídicos sólidos, garantizar la protección de los participantes y reforzar la integración de los países africanos de lengua oficial portuguesa en las buenas prácticas científicas internacionales. La creación de mecanismos regionales de coordinación y la adopción progresiva de referencias ético-jurídicas comunes son pasos decisivos para fortalecer la gobernanza de la investigación y su inserción sostenible en el espacio científico global.

Palabras clave: Investigación Biomédica; Ensayos Clínicos; Estúdio Comparativo.

Introduction

Africa conducts far fewer clinical trials than any other continent: 845, which corresponds to about 1.1% of the 76,331 trials initiated globally in 2023(1). During the period from 1999 to 2023, in Portuguese-speaking African countries (PALOP) – Angola, Cape Verde, Guinea-Bissau, Mozambique, and São Tomé and Príncipe – only 420 of the 17,425 trials conducted across the entire African continent were carried out. The PALOP countries are below the African average – 17 clinical trials – for the same period, with only an average of 8 clinical trials conducted. Specifically, during this period, Angola conducted 47 clinical trials, Cape Verde conducted 24, Guinea-Bissau 98, Mozambique 229, and São Tomé and Príncipe 22(1). The causes for this situation are very diverse and may be related to political, economic, and social realities, but also to the level of development of higher education, biomedical research centers, and national health services. However, there is a specific issue for the PALOP countries that should be highlighted: the Portuguese language as a barrier to access to international training courses promoted in Africa, mainly by the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO), which are invariably in English and/or French(2,3).

It was in this context that CT-Luso (www.ct-luso.com) emerged, an ethical and regulatory training project in the field of clinical trials in Portuguese-speaking African countries, funded by the EDCTP3 Program, a partnership between Europe and developing countries for conducting clinical trials, with the support of the European Commission. It is an aggregating project involving the five PALOP countries, through the drug regulatory authorities (ARM), research ethics committees (CEI), universities, national health institutes, research centers, among other institutions, in each country, and is conducted entirely in Portuguese.

The main objective of CT-Luso is to promote harmonized legislative, institutional, and professional capacity building in the five partner countries as a basic prerequisite for conducting clinical trials. The aim is to establish a Portuguese-speaking hub that is attractive to international consortia, while ensuring the protection of populations and the retention of benefits in the country, thereby developing the quality of healthcare and research applied to endogenous diseases.

In pursuit of this ambitious overall objective, three fundamental stages have been established— legislative, institutional, and professional — with differentiated action plans. The main objectives are: to establish and/or strengthen an ethical and legal framework for conducting clinical trials, to reinforce the operating structure of the institutions involved in biomedical research, coordinating and streamlining their relationship, and to invest in the training of a broad scientific community.

This study focuses exclusively on the first level of intervention – the legislative – with the specific objectives of conducting a survey of the legislation in force and/or in progress in the field of biomedical research and, in particular, clinical trials in the five PALOP countries; to carry out a comparative analysis with International Good Practices, identifying any gaps and making recommendations with a view to aligning national legislation with international guidelines on biomedical research and harmonizing regulations in the five PALOP countries.

Methodology

This is a qualitative study, exploratory and comparative in nature, with a legal-documentary approach. The main technique adopted was documentary analysis, with a corpus of analysis comprising a set of 52 legislative instruments relating to biomedical research and clinical trials, covering legislation in force, pending bills, and proposals under preparation from the five PALOP countries.

The legislative action plan began with a survey of existing legislation and legislative proposals under consideration in the five partner countries, carried out by PALOP lawyers who are members of the international team of lawyers. The Center for Biomedical Law (CDB) at the University of Coimbra collected the data, resulting in the following table.

Table 11. Number of legal instruments in force and under consideration by PALOP

	Number of legal intruments	
Countries	**In force**	**pending**
Angola	6	2
Cape Verde	7	8
Guinea-Bissau	1	4
Mozambique	15	0
São Tomé and Príncipe	3	6

Source: own elaboration.

The numbers of laws in force and pending by country present a heterogeneous scenario, with different levels of regulatory consolidation.

The legislative action plan was developed in two essential stages: the first involved informing, raising awareness, and engaging the Ministries of Health of the PALOP countries; this was followed by internal teamwork leading to the completion of the Comparative Legislative Study.

The first stage began with the CT-Luso coordination team establishing contact with the respective Ministries of Health, both directly and indirectly through the involvement of local facilitators, namely African partners in the project. This made it possible to present CT-Luso to the PALOP Health Ministers in terms of: the framework of the initiative, built on the achievements of the BERC-Luso project that preceded it, and as its ambitious development; the Portuguese coordination of the project and the Mozambican scientific leadership; its objectives and implementation methodologies, through the specification of the eight action programs it encompasses; an organizational chart identifying the 24 partner institutions from six countries; and a timetable(4) explaining the activities to be carried out and the goals to be achieved during the 40-month duration of CT-Luso.

Once CT-Luso and its fundamental objective of ethical and regulatory capacity building as a basis for the implementation of clinical trials in the PALOP countries had been presented, efforts were made to raise awareness of the advantages of capacity building in the country, given the potential direct benefits – qualification of health services through advanced training of professionals, equipment for healthcare facilities and research centers, access to state-of-the-art drugs, research into endemic diseases, etc. – and indirect benefits – creation of services, retention of qualified professionals, etc. From this stage onwards, the involvement of the health ministries of the five PALOP countries was formalized through the appointment of a lawyer to join the CT-Luso and, in particular, the international team of lawyers.

This team consisted of one lawyer per PALOP and four members of the Center for Biomedical Law (CDB) at the University of Coimbra, responsible for coordinating the working group of lawyers and drafting the announced Study. The team, comprising a total of nine lawyers, began work in October 2024, thus initiating the second stage of the legislative action plan.

Since then, 12 working meetings have been held, sometimes within the group of lawyers, sometimes between them and members of the project coordination team, and sometimes at a bilateral level when it came to specific and restricted interaction, to distribute tasks and verify the goals achieved.

The work of the international team of jurists took place in three main stages. First, each of the

African jurists surveyed, in their respective countries, all legislation relating to biomedical research, including clinical trials, identifying the stage of the legislative process at which each piece of legislation was: from those in force to those still in the drafting process. All the information was sent to the CDB, which compiled it.

In a second stage, the CDB analyzed each document individually and as a whole by country to identify the ethical requirements expressed and assess the terms in which these requirements were stated: for example, whether they were robust, given the scope and level of requirements considered, or merely indicated, remaining rather vague. The continuation of this second stage required close cooperation between African lawyers and those of the CDB to assess all the analyses carried out.

This was followed by a third stage of work, consisting of a comparative analysis between the ethical requirements set out in the legislation of the PALOP countries and the ethical and legal requirements demanded by International Good Practices, as defined in Regulation (EU) Nº. 536/2014 of the European Parliament and of the Council of April 16, 2014(5) and the Declaration of Helsinki(6).These practices are based on the protection of human dignity and integrity and the recognition that scientific research must always be subject to respect for fundamental rights, as this is the only way to strengthen public confidence in science and promote a culture of responsibility, solidarity, and respect for the vulnerability of participants. This analysis was carried out in a structured, collaborative, and continuous manner, representing the basis on which future standardization and institutional strengthening actions will be based.

In summary, the methodology employed, based on close collaboration between the parties involved, ensures the robustness and effectiveness of the survey, allowing for the preparation of an accurate diagnosis of regulatory needs that serves as the basis for future actions to strengthen the legal framework in the PALOP countries. In addition, this collaborative work, particularly with various national entities with professional and institutional responsibilities, facilitates dialogue with national political and legislative authorities and, in this way, also raises political awareness for the implementation of regulations and practices.

The meticulous legal analysis work enabled a comparative legislative study to be carried out, which is presented below.

Results and discussion

Comparative overview

Based on a legislative survey of 32 existing laws and 20 laws currently being debated, it was possible to identify the subject matter and scope of each law within the broad field of biomedical research in order to assess the respective level of legislative consolidation. The fundamental criteria used for this purpose were the existence of:

- Specific regulations for clinical trials;
- Clear status for the actions of drug regulatory authorities.

This procedure enabled us to determine the results presented below.

Box 12. Existence of specific regulations for clinical trials and clear statutes for the actions of drug regulatory authorities by PALOP [10]

Countries / Legislation	**EC Regulation**	**ARM statues**
Angola	✓	✓
Cape Verde	✓	✓
Guinea-Bissau	✓	✓
Mozambique	✓	✓
São Tomé and Príncipe	✓	✓

Source: own elaboration.

The analysis concluded that Mozambique currently has the most consolidated legislative framework, with robust and detailed legislation, including specific regulations for clinical trials, good clinical practices, and clear statutes for the actions of regulatory authorities. The prospect of developing legislation in this country translates into advanced implementation, with a solid foundation for internationally aligned practices.

Angola and Cape Verde are at an intermediate stage: both already have structural standards in place and are still developing relevant legislative processes, such as the Clinical and Biomedical Research Law (Angola) – with a final version of the draft law available – and the Biomedical Research Law (Cape Verde) – with a preliminary draft. It is also possible to distinguish between these two countries in terms of their level of legislative consolidation. Angola is at a medium-high level of legislative consolidation with a relevant regulatory framework, but with key legislation still pending, pointing to the prospect of consolidation in the near future. Cape Verde, with structural norms already in force and strategic documents such as the Proposed Law on Biomedical Research in the process of being approved, shows a medium level of legislative consolidation, with the possibility of strengthening the regulatory system in the short term.

Guinea-Bissau and São Tomé and Príncipe, on the other hand, present a more incipient, albeit dynamic, picture, with several legislative proposals pending approval, particularly with regard to the creation of ethics committees, regulatory authorities, and specific standards on clinical trials, such as the Statutes of the National Committee on Health Research Ethics and the Law on the Code of Ethics in Health Research (Guinea-Bissau) – which are currently in the draft bill stage – and the Decree-Law for the creation of the Regulatory Authority for Pharmacy, Medicines, and Health Technologies – for which there is a draft decree. The level of legislative consolidation in São Tomé and Príncipe is low to medium, with a fragile regulatory framework, marked by several legislative proposals pending enactment, pointing to the need to prioritize the creation of regulatory structures and ethics committees. Finally, Guinea-Bissau, in the current context, reveals a low level of legislative consolidation, with a weak legislative system and fundamental norms still being drafted, pointing to the need for intensive support for the development of a basic regulatory framework.

In summary, the analysis carried out identified three distinct patterns, which are reflected in the graph in Figure 1: countries with consolidated and operational legislation, such as Mozambique; countries with structural legislation, but still evolving, such as Angola and Cape Verde; and countries with significant regulatory gaps, such as Guinea-Bissau and São Tomé and Príncipe.

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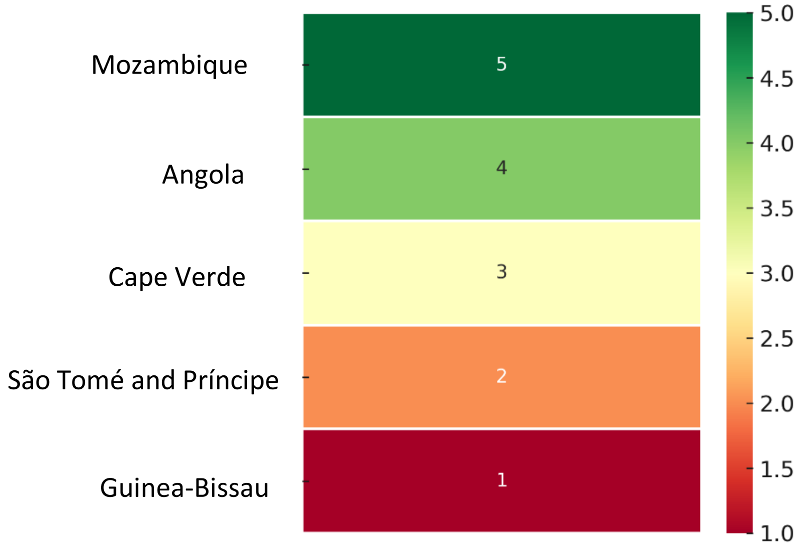
[10] Key: ✓ = In force, ✓= In progress

Figure 1. Table of levels of legislative consolidation in the PALOP countries[11]



Source: own elaboration.

Comparative analysis of ethical and regulatory requirements

One of the main results of the legislative action plan was the comparative assessment of the ethical and regulatory requirements set out in the current legislation and draft legislation of the PALOP countries. The analysis focused on the fundamental elements for the protection of participants(7) and the scientific integrity of clinical trials(7), as required by international good practice. The assessment of the various laws by country showed that all countries recognize the fundamental principles of good clinical practice(6,8,9,10,11), specifically: the protection of human dignity, the requirement for informed consent, the confidentiality of data, and the need for prior review by an ethics committee. However, there are significant differences in the way these requirements are incorporated into the legal systems of the five countries.

In Mozambique, Angola, and Cape Verde, most ethical standards are regulated, although there are still areas for development, particularly with regard to defining the responsibilities of sponsors, investigators, and auditors, monitoring participants after the trial, managing adverse events, and establishing a national clinical trial registry. Guinea-Bissau and São Tomé and Príncipe have more significant gaps, with no provisions on post-trial monitoring, mechanisms for redress, public disclosure of results, or national databases for registering clinical trials. This heterogeneity reinforces the importance of regulatory harmonization, which will ensure equivalent ethical and scientific standards in different countries.

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[11] Key: Level of legislative consolidation assessed based on the number of laws in force and practical implementation.

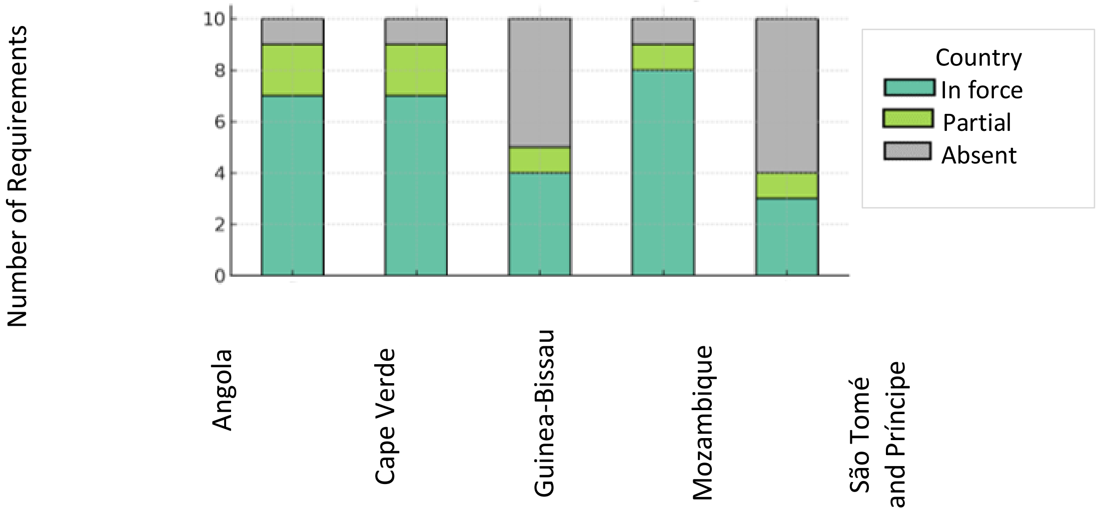
Box 2. Comparative table of ethical and regulatory requirements[12]

Etical/Regulatory Requirement	**Angola**	***Cape Verde***	***Guinea-Bissau***	***Mozambique***	**S. Tomé and Príncipe**
Primacy of human dignity	✔	✔	✔	✔	✔
Informed consent	✔	✔	✔	✔	✔
Data confidentiality	✔	✔	✔	✔	✔
Prior opinion of the ethics committee	✔	✔	✔	✔	✔
Responsibility of the sponsor/investigator	✔	✔	✗	✔	✗
Post-trial monitoring	✗	✓	✗	✗	✗
Urgent safety measures	✗	✓	✗	✗	✗
Public disclosure of trials	✓	✓	✗	✗	✗
National clinical trial database	✗	✗	✗	✗	✗
Insurance/damage compensation	✔	✔	✓	✔	✗

Source: own elaboration.

The data of ethical and regulatory requirements in each of the PALOP countries, presented in detail in the comparative table (Box 2), can also be translated into a graph, allowing for a quick and comprehensive overview of the level of integration of ethical requirements into the respective national legislation.

Figure 2. Comparative graph of ethical and regulatory requirements



Source: own elaboration.

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[12] Key: ✔ In force = Regulated in current legislation, ✓ Partial = Provied for, but lacking detailed relation or practical implementation, ✗ Absent = Not regulated or provided for in current legislation or bills pending.

Cross-cutting weaknesses and challenges

The document analysis revealed some bery positive aspects, but also some significant weaknesses common to all five countries. One of these weaknesses is the lack of public national clinical trial registries[13], which compromises transparency and access to information on approved and ongoing studies. There are also shortcomings in the regulation or urgent safety measures, which are essential for the management of serious adverse events during trials.

Another significant weakness is the absence of clear standards for post-trial monitoring, which limits the adequate follow-up of participants and the assessment of late effects. In addition, regulatory authorities often face human and financial resource constraints, which undermine effective oversight. Finally, there is a gap between the publication of legislation and its effective implementation, especially in institutional contexts with limited technical capacities.

Box 3 identifies the relevant aspects of the procedures in place by country, allowing for easy visualization of cross-cutting weaknesses.

Box 3. Comparative table with cross-cutting weaknesses identified in the PALOP countries[14]

Weakness identified	**Angola**	***Cape Verde***	**Guinea-Bissau**	**Mozambique**	**S. Tomé and Príncipe**
Lack of regulation on adverse events	✓	✓	✗	✓	✗
Insufficient post-trial monitoring	✓	✓	✗	✓	✗
Limited oversight capacity	✓	✓	✗	✓	✗
Disagreement in ethics committees	✓	✓	✗	✗	✓

Source: own elaboration.

The data on relevant aspects of procedures in each country, presented in detail in Box 3, can also be translated into a graph, allowing for quick and comprehensive visualization, as shown in Figure 3.

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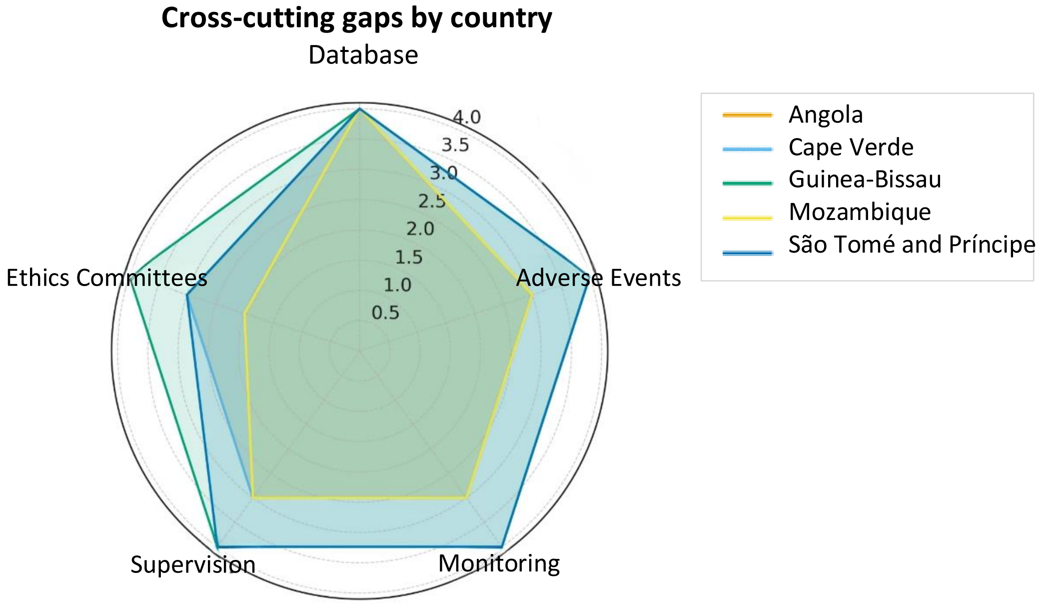
[13] Regulation (EU) N.º 536/2014 of the European Parliament and of the Council provides, in Articles 80 to 82, for the creation and maintenance of a public IT infrastructure for clinical trial data conducted in the European Union, as a good practice in clinical research.

[14] Key: ✗ Total = Total absence, ✓ Partial = Partial existence.

Figure 3. Graph showing cross-cutting weaknesses identified in the PALOP countries



Source: own elaboration.

The results show that, although Angola, Cape Verde, and Mozambique have made significant regulatory progress, they still need to adopt relevant procedures for the implementation of ethical and safety practices. Guinea-Bissau and São Tomé and Príncipe, in turn, need essential structural standards. The results obtained under the CT-Luso project's legislative action plan allow for an in-depth reflection on the current state of biomedical research regulation and, in particular, on clinical trials in the PALOP countries. The comparative analysis reveals a heterogeneous scenario, with different levels of regulatory consolidation: Mozambique stands out with a robust and operational legal framework;

Angola and Cape Verde are in a phase of consolidation; Guinea-Bissau and São Tomé and Príncipe have significant structural gaps.

This heterogeneity confirms that the consolidation of regulator regimes in contexts of low institutional density is a gradual process, dependent on political-administrative, technical, and cultural facts(12,13). The high number of bills pending in the PALOP countries indicates, on the one hand, a growing awareness of regulatory gaps and, on the other, a political and technical commitment to creating the legal conditions for the ethical and safe conduct of clinical trials.

The comparative legislative study shows that all the countries analyzed recognize and incorporate, to varying degrees, the fundamental principles of bioethics and biomedical law — protection of human dignity, informed consent, data confidentiality, and prior review by ethics committees. These principles find theoretical support in documents such as the Declaration of Helsinki(6), the Guidelines of the International Council for Medical Science Organizations(7). Regulation (EU) No. 536/2014, which emphasize the centrality of respect for fundamental rights and transparency in scientific research.

Despite this formal incorporation, the degree to which these principles are operationalized varies substantially. In Mozambique, legislation already provides for detailed mechanisms for the approval, supervision, and accountability of sponsors and researchers. In contrast, Guinea-Bissau and São Tomé and Príncipe have structural weaknesses, such as a lack of rules on post-trial monitoring, the absence of national databases, and undefined mechanisms for redressing harm. This gap between the normative level and practice reflects the challenges of transposing universal ethical principles into legal contexts undergoing institutional development.

The existence of common cross-cutting gaps — the absence of public registries of clinical trials, insufficient standards for adverse event management, and a lack of standardized post-study follow-up protocols—suggests that the PALOP countries are in an intermediate phase of regulatory consolidation, characterized by significant legislative advances but still limited implementation capacity. Such challenges are typical of emerging regulatory systems, which require institutional strengthening, technical training, and regional cooperation(14). Overall, there is a positive trend, with all countries making consistent efforts to align themselves with international best practices. The legislative mapping carried out makes it possible to accurately identify both the regulatory progress already achieved and the critical areas that require priority intervention, constituting a strategic tool for public policy planning and regulatory capacity building(15). In addition, the inclusion of lawyers appointed by the PALOP Ministries of Health in the international working group is a concrete indicator of political and institutional commitment, confirming the relevance of international legal cooperation as a vehicle for capacity building and ethical harmonization.

In summary, the results show that the PALOP countries have the necessary foundations to move towards a harmonized legislative framework, in accordance with the parameters of Regulation (EU) No. 536/2014 and the Helsinki Declaration, ensuring equivalent ethical and scientific standards and promoting their integration into global biomedical research flows. Regulatory harmonization will be crucial for the PALOP countries as a whole to consolidate themselves as an attractive regional cluster for international consortia, combining geographical and ethnic diversity with a solid ethical and legal framework(16).

The strategic recommendations presented in Box 4 summarize the main lines of action identified:

Box 4. Integrative visual summary

Area of Analysis	Current Scenario	Strategic Recommendation
Legislative consolidation	Heterogeneity among the five countries, with different levels of regulatory consolidation	Harmonize legal instruments and develop a reference model for PALOP countries
Ethical coverage	Fundamental rights and informed consent are broadly covered, but gaps remain in monitoring and safety	Create national protocols on minimum ethical requirements and oversight.
Cross-cutting gaps	Lack of national databases, insufficient standards on adverse events, and failures in practical implementation.	Invest in digital platforms, public databases, and technical training.
Institutional capacity	Weak regulatory authorities.	Strengthen the formation of ethics and regulatory committees, promoting interinstitutional cooperation.

Source: own elaboration.

The consolidation of these axes, however, requires a theoretical approach based on the ethics of scientific responsibility and global health governance, in order to ensure that regulatory progress is not limited to the formal transposition of standards, but translates into effective practices for the protection of participants, transparency, and public trust(17). This analytical framework thus provides the basis for the final considerations and policy recommendations that follow in the Conclusion.

Final Considerations

CT-Luso has a decisive role to play here, not only in mapping the current scenario, but also in laying the foundations for a common strategy for ethical, legislative, and institutional capacity building in the field of clinical trials in the PALOP countries. The creation of reference legislative models, adaptable to local realities, can accelerate the process of regulatory alignment, affirming its role in the international biomedical research scenario. Similarly, the implementation of national and regional digital platforms for the registration of clinical trials is a priority, as it increases transparency, reduces information inequalities, and improves the governance of biomedical research(7).

Another critical point identified relates to the role of regulatory authorities and ethics committees. The continuous training of these bodies, combined with the creation of harmonized national protocols for risk management, participant monitoring, and damage repair, is essential to ensure that clinical trials conducted in PALOP countries meet rigorous ethical standards and maximize benefits for local populations. In addition, the promotion of interinstitutional cooperation networks can strengthen the sharing of good practices and optimize resources in a context of budgetary constraints.

In summary, the study reveals a twofold challenge: on the one hand, consolidating the advances already achieved in countries with greater legislative maturity; on the other, offering intensive technical and regulatory support to countries where the regulatory framework still needs further development. The collaborative approach of CT-Luso, involving Ministries of Health, Regulatory Authorities, Ethics Committees, universities, and research centers, is positioned as a turning point for the creation of a solid and sustainable Portuguese-speaking ecosystem for conducting clinical trials.

Thus, the results not only highlight gaps and asymmetries, but also point to clear paths for building a common strategic agenda capable of promoting the qualification of health systems, the inclusion of PALOP countries in the international biomedical research landscape, the gurantee of high ethical and scientific standards in the conduct of clinical trials.

Conflict of interest

The authors declare that there is no conflict of interest.

Contribution of the authors

Barbosa C contributed to the conception/design of the article, writing, and critical review of its content. Dias DM contributed to the conception/design of the article, analysis and interpretation of legislative documents, and writing. Pereira AGD contributed to the critical review of the article's content and approval of the final version. Van-Trier W contributed to the conception/design of the article. Semedo J contributed to the conception/design of the article. Pereira M contributed to the conception/design of the article. Uamba V contributed to the conception/design of the article. Afonso N contributed to the conception/design of the article. Neves MCP contributed to the writing, critical review of the content, and approval of the final version of the article.

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